



Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 517161

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
68516	E21-295890	0172-21	Duplicate

ARTG: 320484

[Document Container URL](#)

Report Information Section

Enter the ARTG of the device or Duplicate DIR in the search box then press Tab to search for the DIR that this report duplicates. If an ARTG has already been entered below it will be entered in the search field for you.

Duplicate DIR No Search:	ARTG Search:	DIR #:
	320484	68783 - J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	05/03/2021
Date of Final Report:	Date of Initial TGA Action:	Reviewed by Team:	Date Response Received:
04/05/2021	05/03/2021	11/05/2021	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter consents to contact by sponsor:
13/10/2021	Healthcare Professional		N/A
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Sponsor		For Team Meeting	

Event Description for Website Publication:

A part of the inserter handle broke and has remained in the bone with the anchor

Clinical Event Information:

The patient underwent a labral repair s22 Hip Arthroscopy. Two MectaLock (J-Lock) PEEK anchors were used to refixing the labrum to the acetabulum with no visual issues. Then the surgeon sent to the agent a picture of an X-ray asking if the image in the X-ray was part of the anchor inserter handle. It appears that a part of the inserter handle has remained in the bone with the anchor. The patient underwent revision surgery to remove the broken part.

The event was reported to the manufacturer on 29.01.2021, but only after the revision surgery, which took place on s22, we were sure that the piece that remained in the patient was part of the Medacta device.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	Alternative Person Phone:	Alternative Person Fax:	Alternative Person Email:

Recorded Problems Observed

Recorded Problems Observed:

Material Integrity Problem -> Break -> Fracture

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Injury -> Foreign Body In Patient -> Device Embedded In Tissue or Plaque

Health Impact

Recorded Health Impacts:

Surgical Intervention -> Device Revision or Replacement ->

Patient Information

Sex:	Weight:	Age:
s22		s22
Patient Focused Corrective Action Taken:	Patient History:	

Patient Outcome/Consequences:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

Reporter Title:

Position:

Address 1:

Country:

Mobile:

Reporter #:

First Name:

Address 2:

Postcode:

Email:

Additional Event Description:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Surname:

Company/Institution:

Town/Suburb:

Phone:

Last External Submission By:

Preferred Contact Method:

State:

Fax:

Initial Reporter Section

As Above?:

Search Reporter By Surname:

Title:

Position:

Address 1:

Postcode:

Mobile:

If No, fill out the following:

Initial Reporter #:

First Name:

Address 2:

Country:

Email:

Surname:

Company/Institution:

Town/Suburb:

Phone:

Allow the device company to contact you about the incident:

☐

Initial Reporter Confidential:

Preferred Contact Method:

State:

Fax:

Device Information Section

Product Exempt (Note: If not exempt, enter ARTG No):

Product Licence Category:

Brand Name:

Model #:

Purchase Date:

Search Device ARTG:

Device Class:

Initial Device Description:

Serial #:

Expiry Date:

Device ARTG #:

GMDN / UMDN Code:

Usage of Device:

Batch #:

Date of Implant:

Therapeutic Licence Type:

GMDN / UMDN Text:

Software Version:

Lot #:

Date of Explant:

		§22	§22 Document 1
Date of Initial Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
	§22	With Reporter	
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	19/07/2019	0

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:		Address 1:
Medacta International SA	45296		
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	29/01/2021	Mr	§22
Contact Surname:	§22		

Supplier Information Section

Supplier Name:	Address 1:		Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
No	Yes	Yes	More information is required	Team B (IIB, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:	
11/05/2021	Not enough information has been provided	Investigation (within DIR) is recommended	
Notes for Team meeting:			
1 other DIR, no recall/pmr, same device same issue currently under investigation. problem is with the disposable introducer in the kit, which has welding failure. it looks like the same issue with the other DIR 68783. But device in this DIR is from different lot, different implantation date. sending to meeting to investigate together.			
Outcomes from Team Meeting:			
lv 3 investigation - investigate together with DIR 68783.			

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:
			Manufacturer documentation:	

04/03/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)		Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	No
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			No	0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine			
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	
Copy Data From:	07/05/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional		Yes	
Initial					
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:
	s22	Unknown - updated information from the manufacturer is required		No	Level 1 Investigation (to complete screening)
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	FINAL LEVEL OF INVESTIGATION:
	Patient	0. No recalls for similar incidents in Australia			Level 3 Investigation (for multiple DIRs/a DII)
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:	EXCEPTION TO INVESTIGATION LEVEL:
	No	No		Yes - some potential factors (up to 3)	1 other DIR. no recall/pmr. same device same issue currently under investigation. problem is with the disposable introducer in the kit, which has welding failure. it looks like the same issue with the other DIR 68783. But device in this DIR is from different lot, different implantation date. sending to meeting to investigate together.
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:
	No	1 incidents		Production of device - manufacture/batch	Routine
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	FINAL LEVEL OF PRIORITY:
				No	Routine
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:	EXCEPTION TO PRIORITY LEVEL:
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
				I discussed issues with one of my peers	Yes

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:
45972	Medacta Australia Pty Ltd	45972

Attention To: s22	Address 1: Unit A1 / 16 Mars Road	Address 2: 	Town/Suburb: LANE COVE	Document 1
State: NSW	Postcode: 2066	Phone: 	Fax: 	
Email: s22@medacta.com.au				
Investigation Information Section - Submitted by Sponsor/Manufacturer				
Device Analysis Results: Batch review performed on 23-Feb-2021: Lot 1924147: 125 items manufactured and released on 24-Mar-2020. Expiration date: 2025-Feb-07. No anomalies found related to the problem. To date, 19 items of the same lot have been already sold without any other similar reported even. Clinical Evaluation performed by Medical Affairs Director: During an arthroscopic surgery of labrum refixation with a PEEK anchor, the tip of the positioning instrument broke, though the surgeon did not perceive the fracture. The tip of the instrument is visible in the postoperative X-rays, it remained in the cannulation of the anchor. We cannot determine the reasons for the fracture with the elements at hand. No clinical cause could be ascertained. We were informed that a different surgeon intervened to remove the broken instrument part; the future clinical pathway of the patient should be totally flawless and no further consequences of the event should be expected. Visual Inspection performed by R&D Project Manager: The component of the MectaLock PEEK inserter has been received and analyzed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analyzed component resulted totally ruined and scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding. However, it's also evident that the component has been subjected to excessive lateral bending as the axis of the component results deviated from the original. This suggests that misuse could have occurred during the anchor's placement or that a not foreseeable condition of use required an excessive force, as the MectaLock PEEK anchors is supposed to be impacted axially only within the predrilled cylindrical pilot hole. Conclusion: The device history record review does not indicate any potentially related manufacturing issue. The component has been subjected to lateral bending as the axis of the component results deviated from the original. This suggests that suboptimal usage occurred during the anchor's placement or that a not foreseeable condition of use required an excessive force, as the MectaLock PEEK anchors are supposed to be impacted axially only within the predrilled cylindrical pilot hole.		Corrective/Preventative Actions: The event is an isolated case and no systematic action is currently indicated as applicable, however, it has been included in our active monitoring system for potential CAPA needs and opportunities.		
Details of Similar Events: 1. MectaLock instruments 05.10.001 MectaLock PEEK Ø2.4 – Short driver Lot. 1924147: this is the 1st event for the family, the first for the reference and lot. This is the first case reported. From the beginning till today, 03-Mar-2021 we have sold 201 pieces considering short and long drivers. The occurrence rate is 1/201=0.5%		Additional Details (use for tables): 		
CAPA# Reference: 				
Risk Assessment				
Frequency: 	Severity: 			
Rating: 		Type Cause and Outcome: 	Number of Similar Events: 	
Expected Rate: 	Actual Rate: 			
Countries Similar Events Also Occurred: 				
Completed Actions: 		Planned Actions and Proposed Timelines: 		
Additional Comments: DIR was closed on 13/10/2021.				

Reason for Level 1 Investigation

Details of Reasons

Reason for Level 1 Investigation	Document 1

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected
EP1-Use may compromise patient health and safety	
EP2-Design/construction may not conform with principles	

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		30/08/2021	28/08/2021

Evidence

Investigation Questions (Level 1 and Level 2):

1.Please provide a detailed manufacturer’s investigation analysis to confirm that it adequately demonstrates the conformity with EP2 design and construction principles.

2.Please send a copy of Instructions for Use (IFU).

Potential Risks

Delays in response by product manufacturers:

☒

Delays in response by incident reporters:

☐

Delays in analysis within the TGA:

☐

Delays in reporting by other sources (e.g. clinical registries):

☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Case Closure

Click [N] to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details										
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	
☐		Sponsor Routine Correspondence	Sponsor Notification Letter		14/05/2021					
☐		TGA Regulatory Action	Regulatory Information Request (s41)		30/07/2021		28/08/2021		s41JA request to the sponsor, Trim number: D21-2903364 s41JA response from the sponsor, Trim number: D21-3154881	
☐		Email (non-regulatory)	Information Request		09/09/2021		09/09/2021		Email sent for obtaining IFU, Trim number: D21-3071339 IFU sent by the sponsor, Trim number: D21-3075072	
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		13/10/2021				Trim number: D21-3211403	

List of Problem Observed Codes - Click [N] to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Material Integrity Problem	Break	Fracture	

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Injury	Foreign Body In Patient	Device Embedded In Tissue or Plaque

Health Impact

Details

Level 1	Level 2	Level 3
Surgical Intervention	Device Revision or Replacement	

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Cause Not Established		

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested
Reviewed, No Further Action Required		

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR: 	Latest Investigation (DII) where this DIR is a Related DIR: 	Investigator: S22	Peer Review: No	
Investigator's Notes: Made a duplicate report after review of annual report and questionnaire response.		Summary Findings: A review of the manufacturer's analysis shows that the welding failed due to the component being subjected to stress of excessive lateral bending. The manufacturer notes that it is not possible to identify a clear or specific root cause for the mode of failure. A review of the warnings and precautions section in the Instructions for Use (IFU) has shown that the breakage of the MectaLock Suture Anchor can occur if any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor. The review of the risk management		Recall Number:

analysis document shows that all necessary actions have been implemented to minimize any potential risk associated with the laser welding integrity. In addition, this is supported by design verification and validation activities which confirmed the effectiveness of the device during its intended use. The sponsor notes that this is an isolated event and a review of the IRIS database has shown that there is only one similar adverse event which was investigated alongside with this DIR. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
						Who sent the device to the TGA?:			Why does the TGA have the sample?:

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disability?:	Consequence:

Other Consequence:	Describe any test (lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For: Document 1

Additional Device Information

Where did you get this device from?:	How reliant is the affected person on correct/safe operation of this device?:
Any other relevant information to aid assessing/investigating the incident?:	

Similar Events

Similar events - how many times?:	Date of Recent Report:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:
Fax:	Email:		

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Town/Suburb:	State:	Postcode:	

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 68516_Sponsor_Complete_Letter		169 Form	

Flow Details : DIR-REQ - Device Incident Request : 296794

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
296794	DIR-REQ		Closed	S22	OPR Administration User	13/10/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	S22	
Signed At	24/02/2022 09:40:47	
Comment		

s22

From: IRIS <IRIS@health.gov.au>
Sent: Friday, 14 May 2021 3:02 PM
To: s22 @medacta.com.au
Subject: DIR 68416 - Sponsor Notification Letter [SEC=OFFICIAL]
Attachments: DIR 68516 - Sponsor Notification Letter.pdf

Dear s22

Please see the attached letter in relation to DIR 68516 (0172-21) - MectaLock instruments MectaLock PEEK Ø2.4 – Short driver- Ligament anchor

Kind regards,

s22

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
 Devices Post Market Monitoring | Medical Devices Surveillance Branch
 Therapeutic Goods Administration (TGA)
 Australian Government Department of Health

Email: IRIS@health.gov.au
 Phone: DST s22
 Phone: IRIS 1800 809 361
 Post: PO Box 100, Woden, ACT 2606
 Courier: 136 Narrabundah Lane, Symonston, ACT 2609

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Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via <https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx>, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the [TGA website](#).

MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:

<https://apps.tga.gov.au/prod/mdir/udir03.aspx>

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.



Australian Government
Department of Health
Therapeutic Goods Administration

**Australian Medical Device
Incident Report Investigation Scheme**

s22
Medacta Australia Pty Ltd
Unit A1 / 16 Mars Road
LANE COVE NSW 2066
Email: s22@medacta.com.au

File Reference: E21-295890
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 68516 - ARTG # 320484 - Ligament anchor

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is being carried out alongside DIR 68783.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact our team on s22 or send an email to: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

14/05/2021

DIR 68516 - ARTG # 320484 - Ligament anchor

Reporter Reference #: 0172-21

Date of Adverse Event:

s22

Date of Initial Report:

05/03/2021

ARTG #:

320484

Brand Name:

MectaLock instruments MectaLock PEEK Ø2.4 – Short driver- Ligament anchor

Device Class:

Class IIb

Model #:

05.10.001

Serial #:

Software Version:

Batch #:

Lot #:

1924147

Manufacturer:

Medacta International SA [45296]

Sponsor:

Medacta Australia Pty Ltd [45972]

Unit A1 / 16 Mars Road

LANE COVE NSW 2066

Contact Name: s22

Phone:

Fax:

Email: s22@medacta.com.au

Reporter:

Mr s22

Complaint Coordinator

Medacta International SA

Strada Regina

Castel San Pietro TI 6874

Email: s22@medacta.ch

Confidential: N/A

Phone: s22

Fax:

Date of Implant:

s22

Date of Explant:

s22

Clinical Event Information:

The patient underwent a labral repair s22 Hip Arthroscopy. Two MectaLock (J-Lock) PEEK anchors were used to refixing the labrum to the acetabulum with no visual issues. Then the surgeon sent to the agent a picture of an X-ray asking if the image in the X-ray was part of the anchor inserter handle. It appears that a part of the inserter handle has remained in the bone with the anchor. The patient underwent revision surgery to remove the broken part.

The event was reported to the manufacturer on 29.01.2021, but only after the revision surgery, which took place on s22, we were sure that the piece that remained in the patient was part of the Medacta device.

Patient Outcome/Consequences:

Device Analysis Results:

Batch review performed on 23-Feb-2021:

Lot 1924147: 125 items manufactured and released on 24-Mar-2020. Expiration date: 2025-Feb-07. No anomalies found related to the problem. To date, 19 items of the same lot have been already sold without any other similar reported even.

Clinical Evaluation performed by Medical Affairs Director:

During an arthroscopic surgery of labrum refixation with a PEEK anchor, the tip of the positioning instrument broke, though the surgeon did not perceive the fracture. The tip of the instrument is visible in the postoperative X-rays, it remained in the cannulation of the anchor. We cannot determine the reasons for the fracture with the elements at hand.

No clinical cause could be ascertained. We were informed that a different surgeon intervened to remove the broken instrument part; the future clinical pathway of the patient should be totally flawless and no further consequences of the event should be expected.

Visual Inspection performed by R&D Project Manager:

The component of the MectaLock PEEK inserter has been received and analyzed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analyzed component resulted totally ruined and scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding. However, it's also evident that the component has been subjected to excessive lateral bending as the axis of the component results deviated from the original. This suggests that misuse could have occurred during the anchor's placement or that a not foreseeable condition of use required an excessive force, as the MectaLock PEEK anchors is supposed to be impacted axially only within the predrilled cylindrical pilot hole.

Conclusion:

The device history record review does not indicate any potentially related manufacturing issue. The component has been subjected to lateral bending as the axis of the component results deviated from the original. This suggests that suboptimal usage occurred during the anchor's placement or that a not foreseeable condition of use required an excessive force, as the MectaLock PEEK anchors are supposed to be impacted axially only within the predrilled cylindrical pilot hole.

Corrective/Preventative Actions:

The event is an isolated case and no systematic action is currently indicated as applicable, however, it has been included in our active monitoring system for potential CAPA needs and opportunities.

Details of Similar Events:

1. MectaLock instruments 05.10.001 MectaLock PEEK Ø2.4 – Short driver Lot. 1924147: this is the 1st event for the family, the first for the reference and lot.

This is the first case reported. From the beginning till today, 03-Mar-2021 we have sold 201 pieces considering short and long drivers. The occurrence rate is $1/201=0.5\%$

Date Completed:

End of DIR 68516

s22

From: s22@Health.gov.au>
Sent: Wednesday, 13 October 2021 5:15 PM
To: s22@medacta.com.au
Subject: Sponsor Completion Letter for DIR 68516 [SEC=OFFICIAL]
Attachments: [D21-3211403] DIR 68516_Sponsor_Complete_Letter.PDF

Dear s22,

Good afternoon. Please find attached sponsor completion letter for DIR 68516. Thanking you.

Kind regards,

Dr s22
Departmental Officer
Devices Post Market Monitoring
Medical Devices Surveillance Branch
Email: s22@health.gov.au
Telephone number : s22

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia

www.tga.gov.au

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Australian Government
Department of Health
Therapeutic Goods Administration

**Australian Medical Device
Incident Report Investigation Scheme**

s22
Medacta Australia Pty Ltd
Unit A1 / 16 Mars Road
LANE COVE NSW 2066
Email: **s22**@medacta.com.au

File Reference: E21-295890
Sent by email

Dear **s22**

DEVICE INCIDENT REPORT DIR 68516 - ARTG # 320484 - Ligament anchor

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact our team on **s22** or

send an email to: IRIS@health.gov.au

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

13/10/2021

DIR 68516 - ARTG # 320484 - Ligament anchor

Reporter Reference #: 0172-21

Date of Adverse Event:

s22

Date of Initial Report:

05/03/2021

ARTG #:

320484

Brand Name:

MectaLock instruments MectaLock PEEK Ø2.4 – Short driver- Ligament anchor

Device Class:

Class IIb

Model #:

05.10.001

Serial #:

Software Version:

Batch #:

Lot #:

1924147

Manufacturer:

Medacta International SA [45296]

Sponsor:

Medacta Australia Pty Ltd [45972]

Unit A1 / 16 Mars Road

LANE COVE NSW 2066

Contact Name: s22

Phone:

Fax:

Email: s22@medacta.com.au

Reporter:

Mr s22

Complaint Coordinator

Medacta International SA

Strada Regina

Castel San Pietro TI 6874

Email: s22@medacta.ch

Confidential: N/A

Phone: s22

Fax:

Date of Implant:

s22

Date of Explant:

s22

Clinical Event Information:

The patient underwent a labral repair s22 Hip Arthroscopy. Two MectaLock (J-Lock) PEEK anchors were used to refixing the labrum to the acetabulum with no visual issues. Then the surgeon sent to the agent a picture of an X-ray asking if the image in the X-ray was part of the anchor inserter handle. It appears that a part of the inserter handle has remained in the bone with the anchor. The patient underwent revision surgery to remove the broken part.

The event was reported to the manufacturer on 29.01.2021, but only after the revision surgery, which took place on s22, we were sure that the piece that remained in the patient was part of the Medacta device.

Patient Outcome/Consequences:

Device Analysis Results:

Batch review performed on 23-Feb-2021:

Lot 1924147: 125 items manufactured and released on 24-Mar-2020. Expiration date: 2025-Feb-07. No anomalies found related to the problem. To date, 19 items of the same lot have been already sold without any other similar reported even.

Clinical Evaluation performed by Medical Affairs Director:

During an arthroscopic surgery of labrum refixation with a PEEK anchor, the tip of the positioning instrument broke, though the surgeon did not perceive the fracture. The tip of the instrument is visible in the postoperative X-rays, it remained in the cannulation of the anchor. We cannot determine the reasons for the fracture with the elements at hand.

No clinical cause could be ascertained. We were informed that a different surgeon intervened to remove the broken instrument part; the future clinical pathway of the patient should be totally flawless and no further consequences of the event should be expected.

Visual Inspection performed by R&D Project Manager:

The component of the MectaLock PEEK inserter has been received and analyzed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analyzed component resulted totally ruined and scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding. However, it's also evident that the component has been subjected to excessive lateral bending as the axis of the component results deviated from the original. This suggests that misuse could have occurred during the anchor's placement or that a not foreseeable condition of use required an excessive force, as the MectaLock PEEK anchors is supposed to be impacted axially only within the predrilled cylindrical pilot hole.

Conclusion:

The device history record review does not indicate any potentially related manufacturing issue. The component has been subjected to lateral bending as the axis of the component results deviated from the original. This suggests that suboptimal usage occurred during the anchor's placement or that a not foreseeable condition of use required an excessive force, as the MectaLock PEEK anchors are supposed to be impacted axially only within the predrilled cylindrical pilot hole.

Corrective/Preventative Actions:

The event is an isolated case and no systematic action is currently indicated as applicable, however, it has been included in our active monitoring system for potential CAPA needs and opportunities.

Details of Similar Events:

1. MectaLock instruments 05.10.001 MectaLock PEEK Ø2.4 – Short driver Lot. 1924147: this is the 1st event for the family, the first for the reference and lot.

This is the first case reported. From the beginning till today, 03-Mar-2021 we have sold 201 pieces considering short and long drivers. The occurrence rate is $1/201=0.5\%$

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Clinical Signs (Level 1)

Injury

Health Impacts (Level 1)

Surgical Intervention

Clinical Signs (Level 2)

Foreign Body In Patient

Health Impacts (Level 2)

Device Revision or Replacement

Type of Problem (Level 1)
Material Integrity Problem

Type of Problem (Level 2)
Break

Cause of Problem (Level 1)

Cause of Problem (Level 2)

No Findings Available

Outcome of Investigation

Reviewed, No Further Action Required

Summary of Investigation:

A review of the manufacturer's analysis shows that the welding failed due to the component being subjected to stress of excessive lateral bending. The manufacturer notes that it is not possible to identify a clear or specific root cause for the mode of failure. A review of the warnings and precautions section in the Instructions for Use (IFU) has shown that the breakage of the MectaLock Suture Anchor can occur if any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor. The review of the risk management analysis document shows that all necessary actions have been implemented to minimize any potential risk associated with the laser welding integrity. In addition, this is supported by design verification and validation activities which confirmed the effectiveness of the device during its intended use. The sponsor notes that this is an isolated event and a review of the IRIS database has shown that there is only one similar adverse event which was also investigated alongside with this DIR. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:

End of DIR 68516



Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 517464

Released by §22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
68783	E21-259665	§22 ID 69823	Final
ARTG: 320484	Document Container URL		

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		§22	18/03/2021
Date of Final Report:	Date of Initial TGA Action:	Reviewed by Team:	Date Response Received:
18/03/2021	18/03/2021	23/03/2021	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter consents to contact by sponsor:
06/10/2021	Doctor		No
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Hospital Administrator		Trend data only	

Event Description for Website Publication:

Anchor introducer snapped off during surgery and not found until follow-up appointment with surgeon.

Clinical Event Information:

Patient was admitted into surgery for right hip arthroscopy and femoral osteotomy and labral repair on the [redacted], Anchor introducer found retained in patient on surgeon appointment. Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon. Additional surgery required for removal of retained anchor introducer on §22

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	Alternative Person Phone:	Alternative Person Fax:	Alternative Person Email:

Recorded Problems Observed

Recorded Problems Observed:

Material Integrity Problem -> Break -> Fracture

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Others -> Insufficient Information ->

Health Impact

Recorded Health Impacts:

Surgical Intervention -> Additional Surgery ->

Patient Information

Sex:	Weight:	Age:
§22		§22 old
Patient Focused Corrective Action Taken:		Patient History:
		NA
Patient Outcome/Consequences:		Additional Event Description:
Additional surgery required for removal of retained anchor introducer on §22		Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon.
Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:
NA	Temporary Injury	Other
Other medical devices currently using/implanted:	Medical Problem Device Used For:	Additional Patients Added:
		Additional surgery to retrieve item

0

Submitting Reporter Section

Search Reporter By Surname:

§22

Reporter Title:

MS

Position:

§22

Address 1:

§22

Country:

Australia

Mobile:

Reporter #:

First Name:

§22

Address 2:

Postcode:

§22

Email:

§22

Surname:

§22

Company/Institution:

§22

Town/Suburb:

§22

Phone:

§22

Last External Submission By:

Preferred Contact Method:

Email

State:

§22

Fax:

Initial Reporter Section

As Above?:

Yes

Search Reporter By Surname:

Title:

Position:

Address 1:

Postcode:

Mobile:

If No, fill out the following:

Initial Reporter #:

First Name:

Address 2:

Country:

Email:

Surname:

Company/Institution:

Town/Suburb:

Phone:

Allow the device company
to contact you about the incident:☐

Initial Reporter Confidential:

Preferred Contact Method:

Device Information Section

Product Exempt (Note: If not exempt, enter ARTG No):

No

Product Licence Category:

Included

Brand Name:

Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted,
non-biodegradable

Model #:

Purchase Date:

Date of Initial Procedure:

§22

Access Contact First Name:

Search Device ARTG:

320484

Device Class:

Class IIb

Initial Device Description:

J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-
biodegradable

Serial #:

Expiry Date:

17/07/2024

Place of Implantation:

Hip

Access Contact Surname:

Device ARTG #:

320484

GMDN / UMDN Code:

36174

Usage of Device:

Batch #:

Ref 05.11.001

Date of Implant:

§22

Reported Device Location:

Place of use

Access Contact Phone:

Therapeutic Licence Type:

Medical Device

GMDN / UMDN Text:

Ligament anchor

Software Version:

Lot #:

1954843

Date of Explant:

Access Contact Title:

Access Contact Fax:

Access Contact Email:

Licence Status:

A

Status Effective Date:

19/07/2019

Additional Devices Added:

0

Document 4

Manufacturer Information Section

Manufacturer Name:

Medacta International SA

Manufacturer Client Id:

45296

Address 1:

Address 2:

Town/Suburb:

State/Province:

Country:

Postcode:

Phone:

Fax:

Email:

Manufacturer Informed:

Date Aware of Adverse Event:

Contact Title:

Contact First Name:

Contact Surname:

Supplier Information Section

Supplier Name:

Medacta

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Australia

Postcode:

Phone:

Fax:

Email:

Website:

Supplier Informed:

Yes

Date of Supplier Contact:

01/03/2021

Contact Title:

Contact First Name:

Contact Surname:

Contact Phone:

Contact Fax:

Contact Email:

Report Status

For website publication:

Yes

Ready for Publication:

Yes

Investigated:

Yes

Investigation Reason:

More information is required

Team Assignment:

Team B (IIB, Is & Im)

Team Priority:

Routine

Team Review

Reviewed by Team:

23/03/2021

Reason Sent To Meeting:

User report

Outcome from team meeting:

Investigation (within DIR) is recommended

Notes for Team meeting:

No DIRs, PMRs or Recalls. User report. Sent to meeting as unsure if this is the correct ARTG. Reviewed on-line IFU and found no mention of an introducer, could this possibly be referring to a component of a surgical kit under a different ARTG entry? (<https://www.medacta.com/EN/resources-med-reviewed-ifu>)

Outcomes from Team Meeting:

Level 2 investigation, send questionnaire

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
18/03/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional			\$22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)	Level 1 Investigation (to complete screening)	Patient	0. No recalls for similar incidents in Australia

Incidents in last 36 months: 	IVD status: 	EXCEPTION TO INVESTIGATION LEVEL: Device not returned. Isolated incident, no other reports. May want to check if this is the correct ARTG entry - introducer may not be included in the ARTG entry may be a surgical kit component. https://www.medacta.com/EN/resources-med - reviewed IFU, no mention of "introducer"		Found Prior To Use: No	Is AE covered by Document 4: No
Incidents Worldwide: 	Number of potential contributing factors: Yes - some potential factors (up to 3)			Reusable: No	Similar events (past 6 months): 1 incidents
Products supplied the last 12 months: 	Specific factors identified: Use of device - according to IFUs, Use of device - interaction with other equipment	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine	3 or more events - batch/model: 	
Products supplied last 24 months: 	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL: 		3 or more events - health district: 	
Products supplied last 36 months: 	Specific sensitivities identified: 			3 or more events - organisation: 	
Products supplied Worldwide: 	Consultations during risk assessment: I did none of the above incidents	Final Risk Assessment: Yes			

Sponsor/Manufacturer Information Section

Search Sponsors: 45972	Name: Medacta Australia Pty Ltd	Client #: 45972
Attention To: §22	Address 1: Unit A1 / 16 Mars Road	Town/Suburb: LANE COVE
State: NSW	Postcode: 2066	Fax:
Email: §22@medacta.com.au		

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results: **Additional information received by Sponsor 03/06/2021** The component of the MectaLock PEEK inserter has been received and analysed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analysed component was received scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding. A deeper analysis on the safety of the device has been carried out by means of further mechanical investigation on equivalent devices sourced from the same production batch, as representative of the component object of this complaint. In particular, the welding between the shaft and the inserter tip has been subject to stress limit tests which confirmed the safety and reliability of the device under load conditions that are commonly expected during a surgery. Therefore, it's not possible to identify a clear or specific root cause for the mode of failure, unless an outstanding condition required a not foreseeable usage during the surgical procedure.	Details of Similar Events:
Additional Details (use for tables): 	CAPA# Reference:
Risk Assessment	
Frequency: 	Severity:
Rating: 	
Type Cause and Outcome: 	Number of Similar Events:
Expected Rate: 	Actual Rate:
Countries Similar Events Also Occurred: 	
Completed Actions: 	Planned Actions and Proposed Timelines:

Additional Comments:

Amended final received 03/06/2021, DIR updated

DIR was closed on 06/10/2021.

Reason for Level 1 Investigation

Details of Reasons

Reason for Level 1 Investigation

Focus of Level 2 Investigation

Details of Focus

Essential Principles

If 'Other' Selected

EP13-Information may not have been provided

EP2-Design/construction may not conform with principles

Sources of Evidence for Level 2

Details of Source

Sources of Evidence

If 'Others' please specify here

Expected Sourcing Date

Date of Evidence Received

Information from Sponsors (e.g. 41JA, Questionnaires, Emails)

27/04/2021

26/04/2021

Evidence

Investigation Questions (Level 1 and Level 2):

1.Please provide the response of the standard questionnaire which contains a detailed manufacturer's investigation analysis to confirm that it adequately demonstrates the conformity with EP2 design and construction principles.

2.Please send a copy of Instructions for Use (IFU).

Potential Risks

Delays in response by product manufacturers:



Delays in response by incident reporters:



Delays in analysis within the TGA:



Delays in reporting by other sources (e.g. clinical registries):



Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Case Closure

Click [N] to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	Document 4
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		26/03/2021	27/04/2021	26/04/2021			
☐		Reporter Routine Correspondence	Reporter Notification Letter		26/03/2021					
☐		TGA Regulatory Action	Regulatory Information Request (s41)		30/07/2021	30/08/2021	28/08/2021		s41JA request to the sponsor, Trim number: D21-2903364, s41JA response from the sponsor, Trim number: D21-3154881	
☐		Email (non-regulatory)	Information Request		09/09/2021	16/09/2021	09/09/2021		Email sent for obtaining IFU, TRIM number: D21-3071339 IFU sent by the sponsor, Trim number: D21-3075072	
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		06/10/2021				Trim number: D21-3178893	
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		06/10/2021				Trim number: D21-3178905	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Material Integrity Problem	Break	Fracture	

Clinical signs symptoms and conditions

Details	
Level 1	Level 2
Others	Insufficient Information

Health Impact

Details	
Level 1	Level 2
Surgical Intervention	Additional Surgery

Investigation Findings

Finding Details	
Investigation Findings (Level 1)	Investigation Findings (Level 2)
No Findings Available	

Investigation Conclusion

Conclusion Details	
Investigation Conclusion (L1)	Investigation Conclusion (L2)
Cause Not Established	

Investigation Outcomes

Outcome Details		
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested
Reviewed, No Further Action Required		

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	Peer Review Completion Date:
		s22	Yes	30/09/2021
Investigator's Notes:		Summary Findings:		Recall Number:
**To be Peer Reviewed by s22 **		A review of the manufacturer's analysis shows that the welding failed due to the component being subjected to stress of excessive lateral bending. The manufacturer notes that it is not possible to identify a clear or specific root cause for the mode of failure. A review of the warnings and precautions section in the Instructions for Use (IFU) has shown that the breakage of the MectaLock Suture Anchor can occur if any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor. The review of the risk management analysis document shows that all necessary actions have been implemented to minimize any potential risk associated with the laser welding integrity. In addition, this is supported by design verification and validation activities which confirmed the effectiveness of the device during its intended use. The sponsor notes that this is an isolated event and a review of the IRIS database has shown that there is only one similar adverse event. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.		

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
		Who sent the device to the TGA?:					Why does the TGA have the sample?:		

Additional Patients

Click [N] to begin entering information.

Patient Details	
Sex:	Weight:
Age:	
Patient History:	
Patient Focused Corrective Action Taken:	
Injured - Extent of Injury:	Was device directly linked to death?:
Was device directly linked to permanent disability?:	
Consequence:	
Other Consequence:	Describe any test (Lab, xray, etc.):
Additional Event Description:	
Medical Problem Device Used For:	

Additional Device Information

Where did you get this device from?:	How reliant is the affected person on correct/safe operation of this device?:
Supplier	
Any other relevant information to aid assessing/investigating the incident?:	

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:
Fax:	Email:		

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Yes		159 Grey Street	
Town/Suburb:	State:	Postcode:	
East Melbourne	VIC	3002	

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 68783 - Original User Report	431 Form		
FILE		R Amended DIR 68783 - Questionnaire Letter - R...	268 Form		
FILE		R Amended DIR 68783 - Questionnaire Letter - R...	1267 Form		

FILE		Peer Review Checklist	94	Form
FILE		DIR 68783_Reporter_Complete_Letter	158	Form
FILE		DIR 68783_Sponsor_Complete_Letter	162	Form

Document 4

Flow Details : DIR-REQ - Device Incident Request : 297807

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
297807	DIR-REQ		Closed	S22	OPR Administration User	06/10/2021 ✓	Normal	0

Signature Details

Role	IRIS Investigator	
User	S22	
Signed At	06/10/2021 11:14:31	
Comment		

s22

From: IRIS <IRIS@health.gov.au>
Sent: Friday, 26 March 2021 12:26 PM
To: s22
Subject: DIR 68783 - Reporter Notification Letter [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Attachments: DIR 68783 - Reporter Notification Letter.pdf

Dear s22

Please see the attached letter in relation to the Device Incident Report (DIR) that you submitted to the Therapeutic Goods Administration (TGA).

Kind regards,

s22

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
 Devices Post Market Monitoring | Medical Devices Surveillance Branch
 Therapeutic Goods Administration (TGA)
 Department of Health

Email: IRIS@health.gov.au
 Phone: DST s22
 Phone: IRIS 1800 809 361
 Post: PO Box 100, Woden, ACT 2606
 Courier: 136 Narrabundah Lane, Symonston, ACT 2609

***Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission. This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met*

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via <https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx>, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the [TGA website](#).

MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:

<https://apps.tga.gov.au/prod/mdir/udir03.aspx>

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.



Australian Government
Department of Health
 Therapeutic Goods Administration

**Australian Medical Device
 Incident Report Investigation Scheme**

MS s22
 Quality and Risk Consultant

File Reference: E21-259665
 Sent by email

s22
 s22
 s22

Email: s22

Dear MS s22,

**DEVICE INCIDENT REPORT DIR 68783 - Medacta J-Lock PEEK Suture - Anchor, soft-tissue
 implanted, non-biodegradable**

Thank you for your recent correspondence concerning a problem experienced with the above device.

The information you provided has been entered into the Medical Device Incident Report Investigation (IRIS) Database, where it will be evaluated against any previous incidents with the same or similar devices. This report is currently under investigation and a copy of the Device Incident Report (DIR) is attached for your reference.

Should you have any questions, please contact our team on s22 or email: IRIS@health.gov.au quoting the above DIR number. The TGA may contact you regarding this report.

Assistance and information regarding product refunds, returns or product compensation should be addressed with the Australian Competition and Consumer Commission (ACCC) via

<https://www.accc.gov.au/consumers/complaints-problems>

If you would like to lodge a complaint regarding the clinical practice of an Australian healthcare professional you should contact the Australian Health Practitioner Regulation Agency (AHPRA) via <https://www.ahpra.gov.au/notifications/make-a-complaint.aspx>, or the Health Care Complaints Commission within your State or Territory. More information on the respective State and Territory health complaint organisations can be accessed via

<https://www.ahpra.gov.au/notifications/further-information/health-complaints-organisations.asp>

Thank you for your support of the Medical Device Incident Report Investigation Scheme.

Yours sincerely
 Signed electronically by

Administrative Officer

Incident Report Investigation Scheme
 Devices Post Market Monitoring Section
 Therapeutic Goods Administration
 26/03/2021

DIR 68783 - Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable

Reporter Reference #: s22 ID 69823

Date of Adverse Event:

s22

Date of Final Report:

18/03/2021

ARTG #:
330998Brand Name:
Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted,
non-biodegradableDevice Class:
Class IIb

Model #:

Serial #:

Software Version:

Batch #:
Ref 05.11.001Lot #:
1954843Manufacturer:
Medacta International SASponsor:
Medacta Australia Pty Ltd
Unit A1 / 16 Mars Road
LANE COVE NSW 2066

Contact Name:

s22

Phone:

s22

Reporter:

Confidential: Yes

Date of Implant:

s22

Date of Explant:

Clinical Event Information:

Patient was admitted into surgery for right hip arthroscopy and femoral osteotomy and labral repair on the [redacted], Anchor introducer found retained in patient on surgeon appointment. Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon. Additional surgery required for removal of retained anchor introducer on s22

Patient Outcome/Consequences:

Additional surgery required for removal of retained anchor introducer on s22

Additional Event Description:

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon.

End of DIR 68783

s22

From: IRIS <IRIS@health.gov.au>
Sent: Friday, 26 March 2021 12:30 PM
To: s22 @medacta.com.au
Subject: DIR 68783 - Questionnaire Letter - Response due COB 27/03/2021 [SEC=OFFICIAL]
Attachments: DIR 68783 - Questionnaire Letter.rtf

Dear s22

Please see the attached **Questionnaire Letter** for action.
***Please note the due date for a response is COB 27 March 2021.**

Kind regards,

s22

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
 Devices Post Market Monitoring | Medical Devices Surveillance Branch
 Therapeutic Goods Administration (TGA)
 Department of Health

Email: IRIS@health.gov.au
 Phone: DST s22
 Phone: IRIS 1800 809 361
 Post: PO Box 100, Woden, ACT 2606
 Courier: 136 Narrabundah Lane, Symonston, ACT 2609

***Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission. This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met*

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via <https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx>, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the [TGA website](#).

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For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.



Australian Government

Department of Health
Therapeutic Goods Administration

**Australian Medical Device
Incident Report Investigation Scheme**

s22

Medacta Australia Pty Ltd
Unit A1 / 16 Mars Road
LANE COVE NSW 2066
Email: s22@medacta.com.au

File Reference: E21-259665

Sent by email

Dear s22

**DEVICE INCIDENT REPORT DIR 68783 - ARTG # 330998 - Anchor, soft-tissue implanted,
non-biodegradable**

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter**, and no later than COB 27/04/2021.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

s22 or email: IRIS@health.gov.au.

Yours sincerely
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

26/03/2021

**- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR**

Document 6

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR

Date: 26/03/2021

DIR: 68783

Manufacturer Name: Medacta International SA [45296]

Question/Requirement

1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number

ARTG:

2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:

- a) To the Australian Market
- b) For Export

YES

NO

☐
☐☐
☐

3) How many of this model have been supplied

In Australia:

Worldwide:

4) How many of this batch (if applicable) have been supplied:

In Australia:

Worldwide:

5) Are you aware of this problem, as reported?

☐☐

6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?

☐☐

7) Have you had any other reports of similar* problems with this product in Australia?

☐☐

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product?

☐

Document 6

☐

If **YES**, how many:

If **YES**, please give details:

9) Please provide details of any action you have taken, or intend to take, regarding this problem

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

☐

Sample of the product/device

☐

Operator's manual

☐

Product Specifications

☐

Technical Service Manual

☐

Descriptive product promotional documentation

☐

Clinical training manual in printed or video form

☐

Instructions for use, as supplied with the device

☐

In-house training documentation

☐

Device Packaging with printed instructions

☐

Evidence of compliance with the Essential Principles

☐

A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.

☐

Service History, and Safety and Performance Test Results

☐

Configuration Information and Documentation

☐

HHE (Health Hazard Evaluation)

12) Additional Information required:

Document 6

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name		Phone	
Signature		Fax	
Position		Email	

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.

Please send the requested information to email address: IRIS@health.gov.au

Document 6

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

<https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use>

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

Reporter Reference #: s22 ID 69823

Date of Adverse Event:
s22Date of Final Report:
18/03/2021

ARTG #:	Brand Name:	
330998	Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable	
Device Class:	Model #:	Serial #:
Class IIb		
Software Version:	Batch #:	Lot #:
	Ref 05.11.001	1954843

Manufacturer:
Medacta International SA [45296]Sponsor:
Medacta Australia Pty Ltd [45972]
Unit A1 / 16 Mars Road
LANE COVE NSW 2066

Contact Name: s22

Phone: s22

Email: s22@medacta.com.au

Fax:

Reporter:

Confidential: Yes

Date of Implant:
s22

Date of Explant:

Clinical Event Information:

Patient was admitted into surgery for right hip arthroscopy and femoral osteotomy and labral repair on the [redacted], Anchor introducer found retained in patient on surgeon appointment.

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon. Additional surgery required for removal of retained anchor introducer on s22

Patient Outcome/Consequences:

Additional surgery required for removal of retained anchor introducer on s22

Additional Event Description:

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

s22

From: IRIS <IRIS@health.gov.au>
Sent: Friday, 26 March 2021 12:33 PM
To: s22 @medacta.com.au
Subject: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021
 [SEC=OFFICIAL]
Attachments: DIR 68783 - Questionnaire Letter.rtf

Dear s22

Please see the amended due date for a response is **COB 27 April 2021**.

Sorry for the confusion.

Kind regards,

s22

Device Support Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch
 Therapeutic Goods Administration (TGA)
 Department of Health

Email: IRIS@health.gov.au

Phone: DST s22

Phone: IRIS 1800 809 361

Post: PO Box 100, Woden, ACT 2606

Courier: 136 Narrabundah Lane, Symonston, ACT 2609

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<https://apps.tga.gov.au/prod/mdir/udir03.aspx>

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.

From: IRIS

Sent: Friday, 26 March 2021 12:30 PM

To: s22 [REDACTED]@medacta.com.au' s22 [REDACTED]@medacta.com.au>

Subject: DIR 68783 - Questionnaire Letter - Response due COB 27/03/2021 [SEC=OFFICIAL]

Dear s22 [REDACTED]

Please see the attached **Questionnaire Letter** for action.

***Please note the due date for a response is COB 27 March 2021.**

Kind regards,

s22 [REDACTED]

Device Support Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch

Therapeutic Goods Administration (TGA)

Department of Health

Email: IRIS@health.gov.au

Phone: DST s22 [REDACTED]

Phone: IRIS 1800 809 361

Post: PO Box 100, Woden, ACT 2606

Courier: 136 Narrabundah Lane, Symonston, ACT 2609

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Australian Government

Department of Health
Therapeutic Goods Administration

**Australian Medical Device
Incident Report Investigation Scheme**

s22

Medacta Australia Pty Ltd
Unit A1 / 16 Mars Road
LANE COVE NSW 2066
Email: s22@medacta.com.au

File Reference: E21-259665

Sent by email

Dear s22

**DEVICE INCIDENT REPORT DIR 68783 - ARTG # 330998 - Anchor, soft-tissue implanted,
non-biodegradable**

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter**, and no later than COB 27/04/2021.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

s22 or email: IRIS@health.gov.au.

Yours sincerely
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

26/03/2021

**- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR**

Document 7

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR

Date: 26/03/2021

DIR: 68783

Manufacturer Name: Medacta International SA [45296]

Question/Requirement

1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number

ARTG:

2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:

- a) To the Australian Market
- b) For Export

YES

NO

☐
☐☐
☐

3) How many of this model have been supplied

In Australia:

Worldwide:

4) How many of this batch (if applicable) have been supplied:

In Australia:

Worldwide:

5) Are you aware of this problem, as reported?

☐☐

6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?

☐☐

7) Have you had any other reports of similar* problems with this product in Australia?

☐☐

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product?

☐

Document 7

☐

If **YES**, how many:

If **YES**, please give details:

9) Please provide details of any action you have taken, or intend to take, regarding this problem

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

☐

Sample of the product/device

☐

Operator's manual

☐

Product Specifications

☐

Technical Service Manual

☐

Descriptive product promotional documentation

☐

Clinical training manual in printed or video form

☐

Instructions for use, as supplied with the device

☐

In-house training documentation

☐

Device Packaging with printed instructions

☐

Evidence of compliance with the Essential Principles

☐

A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.

☐

Service History, and Safety and Performance Test Results

☐

Configuration Information and Documentation

☐

HHE (Health Hazard Evaluation)

12) Additional Information required:

Document 7

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name		Phone	
Signature		Fax	
Position		Email	

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.

Please send the requested information to email address: IRIS@health.gov.au

Document 7

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Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

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Reporter Reference #: s22 ID 69823

Date of Adverse Event:
s22Date of Final Report:
18/03/2021

ARTG #:	Brand Name:	
330998	Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable	
Device Class:	Model #:	Serial #:
Class IIb		
Software Version:	Batch #:	Lot #:
	Ref 05.11.001	1954843

Manufacturer:
Medacta International SA [45296]Sponsor:
Medacta Australia Pty Ltd [45972]
Unit A1 / 16 Mars Road
LANE COVE NSW 2066

Contact Name: s22

Phone: s22

Email: s22@medacta.com.au

Fax:

Reporter:

Confidential: Yes

Date of Implant:
s22

Date of Explant:

Clinical Event Information:

Patient was admitted into surgery for right hip arthroscopy and femoral osteotomy and labral repair on the [redacted], Anchor introducer found retained in patient on surgeon appointment.

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon. Additional surgery required for removal of retained anchor introducer on s22

Patient Outcome/Consequences:

Additional surgery required for removal of retained anchor introducer on s22

Additional Event Description:

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

s22

From: s22@medacta.com.au>
Sent: Friday, 26 March 2021 12:52 PM
To: IRIS
Subject: Re: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Thank you for your correspondence. We will attend to this as soon as possible

s22
s22
Medacta Australia
s22

On 26 Mar 2021, at 12:33, IRIS <IRIS@health.gov.au> wrote:

Dear s22

Please see the amended due date for a response is **COB 27 April 2021**.

Sorry for the confusion.

Kind regards,

s22

Device Support Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health

Email: IRIS@health.gov.au

Phone: DST s22

Phone: IRIS 1800 809 361

Post: PO Box 100, Woden, ACT 2606

Courier: 136 Narrabundah Lane, Symonston, ACT 2609

<image001.gif>

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From: IRIS

Sent: Friday, 26 March 2021 12:30 PM

To: **s22** @medacta.com.au' **s22** @medacta.com.au>

Subject: DIR 68783 - Questionnaire Letter - Response due COB 27/03/2021 [SEC=OFFICIAL]

Dear **s22**

Please see the attached **Questionnaire Letter** for action.

***Please note the due date for a response is COB 27 March 2021.**

Kind regards,

s22

Device Support Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch

Therapeutic Goods Administration (TGA)

Department of Health

Email: IRIS@health.gov.au

Phone: **DST** **s22**

Phone: **IRIS** 1800 809 361

Post: PO Box 100, Woden, ACT 2606

Courier: 136 Narrabundah Lane, Symonston, ACT 2609

<image001.gif>

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<http://www.mailguard.com.au>

[Report this message as spam](#)

<DIR 68783 - Questionnaire Letter.rtf>

Message protected by MailGuard: e-mail anti-virus, anti-spam and content filtering.

<http://www.mailguard.com.au>

s22

From: s22@medacta.ch>
Sent: Monday, 26 April 2021 6:40 PM
To: IRIS
Cc: s22; s22; s22
Subject: R: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021 [SEC=OFFICIAL]
Attachments: DIR 68783 - Questionnaire Letter signed.pdf; ANNEX 1 (Analysis).pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear all,
 as per your request you will find attached the Questionnaire Letter related to the DIR 68783.
 The complaint was registered as Medacta number 0172-21 and already communicated to the TGA with the DIR 68516.
 The item involved in the event is available and it will be sent to your attention as soon as possible.
 Do not hesitate to contact me if you have any issues,
 Kind regards

s22 s22 <i>Regulatory Affairs Department</i> s22@medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 Mob: s22 Fax: +41 91 696 60 66
---	--

From: IRIS <IRIS@health.gov.au>
Date: 26 March 2021 at 12:33:06 AEDT
To: s22@medacta.com.au>
Subject: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021 [SEC=OFFICIAL]

Dear s22
 Please see the amended due date for a response is **COB 27 April 2021**.
 Sorry for the confusion.
 Kind regards,
 s22
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
 Devices Post Market Monitoring | Medical Devices Surveillance Branch
 Therapeutic Goods Administration (TGA)
 Department of Health
 Email: IRIS@health.gov.au
 Phone: DST s22
 Phone: IRIS 1800 809 361
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MDIR Technical assistance is available via [s22](#) or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:

<https://apps.tga.gov.au/prod/mdir/udir03.aspx>

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From: IRIS

Sent: Friday, 26 March 2021 12:30 PM

To: [s22](#) @medacta.com.au' [s22](#) @medacta.com.au>

Subject: DIR 68783 - Questionnaire Letter - Response due COB 27/03/2021 [SEC=OFFICIAL]

Dear [s22](#)

Please see the attached **Questionnaire Letter** for action.

***Please note the due date for a response is COB 27 March 2021.**

Kind regards,

[s22](#)

Device Support Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch

Therapeutic Goods Administration (TGA)

Department of Health

Email: IRIS@health.gov.au

Phone: **DST** [s22](#)

Phone: **IRIS** 1800 809 361

Post: PO Box 100, Woden, ACT 2606

Courier: 136 Narrabundah Lane, Symonston, ACT 2609

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MDIR Technical assistance is available via [s22](#) or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

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<https://apps.tga.gov.au/prod/mdir/udir03.aspx>

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**- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR**

Document 9

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR

Date: 26/04/2021

DIR: 68783

Manufacturer Name: Medacta International SA [45296]

Question/Requirement

1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number

ARTG: 320484

2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:

- a) To the Australian Market
- b) For Export

YES

NO

☒

☐

☒

☐

3) How many of this model have been supplied

In Australia:

s47

Worldwide:

s47

4) How many of this batch (if applicable) have been supplied:

In Australia:

s47

Worldwide:

s47

5) Are you aware of this problem, as reported?

☒

☐

6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?

☒

☐

7) Have you had any other reports of similar* problems with this product in Australia?

☐

☒

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product?

☐

Document 9

☒

If **YES**, how many:

If **YES**, please give details:

9) Please provide details of any action you have taken, or intend to take, regarding this problem

The event is an isolated case and no systematic action is currently indicated as applicable, however it has been included in our active monitoring system for potential CAPA needs and opportunities.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: 19-May-2021

See the annex 1 attached (Analysis)

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

☒

Sample of the product/device

☐

Operator's manual

☐

Product Specifications

☐

Technical Service Manual

☐

Descriptive product promotional documentation

☐

Clinical training manual in printed or video form

☐

Instructions for use, as supplied with the device

☐

In-house training documentation

☐

Device Packaging with printed instructions

☐

Evidence of compliance with the Essential Principles

☐

A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.

☐

Service History, and Safety and Performance Test Results

☐

Configuration Information and Documentation

☐

HHE (Health Hazard Evaluation)

12) Additional Information required:

Document 9

The complaint was registered as Medacta number 0172-21 and communicated to the TGA with the DIR 68516.

Comparing the data received from you with the DIR 68783, you will find here below the incongruence we have found:

Correct data:

ARTG number: 320484

Primary surgery date s22

Lot: 1924147

Correct data:

ARTG number: 330998

Primary surgery date s22

Lot: 1954843

The ARTG number specified in the document (330998) is not correct because related to all-suture anchors while the event is related to PEEK anchors (ARTG n° 320484).

13) If your device is an implantable pacemaker / defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name s22

Phone s22

Signature

Fax s22

Position s22

Email s22@medacta.ch

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.

Please send the requested information to email address: IRIS@health.gov.au

Document 9

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

<https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use>

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

Reporter Reference #: s22 ID 69823

Date of Adverse Event:

s22

Date of Final Report:

18/03/2021

ARTG #:	Brand Name:	
330998	Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable	
Device Class:	Model #:	Serial #:
Class IIb		
Software Version:	Batch #:	Lot #:
	Ref 05.11.001	1954843

Manufacturer:

Medacta International SA [45296]

Sponsor:

Medacta Australia Pty Ltd [45972]

Unit A1 / 16 Mars Road

LANE COVE NSW 2066

Contact Name: s22

Phone: s22

Email: s22@medacta.com.au

Fax:

Reporter:

Confidential: Yes

Date of Implant:

s22

Date of Explant:

Clinical Event Information:

Patient was admitted into surgery for right hip arthroscopy and femoral osteotomy and labral repair on the [redacted], Anchor introducer found retained in patient on surgeon appointment.

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon. Additional surgery required for removal of retained anchor introducer on s22

Patient Outcome/Consequences:

Additional surgery required for removal of retained anchor introducer on s22

Additional Event Description:

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

ANNEX 1 (Analysis)**Clinical Evaluation performed by S22 :**

During an arthroscopic surgery of labrum refixation with a PEEK anchor, the tip of the positioning instrument broke, though the surgeon did not perceive the fracture. The tip of the instrument is visible in the postoperative Xrays, it remained in the cannulation of the anchor. We cannot determine the reasons for the fracture with the elements at hand. No clinical cause could be ascertained. We were informed that a different surgeon intervened to remove the broken instrument part; the future clinical pathway of the patient should be totally flawless and no further consequences of the event should be expected.

Visual Inspection performed by S22 :

The component of the MectaLock PEEK inserter has been received and analysed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analysed component resulted totally ruined and scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding. However, it's also evident that the component has been subjected to excessive lateral bending as the axis of the component results deviated from the original. This suggests that a misuse occurred during the anchor's placement as the MectaLock PEEK anchors is supposed to be impacted axially only within the predrilled cylindrical pilot hole.

Batch review performed on 23-Feb-2021

Lot 1924147: 125 items manufactured and released on 24-Mar-2020. Expiration date: 2025-Feb-07. No anomalies found related to the problem. To date, 19 items of the same lot have been already sold without any other similar reported event

s22

From: s22@Health.gov.au>
Sent: Wednesday, 5 May 2021 6:00 PM
To: s22@svha.org.au
Subject: Sample received DIR 68783 [SEC=OFFICIAL]

Dear MS s22,

Thank you for the sample you have sent to the TGA in regards to your Device Incident report (DIR) 68783 for the (J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable) . The TGA has limited testing capabilities upon receipt of a device and the best way to have a device tested is to send it back to the manufacturer for analysis. The TGA is seeking your permission to send the device onto the manufacturer for extensive testing to assist us with the investigation of the DIR. Without this analysis a root cause would not be able to be determined.

If you do not wish for us to send it to the sponsor for this analysis we are able to send it back to you should you wish to seek independent testing. Again, thanking you.

Kind regards,

Dr s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch
 Email: s22@health.gov.au
 Telephone number : s22

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia

www.tga.gov.au

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P *Please consider the environment before printing this email.*

s22

From: s22@Health.gov.au>
Sent: Wednesday, 12 May 2021 5:06 PM
To: s22
Subject: RE: DIR 68783 [SEC=OFFICIAL]

Hi s22

Thanks a lot for getting back to me. I think we don't need to take any photos of the device and thanks for suggesting though. Please, let me know when you have sent samples and I will send an email to the sponsor letting know about that. Again, thanking you.

Kind regards,

Dr s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch
 Email: s22@health.gov.au
 Telephone number : s22

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia

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From: s22@health.gov.au>
Sent: Wednesday, 12 May 2021 1:21 PM
To: s22@Health.gov.au>
Subject: RE: DIR 68783 [SEC=OFFICIAL]

Hi s22

No Problem we can send it on.
 Would you like us to take any photos of the device.
 If not I will organise for it to out tomorrow.

Happy to do whatever is required.

Kind regards

s22

From: s22@Health.gov.au>
Sent: Wednesday, 12 May 2021 12:38 PM
To: s22@health.gov.au>
Subject: DIR 68783 [SEC=OFFICIAL]

Dear s22

Good afternoon. We recently received the sample from the reporter (s22) regarding DIR 68783 and the sample has been passed to the lab team as it is biohazard. After getting the permission from the reporter, we would like to send the sample to the sponsor as a part of our investigation process.

The address details of the sponsor is given below:

Name: s22
Sponsor's name: Medacta Australia Pty Ltd
Unit A1/ 16 Mars Road LANE COVE
NSW 2066
Contact number : s22

I would really appreciate if the sample is sent to the sponsor by the lab. Please, let me know if you need any further information regarding this. Again, thanking you.

Kind regards,

Dr s22
Departmental Officer
Devices Post Market Monitoring
Medical Devices Surveillance Branch
Email: s22@health.gov.au
Telephone number : s22

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia

www.tga.gov.au

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s22

From: s22@medacta.com.au>
Sent: Tuesday, 22 June 2021 11:37 AM
To: s22
Cc: s22; s22
Subject: RE: DIR 68783 [SEC=OFFICIAL]
Attachments: final_report_0172-21.pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Dr s22

Please find attached the internal analysis your require in relation to DIR 68783.

Please do not hesitate to contact me if I can be of further assistance

Yours faithfully

s22

s22

s22

s22@medacta.com.au
www.medacta.com

Medacta Australia
 Unit A1, 16 Mars Road
 Lane Cove, NSW 2066
 Australia
 Pho: s22
 Mob: s22
 Fax: +612 9420 2578

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We would be grateful if you would also copy the communication to customerservice@medacta.com.au

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From: s22@Health.gov.au>
Sent: Friday, 11 June 2021 3:43 PM
To: s22@medacta.com.au>
Subject: RE: DIR 68783 [SEC=OFFICIAL]

Hi s22

Good afternoon. We contacted you previously to provide us the detailed device analysis of the specimen for DIR 68783 (J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable). Please provide us the detailed device analysis of the specimen received from s22 by COB 2 July, 2021. Again, thanking you.

Kind regards,

Dr s22

Departmental Officer

Devices Post Market Monitoring

Medical Devices Surveillance Branch

Email: s22@health.gov.au

Telephone number : s22

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

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P Please consider the environment before printing this email.

From: s22

Sent: Tuesday, 25 May 2021 9:46 AM

To: s22@medacta.com.au' s22@medacta.com.au>

Subject: DIR 68783 [SEC=OFFICIAL]

Dear s22,

Good morning. We recently received the sample regarding DIR 68783 (J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable) from the reporter (s22). The sample was sent by TGA Lab after seeking permission from the reporter on last week by courier. Could you please provide a date analysis of this specimen for our review which is a part of our investigation ? Again, thanking you.

Kind regards,

Dr s22

Departmental Officer

Devices Post Market Monitoring

Medical Devices Surveillance Branch

Email: s22@health.gov.au

Telephone number : s22

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

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<http://www.mailguard.com.au>

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Complaint nr:	0	1	7	2	-	2	1
	COMPLAINT NUMBER				YEAR		

1. EVENT NOTIFICATION

Reported by	s22	Company name	MEDACTA AUSTRALIA Pty. Ltd
Country	Australia	Date of complaint	January 29, 2021
Surgeon	Mr s22	Hospital	s22
Surgeon of the primary surgery	Mr s22	Date of primary surgery	s22
Surgeon of the revision surgery	Mr s22	Date of revision surgery	s22

2. DEVICES INVOLVED

Product Family	Reference n.	Product Description	Lot n.	SN	Qty
MectaLock instruments	05.10.001	MectaLock PEEK Ø2.4 – Short driver	1924147	NA	1

3. EVENT DESCRIPTION

The patient underwent a labral repair (s22), Hip Arthroscopy. Two MectaLock (J-Lock) PEEK anchors were used for refixing the labrum to the acetabulum with no visual issues. Then the surgeon sent to the agent a picture of an X-ray asking if the image in the X-ray was part of the anchor inserter handle. It appears that a part of the inserter handle has remained in the bone with the anchor. The patient underwent revision surgery to remove the broken part.

The event was reported to the manufacturer on 29.01.2021, but only after the revision surgery, which took place on s22, we were sure that the piece that remained in the patient was part of the Medacta device.

4. INVESTIGATION RESULTS

Clinical Evaluation performed by Medical Affairs Director:

During an arthroscopic surgery of labrum refixation with a PEEK anchor, the tip of the positioning instrument broke, though the surgeon did not perceive the fracture. The tip of the instrument is visible in the postoperative X-rays, it remained in the cannulation of the anchor. We cannot determine the reasons for the fracture with the elements at hand.

No clinical cause could be ascertained. We were informed that a different surgeon intervened to remove the broken instrument part; the future clinical pathway of the patient should be totally flawless and no further consequences of the event should be expected.



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Complaint nr:	0	1	7	2	-	2	1
	COMPLAINT NUMBER				YEAR		

Visual Inspection performed by R&D Project Manager:

The component of the MectaLock PEEK inserter has been received and analyzed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analyzed component was received scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding. A deep analysis of the device has been carried out by means of mechanical testing of equivalent devices sourced from the same production batch as representative of the component involved in this complaint. In particular, the welding between the shaft and the inserter tip has been subjected to stress limit tests which confirmed the safety and reliability of the device under load conditions that are commonly expected during surgery. Therefore, it's not possible to identify a clear or specific root cause for the mode of failure, unless an outstanding condition required an unforeseeable usage during the surgical procedure.



Batch review performed on 23-Feb-2021

Lot 1924147: 125 items manufactured and released on 24-Mar-2020. Expiration date: 2025-Feb-07. No anomalies found related to the problem. To date, 19 items of the same lot have been sold without any similar reported event.

5. ROOT CAUSE

The device history record review does not indicate any potentially related manufacturing issue. Mechanical testing has confirmed reliability of the device under foreseeable loading conditions. It could be that anomalous conditions of application may have resulted in the breakage but no confirmation can be made in this case.

6. CORRECTIVE/PREVENTIVE ACTIONS

The event is an isolated case and no systematic action is currently indicated as applicable, however it has been included in our active monitoring system for potential CAPA needs and opportunities.

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Complaint nr:	0	1	7	2	-	2	1
	COMPLAINT NUMBER				YEAR		

	Function	Name	Signature	Date
Prepared by:	s22	s22	Electronic legal signature	June 01, 2021
Completed by:	s22	s22	Electronic legal signature	June 02, 2021
Verified by: (only if needed)	s22	s22	Electronic legal signature	June 02, 2021

s22

From: s22@medacta.ch>
Sent: Thursday, 3 June 2021 1:16 AM
To: IRIS
Cc: s22; s22
Subject: R: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021 [SEC=OFFICIAL]
Attachments: Internal analysis - Complaint 0172-21 DIR 68516.pdf

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Dear all,

considering the Medacta complaint number **0172-21**, already reported to the TGA with the **DIR 68516**, we have performed some additional tests that you will find summarized in the attachment. Given that the final report (**DIR 68516**) was already sent to the TGA I kindly ask you to update the Visual Inspection previously reported as follows:

The component of the MectaLock PEEK inserter has been received and analysed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analysed component was received scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding.

A deeper analysis on the safety of the device has been carried out by means of further mechanical investigation on equivalent devices sourced from the same production batch, as representative of the component object of this complaint. In particular, the welding between the shaft and the inserter tip has been subject to stress limit tests which confirmed the safety and reliability of the device under load conditions that are commonly expected during a surgery. Therefore, it's not possible to identify a clear or specific root cause for the mode of failure, unless an outstanding condition required a not foreseeable usage during the surgical procedure.

In addition, as per your below request named **DIR 68783**, you should have received the item involved in the Medacta complaint number **0172-21** that was sent to your attention. Please, let us know if any additional information is requested.

Thank you for your collaboration.

Kind regards,

s22
s22
Regulatory Affairs Department
s22@medacta.ch
www.medacta.ch

Medacta International SA

Strada Regina
CH-6874 Castel San Pietro
Switzerland
Pho: s22
Mob: s22
Fax: +41 91 696 60 66

Da: s22
Inviato: lunedì 26 aprile 2021 10:40
A: 'IRIS@health.gov.au' <IRIS@health.gov.au>

Cc: s22 [REDACTED]@medacta.com.au>; s22 [REDACTED]@medacta.com.au>; s22 [REDACTED]
s22 [REDACTED]@medacta.ch>

Oggetto: R: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021 [SEC=OFFICIAL]

Dear all,

as per your request you will find attached the Questionnaire Letter related to the DIR 68783.

The complaint was registered as Medacta number 0172-21 and already communicated to the TGA with the DIR 68516.

The item involved in the event is available and it will be sent to your attention as soon as possible.

Do not hesitate to contact me if you have any issues,
Kind regards

s22 [REDACTED] Complaint Coordinator <i>Regulatory Affairs Department</i> s22 [REDACTED] @medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 [REDACTED] Mob: s22 [REDACTED] Fax: +41 91 696 60 66
---	--

From: IRIS <IRIS@health.gov.au>

Date: 26 March 2021 at 12:33:06 AEDT

To: s22 [REDACTED]@medacta.com.au>

Subject: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021
[SEC=OFFICIAL]

Dear s22 [REDACTED]

Please see the amended due date for a response is **COB 27 April 2021**.

Sorry for the confusion.

Kind regards,

s22 [REDACTED]

Device Support Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health

Email: IRIS@health.gov.au

Phone: **DST** s22 [REDACTED]

Phone: **IRIS** 1800 809 361

Post: PO Box 100, Woden, ACT 2606

Courier: 136 Narrabundah Lane, Symonston, ACT 2609

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Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via <https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx>, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the [TGA website](#).

MDIR Technical assistance is available via [s22](#) or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:

<https://apps.tga.gov.au/prod/mdir/udir03.aspx>

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.

From: IRIS

Sent: Friday, 26 March 2021 12:30 PM

To: [s22](#) @medacta.com.au' [s22](#) @medacta.com.au>

Subject: DIR 68783 - Questionnaire Letter - Response due COB 27/03/2021 [SEC=OFFICIAL]

Dear [s22](#)

Please see the attached **Questionnaire Letter** for action.

***Please note the due date for a response is COB 27 March 2021.**

Kind regards,

[s22](#)

Device Support Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch

Therapeutic Goods Administration (TGA)

Department of Health

Email: IRIS@health.gov.au

Phone: **DST** [s22](#)

Phone: **IRIS** 1800 809 361

Post: PO Box 100, Woden, ACT 2606

Courier: 136 Narrabundah Lane, Symonston, ACT 2609

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MDIR Technical assistance is available via [s22](#) or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:

<https://apps.tga.gov.au/prod/mdir/udir03.aspx>

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Analysis definition

The receipt of the broken component (inserter tip only) initiated an investigation procedure in place within the internal Medacta Quality System in order to assess the reliability of the parts currently on stock and to get the confirmation of the reliability of the current design of the device (fully assembled component: J-Lock inserter - Ø2.4, ref. 66.03.020).



Figure 1 - Received component

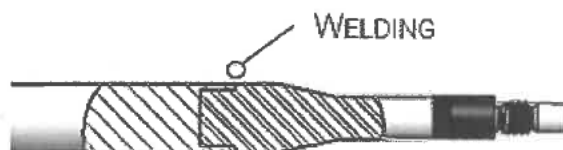


Figure 2 - Tip assembly

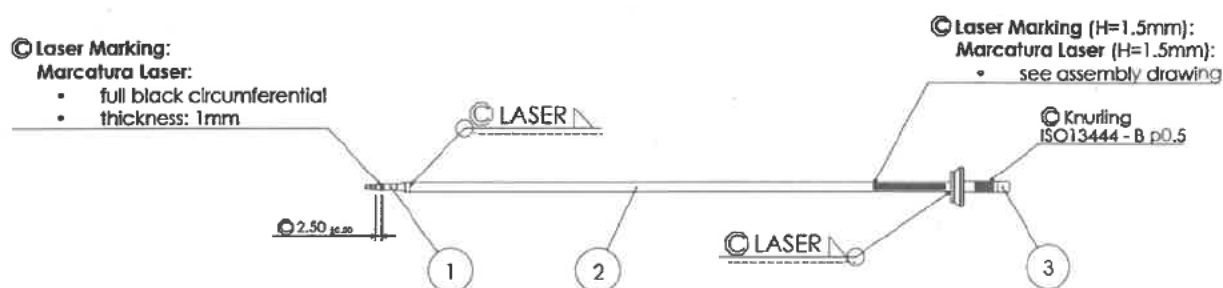


Figure 3 - Complete device J-Lock inserter

The analysis has been carried out within two main activities:

1. Documental inspection – Manufacturing process

The goal of this analysis is to assess the conformity to specifications of all the parts manufactured within the same batch, according to the inspection documents and the sampling plan in force.

2. Design confirmation – welding mechanical investigation

The goal of this analysis is to assess the welding resistance by means of two mechanical test setups, in order to mimic the most common loads that could occur during the device use. The two mechanical tests are:

- 3-points flexion test
- Axial instability test

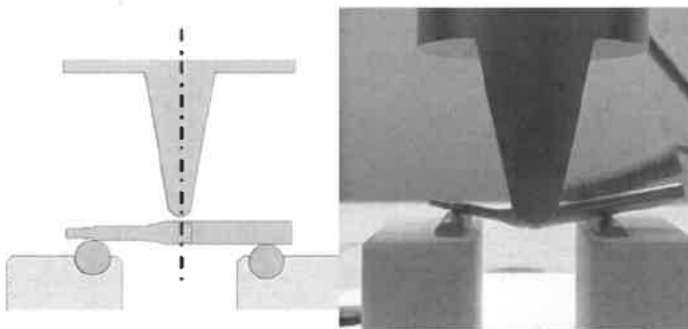
Results

1. Documental inspection – Manufacturing process

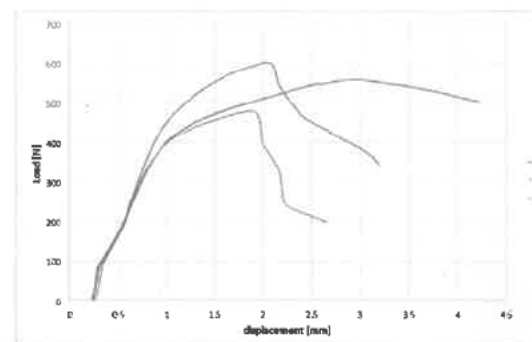
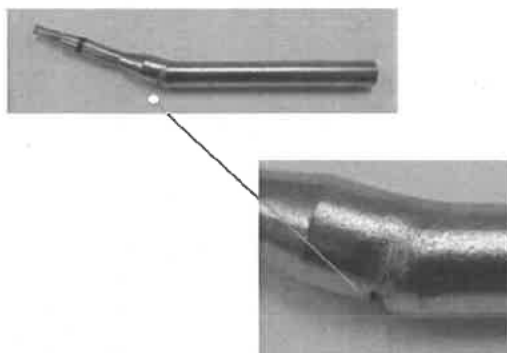
The documental analysis assessed the conformity of the entire batch according to the planned control inspection in place within the existing manufacturing process (welding inspected on 100% of the parts, material specifications respected)

2. Design confirmation – welding mechanical investigation

3-points flexion test

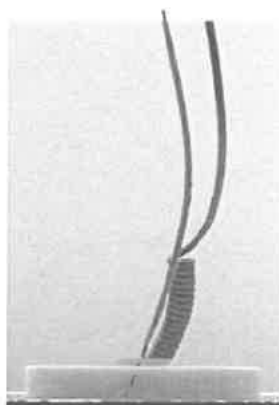


- Pure flexion test, focused on the welding to simulate lateral load
- Mechanical worst case vs. simple bending against surrounding structures

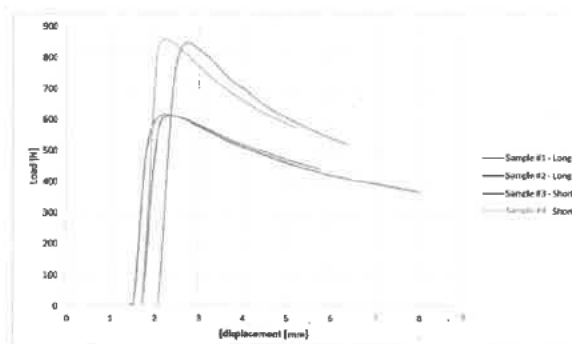
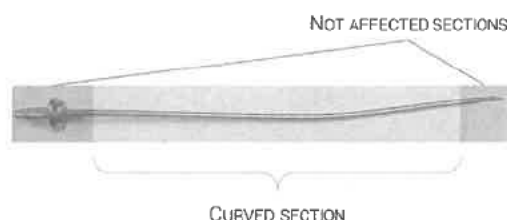


The welding supported max loads of 54Kg, not showing physical separation between the components. This load is considerably out of the normal scale of loads values occurring during a surgery. In a simple leverage with the inserter, the surrounding structures would fail prior to reach that limit.

Axial instability test



- Axial load to simulate stress on the welding during hammering
- Mechanical worst case: constrained hard stop vs. pilot hole



The shaft supported max loads of 85Kg for short and 60Kg for long version. These values exceed a typical insertion in pure bone (no pilot hole). The curvature occurs along the central portion of the shaft, keeping the welding in a safe portion not affected by the resulting flexion.

No torsion test has been considered on the subject inserter since it's evident that in case of excessive torsion stress, within the threaded connection between the PEEK anchor and the inserter's tip, the PEEK thread would fail much before any other metal structure, leaving the inserter unaffected.

Conclusions

A deeper analysis on the safety of the device has been carried out by means of further mechanical investigation on equivalent devices sourced from the same production batch, as representative of the component object of this complaint.

The manufacturing process analysis and the mechanical tests performed provided a confirmation that the actual design can be considered suitable and safe for the expected application.

In particular, the welding between the shaft and the inserter tip has been subject to stress limit tests which confirmed the safety and reliability of the device under load conditions that are commonly expected during a surgery. Therefore, it's not possible to identify a clear or specific root cause for the mode of failure, unless an outstanding condition required a not foreseeable usage during the surgical procedure.

s22

s22

01 Jul 2021

s22

From: s22
Sent: Friday, 10 September 2021 11:44 AM
To: s22
Cc: s22 @medacta.com.au; s22
Subject: RE: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear s22

Good morning. Thank you so much for providing a copy of IFU.

Kind regards,

Dr s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch
 Email: s22 @health.gov.au
 Telephone number : s22

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia

www.tga.gov.au

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From: s22 @medacta.ch>
Sent: Thursday, 9 September 2021 5:55 PM
To: s22 @Health.gov.au>
Cc: s22 @medacta.com.au; s22 @medacta.ch>
Subject: R: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

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Dear s22

You will find attached the MectaLock suture anchors IFU (Ref: 75.09.045 rev. 08) in force.
 At the page number 4, "**Breakage of the MectaLock Suture Anchor can occur if:**", is reported as follows:

- Any lateral loading is applied on the anchor/insertion while inserting the MectaLock anchor

Do not hesitate to contact me if you have any issues.

Kind regards,

s22 s22 Regulatory Affairs Department s22 @medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 Mob: s22 Fax: +41 91 696 60 66
--	--

Da: **s22** [@Health.gov.au](mailto:s22@Health.gov.au)>
 Inviato: giovedì 9 settembre 2021 06:15
 A: **s22** [@medacta.ch](mailto:s22@medacta.ch)>
 Cc: **s22** [@medacta.com.au](mailto:s22@medacta.com.au); **s22** [@medacta.ch](mailto:s22@medacta.ch)>
 Oggetto: RE: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear **s22**

Good afternoon. A review of the manufacturer's investigation shows that the component has been subjected to excessive lateral bending as the axis of the component results deviated from the original. Please provide a copy of Instructions for Use (IFU) for this device and show where it is mentioned in IFU that not doing this 'excessive lateral bending' in a warning or use space. Thanking you.

Kind regards,
Dr s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch
 Email: **s22** [@health.gov.au](mailto:s22@health.gov.au)
 Telephone number : **s22**

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia
www.tga.gov.au

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From: s22
 Sent: Wednesday, 1 September 2021 5:02 PM
 To: s22 @medacta.ch>
 Cc: s22 @medacta.com.au; s22 @medacta.ch>
 Subject: RE: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear s22

Good afternoon. Thank you so much for providing the requested information. We are currently reviewing it. Thanking you.

Kind regards,

Dr s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch
 Email: s22 @health.gov.au
 Telephone number : s22

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia

www.tga.gov.au

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From: s22 @medacta.ch>
 Sent: Saturday, 28 August 2021 1:03 AM
 To: s22 @Health.gov.au>
 Cc: IRIS <IRIS@health.gov.au>; s22 @medacta.com.au; s22 @medacta.ch>
 Subject: R: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

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Dear Dr s22

you will find here below the answers to your requests related to DIR 68783 and 68516:

1. Please provide a description of the adverse events and the rate for those events. Separate the events for Australia and the rest of the world and provide each in a percentage format. Provide a list of complaints and numbers for those similar complaints.

This is the first event reported, no additional instrument breakages have been communicated considering both MectaLock PEEK Ø2.4 short and long drivers. In total, we have sold s47 short and long drivers (MectaLock PEEK Ø2.4).

2. In your detailed device analysis response dated 22 June 2021, it states “the laser welding failed, and the tip component has been detached from the main shaft of the inserter”. Please provide details of your risk mitigation strategies in order to avoid the laser welding failure to ensure the device safety. You will find attached a dedicated rationale.

Do not hesitate to contact me if you have any issues.

Kind regards,

s22 s22 Regulatory Affairs Department s22 @medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 Mob: s22 Fax: +41 91 696 60 66
---	--

From: s22 @Health.gov.au>
Sent: Friday, 30 July 2021 2:34 PM
To: s22 @medacta.com.au>
Subject: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear s22,

Good afternoon. Please find attached section 41JA request for DIR 68783 & 68516. Please note that the requested information must be provided within 20 working days from the date of this letter and no later than **30 August 2021**.
 Thanking you.

Kind regards,
Dr s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch
 Email: s22 @health.gov.au
 Telephone number : s22

Therapeutic Goods Administration
 Department of Health
 PO Box 100
 Woden ACT 2606 Australia
www.tga.gov.au

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Australian Government
Department of Health
Therapeutic Goods Administration

File Reference: E21-259665
Sent by email

s22
Medacta Australia Pty Ltd
Unit A1 / 16 Mars Road
LANE COVE NSW 2066

Email: **s22** [@medacta.com](mailto:s22@medacta.com)

Dear **s22**,

DEVICE INCIDENT REPORT DIR 68783 & 68516
Notice requiring information/documents to be provided
under section 41JA of the Therapeutic Goods Act

I have made a decision under subsection 41JA(1) of the *Therapeutic Goods Act 1989* (the Act) to require you to provide information/documents about Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted, non-biodegradable. I am the delegate of the Secretary of the Department of Health for the purposes of section 41JA of the Act. The information is required for the purposes of the investigation of the above incident report.

You are requested to provide the information/documents listed below including details of any action you have taken in relation to this matter:

1. Please provide a description of the adverse events and the rate for those events. Separate the events for Australia and the rest of the world and provide each in a percentage format. Provide a list of complaints and numbers for those similar complaints.
2. In your detailed device analysis response dated 22 June 2021, it states "the laser welding failed, and the tip component has been detached from the main shaft of the inserter". Please provide details of your risk mitigation strategies in order to avoid the laser welding failure to ensure the device safety.

The requested information must be provided within **20** working days from the date of this letter and no later than **30 August 2021**.

Address for sending the requested information

Please submit all documents in electronic format only. The requested information should be sent to Dr **s22** via:

- Email to: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via:

- post to:

Devices Post Market Monitoring Section
Medical Surveillance Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

- courier to:

Devices Post Market Monitoring Section
Medical Devices Surveillance Branch
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

Please quote file reference E21-259665 in all correspondence relating to this request. This information is essential for the TGA to track and identify all pieces of data in relation to this device.

Please note that failure to comply with this request for information may attract a range of sanctions. These are outlined in Attachment A.

Should you wish to seek a review of my decision to require you to provide the information/documents about Osseo-Frame - Dental implant system your rights of review are outlined in Attachment B.

Please note that in the event that medical devices are cancelled from the ARTG following a notice under subsection 41JA(1) of the Act requiring information/documents to be provided and a proposal to cancel, the Secretary is required under 41GP of the Act to publish in the Commonwealth Gazette or the Department's website particulars of the cancellation of the entry from the ARTG as soon as practicable after the cancellation. The TGA's practice is to publish information on its website about that cancellation including the name of the sponsor and product and the grounds on which the goods were cancelled. This information is updated in the event that the cancellation is subject to internal review or review by the Administrative Appeals Tribunal, or other form of legal review. [For more information see <http://www.tga.gov.au/about/compliance.htm>]

Please contact the undersigned or Dr **s22** on **s22** or email: IRIS@health.gov.au if any aspect of this request for information requires clarification.

Yours sincerely

Signed electronically by

s22

Delegate of the Secretary
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch
Therapeutic Goods Administration

30 July 2021

ATTACHMENT A

41JA Secretary may require information or documents

(1) The Secretary may, by written notice given to a person:

(a) who is an applicant for a conformity assessment certificate that would relate to a kind of medical device; or

(b) who holds a conformity assessment certificate, or an Australian conformity assessment body certificate, that relates to a kind of medical device; or

(ba) who held, at any time during the notice period under subsection (2), a conformity assessment certificate, or an Australian conformity assessment body certificate, that related to a kind of medical device; or

(c) who is an applicant for the inclusion of a kind of medical device in the Register; or

(d) in relation to whom a kind of medical device is included in the Register; or

(da) in relation to whom a kind of medical device was, at any time during the notice period under subsection (2), included in the Register;

require the person to give to the Secretary information or documents, relating to devices of that kind, that are relevant to one or more of the following:

(e) whether the devices comply with the essential principles;

(f) whether the conformity assessment procedures have been applied to the devices or whether requirements, comparable to those procedures, have been applied to the devices;

(g) whether the devices comply with conditions (if any) imposed on a conformity assessment certificate issued in respect of the device or the inclusion of the device in the Register;

(h) whether either of the following has not been complied with in relation to the devices:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or under the regulations;

(i) if the kind of medical device is included in the Register in relation to the person—whether medical devices of that kind are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

(ia) the safety and efficacy of the devices for the purposes for which they are to be used;

(ib) the regulatory history of the devices in another country;

(j) any other matter prescribed by the regulations for the purposes of this paragraph.

(1AA) If a notice is given under subsection (1) to a person covered by paragraph (1)(ba), then paragraphs (1)(e) to (j) (to the extent to which they are relevant) apply in relation to the period the person held the certificate.

(1AB) If a notice is given under subsection (1) to a person covered by paragraph (1)(da), then paragraphs (1)(e) to (j) (to the extent to which they are relevant) apply in relation to the period the kind of medical device was included in the Register.

(1A) The Secretary may, by written notice given to a person who is an applicant for a conformity assessment certificate, require the person to give to the Secretary such further information concerning the application as is specified in the notice.

(1B) Requirements under subsections (1) and (1A) may be included in the same notice.

(1C) The Secretary may, by written notice given to a person who holds a conformity assessment certificate, require the person to give to the Secretary specified information to be used by the Secretary in deciding whether to suspend the certificate under section 41EM, or to revoke the certificate under section 41ET, in relation to the circumstances referred to in paragraph 41ET(1)(e).

(1D) Requirements under subsections (1) and (1C) may be included in the same notice.

(1E) The Secretary may, by written notice given to an Australian corporation that has been an Australian conformity assessment body require the corporation to give to the Secretary specified information, or specified documents, relating to:

- (a) the certification-related activities carried on by the corporation while the corporation was an Australian conformity assessment body; or
- (b) the conditions referred to in subsection 41EWA(5) that applied while the corporation was an Australian conformity assessment body.

(2) For the purposes of paragraphs (1)(ba) and (da), the notice period is the period:

- (a) of the length specified in the regulations; and
- (b) ending on the day before the Secretary gives the notice under subsection (1).

(3) Nothing in this section affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

41JB Complying with the Secretary's requirements

(1) The person must give the information or documents to the Secretary:

- (a) within such reasonable time, being not less than 10 working days from the day on which the notice is given, as is specified in the notice; and
- (b) in such form as is specified in the notice.

(2) The form may require or permit information to be given in accordance with specified software requirements:

- (a) on a specified kind of data processing device; or
- (b) by way of a specified kind of electronic transmission.

Offence for failing to comply with a notice

(3) A person commits an offence if:

- (a) the person is given a notice under section 41JA; and
- (aa) the person is covered by paragraph 41JA(1)(b), (ba), (d) or (da) or subsection 41JA(1E); and
- (b) the person fails to comply with the notice.

Penalty: 500 penalty units.

Note: Failure to comply with the notice might also lead to suspension or revocation of a conformity assessment certificate (see Divisions 3 and 4 of Part 4-4) or suspension or cancellation of the entry of a kind of medical device in the Register (see Part 4-6).

(3A) Subsection (3) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3A): see subsection 13.3(3) of the *Criminal Code*.

(3B) A person commits an offence if:

(a) the person is given a notice under section 41JA; and

(b) the person is covered by paragraph 41JA(1)(b), (ba), (d) or (da) or subsection 41JA(1E); and

(d) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3C) An offence against subsection (3B) is an offence of strict liability.

(3D) Subsection (3B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3D): see subsection 13.3(3) of the *Criminal Code*.

Offences for giving false or misleading information in purported compliance with a notice

(4) A person commits an offence if:

(a) the person is given a notice under section 41JA in relation to a kind of medical device; and

(b) the person gives information in purported compliance with the notice; and

(c) the information is false or misleading in a material particular; and

(d) either:

(i) the use of the kind of medical device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the kind of medical device, if the kind of medical device were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

ATTACHMENT B

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Further information on Section 60 and the Reviewable Initial Decisions can be found at the following TGA webpages:

Section 60 - <https://www.tga.gov.au/publication/guidance-requesting-reconsideration-initial-decision>

Reviewable Initial Decisions - <https://www.tga.gov.au/publication/reviewable-initial-decisions-under-therapeutic-goods-act-regulations-0>

s22

From: s22
Sent: Thursday, 9 September 2021 5:55 PM
To: s22
Cc: s22 @medacta.com.au; s22
Subject: R: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]
Attachments: IFU MectaLock PEEK and MectaLock TI EN 75.09.045 rev.08.pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

You will find attached the MectaLock suture anchors IFU (Ref: 75.09.045 rev. 08) in force.
 At the page number 4, ***“Breakage of the MectaLock Suture Anchor can occur if:”***, is reported as follows:

- Any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor

Do not hesitate to contact me if you have any issues.

Kind regards,

s22 s22 Regulatory Affairs Department s22 @medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 Mob: s22 Fax: +41 91 696 60 66
--	--

Da: s22 @Health.gov.au>
Inviato: giovedì 9 settembre 2021 06:15
A: s22 @medacta.ch>
Cc: s22 @medacta.com.au; s22 @medacta.ch>
Oggetto: RE: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear s22

Good afternoon. A review of the manufacturer's investigation shows that the component has been subjected to excessive lateral bending as the axis of the component results deviated from the original. Please provide a copy of Instructions for Use (IFU) for this device and show where it is mentioned in IFU that not doing this 'excessive lateral bending' in a warning or use space. Thanking you.

Kind regards,

Dr s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch
 Email: s22 @health.gov.au
 Telephone number : s22

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.



This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to them and their culture, and to all Elders both past and present.

P Please consider the environment before printing this email.

From: s22
Sent: Wednesday, 1 September 2021 5:02 PM
To: s22 @medacta.ch>
Cc: s22 @medacta.com.au; s22 @medacta.ch>
Subject: RE: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear s22

Good afternoon. Thank you so much for providing the requested information. We are currently reviewing it.
Thanking you.

Kind regards,

Dr s22
Departmental Officer
Devices Post Market Monitoring
Medical Devices Surveillance Branch
Email: s22 @health.gov.au
Telephone number s22

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

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The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to them and their culture, and to all Elders both past and present.

P Please consider the environment before printing this email.

From: s22 [REDACTED]@medacta.ch>
 Sent: Saturday, 28 August 2021 1:03 AM
 To: s22 [REDACTED]@Health.gov.au>
 Cc: IRIS <IRIS@health.gov.au>; s22 [REDACTED]@medacta.com.au; s22 [REDACTED]@medacta.ch>
 Subject: R: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Dr s22 [REDACTED]

you will find here below the answers to your requests related to DIR 68783 and 68516:

1. Please provide a description of the adverse events and the rate for those events. Separate the events for Australia and the rest of the world and provide each in a percentage format. Provide a list of complaints and numbers for those similar complaints.
 This is the first event reported, no additional instrument breakages have been communicated considering both MectaLock PEEK Ø2.4 short and long drivers. In total, we have sold s47 [REDACTED] short and long drivers (MectaLock PEEK Ø2.4).
2. In your detailed device analysis response dated 22 June 2021, it states "the laser welding failed, and the tip component has been detached from the main shaft of the inserter". Please provide details of your risk mitigation strategies in order to avoid the laser welding failure to ensure the device safety. You will find attached a dedicated rationale.

Do not hesitate to contact me if you have any issues.

Kind regards,

s22 [REDACTED] s22 [REDACTED] <i>Regulatory Affairs Department</i> s22 [REDACTED]@medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 [REDACTED] Mob: s22 [REDACTED] Fax: +41 91 696 60 66
--	--

From: s22 [REDACTED]@Health.gov.au>
 Sent: Friday, 30 July 2021 2:34 PM
 To: s22 [REDACTED]@medacta.com.au>
 Subject: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear s22 [REDACTED],

Good afternoon. Please find attached section 41JA request for DIR 68783 & 68516. Please note that the requested information must be provided within 20 working days from the date of this letter and no later than **30 August 2021**. Thanking you.

Kind regards,
 Dr s22 [REDACTED]
 Departmental Officer
 Devices Post Market Monitoring

Medical Devices Surveillance Branch
Email: s22 [REDACTED]@health.gov.au
Telephone number : s22 [REDACTED]

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia

www.tga.gov.au

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This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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Ref: 75.09.045 rev. 08

CE 2797
2020

Strada Regina
CH - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66
info@medacta.ch - www.medacta.com

Manufactured by:
Medacta International SA
CH-6874 Castel San Pietro - Switzerland

MECTALOCK SUTURE ANCHORS

CAUTION

For U.S. specific instructions for use, please go to www.medacta.com or call toll free 800-901-7836.

SYMBOLS / SIMBOLI / PICTOGRAMMES / PIKTOGRAMME / PICTOGRAMAS / PICTOGRAMAS / PICTOGRAMMES / ΕΙΚΟΝΟΣΥΜΒΟΛΑ

APPLIES TO ALL DEVICES

	Do not reuse / Non riutilizzare / Niet hergebruiken / Nicht wiederverwenden / No reutilizable / Não reutilizar / Ne pas réutiliser / Μην επαναχρησιμοποιείτε
	Do not resterilize / Non risterilizzare / Niet resteriliseren / Bitte nicht re-sterilisieren / No resterilize / Não resterilizar / Ne pas restériliser / Να μην αποστειρωθεί ξανά
	Caution, read the accompanying documents / Attenzione, consultare i documenti di accompagnamento / Opgelet, raadpleeg de bijgeleverde documenten / Achtung, Begleitdokumente beachten / Atención, consulte los documentos que se acompañan / Atenção, consultar os documentos de acompanhamento / Attention, consulter les documents d'accompagnement / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα
	Consult instructions for use / Consultare le istruzioni di utilizzo / Gebruiksaanwijzing / Bitte lesen Sie die Gebrauchsanweisung / Consulte las Instrucciones antes de su uso / Consulte as instruções de uso / Consultez les instructions d'utilisation / Οδηγίες χρήσης
	Do not expose to sunlight / Non esporre alla luce del sole / Niet blootstellen aan zonlicht / Vor Sonnenlicht schützen / No exponer a la luz solar / Não expor à luz solar / Ne pas exposer à la lumière du soleil / Μην εκθέτετε σε ηλιακό φως
	Store in a dry place / Conservare in luogo asciutto / Droog bewaren / Trocken aufbewahren / Conservar en lugar seco / Conservar em local seco / Conserver au sec / Φυλάσσετε σε ξηρό χώρο
	Do not use if package is damaged / Non utilizzare se la confezione è danneggiata / Niet gebruiken als verpakking beschadigd is / Bitte nicht verwenden, falls Verpackung beschädigt ist / No utilize si el envoltorio está dañado / Não utilizar se a embalagem estiver violada / Ne pas utiliser si l'emballage est abîmé / Να μην χρησιμοποιηθεί εάν η συσκευασία είναι κατεστραμμένη
	Use by / Utilizzare entro il / Te gebruiken voor / Zu verwenden bis / Utilizar antes de / A utilizar antes de / A utiliser avant / Ημερομηνία λήξης
	Lot number / Numero di lotto / Nummer van de partij / Waren-Lot-Nummer / Número de lote / Número de lote / Numéro de lot / Αριθμός παρτίδας
	Reference number / Riferimento commerciale / Handelsreferentie / Referenznummer / Numero de Referencia / Referência comercial / Référence commerciale / Νούμερο παραπομπής
	Sterilized with ethylene oxide / Sterilizzato con ossido di etilene / Gesteriliseerd met ethylenoxide / Ethylenoxid-sterilisiert / Esterilizado con óxido de etileno / Esterilizado com óxido de etileno / Stérilisé à l'oxyde d'éthylène / Αποστειρωμένο με οξείδιο του αιθυλενίου
	MR Unsafe / Non sicuro per RM / MR onveilig / MR ungeeignet / Inseguro RM / Não seguro para RM / MR non sécurisé / Μη ασφαλές στην μαγνητική τομογραφία
	Manufacturer / Produttore / Fabrikant / Hersteller / Fabricante / Fabricante / Fabricant / Κατασκευαστής

APPLIES TO MECTALOCK TI

	MR Conditional / A compatibilità condizionata con la risonanza magnetica / MR-conditioneel / Bedingt MR geschikt / Compatibles con RM bajo ciertas condiciones / Qualificado para ressonância magnética / RM conditionnelle / Μαγνητικός συντονισμός υπό προϋποθέσεις
--	---

APPLIES TO MECTALOCK PEEK

	MR Safe / Sicuro per RM / MR veilig / MR geeignet / Seguro para RM / Seguro para RM / Compatible avec RM / Ασφαλές στην μαγνητική τομογραφία
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Index

ENGLISH: MECTALOCK SUTURE ANCHORS - INSTRUCTIONS FOR USE	3
ITALIANO: MECTALOCK SUTURE ANCHORS - ISTRUZIONI PER L'USO	10
NEDERLANDS: MECTALOCK SUTURE ANCHORS - GEBRUIKSIINSTRUCTIES	Errore. Il segnalibro non è definito.
DEUTSCH: MECTALOCK SUTURE ANCHORS - GEBRAUCHSANWEISUNGEN	18
ESPAÑOL: MECTALOCK SUTURE ANCHORS - INSTRUCCIONES DE USO	34
PORTUGUÊS: MECTALOCK SUTURE ANCHORS - INSTRUÇÕES DE UTILIZAÇÃO	42
FRANÇAIS: MECTALOCK SUTURE ANCHORS - INSTRUCTIONS D'UTILISATION	50
ΕΛΛΗΝΙΚΑ: MECTALOCK SUTURE ANCHORS - ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ	58

ENGLISH: MECTALOCK SUTURE ANCHORS - INSTRUCTIONS FOR USE

Important notice: the device(s) can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.

1. GENERAL

Before any surgery, the surgeon must be familiar with the product literature and operative technique and must read carefully these instructions for use. Patient selection is as important as implant placement or positioning. Unsuitable functional requirements may contribute to reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed.

2. PRODUCT DESCRIPTION

These instructions for use are intended for all products described here below.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

Medacta MectaLock PEEK (knotless) and MectaLock TI (preloaded) are manufactured respectively in PolyEtherEtherKeton (PEEK) or Titanium alloy. The MectaLock Suture Anchors are provided with sutures directly preloaded into the implant (MectaLock TI) or placed directly into the final packaging (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003		
05.10.011	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.012		

Material Specifications

Anchors: PolyEtherEtherKeton (PEEK) [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Driver shaft/body: Stainless steel

Driver Handle: Polycarbonate medical grade

Suture: non-absorbable USP#2/EP#5 HS Fiber 39" Ultra-High molecular weight polyethylene (average diameter: 0.500-0.599mm)

3. INTENDED USE / INDICATIONS

The non-absorbable suture anchors are intended to:

- MectaLock TI Suture anchors: soft tissue refixation within the shoulder joint (i.e.: cuff rotator repair, biceps tenodesis)
- MectaLock PEEK Suture anchors: treatment of the hip and shoulder instability by means of the refixation of the acetabular or glenoidal labrum to the bone

The device is indicated for use in both arthroscopic and open surgical procedures. After the suture is anchored to the bone, it is used to reattach soft tissues to the bone, including the following system specific indications:

- MectaLock TI Suture anchors: soft tissue refixation within the shoulder joint
- MectaLock PEEK Suture anchors: treatment of the hip and shoulder instability by means of the refixation of the acetabular or glenoidal labrum to the bone

The suture anchor system in that way stabilizes the damaged soft tissue, in combination with appropriate postoperative immobilization, throughout the healing period.

4. CONTRAINDICATIONS

- Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation
- Pathological conditions of bone which adversely affect the MectaLock Suture Anchors
- Physical condition that would eliminate, or tend to eliminate, adequate implant support or retard healing
- Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period
- Attachment of artificial ligament or other implants
- Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials

5. WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the dedicated instruments specially designed for that range of implants. Surgeon must choose proper implant size based on specific procedure and patient history. Malpositioning may reduce implant longevity and lead to early implant failure. The disposable driver is single use and must be disposed of according to hospital policy and procedure.

One Medacta label for each device must be properly applied to the Medacta Implant Card provided, and delivered to the patient.

Ensure the MectaLock Suture Anchors are used with the corresponding compatible reusable drill bit. Use the corresponding compatible reusable drill bit to create the pilot hole to create the pilot socket. Maintain proper alignment during insertion of the anchor and prevent disengagement from the driver. The risk of MectaLock Suture Anchor breakage during implantation is reduced by following the specified instructions for use listed below. Proper selection and placement of the implant are important considerations in the successful utilization of this device. Proper orientation and alignment of instruments is important during implantation of the MectaLock Suture Anchor to minimize possible breakage of the anchor. Breakage of the MectaLock Suture Anchor can occur if:

- The pilot hole, where expected, is not drilled to the proper depth
- The MectaLock Suture Anchor is not properly aligned with the pilot hole, where expected
- Any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor
- The MectaLock Suture Anchor driver is used for prying

Do not disengage the sutures from the disposable driver while inserting the MectaLock TI Suture Anchor before the final positioning depth is reached. Do not use any other suture other than non-absorbable USP#2/EP#5 UHMWPE suture.

MRI Compatibility

MectaLock TI:

Non-clinical testing has demonstrated titanium implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions. Static magnetic field of 1.5 Tesla and 3 Tesla, with:

- Maximum spatial field gradient of 12,800 G/cm (128 T/m)
- Maximum force product of 231,000,000 G²/cm (231 T²/m)

Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode). Under the scan conditions defined above, titanium implants expected to produce a maximum temperature rise of less than:

- 1.5°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of ≈1.3°C (2 W/kg, 1.5 Tesla)
- 3.0°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of ≈2.3°C (2 W/kg, 3 Tesla)

after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20.5 mm from the titanium implant when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

The MectaLock PEEK Suture Anchors are MR Safe.

6. MEDACTA INTERNATIONAL IMPLANTS

Medacta International is not responsible for the use of its implant components in combination with a component from another manufacturer (unless otherwise specified by Medacta International in the surgical steps), therefore we advise against such a use. The MectaLock Suture Anchors should never be reimplanted. While an implant may appear undamaged, microscopic imperfections may occur and cause implant failure. The operating surgeon must be aware that even a very small superficial damage, caused for instance by a sharp tool or electrocautery, can have an influence on the endurance of the device and can lead to failure. Medacta MectaLock Suture Anchors are non-pyrogenic.

7. RISK FACTORS

The following risk factors, individually or together, may result in poor clinical outcomes:

- Inadequate bone quality, (e.g. osteoporosis, osteopenia)
- Systemic diseases or metabolic disorders
- History of infections or recurrent falls
- Drug dependence and abuse of alcohol and medicaments
- Mental incapacity of patient to understand the instructions of the physician and to comply with them
- Local bone tumors

8. INSTRUCTIONS FOR USE

PREOPERATIVE PHASE

The surgeon should verify possible patient physical limitations and mental deficiencies and he should also discuss with the patient all the details of the procedure and implant. The discussion should consider the limitations of the procedure and the constraints imposed by the selected implant. The factors which could limit the performance and

stability of the implant, e.g. level of activity, should be set out to improve the patient's chances to avoid complications. The necessity to follow the postoperative instructions given by the surgeon should be fully understood by the patient. A stock of sterile implants of suitable sizes must be available and checked by the operator before surgery.

9. HANDLING

To avoid scratching or damaging the implants, these should be handled with the utmost care by qualified personnel and in an environment where conditions of hygiene are controlled. The implants should be kept in their undamaged packages.

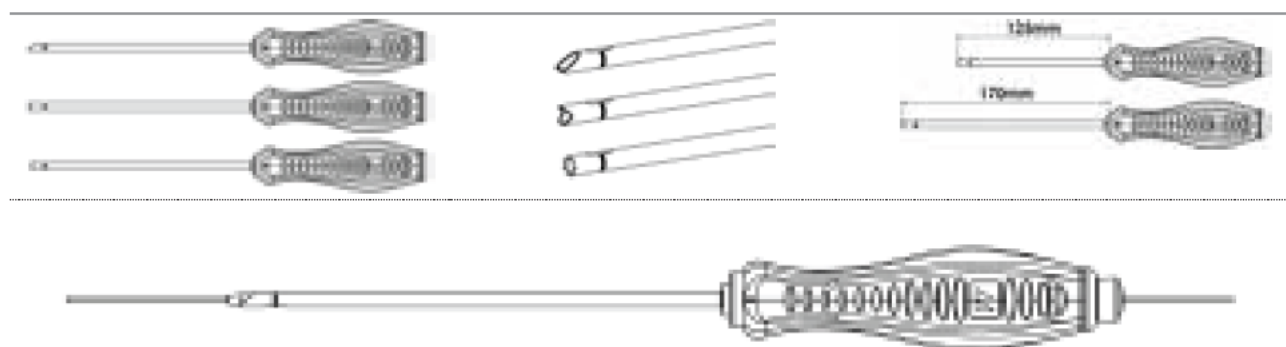
10. SURGICAL TECHNIQUE

The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical techniques (brochure and video) and products are available on request. Careful preoperative planning is essential.

MECTALOCK PEEK SUTURE ANCHOR

- Pass the USP#2/EP#5 HS Fiber 39" UHMWPE suture through soft tissue with surgeon's preferred suture-passing technique; let the two strands of the suture come out from the patient through the arthroscopic portal
- Find the desired location for the placement of the MectaLock PEEK anchor; insert a percutaneous guidewire (max Ø1.5mm) through the proper arthroscopic portal to reach the desired location
- A dedicated aimer can be used as a drill guide and to aid in pointing the location of the pilot hole in the bone. Insert the Medacta

Arthroscopic Aimer coupled with a cannulated obturator over the guidewire; the surgeon can choose between different aimer's tip according to his preference and the anatomical structures to be treated. Aimers and obturators are provided in two different lengths:



Aimers/obturators and drills can be coupled according to the following table:

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

- Using the corresponding compatible reusable drill bit, create a hole in the bone in the desired location for the placement of the MectaLock PEEK anchor
- Make sure to drill until the distal depth mark of the drill is aligned with the distal depth mark of the aimer or until the drill is mechanically blocked against the aimer



Load the MectaLock PEEK anchor with the sutures coming out of the portal: while firmly holding the two strands of the suture with one hand, align them with the slot of the anchor's tip. Gently push the anchor against the suture to let it clip into the tip's eyelet.



Rotate the anchor clockwise by 90°

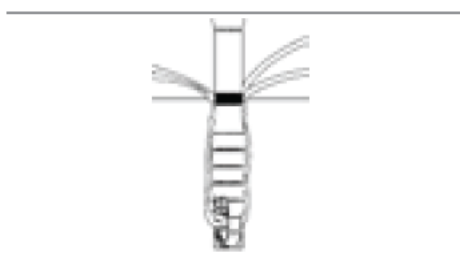


Align the main axis of the driver with the suture (1) and then, while still holding the suture gently tensioned, slide the anchor over the suture (2) towards the patient through the arthroscopic portal, until the pilot hole is reached.



Once reaching the pilot hole, regulate the suture tension according to the surgeon's preference and tap the plastic handle of the driver until the MectaLock PEEK anchor is correctly placed. The correct depth is achieved when the distal laser marking is flush with the bone surface.

- Unscrew the disposable driver
- Palpate the repaired soft tissue using an arthroscopic probe to ensure that the repair is secure
- Cut and remove sutures in excess



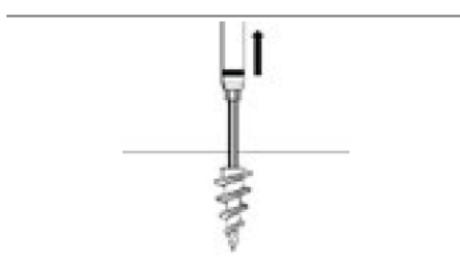
MECTALOCK TI SUTURE ANCHOR

- Find the desired location for the placement of the MectaLock TI anchor; insert the preloaded driver with the MectaLock TI anchor through the proper arthroscopic portal to reach the desired location.
- Gently tap on the back handle of the disposable driver to let the MectaLock TI anchor's tip pierce the bone in the chosen spot; while keeping a gentle axial force on the disposable driver, screw the MectaLock TI anchor into the bone until the distal laser marking on the driver is flush with the bone surface.



Unlock the sutures from the plastic handle and gently disengage the driver's tip from the MectaLock TI anchor, pulling the driver out through the arthroscopic portal.

- Manage the 2x USP#2/EP#5 HS Fiber 39" UHMWPE sutures through soft tissue with surgeon's preferred suture-passing and knotting technique
- Palpate the repaired soft tissue using an arthroscopic probe to ensure that the repair is secure
- Cut and remove suture in excess



11. POSTOPERATIVE CARE AND FOLLOW-UP

The surgeon should caution the patients to control their level of activity and avoid excessive loads on the operated limb. Moreover, the surgeon should make the patients aware of the precautions to be taken in terms of exercises, treatments and limitations on activities, any limitations reported on the label, as well as exposure to magnetic fields. The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans. Periodic follow-up are recommended to make comparisons with the immediate postoperative condition and anticipate implant related complications. Excessive physical activity, and operated limb traumas may cause early failure of the implant. If the case occurs, it is necessary to place the patient under supervision, evaluate the possible progression of the deterioration, and weigh the benefit of early revision.

12. ADVERSE EFFECTS AND COMPLICATIONS

Adverse effects that can occur in the reattachment of soft tissue to bone in orthopedic surgical procedures:

- Infection, both deep and superficial
- Allergies, mild inflammatory and foreign body reactions to implant material

Some adverse effects can ultimately lead to death.

General complications include:

- Venous thrombosis with/without pulmonary embolism
- Cardiovascular or pulmonary disturbances
- Haematomas
- Systemic allergic reactions
- Systemic pain

13. PACKAGING

The MectaLock Suture Anchors are supplied in single-use packages. For components delivered sterile, the sterilization method is indicated on the label. The expiration date must be checked on the label as well as the package integrity to ensure that sterility of the contents has not been compromised. If the package is damaged or has been previously opened, do not use the component. Do not re-sterilize.

14. STORAGE

The packages must be stored in a cool, dry place, away from light.

15. TRADEMARKS

Medacta is registered trademark of Medacta International SA, Castel San Pietro, Switzerland.

The reference text is the English text.

Last update: July 2020

ITALIANO: MECTALOCK SUTURE ANCHORS - ISTRUZIONI PER L'USO

Avviso importante: i dispositivi devono essere prescritti e impiantati solo da un medico chirurgo in possesso dell'autorizzazione a svolgere questo tipo di intervento.

1. INFORMAZIONI GENERALI

Prima di qualsiasi intervento, il chirurgo deve conoscere bene la letteratura del prodotto e la tecnica operatoria e leggere attentamente le presenti istruzioni per l'uso. La selezione del paziente è importante nella posa o nel posizionamento di un impianto. Requisiti funzionali non appropriati possono contribuire a ridurre la durata dell'impianto. Prestare attenzione alle avvertenze e seguire rigorosamente le istruzioni per l'uso.

2. DESCRIZIONE DEL PRODOTTO

Le presenti istruzioni per l'uso riguardano i prodotti di seguito descritti.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

I prodotti Medacta MectaLock PEEK (senza nodi) e MectaLock TI (precaricati) sono fabbricati rispettivamente in polietere etere chetone (PolyEther Ether Ketone, PEEK) o in lega di titanio. L'ancora per sutura MectaLock viene fornita con suture precaricate direttamente nell'impianto (MectaLock TI) o inserite direttamente nell'imballaggio finale (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003		
05.10.011	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.012		

Specifiche dei materiali

Ancore: polietere etere chetone (PEEK) [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Asta e corpo del driver: acciaio inox

Manico del driver: policarbonato per uso medico

Sutura: non riassorbibile USP#2/EP#5 HS Fibra 39" Polietilene ad altissimo peso molecolare (UHMWPE) (diametro medio: 0.500-0.599mm)

3. UTILIZZO PREVISTO

Le ancore per sutura non riassorbibili sono destinate a:

- Ancore per sutura MectaLock TI: rifissazione dei tessuti molli all'interno dell'articolazione della spalla (cioè: riparazione dei rotatori della cuffia, tenodesi del bicipite)
- Ancore per sutura MectaLock PEEK: trattamento dell'instabilità dell'anca e della spalla attraverso la rifissazione all'osso del labbro acetabolare o glenoidale

Il dispositivo è indicato per l'uso sia in procedure artroscopiche sia in chirurgie aperte. Dopo che la sutura è stata ancorata all'osso, l'ancora viene utilizzata per riattaccare i tessuti molli all'osso, con le indicazioni dei seguenti specifici sistemi:

- Ancore per sutura MectaLock TI: rifissazione dei tessuti molli all'interno dell'articolazione della spalla
- Ancore per sutura MectaLock PEEK: trattamento dell'instabilità dell'anca e della spalla attraverso la rifissazione all'osso del labbro acetabolare o glenoidale

Il sistema di ancore per sutura stabilizza i tessuti molli danneggiati durante il periodo di convalescenza, insieme ad un'adeguata immobilizzazione post-operatoria.

4. CONTROINDICAZIONI

- Condizioni patologiche dei tessuti molli da riparare o ricostruire che influirebbero negativamente sulla fissazione della sutura
- Condizioni patologiche dell'osso che influenzano negativamente le ancore per sutura MectaLock
- Condizioni fisiche che eliminerebbero, o tenderebbero ad eliminare, un adeguato supporto implantare o ritarderebbero la guarigione
- Condizioni che tendono a ridurre la capacità o la volontà del paziente nel limitare le proprie attività o nel seguire le indicazioni in fase di convalescenza
- Attacco di legamenti artificiali o di altri impianti
- Sensibilità a corpi estranei, allergie note o sospette a materiali per impianti e/o strumenti

5. AVVERTENZE E PRECAUZIONI

L'esito positivo dell'intervento dipende dalla conformità alla tecnica operatoria fornita e all'uso appropriato della strumentazione dedicata, appositamente progettata per quel range di impianti. Il chirurgo deve scegliere la taglia corretta dell'impianto sulla base della procedura specifica e sull'anamnesi del paziente. Il malposizionamento può ridurre la durata implantare e causarne il fallimento precoce. Il driver usa e getta è monouso e deve essere smaltito secondo le politiche e le procedure dell'ospedale. Per ogni impianto deve essere correttamente applicata sulla tessera per il portatore d'impianto un'etichetta Medacta e consegnata al paziente.

Per ogni impianto deve essere correttamente applicata sulla tessera per il portatore d'impianto un'etichetta Medacta e consegnata al paziente.

Assicurarsi che le ancore per sutura MectaLock vengano utilizzate con la corrispondente punta da trapano riutilizzabile compatibile. Per creare il foro guida utilizzare la punta da trapano riutilizzabile compatibile corrispondente. Mantenere un corretto allineamento durante l'inserimento dell'ancora ed evitare il distacco dall'inseritore. Il rischio di rottura dell'ancora per sutura MectaLock durante le fasi di posizionamento dell'impianto è ridotto se si seguono le istruzioni per l'uso di seguito elencate. La corretta selezione e l'inserimento dell'impianto sono fattori importanti per il successo dell'utilizzo di questo dispositivo. Il corretto orientamento e allineamento degli strumenti è importante nelle fasi di impianto della sutura MectaLock. Assicurarsi il fissaggio dei dispositivi per ridurre al minimo la possibilità di rottura dell'ancora. La rottura dell'ancora per sutura MectaLock può verificarsi se:

- il foro guida, ove previsto, non viene praticato alla giusta profondità
- l'ancora per sutura MectaLock non è allineata correttamente con il foro guida, ove previsto
- venisse applicato un eventuale carico laterale durante le fasi di ancoraggio/inserimento dell'ancora MectaLock
- l'ancora per sutura MectaLock venisse utilizzate per fare leva

Non sganciare le suture dal driver monouso in fase di inserimento dell'ancora per sutura MectaLock TI prima di aver raggiunto la profondità di posizionamento definitiva. Non utilizzare un'altra sutura se non la sutura non riassorbibile USP#2/EP#5 in UHMWPE.

Compatibilità MRI

MectaLock TI:

Test non clinici hanno dimostrato che gli impianti in titanio sono a compatibilità condizionata con la risonanza magnetica. Un paziente con questo dispositivo può essere esaminato in sicurezza con un dispositivo a risonanza magnetica che soddisfi le seguenti condizioni. Campo magnetico statico di 1,5 Tesla e 3 Tesla, con:

• Gradiente di campo spaziale massimo di 12.800 G/cm (128 T/m)

• Prodotto di forza massima di 231.000.000 G²/cm (231 T²/m)

Tasso di assorbimento specifico (SAR) massimo stimato teoricamente per l'intero corpo (WBA) di 2 W/kg (modalità di funzionamento normale). Nelle condizioni di scansione sopra definite, si prevede che gli impianti in titanio producano un aumento massimo della temperatura inferiore a:

• 1,5°C (2 W/kg, 1,5 Tesla) aumento di temperatura correlato alla RF con un aumento della temperatura di fondodi ≈1,3°C (2 W/kg, 1,5 Tesla)

• 3,0°C (2 W/kg, 3 Tesla) Aumento della temperatura relativa alla RF con un aumento della temperatura di fondodi ≈2,3°C (2 W/kg, 3 Tesla)

dopo 15 minuti di scansione continua.

Nei test non clinici, l'artefatto dell'immagine causato dal dispositivo si estende di circa 20,5 mm dall'impianto in titanio quando questo viene ripreso con una sequenza di impulsi di eco a gradiente e un sistema di risonanza magnetica 3 Tesla.

Le ancore per sutura MectaLock PEEK sono sicure per la RM.

6. IMPIANTI MEDACTA INTERNATIONAL

Medacta International non è responsabile dell'uso dei suoi componenti in associazione a componenti di altri produttori (fatte salve diverse specifiche di Medacta International nella tecnica chirurgica), sconsigliamo pertanto tale pratica. Le ancore per sutura MectaLock non devono essere mai reimpiantate. Anche qualora un impianto sembri apparentemente integro, possono essere presenti imperfezioni microscopiche in grado di provocare il cedimento dell'impianto. Il chirurgo deve essere consapevole che anche danni superficiali minimi, provocati per esempio con uno strumento affilato o di elettrocauterizzazione, possono incidere sulla resistenza del dispositivo e provocarne la rottura. Le ancore per sutura MectaLock Medacta sono prodotti non pirogenici.

7. FATTORI DI RISCHIO

I seguenti fattori di rischio, singolarmente o in associazione, tendono ad avere effetti negativi sull'esito dell'intervento:

- Inadeguata qualità dell'osso, (per esempio osteoporosi, osteopenia)
- Malattie sistemiche e disordini metabolici
- Esiti di infezioni o fallimenti recenti
- Dipendenza da droghe e abuso di alcool e medicinali
- Incapacità mentale del paziente di capire le indicazioni del medico e di attenersi ad esse
- Tumori ossei locali

8. MODALITÀ D'USO

FASE PRE-OPERATORIA

Il chirurgo dovrebbe verificare le limitazioni fisiche e le deficienze mentali del paziente e dovrebbe trattare con il paziente tutti i particolari dell'intervento e dell'impianto. Durante il colloquio, il chirurgo deve informare il paziente dei limiti della procedura e dei vincoli imposti dall'impianto selezionato. I fattori che potrebbero limitare le performance e la stabilità dell'impianto, come il livello di attività fisica, devono essere chiariti per migliorare le possibilità del paziente di evitare complicanze. Il paziente deve comprendere appieno la necessità di seguire le istruzioni post-operatorie impartite dal chirurgo. Deve essere disponibile una scorta di impianti sterili di taglie idonee, controllata dall'operatore prima dell'intervento.

9. MANIPOLAZIONE

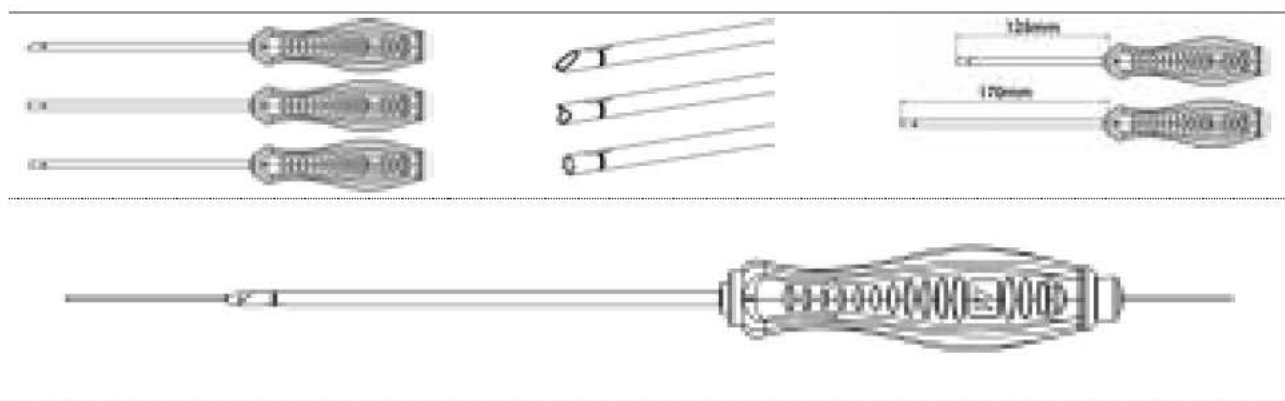
Per evitare danni o graffi, gli impianti devono essere manipolati con la massima attenzione dal personale qualificato in un ambiente con condizioni igieniche controllate. Gli impianti devono essere conservati nelle loro confezioni integre.

10. TECNICA CHIRURGICA

Il chirurgo deve essere esperto della tecnica operatoria. Informazioni aggiuntive sui prodotti e le tecniche operatorie (brochure e video) sono disponibili su richiesta. È fondamentale un'attenta pianificazione pre-operatoria.

ANCORA PER SUTURA MECTALOCK PEEK

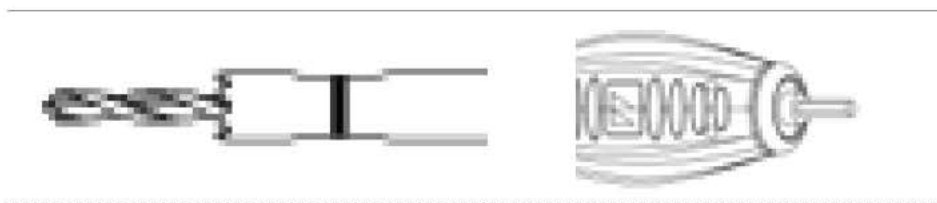
- Far passare la sutura USP#2/EP#5 HS Fibra 39" in UHMWPE attraverso i tessuti molli utilizzando la tecnica preferita dal chirurgo; lasciare che i due fili della sutura fuoriescano dal paziente attraverso l'ingresso artroscopico
- Trovare la posizione desiderata per il posizionamento dell'ancora MectaLock PEEK; inserire un filo guida percutaneo (max Ø1.5mm) attraverso l'apposito ingresso artroscopico al fine di raggiungere la posizione desiderata
- Può essere utilizzata una guida dedicata per la punta del trapano e per aiutare a indicare la posizione del foro guida nell'osso. Inserire la guida artroscopica Medacta accoppiata ad un otturatore cannulato sopra il filo guida; il chirurgo può scegliere tra diverse punte per la guida a seconda delle sue preferenze e delle strutture anatomiche da trattare. Le guide e gli otturatori sono disponibili in due diverse lunghezze:



Le guide/otturatori e le punte per trapano possono essere combinati secondo la seguente tabella:

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

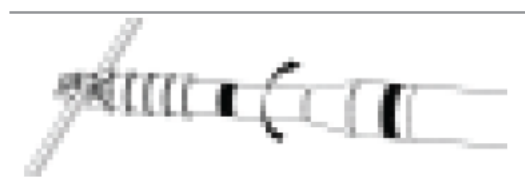
- Assicurarsi di forare fino a quando la tacca di profondità distale della punta da trapano non risulti allineata con la tacca di profondità distale della guida o fino a quando la punta da trapano non risulterà meccanicamente bloccata contro quest'ultima
- Usando l'apposita punta da trapano riutilizzabile compatibile, creare un foro nell'osso nella posizione desiderata per il posizionamento dell'ancora MectaLock PEEK



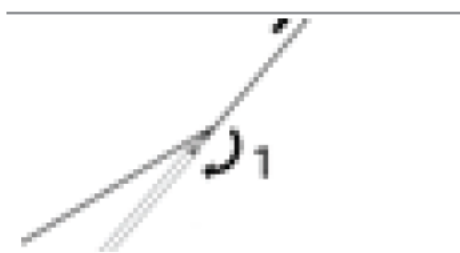
Caricare l'ancora MectaLock PEEK con le suture che escono dall'ingresso: tenendo saldamente i due fili della sutura con una mano, allinearli con la fessura della punta dell'ancora. Spingere delicatamente l'ancora contro la sutura per lasciarla agganciare all'occhiello della punta



Ruotare l'ancora di 90° in senso orario.



Allineare l'asse principale del driver con la sutura (1) e quindi, tenendo sempre la sutura leggermente tesa, far scorrere l'ancora sulla sutura (2) verso il paziente attraverso l'ingresso artroscopico, fino a raggiungere il foro guida



Una volta raggiunto il foro guida, regolare la tensione della sutura secondo le preferenze del chirurgo e picchiare il manico in plastica del driver fino a quando l'ancora MectaLock PEEK sarà posizionata correttamente. La profondità corretta si ottiene quando la marcatura laser distale è a filo con la superficie ossea

- Svitare il driver monouso
- Palpare i tessuti molli riparati usando una sonda artroscopica per garantire che la riparazione sia sicura
- Tagliare e rimuovere le suture in eccesso



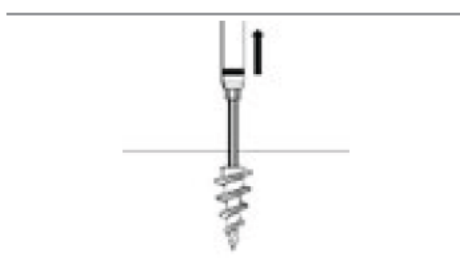
ANCORA PER SUTURA MECTALOCK TI

- Trovare la posizione desiderata per il posizionamento dell'ancora MectaLock TI; inserire il driver precaricato con l'ancora MectaLock TI attraverso l'apposito ingresso artroscopico al fine di raggiungere la posizione desiderata
- Picchiare delicatamente il manico posteriore dell'inseritore monouso per lasciare che la punta dell'ancora MectaLock TI fori l'osso nel punto scelto; mantenendo una leggera forza assiale sull'inseritore monouso, avvitare l'ancora MectaLock TI nell'osso fino a quando la marcatura laser distale sull'inseritore è a filo con la superficie ossea



Sbloccare le suture dal manico in plastica e sganciare delicatamente la punta dell'inseritore dall'ancora MectaLock TI, tirando fuori l'inseritore attraverso l'ingresso artroscopico

- Far passare le due suture USP#2/EP#5 HS Fiber 39" in UHMWPE attraverso i tessuti molli con la tecnica preferita dal chirurgo per il passaggio della sutura e la sua annodatura
- Palpare i tessuti molli riparati usando una sonda artroscopica per garantire che la riparazione sia sicura
- Tagliare e rimuovere le suture in eccesso



11. CURE POST-OPERATORIE E CONTROLLO

Il medico dovrebbe avvisare i pazienti di controllare il livello della loro attività per evitare carichi eccessivi sull'arto operato. Inoltre, il chirurgo deve informare il paziente delle precauzioni da adottare in termini di attività fisica, terapie e limitazioni alle attività, eventuali limitazioni riportate in etichetta nonché dell'esposizione ai campi magnetici. Il paziente deve essere avvisato anche del fatto che gli impianti possono incidere sui risultati di esami di tomografia computerizzata (TC) o di imaging di risonanza magnetica (MRI). Si raccomandano periodici follow-up per effettuare dei confronti con la immediata condizione postoperatoria ed anticipare complicanze relative all'impianto. Un'eccessiva attività fisica e traumi all'arto operato possono causare fallimenti precoci dell'impianto. Qualora questo avvenga, è necessario porre il paziente sotto supervisione, valutare il possibile avanzamento della deteriorazione e soppesare i vantaggi di una revisione precoce.

12. EFFETTI INDESIDERATI E COMPLICANZE

Effetti indesiderati che possono verificarsi nel riattaccare i tessuti molli alle ossa nelle procedure chirurgiche ortopediche:

- Infezione, sia profonda che superficiale
- Allergie, leggeri processi infiammatori e reazioni a corpi estranei nell'impiantare il materiale

Alcuni effetti avversi possono portare alla morte.

Complicanze generali includono:

- Trombosi venosa con/senza embolia polmonare
- Disturbi cardiovascolari o polmonari
- Ematomi
- Reazioni allergiche sistemiche
- Dolore sistemico

13. IMBALLAGGIO

Le ancore per suture MectaLock sono fornite in confezioni monouso. Per i componenti consegnati sterili, il metodo di sterilizzazione è riportato in etichetta. Controllare la data di scadenza sull'etichetta e l'integrità della confezione per accertarsi che la sterilità del contenuto non sia stata compromessa. Se la confezione è danneggiata o se è stata precedentemente aperta, non usare il componente. Non risterilizzare.

14. CONSERVAZIONE

Le ancore per suture MectaLock sono fornite in confezioni monouso. Per i componenti consegnati sterili, il metodo di sterilizzazione è riportato in etichetta. Controllare la data di scadenza sull'etichetta e l'integrità della confezione per accertarsi che la sterilità del contenuto non sia stata compromessa. Se la confezione è danneggiata o se è stata precedentemente aperta, non usare il componente. Non risterilizzare.

15. TRADEMARKS

Medacta è un marchio registrato di Medacta International SA, Castel San Pietro, Svizzera.

Il testo di riferimento è in lingua inglese.

Ultimo aggiornamento: Luglio 2020

NEDERLANDS: MECTALOCK SUTURE ANCHORS - GEBRUIKSIINSTRUCTIES

Belangrijke mededeling: het apparaat mag alleen worden voorgeschreven en worden geïmplantéerd door een dokter die wettelijk deze vorm van chirurgie mag uitvoeren.

1. ALGEMEEN

Voor elke vorm van chirurgie moet de chirurg de literatuur over het product en de operatieve techniek kennen en hij dient met volle aandacht deze gebruiksinstructies te lezen. De juiste selectie van patiënten is even belangrijk als de plaatsing of het positioneren van het implantaat. Ongeschikte functionele eisen kunnen bijdragen tot een kortere levensduur van het implantaat. Men dient letten op deze waarschuwingen en men dient de gebruiksaanwijzingen strikt volgen.

2. BESCHRIJVING VAN HET PRODUCT

Deze gebruiksaanwijzingen zijn bedoeld voor alle producten die hieronder worden beschreven.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

Medacta MectaLock PEEK (knooploos) en MectaLock TI (voorgespannen) zijn vervaardigd uit polyetheretherketone (PEEK) of uit titaniumlegering. De MectaLock Hechtankers zijn voorzien van hechtingen die rechtstreeks voorgespannen zijn in het implantaat (MectaLock Ti) of rechtstreeks geplaatst zijn in de definitieve verpakking (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003		
05.10.011	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.012		

Materiaalspecificaties

Ankers: polyetheretherketon (PEEK) [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Driver steel/lichaam: roestvrij staal

Driver handvat: Polycarbonaat medische kwaliteit

Hechting: niet resorbeerbaar USP#2/EP#5 HS Fiber 39" polyethyleen met ultrahoog molecuulgewicht (gemiddelde diameter: 0.500-0.599mm)

3. GEBRUIKSAANWIJZING

De niet-resorbeerbare hechtankers zijn bedoeld om:

- MectaLock TI Hechtankers: herfixeren van zacht weefsel in het schoudergewricht.(d.w.z.: herstel van cuff rotator, biceps tenodesis)
- MectaLock PEEK Hechtankers: behandeling van heup en schouder instabiliteit door het herfixeren van de acetabulaire of glenoidale labrum aan het bot

Het hulpmiddel is bestemd voor gebruik in zowel artroscopische als open chirurgische ingrepen. Nadat de hechting in het bot wordt geankerd, wordt het gebruikt om zacht weefsel terug aan te hechten. Inclusief de volgende systeem specifieke aanwijzingen:

- MectaLock TI Hechtankers: herfixatie van zacht weefsel in het schoudergewricht
- MectaLock PEEK Hechtankers: behandeling van heup en schouder instabiliteit door middel van het heraanhechten van het acetabulaire of glenoidale labrum aan het bot

Het hechtanker systeem stabiliseert op die manier het beschadigde zachte weefsel, in combinatie met de passende postoperatieve immobilisatie, gedurende de revalidatieperiode.

4. CONTRA-INDICATIES

- Pathologische omstandigheden van het te herstellen zachte weefsel die de hechtingsfixatie aantasten
- Pathologische omstandigheden van het bot die de MectaLock Hechtankers aantasten
- Pathologische omstandigheden die de adequate ondersteuning van het implantaat zouden elimineren, trachten te elimineren of de genezing zouden vertragen
- Omstandigheden die het vermogen of bereidheid van de patient trachten te limiteren of activiteiten beperken of het limiteren bepaalde richtingen tijdens de revalidatieperiode
- Het aanhechten van artificiële ligamenten en andere implantaten
- Gevoeligheid aan vreemde stoffen, bekende of verwachte allergies aan het implantaat en/of instrumentent

5. WAARSCHUWINGEN UND VOORZORGEN

Het succes van de operatie hangt af van of de operatieve techniek nauw gevolgd wordt en het correct gebruik van de speciaal hiervoor gebruikte instrumenten die ook speciaal ontworpen zijn voor dat gamma van implantaten. De chirurg moet de gepaste implantaat grootte kiezen gebaseerd op de specifieke procedure en de achtergrond van de patient. Verkeerd positioneren kan de levensduur van het implantaat verminderen en leiden tot het vroegtijdig falen van het implantaat. De wegwerpbare kop is voor enkel gebruik en moet worden weggeworpen volgens het beleid en de procedure van het ziekenhuis.

Eén Medacta-label voor elk hulpmiddel, moet correct aangebracht worden op de meegeleverde Medacta-implantaatkaart en aan de patient meegegeven worden.

Verzeker u ervan dat de Mectalock Hechtankers gebruikt worden met de bijhorende compatibele herbruikbare boor. Gebruik de bijhorende herbruikbare compatibele boor voor het maken van het boorgat. Behoudt de correcte uitlijning gedurende de insertie van het anker en voorkom ontkoppeling van de kop/motor. Het risico dat het MectaLock Hechtanker breekt tijdens de implantatie is gereduceerd door de volgende specifieke instructies voor gebruik hieronder gelijst. De gepaste selectie en plaatsing van het implantaat zijn belangrijke overwegingen in het succesvol gebruik van het hulpmiddel. De gepaste orientatie en uitlijning van de instrumenten zijn belangrijk gedurende de implantatie van de MectaLock Hechtankers. Anker om mogelijke breuk van het anker te minimaliseren. Breuk van de Mectalock Hechtanker kon zich voordoen als:

- Het boorgat, niet geboord is tot de gepaste diepte waar nodig
- Het MectaLock Hechtanker niet gepast uitgelijnd is met het boorgat, waar nodig
- Elke laterale belading wordt toegepast op het anker/insertor tijdens het aanbrengen van het MectaLock anker
- De driver van het MectaLock Hechtanker wordt gebruik om te prikken

Koppel de hechtingen niet los van de wegwerpbare driver wanneer de MectaLock TI Hechtanker wordt ingebracht voordat de finale dieptepositie is bereikt. Gebruik geen andere hechting dan niet-resorbabeerbare USP#2/EP#5 UHMWPE hechting.

Compatibiliteit met MRI

MectaLock TI:

Niet-klinische tests hebben aangetoond dat titanium implantaten MR Conditioneel zijn. Een patiënt met dit apparaat kan veilig worden gescand in een magnetisch resonantiesysteem die aan de volgende voorwaarden voldoet. Statisch magnetisch veld van 1,5 Tesla en 3 Tesla, met:

- Maximale ruimtelijke veldgradiënt van 12.800 G/cm (128 T/m)
- Maximale kracht product van 231.000.000 G²/cm (231 T²/m)

Theoretisch geschatte maximale gemiddelde absorptiesnelheid van het gehele lichaam (WBA) van 2 W/kg (normale bedrijfsmodus). Onder de hierboven gedefinieerde scancondities zullen titanium implantaten naar verwachting een maximale temperatuurstijging van minder dan:

- 1,5°C (2 W/kg, 1,5 Tesla) RF-gerelateerde temperatuurstijging veroorzaken met eenachtergrondtemperatuurstijging van ≈1,3°C (2 W/kg, 1,5 Tesla)
- 3,0°C (2 W/kg, 3 Tesla) RF-gerelateerde temperatuurstijging veroorzaken met eenachtergrondtemperatuurstijging van ≈2,3°C (2 W/kg, 3 Tesla)

na 15 minuten continu scannen.

In niet-klinische tests, het beeld artefact veroorzaakt door het apparaat strekt zich uit ongeveer 20,5 mm van het titanium implantaat wanneer belicht met een gradiënt echopuls volgorde en een 3 Tesla magnetische resonantie systeem.

De MectaLock PEEK Hechtankers zijn compatibel met MRI.

6. IMPLANTATEN MEDACTA INTERNATIONAL

Medacta International is niet verantwoordelijk voor het gebruik van zijn implantaatcomponenten in combinatie met een component van een andere fabrikant (tenzij anderszins gespecificeerd door Medacta International in de chirurgische techniek) en daarom raden we een dergelijk gebruik niet aan. De Mectalock Hechtankers mogen nooit herimplanteerd worden. Terwijl een implantaat onbeschadigd mag lijken, kunnen microscopische onvolmaaktheden optreden en dit kan leiden tot het niet goed functioneren van het implantaat. De chirurg die opereert moet er zich bewust van zijn, dat zelfs de meest geringe oppervlakkige beschadiging, bij voorbeeld veroorzaakt door een scherp stuk gereedschap op elektrocauterisatie, een invloed kan hebben op de levensduur van het apparaat en tot een breuk kan leiden. Medacta Mectalock Hechtankers producten zijn niet brandbaar.

7. WAARSCHUWING

De volgende risicofactoren, apart of samen, kunnen resulteren in slechte klinische uitkomsten:

- Inadequate botkwaliteit, (bv, osteoporose, osteopenie)
- Systemische ziekte of metabolische afwijkingen
- Voorgeschiedenis van infecties en regelmatig vallen
- Drug verslaving en alcohol en medicijn misbruik
- Mentale incapaciteit van de patiënt om de instructies van de arts te begrijpen en uit te voeren
- Lokale bottumoren

8. GEBRUIKSAANWIJZING

PRE-OPERATIEVE FASE

De arts moet nagaan of de patiënt fysieke of mentale beperkingen heeft, en moet met de patiënt alle details van de procedure overlopen. Het gesprek zou de limitaties van de procedure en de contra-indicaties opgelegd door het gekozen implantaat, moeten behandelen. De factoren die de prestaties en de stabiliteit van het implantaat kunnen beïnvloeden, bijvoorbeeld het activiteitsniveau, dient men te bepalen om de kansen van de patiënt te verbeteren om complicaties te vermijden. De noodzakelijkheid van het volgen van de post-operatieve instructies die de chirurg geeft, dient volledig door de patiënt begrepen te worden. Een voorraad van steriele implantaten van passende maten dienen beschikbaar te zijn en dient voor de uitvoerende gecontroleerd te worden voor de operatie.

9. BEHANDELING

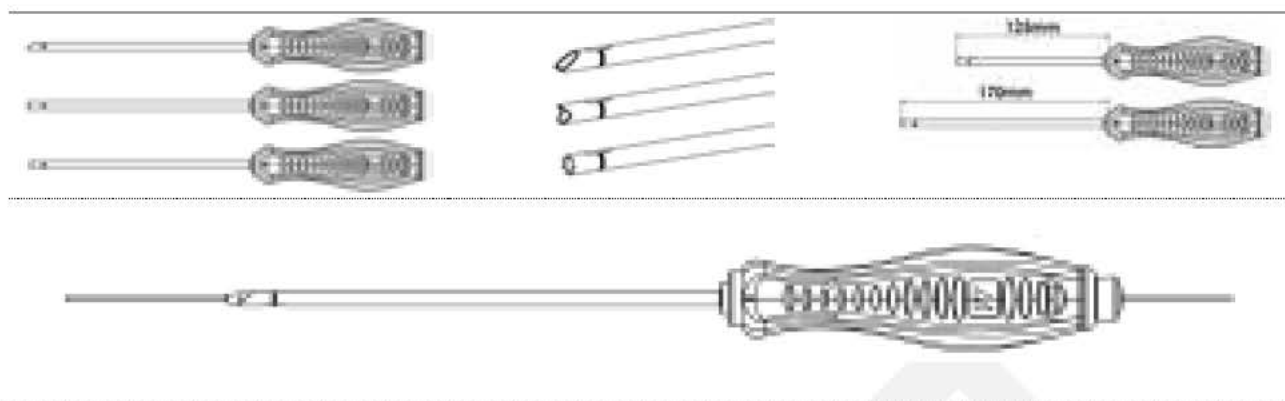
Om te vermijden dat men de implantaten krast of beschadigt, dient gekwalificeerd personeel met uiterste voorzichtigheid hiermee om te gaan, in een omgeving waarbij hygiënische condities in acht genomen worden. Men dient de implantaten in hun onbeschadigde verpakking te houden.

10. CHIRURGISCHE TECHNIK

De chirurg dient de chirurgische techniek grondig te kennen. Extra informatie over de chirurgische techniek (brochure en video) en producten kan men op verzoek ontvangen. Zorgvuldige pre-operatieve planning is essentieel.

MECTALOCK PEEK HECHTANKER

- Ga door het zachte weefsel met de USP#2/EP#5 HS Fiber 39" UHMWPE hechting door gebruik te maken van de chirurg zijn voorkeursstechniek; laat de twee strengen van de hechting uit de patiënt komen via de arthroscopische opening
- Vindt de gewenste locatie voor de plaatsing van de MectaLock PEEK anker, breng de percutane geleidingsdraad in de daartoe gepaste arthroscopische opening om de gewenste locatie te bereiken
- Een toegewijde richter kan gebruikt worden als boorgeleider en helpen om de locatie van het boorgat aan te duiden in het bot. Breng de Medacta Arthroscopische richter, gekoppeld met de gecanuleerde obturatoren over de geleidingsdraad; de chirurg kan kiezen uit de tip van de richter, afhankelijk van zijn voorkeur, en de anatomische structuren die behandeld dienen te worden. Richters en obturatoren worden aangeboden in twee verschillende maten



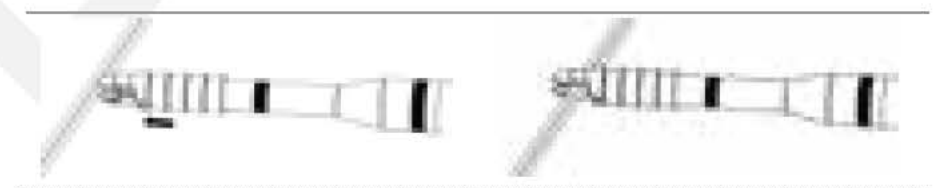
Richters/obturatoren en boren kunnen gekoppeld worden volgens de volgende tabel:

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

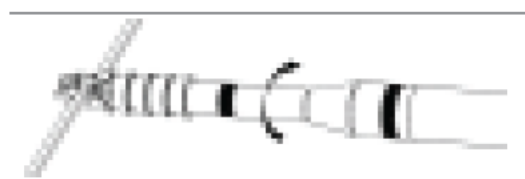
- Wees er zeker van te boren tot de distale dieptemarkering van de boor uitgelijnd is met de distale dieptemarkering van de richter of tot de boor mechanisch geblokkeerd wordt op de richter
- Gebruik de bijhorende herbruikbare compatibele boor, maak een gat in het bot op de gewenste locatie voor de plaatsing van het MectaLock PEEK anker



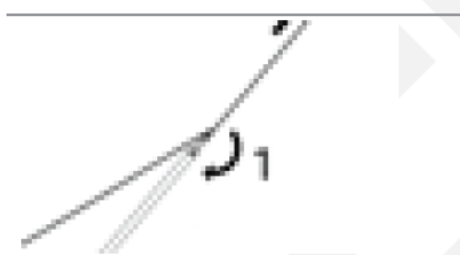
Span het MectaLock PEEK anker met de hechtingen die uit de opening komen: houdt terwijl de strengen van de hechting stevig met de hand vast, lijn ze uit met de groef van het ankertip. Duw het anker zachtjes tegen de hechting om het te laten vastklemmen in het oogje van de tip



Roteer het anker rechtsom met 90°



Uitlijn de hoofdas van de kop met de hechting (1) om daarna, terwijl de hechting nog steeds zachtjes wordt gespannen, het anker over de hechting te schuiven (2) naar de patiënt toe door de arthroskopische opening, tot het boorgat bereikt is



Eénmaal het boorgat bereikt, reguleer de hechtingsspanning volgens de voorkeur van de chirurg en tik op het plastieken handvat van de driver tot het MectaLock PEEK anker correct geplaatst is. De correcte diepte is bereikt wanneer de distale lasermarkering gelijk is met het botoppervlak

- Schroef de driver los
- Palpeer het gerepareerde zachte weefsel door gebruik te maken van een artroscopische sonde en er zich van te verzekeren dat het herstel veilig is
- Knip en verwijder de overtollige hechtingen



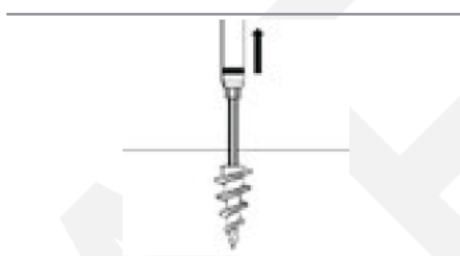
MECTALOCK TI HECHTANKER:

- Zoek de gewenste locatie voor de plaatsing van het MectaLock TI anker; plaats de voorgespannen driver met de MectaLock TI anker door de passende artroscopische opening om de gewenste locatie te bereiken
- Tik zachtjes op de rug van het handvat van de wegwerpbare driver om de tip van het MectaLock TI anker door het bot te laten boren op de gekozen plaats; terwijl er een axiale kracht wordt gehouden op de wegwerpbare driver, schroef het MectaLock TI anker in het bot tot de distale laser markering op de driver gelijk staat aan de botoppervlakte



Maak de hechtingen los van het plasticen handvat en maak de tip van de driver zachtjes los van het MectaLock TI anker, verwijder de driver via de arthroscopische opening

- Leidt de 2x USP#2/EP#5 HS Fiber 39" UHMWPE hechtingen door het zachte weefsel en maak een knoop door gebruik te maken van de chirurg zijn voorkeurstechiek
- Palpeer het gerepareerde zachte weefsel door gebruik te maken van een arthroscopische sonde en er zich van te verzekeren dat het herstelt eilig is
- Knip en verwijder de overvloedige hechtingen



11. POSTOPERATIEVE ZORG EN FOLLOW-UP

De arts moet de patiënt verwittigen dat ze hun activiteitsniveau moeten controleren en excessieve krachten op het geopereerde been moeten vermijden. Verder dient de chirurg de patiënt op de hoogte te stellen van de voorzorgsmaatregelen die men moet nemen in termen van oefeningen, behandelingen en beperkingen wat betreft activiteiten, beperkingen die men op het label vermeldt vindt, als ook blootstelling aan magnetische velden. Men moet de patiënt vertellen, dat implantaten de resultaten van computer tomografie (CT) of magnetic resonance imaging (MRI) scans kunnen beïnvloeden. Regelmatige opvolging worden aangeraden om vergelijkingen te maken met de onmiddellijke post operatieve toestand en om implantaat gerelateerde complicaties te voorzien. Overmatig lichamelijke activiteiten en traumas aan de geopereerde benen kunnen een voortijdig falen van het implantaat veroorzaken. Als dit ook echt gebeurt, is het noodzakelijk de patiënt onder supervisie te plaatsen, de mogelijk voortgang van de verslechtering te evalueren en het voordeel van vroege revisie af te wegen.

12. ONGEWENSTE GEVOLGEN EN COMPLICATIES

Ongewenste effecten kunnen optreden tijdens het heraanhechten van het zachte weefsel aan het bot in chirurgische orthopedische procedures:

- Diepe en oppervlakkige infectie
- Allergieën, milde ontsteking en afstoot reacties op het geïmplanteed materiaal

Sommige bijwerkingen kunnen ten lange leste tot de dood leiden.

Algemene complicaties houden onder meer in:

- Veneuze trombose met/zonder pulmonaire embolie
- Cardiovasculaire of pulmonaire stoornissen
- Hematoma's
- Systemische allergische reacties
- Systemische pijn

13. VERPAKKING

De Mectalock Hechtankers worden geleverd in verpakkingen voor eenmalig gebruik. Bij componenten die men steriel levert, wordt de methode van sterilisatie op het label aangeduid. De vervaldatum moet op het label gecontroleerd worden en ook of de verpakking geheel intact is. Men moet er zeker van zijn dat alles nog steeds steriel is. Als de verpakking beschadigd is of eerder geopend werd, dient u de componenten niet te gebruiken. Niet opnieuw steriliseren.

14. OPSLAG/BEWAREN

De verpakking moet opgeslagen worden op een koele, droge plek zonder licht.

15. MERKNAMEN

Medacta is een gedeponeerd handelsmerk van Medacta International SA, Castel San Pietro, Zwitserland.

De tekst waarnaar gerefereerd wordt is de Engelse tekst.

Laatste Update: Juli 2020

DEUTSCH: MECTALOCK SUTURE ANCHORS - GEBRAUCHSANWEISUNGEN

Wichtiger Hinweis: Die Komponente(n) darf/dürfen nur durch einen Arzt verordnet oder implantiert werden, der über die rechtliche Zulassung zur Durchführung dieser Operation verfügt.

1. ALLGEMEINES

Vor einer Operation muss der Chirurg mit der Literatur zum Produkt und der Operationstechnik vertraut sein und diese Gebrauchsanweisungen sorgfältig studieren. Die Patientenauswahl ist genauso wichtig, wie die Platzierung oder das Ausrichten des Implantats. Ungeeignete funktionelle Anforderungen können zu einer verkürzten Lebensdauer des Implantats führen. Die Warnungen müssen beachtet und die Gebrauchsanweisungen strikte befolgt werden.

2. PRODUKTBESCHREIBUNGEN

Diese Gebrauchsanweisungen sind für alle nachstehend beschriebenen Produkte bestimmt.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

Medacta MectaLock PEEK (knotenfrei) und MectaLock TI (vorgeladen) werden aus PolyEtherEtherKeton (PEEK) or Titan hergestellt. Die MectaLock Fadenanker kommen mit Fäden vorgeladen (MectaLock TI) oder mit Fäden, die sich in der Blisterverpackung befinden (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003		
05.10.011	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.012		

Material Specifications

Anker: PolyEtherEtherKeton (PEEK) [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Einbringer: rostreier Stahl

Handgriff Einbringer: Polycarbonat, medical grade

Faden: nicht resorbierbar, USP#2/EP#5 HS Fiber 39" Ultra-High molecular weight polyethylene (Durchmesser: 0.500-0.599mm)

3. VERWENDUNGSZWECK

Die nichtresorbierbaren Anker dienen der:

- MectaLock TI Faden Anker: Weichteilrefixation innerhalb des Schultergelenks (z.B.: Rotatorenmanschettenruptur, Bizeps tenodesis)
- MectaLock PEEK Faden Anker: Behandlung der Hüft-, und Schulterinstabilität durch refixieren des acetabulären oder glenoidalen Labrums an den Knochen

Das Produkt ist sowohl für den Einsatz bei arthroskopischen als auch bei offenen chirurgischen Eingriffen geeignet. Nachdem der Fadenanker im Knochen verankert ist, können die Fäden zur Wiederbefestigung von Weichteilen am Knochen verwendet, einschließlich der folgenden systemspezifischen Indikationen:

- MectaLock TI Faden Anker: Weichteilrefixierung innerhalb des Schultergelenks
- MectaLock PEEK Faden Anker: Behandlung der Hüft-, und Schulterinstabilität durch refixieren des acetabulären oder glenoidalen Labrums an den Knochen

Die Faden Anker stabilisieren somit das beschädigte Weichteilgewebe. In Kombination mit der entsprechenden postoperativen Immobilisation während des Heilungsprozesses.

4. KONTRAINDIKATIONEN

- Pathologische Umstände des Weichteilgewebes die sich negativ auf die Fadenfixierung auswirken können
- Pathologische Umstände des Knochens welche sich nachteilig auf den MectaLock Faden Anker auswirken können
- Körperliche Bedingungen die eine Einheilung vermeiden, oder behindern könnten
- Umstände, die den Patienten daran hindern könnten, seine Aktivitäten entsprechend einzuschränken oder den ärztlichen Anweisungen während der Heilphase Folge zu leisten
- Anbringung von Kunstbändern oder anderen Implantaten
- Fremdkörperempfindlichkeit, bekannte oder vermutete Allergien betreffend Implantat und/oder Instrumentenmaterial

5. WARNHINWEISE

Der Erfolg der Operation hängt von der Einhaltung der zur Verfügung gestellten Operationstechnik und dem korrekten Gebrauch der dafür bestimmten Instrumente ab, die speziell für diese Art von Implantaten konzipiert wurden. Der Chirurg muss die korrekte Implantatgröße basierend auf OP Technik und Patientengeschichte wählen. Fehlplatzierung könnte die Langlebigkeit des Implantats reduzieren und zu einem vorzeitigen Versagen des Implantats führen. Der zum Einmalgebrauch gedachte Einbringer muss im Einklang mit den Krankenhausregeln und Prozeduren entsorgt werden.

Ein Medacta-Etikett für jedes Implantat muss ordnungsgemäß auf dem mitgelieferten Medacta-Implantatpass angebracht und an den Patienten abgegeben werden.

Stellen Sie sicher, dass die MectaLock Faden Anker ausschliesslich mit den dafür vorgesehenen Bohrer verwendet werden. Verwenden Sie den vorgesehenen, kompatiblen, wiederverwendbaren Bohrer um das Bohrloch herzustellen. Stellen Sie sicher, dass während des Einbringens des Ankers. Die Gefahr eines Bruchs des MectaLock Faden Ankers während der Implantation wird durch genaues befolgen der untenstehenden Anweisung entgegengewirkt. Genaue Auswahl und Platzierung des Implantates sind wichtige Berücksichtigungen für eine erfolgreiche Anwendung des Produkts. Genaue Orientierung und Ausrichtung der Instrumente ist wichtiger Bestandteil während der Implantation der MectaLock Faden. Anker um das Risiko eines möglichen Bruchs des Implantates zu vermeiden. Ein Bruch des MectaLock Faden Anker kann in folgenden Fällen auftreten:

- das Bohrloch hat nicht die notwendige Tiefe
- der MectaLock Faden Anker ist nicht korrekt mit dem Bohrloch ausgerichtet
- jedwede seitliche Last, die während des Platzierens auf den Einbringer oder den MectaLock Anker aufgebracht wird
- der MectaLock Faden Anker Einbringer wird als Hebel benutzt

Entfernen Sie nicht die Fäden aus dem zum Einmalgebrauch vorgesehenen Einbringer während Sie den MectaLock Ti Faden Anker einbringen, bevor sich der Anker in der finalen Position und der richtigen Einbringtiefe befindet. Benutzen Sie keine anderen Fäden als die zur Verfügung gestellten, nicht resorbierbaren USP#2/EP#5 UHMWPE.

MRI-Kompatibilität

MectaLock TI:

Nicht-klinische Tests haben gezeigt, dass Titanimplantate bedingt MR-sicher sind. Ein Patient mit diesem Implantat kann sicher einem MR ausgesetzt werden, welches die folgenden Anforderungen erfüllt. Statisches Magnetfeld von 1,5- oder 3,0 Tesla mit einem höchsten räumlichen:

•Feldgradienten von 12.800 G / cm (128 T / m) Maximales

•Gradient-Feld-Produkt von 231.000.000 G2 / cm (231 T2 / m)

Theoretisch geschätzter maximaler - über den ganzen Körper gemittelter - spezifische Absorptionsrate von 2 W / kg (normale Betriebsart). Unter den oben definierten Scanbedingungen ist eine maximale Erwärmung des Titan Implantats von nicht mehr als:

•1,5°C (2 W/kg, 1,5 Tesla) HF-bedingter Temperaturanstieg mit a Hintergrundtemperaturanstieg von ~ 1,3 °C (2 W / kg, 1,5 Tesla)

•3,0°C (2 W/kg, 3 Tesla) HF-bedingter Temperaturanstieg mit a Hintergrundtemperaturanstieg von ~ 2,3 °C (2 W / kg, 1,5 Tesla)

nach 15 Minuten fortwährenden Scannen.

Bei nicht-klinischen Tests erstreckt sich das Bildartefakt bei einem 3 Tesla MR, welches durch das Implantat verursacht wird, ungefähr 20,5 mm über das Titanimplantat hinaus.

MectaLock PEEK Fadenanker ist MR geeignet.

6. IMPLANTATE VON MEDACTA INTERNATIONAL

Medacta International ist nicht verantwortlich für die Verwendung seiner Implantatkomponenten in Kombination mit einer Komponente eines andern Herstellers (sofern dies nicht von Medacta International in der Operationstechnik ausdrücklich spezifiziert wird); wir raten deshalb von einer solchen Verwendung ab. Die MectaLock Suture Anchors sind nicht zur Wiederverwendung gedacht. Auch wenn ein Implantat unbeschädigt erscheint, können mikroskopische Mängel vorhanden sein und zum Versagen des Implantats führen. Der operierende Chirurg muss sich bewusst sein, dass ein auch nur kleiner oberflächlicher Schaden, verursacht z. B. durch ein scharfes Werkzeug oder Elektrokauter, einen Einfluss auf die Standzeit der Komponenten haben und zur Fraktur führen kann. Medacta MectaLock Suture Anchors Produkte sind nicht-pyrogen.

7. ACHTUNG

Die folgenden Risikofaktoren, einzeln oder zusammen, können zu schlechten klinischen Ergebnissen führen:

- Schlechte Knochenqualität (z.B. Osteoporose, Osteopenie)
- Systemerkrankungen und metabolische Störungen
- Aktenkundige Infektionen oder erneutes Auftreten
- Drogen-,Medikamenten-, Alkoholabhängigkeit
- Geistige Unfähigkeit des Patienten den Anweisungen des Operateurs folge zu leisten
- Lokale Knochentumore

8. ANWENDUNGSVORSCHRIFT

VOR DER OPERATION

Der Operateur muss mögliche körperliche und geistige Beschränkungen des Patienten im Vorfeld erfassen und ihn detailliert über den Eingriff und das Implantat informieren. In der Besprechung sollten die Grenzen des Verfahrens und Einschränkungen durch das gewählte Implantat angesprochen werden. Die Faktoren, die die Leistung und die Stabilität des Implantats beeinträchtigen könnten, wie z. B. Aktivitätsgrad, sollten ausgeführt werden, um die Chancen des Patienten zu vergrößern, Komplikationen zu vermeiden. Der Patient muss verstehen, dass die postoperativen Anweisungen des Chirurgen strikt befolgt werden müssen. Vor der Operation müssen genügend sterile Implantate der geeigneten Größe vorhanden sein und durch den Operateur geprüft werden.

9. UMGANG MIT DEN IMPLANTATEN

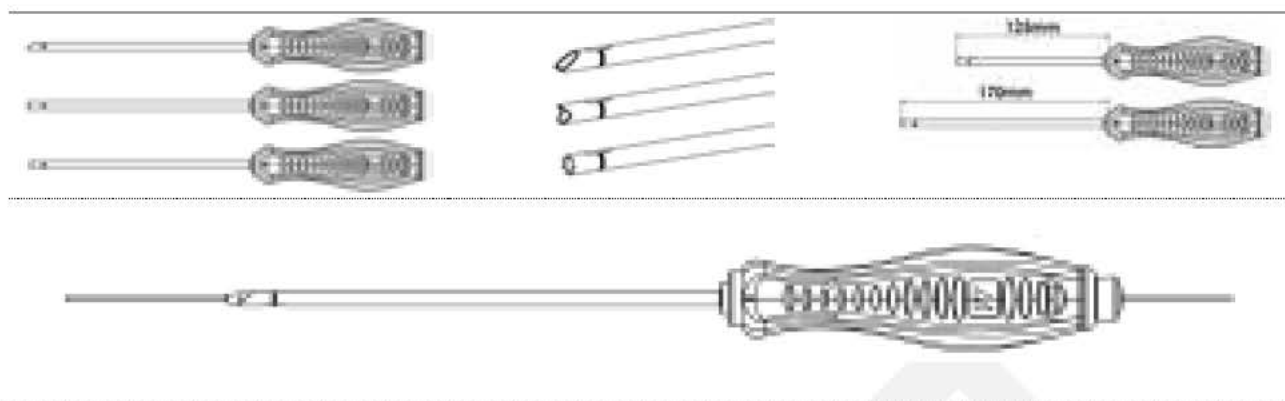
Um Zerkratzen oder Beschädigen der Implantate zu vermeiden, sollte nur qualifiziertes Personal in einer hygienekontrollierten Umgebung mit größtmöglicher Sorgfalt hantieren. Die Implantate sollten in ihren unbeschädigten Verpackungen verbleiben.

10. OPERATIONSTECHNIK

Der Chirurg muss mit der Operationstechnik vollkommen vertraut sein. Weitere Informationen zur Operationstechnik (Broschüre und Video) und Produkte sind auf Anfrage verfügbar. Eine sorgfältige präoperative Planung ist grundlegend.

MECTALOCK PEEK FADEN ANKER

- Nutzen Sie die 2x USP#2/EP#5 HS Fiber 39" UHMWPE Fäden um mit dem vom Operateur bevorzugten Weichteilpenetrator das Weichteil zu durchstechen und anschliessend aufzuknoten; Beide Fadenenden durch das Portal ausführen
- Suchen Sie die korrekte Stelle an welcher Sie den MectaLock PEEK Anker platzieren wollen; Führen Sie einen Führungsdraht (max Ø1.5mm) durch das entsprechende Portal um die korrekt Stelle zu erreichen
- Ein spezielles Zielgerät kann als Bohrhülse zur Führung des Bohrers und zum Anzielen des Bohrloches verwendet werden. Führen Sie die dafür vorgesehene arthroskopische Bohrhülse, die mit dem knülierten Obturator versehen ist über den Führungsdraht ins Gelenk; Dem Operateur stehen verschiedenen Spitzenkonfigurationen zur Verfügung, je nach Präferenz und anatomischer Gegebenheit. Zielgeräte und Obturatoren werden in zwei Nutzlängen zur Verfügung gestellt:



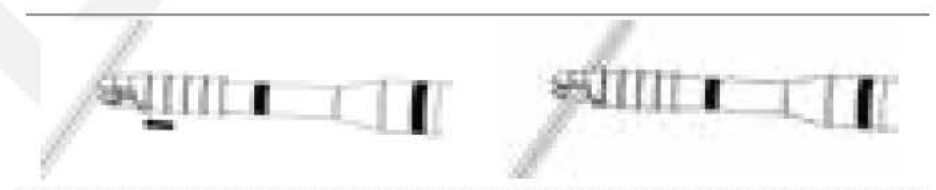
Zielgeräte/Obturatoren und Bohrer können wie folgt verbunden werden:

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

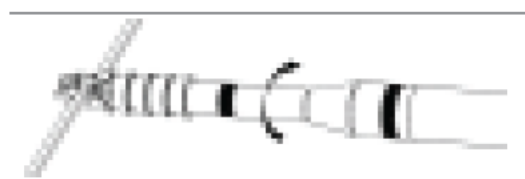
- Benutzung des korrekten, kompatiblen, wiederverwendbaren Bohrers, Bohren eines Lochs an der gewünschten Stelle um den MectaLock PEEK Anker zu platzieren
- Stellen Sie sicher, dass Sie bis zur Übereinstimmung der Lasermarkierung des Bohrers und der Zielhülse bohren oder bis zum mechanischen Anschlag



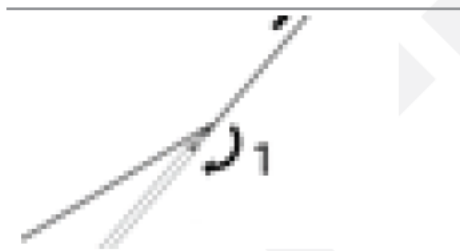
Beladen Sie den MectaLock PEEK Anker mit den Fäden die Sie aus dem Portal geleitet haben: während Sie die zwei Fäden mit einer Hand unter Spannung halten, richten Sie die Nut des Ankers mit den Fäden aus. Durch einen leichten Druck gegen die Fäden, rutschen diese sicher ins Eylet des Ankers



Drehen Sie den Anker um 90° im Uhrzeigersinn

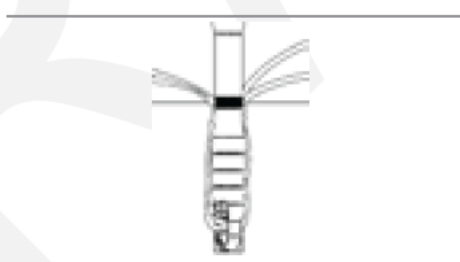


Richten Sie den Einbringer parallel zu den Fäden aus (1), während Sie diese weiterhin leicht gespannt halten, schieben Sie den Anker entlang der Fäden durch das Portal zum Bohrloch



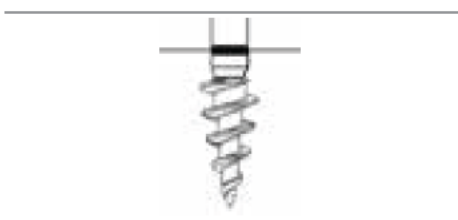
Sobald Sie das Bohrloch erreicht haben stellen Sie die gewünschte Spannung ein und klopfen auf den Kunststoffgriff bis der MectaLock PEEK Anker korrekt platziert ist. Die korrekte Tiefe ist erreicht, sobald die Lasermarkierung am Knochen ansteht

- Durch linksdrehen des Einbringers lösen Sie diesen vom Anker
- Palpieren Sie das refixierte Weichteilgewebe mithilfe eine Tasthakens um sicherzustellen, dass die Refixation erfolgreich war
- Schneiden Sie die Faden ab und entfernen diese



MECTALOCK TI FADEN ANKER

- Identifizieren Sie die korrekte Stelle an welcher Sie den MectaLock TI Anker platzieren möchten; Führen Sie den vorgeladenen MectaLock TI Anker Einbringer durch das vorgesehene Portal um die gewünschte Stelle zu erreichen
- Klopfen Sie leicht auf den Handgriff des zum Einmalgebrauch gedachten Einbringers, damit sich die Spitze des MectaLock TI Ankers an der vorgesehenen Stelle in den Knochen bohrt; durch leichten axialen Druck auf den Einbringer und gleichzeitigem Eindrehen des MectaLock TI Ankers in den Knochen bis die Lasermarkierung am Knochen ansteht, wird dieser korrekt platziert



Befreien Sie die Fäden aus der Fadenhalterung im Handgriff und ziehen Sie den Einbringer durch das Portal ab

- Nutzen Sie die 2x USP#2/EP#5 HS Fiber 39" UHMWPE Fäden um mit dem vom Operateur bevorzugten Weichteilpenetrator das Weichteil zu durchstechen und anschliessend aufzuknoten
- Palpieren Sie das refixierte Weichteilgewebe mithilfe eine Tasthakens um sicherzustellen, dass die Refixation erfolgreich war
- Schneiden Sie die Faden ab und entfernen diese



11. POSTOPERATIVE NACHSORGE UND NACHVERFOLGUNG

Der Operateur sollte die Patienten zur Vorsicht ermahnen um eine Überlastung der operierten Stelle zu verhindern. Der Chirurg sollte die Aufmerksamkeit des Patienten auf die Vorsichtsmaßnahmen, die bezüglich Übungen, Behandlungen und Aktivitätseinschränkungen notwendig sind, jegliche deklarierte Einschränkungen und auf die Exposition von Magnetfeldern lenken. Dem Patienten muss gesagt werden, dass Implantate die Ergebnisse von Aufnahmen mit Computertomographie (CT) oder Magnetresonanztomographie (MRI) beeinträchtigen kann. Regelmässige Nachuntersuchungen sollten eventuellen Komplikationen entgegenwirken. Übermässige körperliche Aktivität kann zu einem Implantatversagen führen. Nötigenfalls sollte der Patient überwacht, das Fortschreiten der Verschlechterung überprüft und der Nutzen einer frühen Revision abgewägt werden.

12. UNERWÜNSCHTE EREIGNISSE UND KOMPLIKATIONEN

Unerwünschte Ereignisse, die durch die Refixierung von Weichteilgewebe an Knochen im Rahmen orthopädischer Eingriffe auftreten können:

- Infektionen, tiefe und oberflächliche
- Allergien, leichte Entzündungen und Fremdkörperreaktionen aufgrund einer Implantatunverträglichkeit

Einige unerwünschte Wirkungen können letztendlich zum Tod führen.

Allgemeine Komplikationen beinhalten:

- Venenthrombose mit/ohne Lungenembolie
- Kardiovaskuläre oder pulmonale Störungen
- Hämatome
- Systemische allergische Reaktionen
- Systemische Schmerzen.

13. VERPACKUNG

Die MectaLock Suture Anchors sind für den Einmalgebrauch. Bei steril gelieferte Komponenten ist die Sterilisationsmethode auf dem Etikett angegeben. Das Ablaufdatum auf dem Etikett und die Integrität der Verpackung müssen geprüft werden, um sicherzustellen, dass die Sterilität nicht beeinträchtigt wurde. Verwenden Sie die Komponente nicht, wenn die Packung beschädigt ist oder zuvor geöffnet wurde. Nicht erneut sterilisieren

14. AUFBEWAHRUNG

Die Packungen müssen an einem kühlen, trockenen Ort vor Licht geschützt aufbewahrt werden.

15. MARKENZEICHEN

Medacta ist das eingetragene Markenzeichen von Medacta International SA, Castel San Pietro, Schweiz.

Der englische Text ist maßgeblich.

Stand: Juli 2020

ESPAÑOL: MECTALOCK SUTURE ANCHORS - INSTRUCCIONES DE USO

Aviso importante: el o los dispositivos deben ser prescritos e implantados por personal médico debidamente autorizado para realizar este tipo de cirugía.

1. ASPECTOS GENERALES

Antes de la intervención, el cirujano debe familiarizarse con la documentación del producto, con la técnica quirúrgica y leer detenidamente estas instrucciones de uso. La selección del paciente es tan importante como la colocación o el posicionamiento del implante. Unos requisitos funcionales inadecuados pueden contribuir a reducir la vida útil del implante. Deben tenerse en cuenta todas las advertencias y respetarse estrictamente todas las instrucciones de uso.

2. DESCRIPCIÓN DEL PRODUCTO

Estas instrucciones de uso se refieren a todos los productos descritos a continuación.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

Los Medacta MectaLock PEEK (sin nudo) y MectaLock TI (preanudados) se manufacturan en PolyEtherEtherKeton (PEEK) o aleación de Titanio, respectivamente. Las anclas de sutura MectaLock se suministran directamente anudadas al implante (MectaLock TI) o colocadas directamente en el envase final (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003		
05.10.011	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.012		

Material Specifications

Anclas : PolyEtherEtherKeton (PEEK). [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Eje y cuerpo de la guía: Acero inoxidable

Mango de la guía: Policarbonato de grado médico

Sutura: Polietileno de Ultra bajo peso molecular no-absorbible USP#2/EP#5 HS Fiber 39" (diámetro medio: 0.500-0.599mm)

3. UTILIZACIÓN

Las anclas para sutura no absorbibles se han diseñado para:

- Anclas para sutura MectaLock TI: re-fijación del tejido blando dentro de la articulación del hombro (p.ej. Reparación del manguito rotador, tenodesis del bíceps)
- Anclas para sutura MectaLock PEEK: tratamiento de la inestabilidad de la cadera y del hombro mediante la re-fijación del labrum acetabular o glenoidea al hueso

El ancla está indicado tanto en cirugías artroscópicas como abiertas. Una vez la sutura está anclada el hueso, se utiliza para religar el tejido blando al hueso, incluyendo las siguientes indicaciones específicas del sistema:

- Anclas para sutura MectaLock TI: re-fijación del tejido blando dentro de la articulación del hombro
- Anclas para sutura MectaLock PEEK: tratamiento de la inestabilidad de la cadera y del hombro mediante la re-fijación del labrum acetabular o glenoidea al hueso

De esta forma, el ancla para sutura estabiliza el tejido blando dañado, combinado con la adecuada inmovilización postoperatoria, a lo largo del periodo de curación.

4. CONTRAINDICACIONES

- La patología de los tejidos blandos reparar o reconstruir que puede afectar adversamente la fijación de la sutura
- Las condiciones patológicas del hueso que pueden afectar adversamente las anclas de sutura MectaLock
- Las condiciones físicas que pueden eliminar o tender a eliminar el adecuado soporte al implante o retrasar la curación.
- Las condiciones que tiendan a eliminar la capacidad o la voluntad del paciente para restringir actividades o seguir las instrucciones durante el período de recuperación
- Sobre posición de ligamentos artificiales u otros implantes
- Sensibilidad a cuerpos extraños, alergias conocidas o sospechadas a los materiales del implante o de los instrumentals

5. ADVERTENCIAS

El éxito de la intervención depende del respeto de la técnica quirúrgica indicada y el uso correcto del instrumental específico, especialmente diseñado para esa gama de implantes. El cirujano debe escoger la talla adecuada de implante basándose en el procedimiento específico y el historial del paciente. Un posicionamiento incorrecto puede reducir la longevidad del implante y producir un fallo anticipado del mismo. La guía desechable es de un solo uso y debe eliminarse según las normativas y procedimientos del hospital.

Se debe aplicar correctamente la etiqueta de cada dispositivo de Medacta en la Tarjeta de Implante Medacta suministrada y entregarla al paciente.

Asegurar que las anclas de sutura MectaLock se usan con la adecuada broca reutilizable. Usar la adecuada broca reutilizable para realizar el hueco piloto. Eliminar la alineación adecuada durante la inserción del ancla evitando que se suelte de la guía. El riesgo de rotura del ancla de sutura MectaLock durante la implantación se reduce si se siguen las instrucciones específicas de uso que siguen.

La adecuada selección y colocación del implante son consideraciones importantes para la satisfactoria utilización del elemento. Es importante la adecuada orientación y alineación de los instrumentos durante la implantación de la sutura Masterlock. Verificar la fijación del ancla para minimizar las posibilidades de su rotura. Una rotura del ancla de sutura MectaLock puede ocurrir si:

- El hueco piloto no se ha perforado hasta la profundidad adecuada, aunque sea en la posición adecuada
- El ancla de sutura MectaLock no está correctamente alineado con el hueco piloto tal como se había previsto
- Se aplica una fuerza lateral en el ancla o la guía durante la inserción del ancla MectaLock
- Se usa el ancla de sutura MectaLock para hacer palanca

No separar las suturas de la guía desechable mientras se inserta el ancla de sutura MectaLock, antes de alcanzar la profundidad final de posicionamiento. No utilizar otras suturas que no sean las no-absorbibles USP#2/EP#5 UHMWPE.

Compatibilidad con imágenes por resonancia magnética

MectaLock TI:

Las pruebas no clínicas han demostrado que los implantes de titanio son compatibles con la RM bajo ciertas condiciones. Un paciente con este dispositivo puede ser escaneado con seguridad en un sistema de resonancia magnética que cumpla con las siguientes condiciones. Campo magnético estático de 1,5 Tesla y 3 Tesla, con:

- Gradiente de campo espacial máximo de 12.800 G/cm (128 T/m)

- Producto de fuerza máxima de 231.000.000 G²/cm (231 T²/m)

Tasa de absorción específica (SAR) máxima, promediada para todo el cuerpo (WBA) de 2 W/kg (Modo de funcionamiento normal, estimación teórica). BBajo las condiciones de escaneo definidas anteriormente, los implantes de titanio esperaban producir un aumento máximo de temperatura de menos de:

- 1,5°C (2 W/kg, 1,5 Tesla) Aumento de temperatura relacionado con la RF con un aumento de latemperatura de fondo de ≈1.3°C (2 W/kg, 1,5 Tesla)

- 3.0°C (2 W/kg, 3 Tesla) Aumento de temperatura relacionado con la RF con un aumento de la temperaturade fondo de ≈2.3°C (2 W/kg, 3 Tesla)

después de 15 minutos de escaneo continuo.

En las pruebas no clínicas, el artefacto de imagen causado por el dispositivo se extiende aproximadamente 20,5 mm desde desde el implante de titanio cuando se le toma una imagen con una secuencia de pulso de eco gradiente y un sistema de resonancia magnética de 3 Tesla.

Los anclajes de sutura MectaLock PEEK son seguros para RM.

6. LOS IMPLANTES MEDACTA INTERNATIONAL

Medacta International declina toda responsabilidad en el caso de utilizarse sus componentes de implantes en combinación con componentes de otros fabricantes (salvo que Medacta International lo especifique de manera precisa en la técnica quirúrgica); de ahí, que desaconsejamos su uso. Los MectaLock Suture Anchors no se pueden reimplantar. Aunque puede parecer que un implante está en perfectas condiciones, existe la posibilidad de que presente imperfecciones microscópicas que pueden provocar el fallo del implante. El cirujano a cargo de la intervención debe ser consciente de que incluso el daño superficial más leve, provocado, por ejemplo, por una herramienta afilada o una electrocauterización, puede influir en la durabilidad del dispositivo y provocar una fractura. Los productos MectaLock Suture Anchors de Medacta son no pirogénicos.

7. ATENCIÓN

Los factores de riesgo siguientes, de forma independiente o combinada, pueden tener como resultado resultados clínicos deficientes:

- Calidad ósea inadecuada (como osteoporosis, osteopenia)
- Enfermedades sistémicas y trastornos metabólicos
- Historia de infección o caídas recurrentes
- Dependencia de drogas y abuso de alcohol y medicamentos
- Incapacidad mental del paciente para entender las instrucciones del especialista y cumplir con ellas
- Tumores óseos locales

8. MODO DE EMPLEO

EN EL PREOPERATORIO

El cirujano debería verificar las posibles limitaciones físicas del paciente y debería también discutir con el paciente todos los detalles del procedimiento y el implante. La conversación debe tener en cuenta las limitaciones del procedimiento y las limitaciones impuestas por el implante seleccionado. Los factores que podrían limitar el rendimiento y la estabilidad del implante, por ejemplo, el nivel de actividad, deben explicarse en detenimiento a fin de mejorar las posibilidades del cliente de evitar complicaciones. El paciente debe comprender plenamente la necesidad de seguir las instrucciones postoperatorias prescritas por el cirujano. Antes de la operación, debe haber una cantidad adecuada de implantes estériles de tamaños adaptados a disposición del cirujano responsable de la intervención y este debe proceder a su comprobación.

9. MANIPULACIÓN

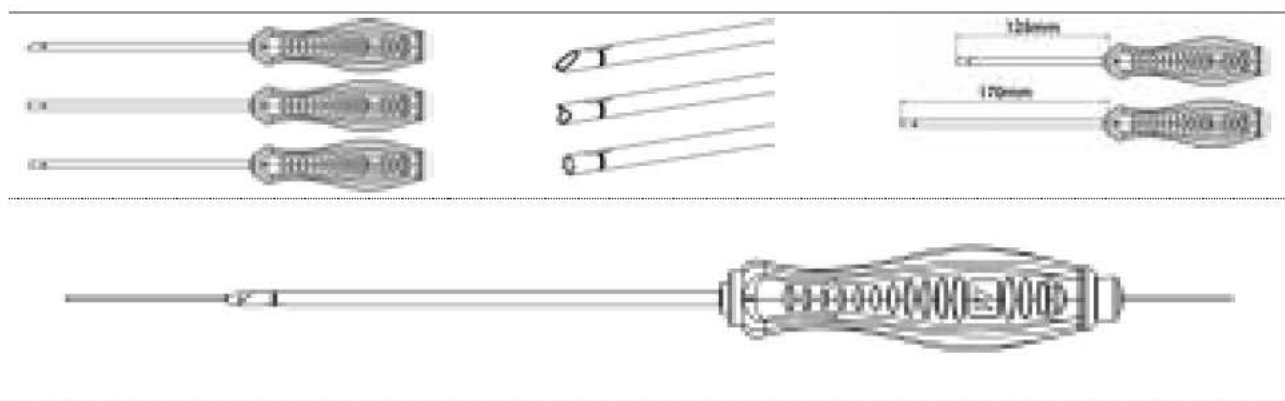
Para evitar provocar arañazos o daños en los implantes, estos deben manejarse con el máximo cuidado por parte de personal cualificado en un entorno con unas condiciones de higiene controladas. Los implantes deben conservarse en sus embalajes sin abrir.

10. TÉCNICA QUIRÚRGICA

El cirujano debe estar totalmente familiarizado con la técnica quirúrgica. Se podrá solicitar información adicional acerca de las técnicas y los productos quirúrgicos (folleto y vídeo). Una planificación preoperatoria cuidadosa resulta esencial.

ANCLA DE SUTURA MECTALOCK PEEK

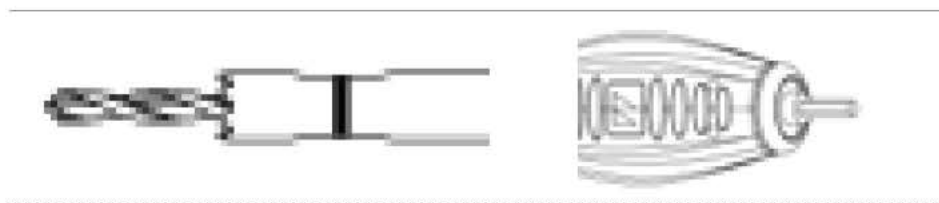
- Pasar la sutura USP#2/EP#5 HS Fiber 39" UHMWP a través del tejido blando según la técnica preferida por el cirujano; dejar al exterior, por el portal de artroscopia, los extremos de la sutura
- Encontrar la posición deseada para colocar el ancla MectaLock PEEK; insertar una guía percutánea (max O/ 1,5mm) a través del portal artroscópico para alcanzar la posición deseada
- Se puede utilizar una guía específica para guiar la broca e indicar la posición del hueco piloto en el hueso. Insertar la guía Artroscópica Medacta unida a un obturador canulado a lo largo del hilo guía; el cirujano puede escoger entre varios extremos de guía según sus preferencias y de la estructura anatómica a tratar. Las guías y los obturadores se suministran en dos longitudes distintas



Guías y obturadores se pueden acoplar según la tabla que sigue:

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

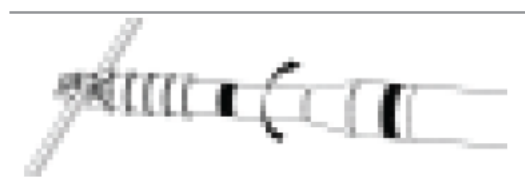
- Utilizando la broca reutilizable adecuada, realizar el hueco en el agujero en la posición deseada para colocar el MectaLock PEEK
- Asegurarse de brocar hasta que la marca distal de profundidad de la broca esté alineada con la marca distal de profundidad de la guía o hasta que la broca quede físicamente bloqueada contra la guía



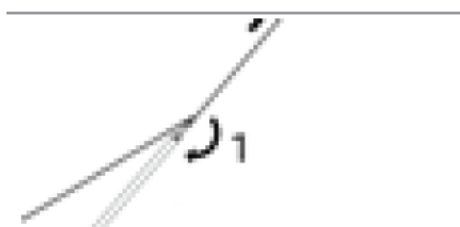
Cargar el ancla MectaLock PEEK con las suturas que salen por el portal; mientras se sujetan firmemente con una mano los dos extremos de la sutura, alinearlas con el extremo de la punta del ancla. Empujar suavemente el ancla contra la sutura para conseguir bloquearla en el ojete de la punta



Rotar el ancla 90° en sentido horario



Alinear el eje principal de la guía con la sutura (1) y después, manteniendo la sutura con una suave tensión, deslizar el ancla a lo largo de la sutura (2) hacia el paciente a través del porta artroscópico, hasta alcanzar el hueco piloto



Una vez alcanzado el hueco piloto, regular la tensión según las preferencias del cirujano y golpear suavemente el mango plástico de la guía hasta que el ancla Mectalock PEEK esté correctamente colocado. Se ha alcanzado la profundidad correcta cuando la marca laser distal está a nivel de la superficie del hueso

- Desatornillar la guía de un solo uso
- Palpar el tejido blando reparado utilizando una sonda artroscópica para asegurar que la reparación es firme
- Cortar y retirar los sobrantes de sutura



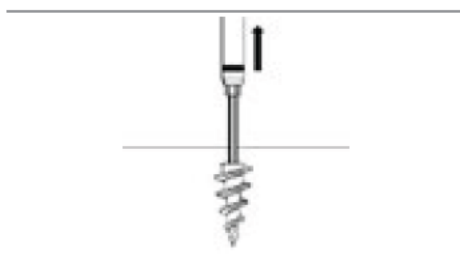
ANCLA DE SUTURA MECTALOCK TI

- Localizar la posición deseada para colocar el ancla MectaLock TI; insertar la guía precargada con el ancla MectaLock TI a través del portal artroscópico adecuado para alcanzar la posición deseada
- Golpear suavemente la parte posterior del mango de la guía desechable para que la punta del ancla penetre en el lugar elegido; manteniendo una suave fuerza axial en la guía desechable, atornillar el ancla MectaLock TI al hueso hasta que la marca laser distal de la guía resulte a nivel del hueso



Separar las suturas del mango plástico y separar el extremo de la guía del ancla MectaLock TI, retirando la guía a través del portal artroscópico

- Pasar las 2 suturas USP#2/EP#5 HS Fiber 39" UHMWPE a través del tejido blando según las técnicas de pasado y anudado preferidas por el cirujano
- Palpar el tejido blando reparado utilizando una sonda artroscópica para asegurar que la reparación es firme
- Cortar y retirar los sobrantes de sutura



11. CUIDADOS POSTOPERATORIOS Y SEGUIMIENTO

El cirujano debería advertir a los pacientes que controlen su nivel de actividad y que eviten cargas excesivas en el miembro operado. Asimismo, el cirujano debería informar al paciente de las precauciones que debe tomar en términos de ejercicio, tratamientos y limitaciones de actividad, de cualquier limitación indicada en la etiqueta, además de la exposición a campos magnéticos. Debe informarse al paciente de que los implantes pueden afectar a los resultados de pruebas diagnósticas como TAC y resonancias magnéticas. Se recomienda un seguimiento periódico para hacer comparaciones con la condición en el postoperatorio inmediato y anticipar cualquier complicación relacionada con el implante. Una actividad física excesiva y cualquier traumatismo en el miembro operado puede provocar un fallo temprano en el implante. Si se diera el caso, será necesario que el paciente quede bajo observación, para valorar el posible avance del deterioro y sopesar las ventajas de una revisión anticipada.

12. EFECTOS SECUNDARIOS Y COMPLICACIONES

Algunos efectos adversos pueden ocurrir en la re-sujección del tejido blando al hueso en los procedimientos de cirugías ortopédicas:

- Infección, tanto superficial como profunda
- Alergicas, inflamación y reacción al material del implante como cuerpo extraño

Algunos efectos secundarios adversos pueden tener como consecuencia final el fallecimiento del paciente

Entre las complicaciones generales se incluyen:

- Trombosis venosa con o sin embolia pulmonar
- Trastornos cardiovasculares o pulmonares
- Hematomas
- Reacciones alérgicas sistémicas
- Dolor sistémico

13. ACONDICIONAMIENTO

Los MectaLock Suture Anchors se suministran en paquetes estériles de un único uso. Para los componentes entregados esterilizados, el método de esterilización figura en la etiqueta. Ha de comprobarse la fecha de caducidad que figura en la etiqueta, así como la integridad del embalaje a fin de garantizar que no se ha puesto en peligro la esterilidad del contenido. Si el embalaje presenta daños o se ha abierto previamente, no utilice el componente. No volver a esterilizar.

14. ALMACENAMIENTO

Los embalajes deben guardarse en un lugar fresco y seco, protegidos de la luz.

15. TRADEMARKS

Medacta es una marca comercial registrada de Medacta International SA, Castel San Pietro, Suiza.

El texto de referencia es el texto en inglés.

Last update: julio 2020

PORTUGUÊS: 3D METAL TIBIAL CONES - INSTRUÇÕES DE UTILIZAÇÃO

Aviso importante: o(s) dispositivo(s) só pode(m) ser prescrito(s) e implantado(s) por um médico legalmente autorizado a realizar este tipo de cirurgia

1. GENERALIDADES

Antes de qualquer cirurgia, o médico cirurgião tem de estar familiarizado com a literatura e com a técnica operatória relacionadas com o produto e tem de ler atentamente estas instruções de utilização. A seleção do doente é tão importante como a colocação ou posicionamento do implante. Exigências funcionais inadequadas podem contribuir para reduzir a longevidade do implante. Os avisos não podem ser ignorados e as instruções de utilização têm de ser estritamente seguidas

2. DESCRIÇÃO DO PRODUTO

Estas instruções de utilização destinam-se a todos os produtos descritos abaixo.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

MectaLock PEEK (sem nós) e MectaLock TI (precarregado) da Medacta são produzidos respectivamente em PoliEterEterCetona (PEEK) e em liga de Titânio. As suturas ancoradas MectaLock são fornecidas com suturas directamente precarregadas no implante (MectaLock Ti) ou colocadas directamente na embalagem final (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.011		
05.10.012		

Especificações do material

Ancoras: PoliEterEterCetona (PEEK) [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Guia corpo: Aço inoxidável

Punho guia: Policarbonato de grau médico

Sutura: não-reabsorvível USP#2/EP#5 HS Fiber 39" PE de elevado peso molecular (UHMWPE) (diâmetro médio: 0.500-0.599mm)

3. USO PREVISTO

As suturas ancoradas não-reabsorvíveis destinam-se a:

- Sutures ancoradas MectaLock TI: refixação de tecidos moles na articulação do ombro (i.e.: reparação rotador da coifa, tenodese do biceps)
- Sutures ancoradas MectaLock PEEK: tratamento da instabilidade da anca e do ombro através da refixação do labrum acetabular ou glenoidal ao osso

O dispositivo é indicado para uso em procedimentos de artroscopia ou cirurgia aberta. Após ancorar a sutura ao osso, esta é usada para reconectar tecidos moles ao osso, incluindo as seguintes indicações específicas do sistema:

- Sutures ancoradas MectaLock TI: refixação de tecidos moles na articulação do ombro
- Sutures ancoradas MectaLock PEEK: tratamento da instabilidade da anca e do ombro através da refixação do labrum acetabular ou glenoidal ao osso

O sistema de suturas ancoradas estabiliza os tecidos moles danificados, em combinação com imobilização no pós-operatório através do período de cicatrização.

4. CONTRA-INDICAÇÕES

- Condições patológicas nos tecidos moles a serem reparados ou reconstruídos que poderão afectar adversamente a fixação da sutura
- Condições patológicas do osso que afectam adversamente as suturas ancoradas MectaLock
- Condição física que eliminaria, ou tenderia a eliminar, o suporte adequado para o implante ou atrasaria a cicatrização
- Condições que tendem a limitar a capacidade ou vontade do paciente em restringir actividades ou em seguir instruções durante o período de cicatrização
- Conexão de ligamentos artificiais ou outros implantes
- Sensibilidade a corpos estranhos, alergias conhecidas ou suspeitadas aos materiais do implante e/ou instrumentos

5. ADVERTÊNCIAS

O sucesso do procedimento cirúrgico depende do cumprimento da técnica operatória disponibilizada, bem como da utilização adequada dos instrumentos dedicados que foram concebidos especificamente para essa gama de implantes. O cirurgião deve escolher o implante do tamanho indicado baseando-se no procedimento específico e na história do paciente. O posicionamento incorreto pode reduzir a longevidade do implante e despoletar a falha antecipada do implante. O guia descartável é de uso único e deve ser descartado de acordo com a política e procedimentos hospitalares.

Uma etiqueta para cada dispositivo Medacta tem de ser aplicada correctamente no Cartão de Implante Medacta fornecido e entregue ao paciente.

Garantir que as suturas ancoradas MectaLock são usadas com a broca compatível reusável correspondente. Usar a broca compatível reusável correspondente para criar o furo piloto. Manter o alinhamento adequado durante a inserção da ancora e prevenir que se desengate da guia. O risco de quebrar a sutura ancorada MectaLock durante a implantação é reduzido se se seguirem as instruções de uso especificadas a seguir. Seleção e colocação adequadas do implante são considerações importantes a ter para uma utilização bem sucedida deste dispositivo. Orientação e alinhamento adequados dos instrumentos é importante durante a implantação da sutura

MectaLock. Ancorar para minimizar uma possível ruptura da ancora. Ruptura da sutura ancorada MectaLock pode acontecer se:

- O furo piloto, onde esperado, não foi feito na profundidade adequada
- A sutura ancorada MectaLock não for alinhada adequadamente com o furo piloto, onde esperado
- Qualquer carregamento lateral for aplicado na ancora/aplicador aquando da inserção da ancora MectaLock
- O guia da sutura ancorada MectaLock for usado para alavancar

Não desmontar as suturas do guia descartável durante a inserção da sutura ancorada MectaLock TI antes de chegar à posição/ profundidade final. Não usar outras suturas que não sejam as suturas de UHMWPE não-reabsorvíveis USP#2/EP#5.

Compatibilidade com IRM

MectaLock TI:

Os testes não-clínicos demonstraram que os implantes de titânio são qualificados para ressonância magnética. Um paciente com este dispositivo pode ser escaneado com segurança em um sistema de RM que atenda às seguintes condições. Campo magnético estático de 1,5 Tesla e 3 Tesla, com:

- Campo espacial máximo Gradiente de 12.800 G/cm (128 T/m)

- Força máxima de produto de 231.000.000 G²/cm (231 T²/m)

Taxa de absorção específica (SAR) máxima estimada teoricamente de 2 W/kg (Modo Normal de Operação). Sob as condições de varredura definidas acima, os implantes de titânio deverão produzir um aumento máximo de temperatura inferior a:

- 1,5°C (2 W/kg, 1,5 Tesla) Aumento de temperatura relacionado à RF com um aumento de temperatura profundo de ≈1,3°C (2 W/kg, 1,5 Tesla)

- 3,0°C (2 W/kg, 3 Tesla) Aumento de temperatura relacionado à RF com um aumento de temperatura profundo de ≈2,3°C (2 W/kg, 3 Tesla)

após 15 minutos de escaneamento contínua.

Em testes não clínicos, o artefato de imagem causado pelo dispositivo se estende aproximadamente 20,5 mm do implante de titânio quando imitado com uma sequência de pulso de eco gradiente e um sistema de ressonância magnética de 3 Tesla.

As suturas ancoradas MectaLock PEEK são seguras para MR.

6. IMPLANTES MEDACTA INTERNATIONAL

A Medacta International não é responsável pela utilização dos seus componentes de implantes em combinação com um componente de outro fabricante (salvo indicação em contrário pela Medacta International nas instruções da técnica cirúrgica), por conseguinte, advertimos contra essa utilização. Os MectaLock Suture Anchors nunca devem ser reimplantados. Embora um implante possa não aparentar danos, poderão ocorrer imperfeições microscópicas que, por sua vez, provocarão a falha do implante. O médico cirurgião tem de ter em atenção que mesmo um dano superficial muito pequeno, causado por exemplo por uma ferramenta afiada ou por eletrocauterização, pode ter influência na resistência do dispositivo e resultar na fratura do mesmo. Os produtos MectaLock Suture Anchors da Medacta não são pirogénicos.

7. ATENÇÃO

Os fatores de risco seguintes, individualmente ou em conjunto, podem resultar em maus resultados clínicos:

- Qualidade óssea inadequada (por exemplo, osteoporose, osteopenia)
- Doenças sistêmicas e distúrbios metabólicos
- História de infecções ou quedas recorrentes
- Dependência de drogas e abuso de álcool e medicamentos
- Incapacidade mental do paciente para entender as instruções do médico e poder cumpri-las
- Tumores ósseos locais

8. MODO DE UTILIZAÇÃO

FASE PRÉ-OPERATÓRIA

O cirurgião deve verificar possíveis limitações físicas e deficiências mentais do paciente, devendo também discutir com o mesmo todos os detalhes do procedimento e do implante. A discussão deverá incluir as limitações do procedimento, bem como os constrangimentos impostos pelo implante selecionado. Deverão ser também abordados os fatores que podem limitar o desempenho e a estabilidade do implante, como por exemplo, o nível de atividade, de modo a aumentar a probabilidade de o doente evitar complicações. A necessidade de seguir as instruções pós-operatórias facultadas pelo médico deverão ser inteiramente compreendidas pelo doente. Um número de implantes estéreis de tamanhos adequados deverão estar disponíveis e ser verificados pelo médico antes da cirurgia.

9. MANUSEAMENTO

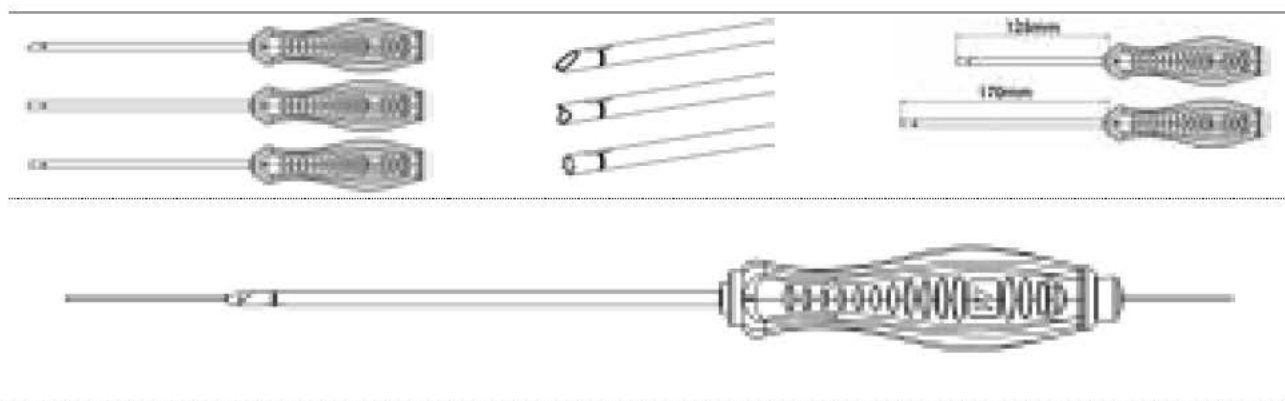
Para evitar riscos ou danos nos implantes, estes deverão ser manuseados com o máximo cuidado por pessoal qualificado, num ambiente onde as condições de higiene estão controladas. Os implantes deverão ser mantidos nas respetivas embalagens intactas.

10. TÉCNICA CIRÚRGICA

O médico cirurgião deverá estar totalmente familiarizado com a técnica cirúrgica. Mediante pedido, estão disponíveis informações suplementares sobre as técnicas cirúrgicas (brochura e vídeo) e os produtos. É essencial uma planificação cuidadosa pré-operatória.

SUTURA ANCORADA MECTALOCK PEEK

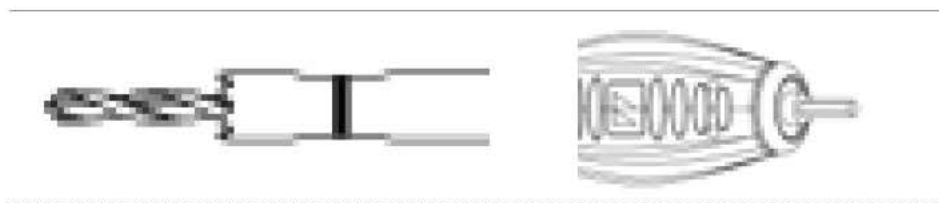
- Passar a sutura de UHMWPE USP#2/EP#5 HS Fiber 39" através dos tecidos moles usando a técnica de passagem de sutura preferida do cirurgião; deixar as duas vertentes da sutura saírem do paciente através do portal artroscópico
- Encontrar a localização desejada para a colocação da ancora MectaLock PEEK; inserir um fio-guia percutâneo (máx Ø1.5mm) através do portal artroscópico adequado para chegar à localização desejada
- Um apontador dedicado pode ser usado como guia da broca e pode ajudar a apontar a localização do furo piloto no osso. Inserir o Apontador Artroscopico Medacta acompanhado de um obturador canulado sobre o fio-guia; o cirurgião pode escolher diferentes pontas para o apontador de acordo com a sua preferência e com as estruturas anatómicas que devem ser tratadas. Apontadores e obturadores são fornecidos em dois comprimentos diferentes



Apontadores/obturadores e brocas podem ser acoplados seguindo a tabela seguinte:

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

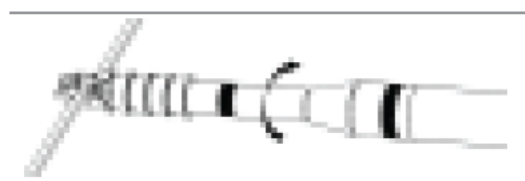
- Usar a broca compatível reusável correspondente para criar o furo piloto, fazer um furo no osso na localização desejada para o posicionamento da ancora MectaLock PEEK
- Garantir que a perfuração se faz até que a marca da profundidade distal da broca seja alinhada com a marca da profundidade distal do apontador ou até que a broca se bloqueie mecanicamente contra o apontador



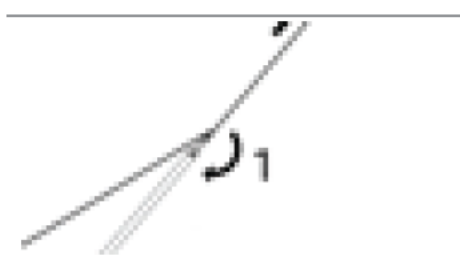
Carregar a ancora MectaLock PEEK com as suturas que saem do portal: enquanto se segura firmemente as duas vertentes da sutura com uma mão, alinhá-las com a ranhura da ponta da ancora. Empurrar suavemente a ancora contra a sutura para permitir que se clipe no orifício da ponta



Rodar a ancora no sentido horário de 90°

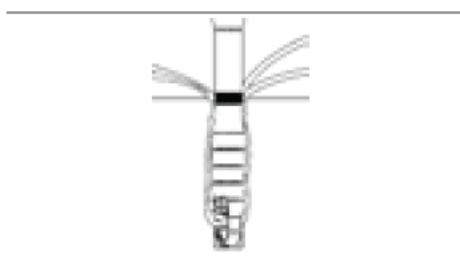


Alinhar o eixo principal da guia com a sutura (1) e depois, enquanto se segura a sutura tensionada suavemente, deslizar a ancora sobre a sutura (2) na direção do paciente através do portal artroscopico, até que o furo piloto seja alcançado



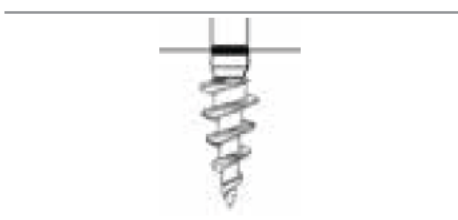
Uma vez atingido o furo piloto, regular a tensão da sutura de acordo com a preferência do cirurgião e bater no punho de plástico da guia até que a ancora MectaLock PEEK seja posicionada correctamente. A profundidade correcta é alcançada quando a marca de laser distal é nivelada com a superfície do osso

- Desaparafusar o guia descartável
- Palpar os tecidos moles reparados usando uma sonda artroscópica para garantir que a reparação é segura
- Cortar e remover suturas em excesso



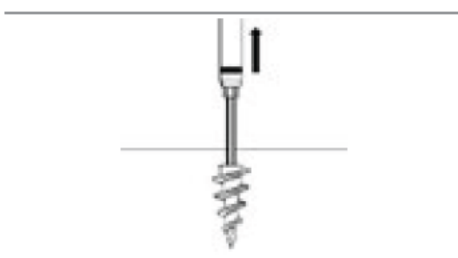
Sutura ancorada MectaLock TI

- Encontrar a localização desejada para a colocação da ancora MectaLock TI; inserir o guia precarregado com a ancora MectaLock TI através do portal artroscópico adequado para chegar à localização desejada
- Bater suavemente no punho preto do guia descartável para permitir que a ponta da ancora MectaLock TI fure osso no local escolhido; enquanto se mantém uma força axial suave no guia descartável, aparafusar a ancora MectaLock TI ao osso até que a marca laser distal no guia esteja ao nível da superfície do osso



Desbloquear as suturas do ponto preto e desengatar suavemente a ponta do guia da ancora MectaLock TI, puxando o guia para for a através do portal artroscopico

- Gerir as 2 suturas de UHMWPE USP#2/EP#5 HS Fibra 39" através dos tecidos moles com as técnicas de passagem de suturas e de amarração de nós preferidas do cirurgião
- Palpar os tecidos moles reparados usando uma sonda artroscópica para garantir que a reparação é segura
- Cortar e remover sutura em excess



11. CUIDADOS PÓS-OPERATÓRIOS E ACOMPANHAMENTO

O cirurgião deve alertar os pacientes para controlar seu nível de atividade e evitar cargas excessivas no membro operado. Além disso, o médico cirurgião deverá alertar os doentes para as precauções a serem tomadas em termos de exercícios, tratamentos e limitações em certas atividades, quaisquer limitações indicadas no rótulo, bem como a exposição a campos magnéticos. O doente tem de ser informado que os implantes podem afetar os resultados de exames de tomografias computadorizadas (TC) ou imagiologia por ressonância magnética (IRM). Recomenda-se acompanhamento periódicos para fazer comparações com a condição pós-operatória imediata e antecipar complicações relacionadas com o implante. Atividade física excessiva e traumatismos dos membros operados podem levar a uma falha precoce do implante. Se essa situação se verificar, é necessário colocar o doente sob supervisão, avaliar a possível progressão da deterioração do implante e contemplar o benefício de uma cirurgia de revisão antecipada.

12. EFEITOS INDESEJÁVEIS E COMPLICAÇÕES

Efeitos adversos que podem ocorrer durante a reconexão dos tecidos moles ao osso durante procedimentos cirúrgicos ortopédicos:

- Infecção, tanto profunda como superficial
 - Alergias, reações inflamatórias leves e reações de corpo estranho ao material do implante
- Alguns efeitos adversos poderão levar à morte.

As complicações gerais incluem:

- Trombose venosa com/sem embolismo pulmonar
- Distúrbios pulmonares ou cardiovasculares
- Hematomas
- Reações alérgicas sistêmicas
- Dor a nível sistémico

13. ACONDICIONAMENTO

Os MectaLock Suture Anchors são fornecidos em embalagens de uso único. Para os componentes disponibilizados esterilizados, o método de esterilização encontra-se indicado no rótulo. Tem de ser verificada a data de validade no rótulo, bem como a integridade da embalagem, de modo a assegurar que a esterilidade do conteúdo da mesma não foi comprometida. Se a embalagem estiver danificada ou tiver sido aberta, não utilize o componente. Não reesterilizar.

14. ARMAZENAGEM

As embalagens têm de ser guardadas num local fresco, seco e ao abrigo da luz.

15. MARCA REGISTADAS

Medacta é uma marca comercial registada da Medacta International SA, Castel San Pietro, Suíça.

O texto de referência é o texto em inglês.

Última actualização: julho 2020

FRANÇAIS: MECTALOCK SUTURE ANCHORS - INSTRUCTIONS D'UTILISATION

Important: le(s) dispositif(s) ne peu(ven)t être prescrit(s) et implanté(s) que par un médecin disposant d'une autorisation légale pour effectuer ce type de chirurgie.

1. GENERALITIES

Avant toute intervention chirurgicale, le chirurgien doit bien connaître les documents relatifs au produit et à la technique opératoire, et doit lire attentivement ce mode d'emploi. La sélection des patients est aussi importante que le placement et le positionnement de l'implant. Des exigences fonctionnelles inappropriées peuvent contribuer à réduire la durée de vie de l'implant. Les avertissements doivent être respectés, et le mode d'emploi doit être scrupuleusement suivi.

2. DESCRIPTION DU PRODUIT

Ce mode d'emploi est destiné à tous les produits décrits ci-dessous.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

Medacta MectaLock PEEK (sans noeuds) et Medacta MectaLock TI (préchargé) sont fabriqués respectivement en PolyEtherEtherKeton (PEEK) ou en alliage de titane. Les ancrs MectaLock sont fournis avec des sutures directement préchargées dans l'implant (MectaLock TI) ou directement dans l'emballage final (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002		
05.10.003		
05.10.011	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.012		

Material Specifications

Ancre: PolyEtherEtherKeton (PEEK) [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock Ti]

Corps de l'impacteur: acier inoxydable

Poignée de l'impacteur: polycarbonate de qualité médicale

Suture: USP # 2 / EP # 5 HS Fibre 39 "non résorbable Polyéthylène à poids moléculaire ultra-élevé (diamètre moyen: 0.500-0.599mm)

3. UTILISATION PRÉVUE

- Les ancrs MectaLock Ti: refixation des tissus mous dans l'articulation de l'épaule (c.-à-d. réparation du rotateur de la coiffe, ténodèse du biceps)
- Les ancrs MectaLock PEEK: traitement de la hanche et de l'instabilité de l'épaule par la ré-fixation du labrum acétabulaire ou glénoïdien à l'os

Le dispositif est indiqué dans des procédures chirurgicales arthroscopiques ou ouvertes. Une fois la suture ancrée à l'os, elle est utilisée pour rattacher les tissus mous à l'os, y compris les indications suivantes spécifiques au système :

- Les ancrs MectaLock Ti: refixation des tissus mous dans l'articulation de l'épaule
- Les ancrs MectaLock PEEK: traitement de l'instabilité de la hanche et de l'épaule au moyen de la ré-fixation du labrum cotyloïdien ou glénoïdien sur l'os

Le système d'ancres de suture stabilise ainsi les tissus mous endommagés, en combinaison avec une immobilisation postopératoire appropriée, pendant toute la période de cicatrisation.

4. CONTRE-INDICATIONS

- Conditions pathologiques dans les tissus mous à réparer ou à reconstruire qui pourraient nuire à la fixation par suture
- Conditions pathologiques de l'os qui affectent la tenue des ancrs MectaLock
- Condition physique qui éliminerait ou aurait tendance à éliminer un soutien adéquat aux implants ou retarderait la guérison
- Des conditions qui tendent à limiter la capacité ou la volonté du patient à restreindre ses activités ou à suivre les instructions pendant la période de guérison
- Fixation d'un ligament artificiel ou d'autres implants
- Sensibilité au corps étranger, allergies connues ou suspectées aux implants et / ou aux instruments

5. AVERTISSEMENT

Le succès de l'opération dépend de la conformité avec la technique opératoire utilisée, et de l'utilisation appropriée des instruments dédiés qui sont spécialement conçus pour cette gamme d'implants. Le chirurgien doit choisir une taille d'implant appropriée en fonction de la procédure spécifique et des antécédents du patient. Un mauvais positionnement peut réduire la longévité de l'implant et conduire à son échec anticipé. Le manche-impacteur est à usage unique et doit être éliminé conformément à la politique et à la procédure de l'hôpital.

Pour chaque dispositif, une étiquette Medacta doit être correctement apposée sur le passeport implant Medacta, fourni et remis au patient.

Assurez-vous que les ancrs MectaLock sont utilisées avec les mèches réutilisable compatible correspondant. Utilisez la mèche réutilisable compatible correspondante pour créer le trou pilote. Maintenez un alignement correct lors de l'insertion de l'ancre et empêchez le dégagement du manche-impacteur. Le risque de rupture des ancrs MectaLock lors de l'implantation est réduit en suivant les instructions d'utilisation indiquées ci-dessous. Une sélection et un placement corrects de l'implant sont des considérations importantes pour une utilisation réussie de cet dispositif. L'orientation et l'alignement corrects des instruments sont importants lors de l'implantation des MectaLock afin de minimiser les risques de rupture de l'ancre. Une rupture de l'ancre MectaLock peut se produire si:

- Le trou pilote, si prévu, n'est pas foré à la profondeur appropriée
- L'ancrage de la MectaLock n'est pas correctement aligné avec le trou pilote, si nécessaire
- Une charge latérale est appliquée sur l'ancre / le manche-impacteur lors de l'insertion de l'ancre MectaLock
- L'impacteur des MectaLock est utilisé pour fouiner

Ne dégagez pas les sutures du manche-impacteur jetable lors de l'insertion de l'ancre MectaLock TI avant que la profondeur de positionnement finale ne soit atteinte. N'utilisez aucune autre suture que la suture non résorbable USP # 2 / EP # 5 UHMWPE.

Compatibilité IRM

MectaLock TI:

Des tests non cliniques ont démontré que les implants en titane sont conditionnels à la RM. Un patient auquel ce dispositif a été implanté peut être examiné en toute sécurité dans un système de RM répondant aux conditions suivantes. Champ magnétique statique de 1,5 Tesla et 3 Tesla, avec:

- Gradient de champ spatial maximum de 12 800 G/cm (128 T/m)

- Force produite maximale de 231.000.000 G²/cm (231 T²/m)

Estimation théorique du maximum du corps entier moyenne (WBA) taux d'absorption spécifique (TAS) de 2 W/kg (mode de fonctionnement normal). Dans les conditions de balayage définies ci-dessus, les implants en titane devraient produire une augmentation de température maximale inférieure à :

- Augmentation de la température liée aux RF de 1,5°C (2 W/kg, 1,5 Tesla) avec une augmentation de la température de fond de ≈1,3°C (2 W/kg, 1,5 Tesla)

- Augmentation de la température liée aux RF de 3,0°C (2 W/kg, 3 Tesla) avec une augmentation de la température de fond de ≈2,3°C (2 W/kg, 3 Tesla)

après 15 minutes d'analyse continue.

Dans les tests non cliniques, l'artefact d'image causé par l'appareil s'étend à environ 20,5 mm de l'implant en titane lorsqu'il est imagé avec une séquence d'impulsions d'écho de gradient et un système de RM de 3 Tesla.

Les ancrs MectaLock PEEK sont compatible avec IRM.

6. IMPLANTS MEDACTA INTERNATIONAL

Medacta International n'est pas responsable de l'utilisation de ses composants associée à un composant fourni par un autre fabricant (sauf indication contraire de Medacta International pour la technique chirurgicale), par conséquent, nous déconseillons une telle utilisation. Les MectaLock Suture Anchors ne doivent jamais être réimplantés. Alors qu'un implant peut sembler intact, les imperfections microscopiques peuvent exister et provoquer une défaillance de l'implant. Le chirurgien doit être conscient que même un très léger dommage superficiel, causé par exemple par un instrument ou par une forte hémostase au bistouri électrique, peut avoir une influence sur la survie de l'appareil et peut conduire à sa rupture. Les produits MectaLock Suture Anchors de Medacta sont non-pyrogènes.

7. ATTENTION

Les facteurs de risque suivants, individuellement ou conjoints, peuvent aboutir à de faibles résultats cliniques:

- Qualité osseuse inadéquate (par exemple, ostéoporose, ostéopénie)
- Maladies systémiques ou troubles métaboliques
- Antécédents d'infections ou de chutes
- Toxicomanie et l'abus d'alcool et de médicaments
- Incapacité mentale du patient à comprendre les instructions du médecin et à s'y conformer
- Tumeurs osseuses locales

8. MODE D'UTILISATION

PHASE PRÉOPÉRATOIRE

Le chirurgien doit vérifier les éventuels handicaps physiques et déficiences mentales des patients, et il doit également discuter avec le patient de tous les détails concernant l'intervention et les implants. La discussion doit tenir compte des limites de l'intervention et des contraintes imposées par l'implant sélectionné. Les facteurs pouvant limiter les performances et la stabilité de l'implant, par exemple le niveau d'activité, doivent être définis pour améliorer les chances du patient d'éviter des complications. La nécessité de suivre les instructions post-opératoires fournies par le chirurgien doit être pleinement comprise par le patient. Un stock d'implants stériles de tailles appropriées doit être disponible et contrôlé par l'opérateur avant l'opération.

9. MANIPULATION

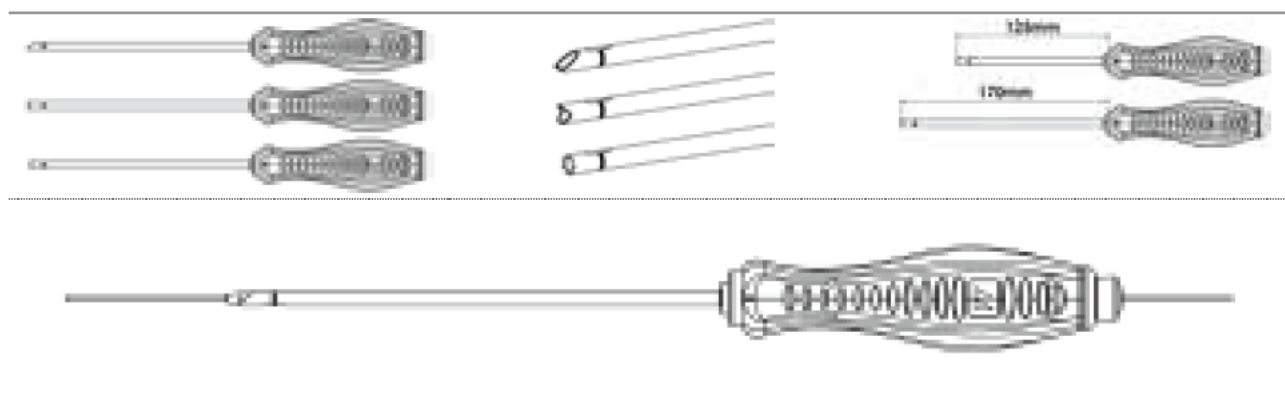
Pour éviter de rayer ou d'endommager les implants, ils doivent être manipulés avec le plus grand soin par du personnel qualifié dans un environnement où les conditions d'hygiène sont contrôlées. Les implants doivent être conservés dans leur emballage en bon état.

10. TECHNIQUE CHIRURGICALE

Le chirurgien doit bien connaître la technique opératoire. Des renseignements supplémentaires sur les techniques chirurgicales (brochure et vidéo) et les produits sont disponibles sur demande. Une planification préopératoire minutieuse est essentielle.

LES ANCRES MECTALOCK PEEK

- Passer la suture USP # 2 / EP # 5 HS Fibre 39 "UHMWPE à travers les tissus mous avec la technique de passage de suture préférée du chirurgien; laisser les deux brins de la suture sortir du patient par le portail arthroscopique
- Recherchez l'emplacement souhaité pour l'emplacement de l'ancre MectaLock PEEK. insérer un fil-guide percutané (Ø max. 1,5 mm) à travers le portail arthroscopique approprié pour atteindre l'emplacement souhaité
- Un viseur dédié peut être utilisé comme guide de forage et pour aider à pointer l'emplacement du trou pilote dans l'os. Insérer le viseur Arthroscopique Medacta couplé à un obturateur canulé sur le fil guide; le chirurgien peut choisir entre différentes pointes de viseur en fonction de ses préférences et des structures anatomiques à traiter. Les viseurs et les obturateurs sont fournis en deux longueurs différentes:



Les viseurs / obturateurs et les mèches peuvent être couplés selon le tableau suivant::

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

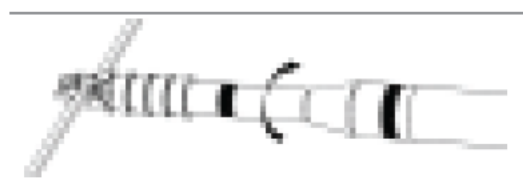
- En utilisant la mèche réutilisable compatible correspondant, créez un trou dans l'os à l'emplacement souhaité pour la mise en place de l'ancre MectaLock PEEK
- Veillez à percer jusqu'à ce que la marque de profondeur distale de la mèche soit alignée avec la marque de profondeur distale du viseur ou jusqu'à ce que la mèche soit mécaniquement bloquée contre le viseur



Chargez l'ancre MectaLock PEEK avec les sutures sortant du portail: tout en maintenant fermement les deux brins de la suture avec une main, alignez-les avec la fente de la pointe de l'ancre. Poussez délicatement l'ancre contre la suture pour la laisser se fixer dans l'oeillet de la pointe



Faites pivoter l'ancre dans le sens des aiguilles d'une montre de 90°



Aligner l'axe principal du manche-impacteur avec la suture (1) puis, tout en maintenant la suture sous tension, faire glisser l'ancre sur la suture (2) vers le patient à travers le portail arthroscopique jusqu'à ce que le trou pilote soit atteint.



Une fois atteint le trou pilote, réglez la tension de la suture en fonction de la préférence du chirurgien et appuyez sur la poignée en plastique du manche-impacteur jusqu'à ce que l'ancre MectaLock PEEK soit correctement placée. La profondeur correcte est atteinte lorsque le marquage laser distal affleure la surface de l'os

- Dévissez le manche-impacteur jetable
- Palper les tissus mous réparés à l'aide d'une sonde arthroscopique pour s'assurer que la réparation est sécurisée
- Couper et enlever les sutures en excès



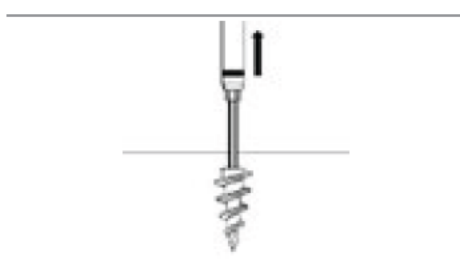
LES ANCRES MECTALOCK TI

- Recherchez l'emplacement souhaité pour l'emplacement de l'ancre MectaLock TI. insérer le manche-impacteur préchargé avec l'ancre MectaLock TI dans le portail arthroscopique approprié pour atteindre l'emplacement souhaité
- Tapotez doucement à l'arrière de poignée du manche-impacteur jetable pour permettre à la pointe de l'ancre MectaLock TI de percer l'os à l'endroit choisi; tout en gardant une légère force axiale sur le manche-impacteur jetable, vissez l'ancre MectaLock TI dans l'os jusqu'à ce que le marquage laser distal du manche -impacteur affleure la surface de l'os



Débloquez les sutures du manche-impacteur en plastique et dégagez délicatement la pointe du conducteur de l'ancre MectaLock TI, tirant le manche-impacteur par le portail arthroscopique

- Gérer les sutures 2x USP # 2 / EP # 5 HS Fibre 39" UHMWPE à travers des tissus mous avec la technique de passage des sutures et de nouage préférée par le chirurgien
- Palper les tissus mous réparés à l'aide d'une sonde arthroscopique pour s'assurer que la réparation est sécurisée
- Couper et enlever les sutures en excès



11. SOINS POSTOPÉRATOIRES ET SUIVI

Le chirurgien doit avertir les patients de contrôler leur niveau d'activité et d'éviter les charges excessives sur le membre opéré. En outre, le chirurgien doit informer le patient sur les précautions à prendre en termes d'exercices, de traitements et de limitations dans le cadre des activités, des restrictions signalées sur la notice d'instruction, ainsi que sur l'exposition aux champs magnétiques. Le patient doit être informé que les implants peuvent affecter les résultats de la tomodensitométrie (TDM) ou de l'imagerie par résonance magnétique (IRM). Le suivi périodique est recommandé pour faire des comparaisons avec l'état post-opératoire immédiat et anticiper les complications liées aux implants. Une activité physique excessive et des traumatismes des membres opérés peuvent causer une défaillance précoce de l'implant. Si le cas se produit, il est nécessaire de placer le patient sous surveillance, d'évaluer la progression possible de la détérioration, et considérer les avantages de la reprise anticipée.

12. EFFETS INDESIRABLES ET COMPLICATIONS

Effets indésirables pouvant survenir lors du re-attachement des tissus mous sur les os lors d'interventions chirurgicales orthopédiques:

- Infection, profonde et superficielle
- Allergies, réactions inflammatoires légères, réaction à corps étranger aux matériaux des implants

Enfin, certains effets indésirables peuvent même conduire au décès.

Les complications générales comprennent:

- Thrombose veineuse avec/sans embolie pulmonaire
- Troubles cardiovasculaires ou pulmonaires
- Hématomes
- Réactions allergiques systémiques
- Douleurs systémiques

13. CONDITIONNEMENT

Les MectaLock Suture Anchors sont fournis en emballage à usage unique. Pour les composants livrés stériles, le procédé de stérilisation est indiqué sur l'étiquette. La date de péremption doit être vérifiée sur l'étiquette ainsi que l'intégrité de l'emballage afin de s'assurer que la stérilité du contenu n'a pas été compromise. Si l'emballage est endommagé ou a été ouvert, ne pas utiliser le composant. Ne pas re-stériliser.

14. STOCKAGE

Les emballages doivent être stockés dans un endroit frais et sec, à l'abri de la lumière.

15. TRADEMARKS

Medacta est une marque déposée de Medacta International SA, sise à Castel San Pietro, en Suisse.

Le texte de référence est le texte anglais.

Dernière mise à jour: Juillet 2020

ΕΛΛΗΝΙΚΑ: MECTALOCK SUTURE ANCHORS - ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

Σημαντική προειδοποίηση: η μία ή περισσότερες συσκευές μπορούν να συνταγογραφηθούν και να εμφυτευτούν μόνο από ιατρό νομίμως εξουσιοδοτημένο να εκτελεί αυτόν τον τύπο χειρουργικής επέμβασης..

1. ΓΕΝΙΚΑ

Πριν από οποιαδήποτε χειρουργική επέμβαση, ο χειρουργός πρέπει να εξοικειώνεται με τη βιβλιογραφία του προϊόντος και τη χειρουργική τεχνική και πρέπει να διαβάζει προσεκτικά αυτές τις οδηγίες χρήσης. Η επιλογή του ασθενή είναι το ίδιο σημαντική με την τοποθέτηση του εμφυτεύματος. Ακατάλληλες λειτουργικές απαιτήσεις μπορεί να συμβάλλουν στη μείωση της ζωής του εμφυτεύματος. Πρέπει να δοθεί βάρος στις προειδοποιήσεις, και να τηρηθούν αυστηρά οι οδηγίες χρήσης.

2. ΠΕΡΙΓΡΑΦΗ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

Αυτές οι οδηγίες χρήσης προορίζονται για όλα τα προϊόντα που περιγράφονται εδώ παρακάτω.

CATALOGUE NUMBER	ANCHOR DESCRIPTION	COMPATIBLE REUSABLE DRILL N.
05.11.001	MectaLock PEEK Ø2.4 Long driver	05.11.10.0035
05.11.002	MectaLock PEEK Ø2.9 Long driver	05.11.10.0036
05.11.003	MectaLock PEEK Ø3.4 Long driver	05.11.10.0037
05.10.001	MectaLock PEEK Ø2.4 Short driver	05.10.10.0015
05.10.002	MectaLock PEEK Ø2.9 Short driver	05.10.10.0016
05.10.003	MectaLock PEEK Ø3.4 Short driver	05.10.10.0017
05.10.011	MectaLock TI Ø5.0	Not needed
05.10.012	MectaLock TI Ø6.5	Not needed

Τα Medacta MectaLock PEEK (Χωρίς κόμπι) and MectaLock TI (προφορτωμένο) κατασκευάζονται αντίστοιχα από PEEK ή κράμα τιτανίου. Οι άγκυρες ραμμάτων MectaLock φέρουν ράμματα προφορτωμένα πάνω στο εμφύτευμα (MectaLock TI) ή είναι τοποθετημένα απευθείας πάνω στην τελική συσκευασία (MectaLock PEEK).

CATALOGUE NUMBER	ANCHOR FAMILY	INCLUDED SUTURES
05.11.001	MectaLock PEEK	1x USP#2/EP#5 HS Fiber 39" UHMWPE suture
05.11.002		
05.11.003		
05.10.001		
05.10.002	MectaLock TI	2x USP#2/EP#5 HS Fiber 39" preloaded sutures
05.10.003		
05.10.011		
05.10.012		

Προδιαγραφές υλικού

Άγκυρες: PolyEtherEtherKeton (PEEK) [MectaLock PEEK]; Ti6Al4V ELI ISO 5832-3 [MectaLock TI]

Σώμα/στειλός :Ατσάλι

Λαβή: Ιατρικό πολυκαρβονικό

Ράμμα:μη απορροφήσιμο USP#2/EP#5 HS Fiber 39" πολυαιθυλένιο υπέρ-υψηλού μοριακού βάρους(μέση διάμετρος: 0.500-0.599mm)

3. ΠΡΟΒΛΕΠΟΜΕΝΗ ΧΡΗΣΗ

Οι μη απορροφήσιμες άγκυρες ραμμάτων χρησιμοποιούνται για:

- MectaLock TI Suture anchors:στερέωση μαλακών ιστών μέσα στην άρθρωση του ώμου(π.χ.: διόρθωση του cuff rotator , biceps tenodesis)
- MectaLock PEEK Suture anchors:αντιμετώπιση της αστάθειας του ισχίου και του ώμου δια της στερέωσης του επιχείλιου χόνδρου της κοτύλης ή της ωμογλήνης

Η συσκευή ενδείκνυται για χρήση τόσο σε αρθροσκοπικές όσο και σε ανοικτές χειρουργικές επεμβάσεις. Αφού το ράμμα αγκυρωθεί στο οστό, χρησιμοποιείται για την επανασύνδεση των μαλακών ιστών στο οστό, συμπεριλαμβανομένων των ακόλουθων ειδικών ενδείξεων του συστήματος:

- Άγκυρες ραμμάτων MectaLock TI :στερέωση μαλακών ιστών μέσα στην άρθρωση του ώμου
- Άγκυρες ραμμάτων MectaLock PEEK :αντιμετώπιση της αστάθειας του ισχίου και του ώμου δια της στερέωσης του επιχείλιου χόνδρου της κοτύλης ή της ωμογλήνης

Το σύστημα αγκυρας ράμματος μ' αυτό τον τρόπο σταθεροποιεί τον κατεστραμμένο μαλακό ιστό,σε συνδυασμό με την κατάλληλη μετεγχειρητική ακινητοποίηση, σε όλη την περίοδο θεραπείας.

4. ΑΝΤΕΝΔΕΙΞΕΙΣ

- Παθολογικές καταστάσεις του μαλακού ιστού που θα διορθωθεί και/ ή οποίες θα μπορούσαν να επηρεάσουν αρνητικά την στερέωση του ράμματος
- Παθολογικές καταστάσεις του οστού που θα μπορούσαν να επηρεάσουν αρνητικά τις άγκυρες ράμματος MectaLock
- Φυσικές καταστάσεις που θα εμόδιζαν την ικανοποιητική υποστήριξη του εμφυτεύματος ή θα καθυστερούσαν την θεραπεία
- Καταστάσεις που μειώνουν την ικανότητα ή την προθυμία του ασθενούς να ακολουθήσει τις οδηγίες κατά την αποθεραπεία
- ύπαρξη τεχνητών συνδέσμων ή άλλων εμφυτευμάτων
- Ευαισθησία σε ξένο σώμα, γνωστές αλλεργίες στα υλικά των εμφυτευμάτων και/ ή των εργαλείων

5. ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ

Η επιτυχία της επέμβασης εξαρτάται από τη συμμόρφωση με την παρεχόμενη χειρουργική τεχνική, καθώς και τη σωστή χρήση των αποκλειστικών εργαλείων που έχουν σχεδιαστεί ειδικά για αυτή τη σειρά εμφυτευμάτων. Ο χειρουργός πρέπει να διαλέξει το κατάλληλο μέγεθος του εμφυτεύματος με βάση την συγκεκριμένη επέμβαση ή το ιστορικό του ασθενούς. Η εσφαλμένη τοποθέτηση μπορεί να μειώσει τη διάρκεια ζωής του εμφυτεύματος και να οδηγήσει σε πρόωμη αστοχία του εμφυτεύματος. Ο εισαγωγέας είναι μιας χρήσης και πρέπει να απορρίπτεται σύμφωνα με τις διαδικασίες του νοσοκομείου.

Μια ετικέτα Medacta για κάθε συσκευή πρέπει να εφαρμοστεί σωστά στην κάρτα εμφύτευσης υλικών χειρουργείου Medacta που παρέχεται και παραδίδεται στον ασθενή.

Βεβαιωθείτε ότι οι άγκυρες ράμματος MectaLock χρησιμοποιούνται με την αντίστοιχη επαναχρησιμοποιήσιμη φρέζα. Χρησιμοποιήστε την αντίστοιχη επαναχρησιμοποιήσιμη φρέζα για να κάνετε την πιλοτική οπή. Διατηρήστε την ευθυγράμμιση κατά την εισαγωγή της άγκυρας και μην την αποσυνδέετε από τον εισαγωγέα. Ο κίνδυνος να σπάσουν οι άγκυρες ράμματος MectaLock κατά την εμφύτευση μειώνεται αν ακολουθούνται οι πατακάτω οδηγίες. Η κατάλληλη επιλογή και τοποθέτηση του εμφυτεύματος είναι σημαντικά στοιχεία στην επιτυχή χρήση της συσκευής. Η κατάλληλη ευθυγράμμιση του εργαλείου είναι σημαντική κατά την εμφύτευση της άγκυρας. για να αποφευχθεί η πιθανή θραύση της. Θραύση της άγκυρας ράμματος MectaLock μπορεί να συμβεί αν:

- η πιλοτική οπή δεν έχει το απαιτούμενο βάθος
- η άγκυρα ράμματος MectaLock δεν ευθυγραμμισθεί με την πιλοτική οπή όπως πρέπει
- εφαρμοσθεί πλάγια φόρτιση στην άγκυρα ή στον εισαγωγέα καθώς την τοποθετούμε
- αν η άγκυρα ράμματος χρησιμοποιηθεί σαν μοχλός

Μην αποσυνδέετε τα ράμματα από τον εισαγωγέα καθώς εισάγετε την άγκυρα ράμματος MectaLock, πριν φτάσετε το τελικό βάθος τοποθέτησης. Μην χρησιμοποιείτε άλλο ράμμα εκτός από το μη απορροφήσιμο ράμμα USP#2/EP#5 UHMWPE.

Συμβατότητα με MRI MectaLock TI:

Οι μη κλινικές δοκιμές έχουν δείξει ότι τα εμφυτεύματα τιτανίου είναι MR υπό όρους. Ένας ασθενής με αυτήν τη συσκευή μπορεί να σαρωθεί με ασφάλεια σε ένα σύστημα μαγνητικού συντονισμού υπό τις ακόλουθες προϋποθέσεις. Στατικό μαγνητικό πεδίο 1,5 Tesla και 3 Tesla, με:

- Μέγιστος βαθμός χωρικού πεδίου 12.800 G / cm (128 T / m)
- Μέγιστο προϊόν δύναμης 231.000.000 G2 / cm (231 T2 / m)

Θεωρητικά εκτιμώμενος μέγιστος ειδικός ρυθμός απορρόφησης (WBA) μέσης τιμής ολόκληρου σώματος (SAR) 2 W / kg (Κανονικός τρόπος λειτουργίας). Υπό τις συνθήκες σάρωσης που ορίζονται παραπάνω, τα εμφυτεύματα τιτανίου αναμένεται να παράγουν μέγιστη αύξηση θερμοκρασίας μικρότερη από:

- 1,5 ° C (2 W / kg, 1,5 Tesla) Αύξηση θερμοκρασίας σχετιζόμενη με RF με αύξηση θερμοκρασίαςυποστρώματος ≈ 1.3 ° C (2 W / kg, 1,5 Tesla)
- 3,0 ° C (2 W / kg, 3 Tesla) Αύξηση θερμοκρασίας που σχετίζεται με RF με αύξηση θερμοκρασίαςυποστρώματος $2,3$ ° C (2 W / kg, 3 Tesla)

μετά από 15 λεπτά συνεχούς σάρωσης.

Σε μη κλινικές δοκιμές, το τεχνούργημα εικόνας που προκαλείται από τη συσκευή εκτείνεται περίπου 20,5 mm από το εμφύτευμα τιτανίου όταν απεικονίζεται με μια ακολουθία παλμού ηχούς κλίσης και ένα σύστημα 3 Tesla MR..

Οι άγκυρες ραμμάτων MectaLock PEEK είναι ασφαλείς στην μαγνητική τομογραφία.

6. ΕΜΦΥΤΕΥΜΑΤΑ ΤΗΣ MEDACTA INTERNATIONAL

Η Medacta International δεν είναι υπεύθυνη για τη χρήση των συστατικών εμφυτευμάτων της σε συνδυασμό με συστατικό μέρος άλλου κατασκευαστή (εκτός αν η Medacta International προσδιορίζει διαφορετικά στη χειρουργική τεχνική), και συνεπώς αποθαρρύνουμε τέτοιου είδους χρήση. Τα τμήματα του MectaLock Suture Anchors εξωφλοιδούς μηριαίου κουμπιού στερέωσης δεν πρέπει να ξαναχρησιμοποιούνται. Αν και ένα εμφύτευμα μπορεί να μοιάζει ότι δεν φέρει ζημιά, ενδέχεται να προκύψουν μικροσκοπικές ατέλειες και να προκαλέσουν αστοχία του εμφυτεύματος. Ο χειρουργός πρέπει να γνωρίζει ότι ακόμα και πολύ μικρή επιφανειακή βλάβη, η οποία, για παράδειγμα, έχει προκληθεί από αιχμηρό εργαλείο ή ηλεκτροκαυτηρίαση, μπορεί να επηρεάσει την αντοχή της συσκευής και να οδηγήσει σε κάταγμα. Τα προϊόντα MectaLock Suture Anchors Medacta είναι μη πυρετογόνα.

7. ΠΡΟΣΟΧΗ

Οι παρακάτω παράγοντες κινδύνου, μεμονωμένα ή από κοινού, μπορεί να οδηγήσει σε κακή κλινική έκβαση:

- Ανεπαρκής ποιότητα οστού(οστεοπόρωση, οστεοπενία)
- Συστημικές Νόσοι Και Μεταβολικές Διαταραχές
- Ιστορικό λοιμώξεων και επαναλαμβανόμενων πτώσεων
- εξωφλοιώδους μηριαίου κουμπιού στερέωσης
- Διανοητική ανικανότητα του ασθενούς να κατανοήσει τις οδηγίες του γιατρού και να συμμορφωθεί με αυτές
- Τοπικοί όγκοι στα οστά

8. ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

Προεγχειρητικό στάδιο

Ο χειρουργός πρέπει να εκτιμήσει τους πιθανούς φυσικούς περιορισμούς του ασθενούς και την διανοητική ανεπάρκεια και πρέπει επίσης να συζητήσει με τον ασθενή όλες τις λεπτομέρειες της επέμβασης και του εμφυτεύματος. Η συζήτηση θα πρέπει να εξετάσει τόσο τους περιορισμούς της επέμβασης όσο και τους περιορισμούς που επιβάλλει το επιλεγμένο εμφύτευμα. Οι παράγοντες που θα μπορούσαν να περιορίσουν την απόδοση και σταθερότητα του εμφυτεύματος, π.χ. επίπεδο δραστηριότητας, θα πρέπει να εξηγηθούν ώστε να βελτιωθούν οι πιθανότητες να αποφύγει ο ασθενής επιπλοκές. Η αναγκαιότητα τήρησης των μετεγχειρητικών οδηγιών που θα δώσει ο χειρουργός θα πρέπει να γίνει πλήρως κατανοητή από τον ασθενή. Πρέπει να είναι διαθέσιμο αποθεματικό στείρων εμφυτευμάτων κατάλληλων μεγεθών και να ελέγχεται από τον χειριστή πριν τη χειρουργική επέμβαση.

9. ΧΕΙΡΙΣΜΟΣ

Για να αποφευχθεί το γρατζούνισμα ή η βλάβη στα εμφυτεύματα, ο χειρισμός τους θα πρέπει να γίνεται με υπέρτατη προσοχή από εξειδικευμένο προσωπικό σε περιβάλλον ελεγχόμενων συνθηκών υγιεινής. Τα εμφυτεύματα θα πρέπει να φυλάσσονται στις άθικτες συσκευασίες τους.

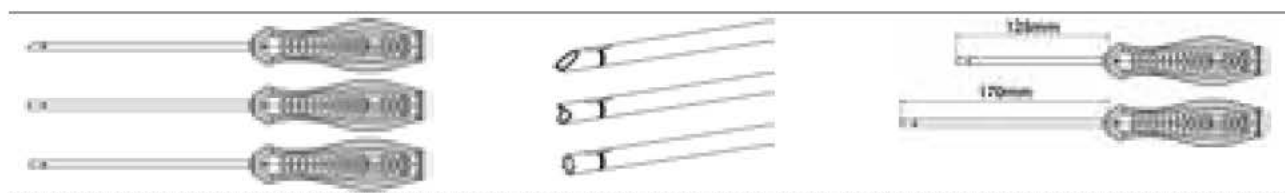
10. ΧΕΙΡΟΥΡΓΙΚΗ ΤΕΧΝΙΚΗ

Ο χειρουργός θα πρέπει να είναι εξοικειωμένος με τη χειρουργική τεχνική. Συμπληρωματικές πληροφορίες σχετικά με τις χειρουργικές τεχνικές (φυλλάδιο και βίντεο) και προϊόντα είναι διαθέσιμα αν ζητηθούν. Είναι απαραίτητος ο προσεκτικός προεγχειρητικός σχεδιασμός.

ΑΓΚΥΡΕΣ ΡΑΜΜΑΤΟΣ MECTALOCK PEEK

- Περάστε το ράμμα USP#2/EP#5 HS Fiber 39" UHMWPE μέσα από τους μαλακούς ιστούς με την προτιμώμενη μέθοδο του χειρουργού. Αφήστε τις δύο άκρες του ράμματος έξω από τον ασθενή μέσω της αρθροσκοπικής εισόδου
- Βρείτε την επιθυμητή θέση για την τοποθέτηση της άγκυρας MectaLock PEEK. Εισάγετε υποδόρια ένα οδηγό σύρμα (max Ø1.5mm) μέσω της κατάλληλης αρθροσκοπικής εισόδου για να φτάσετε την επιθυμητή θέση
- Ένα ειδικό σκόπευτρο μπορεί να χρησιμοποιηθεί σαν οδηγός φρέζας για να βοηθήσει ώστε να δείχνει την θέση της πιλοτικής οπής στο οστό. Εισάγετε το αρθροσκοπικό σκόπευτρο της Medacta μαζί με την αυλοφόρο κάνουλα πάνω από το σύρμα-οδηγό. Ο χειρουργός μπορεί να διαλέξει ανάμεσα σε διαφορετικά άκρα σκόπευτρου ανάλογα

με την προτίμησή του και την ανατομία της περιοχής . Τα σκόπευτρα και οι κάνουλες παρέχονται σε δύο διαφορετικά μήκη



Τα σκόπευτρα, οι κάνουλες και οι φρέζες ταιριάζουν σύμφωνα με τον ακόλουθο πίνακα:

AIMER		OBTURATOR		REUSABLE DRILL BIT	
CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION	CATALOGUE N.	DESCRIPTION
05.11.10.0030	Crown tip Long	05.11.10.0033	Obturator Long	05.11.10.0035	Drill Ø2.4 Long
05.11.10.0031	Fishmouth tip Long			05.11.10.0036	Drill Ø2.9 Long
05.11.10.0032	Fork tip Long			05.11.10.0037	Drill Ø3.4 Long
05.10.10.0010	Crown tip Short	05.10.10.0013	Obturator Short	05.10.10.0015	Drill Ø2.4 Short
05.10.10.0011	Fishmouth tip Short			05.10.10.0016	Drill Ø2.9 Short
05.10.10.0012	Fork tip Short			05.10.10.0017	Drill Ø3.4 Short

- Χρησιμοποιώντας την αντίστοιχη συμβατή φρέζα , κάντε μια οπή στο οστόστην επιθυμητή θέση για την τοποθέτηση της άγκυρας ραμμάτων MectaLock PEEK
- Βεβαιωθείτε ότι τρυπήσατε μέχρι το περιφερειακό σημάδι της φρέζας να ευθυγραμμισθεί με το περιφερικό σημάδι βάθους του σκόπευτρου ή μέχρι η φρέζα να τερματίσει μηχανικά πάνω στο σκόπευτρο



Φορτώστε την άγκυρα MectaLock PEEK με τα ράμματα να βγαίνουν έξω από την είσοδο. Καθώς κρατάτε τις δύο άκρες του ράμματος με το ένα χέρι , ευθυγραμμίστε τα με την σχισμή στο άκρο της άγκυρας. Απαλά σπρώξτε την άγκυρα προς το ράμμα για να κουμπώσει μέσα στο μάτι του άκρου



Περιστρέψτε την άγκυρα δεξιόστροφα κατά 90°



Ευθυγραμμίστε τον κύριο άξονα του εισαγωγέα με το ράμμα (1) και έπειτα , ενώ ακόμα κρατάτε το πάμμα ελαφρά τεντωμένο , γλυστρήστε την άγκυρα πάνω στο ράμμα (2) προς τον ασθενή μέσα από την αρθροσκοπική πύλη, μέχρι να φτάσετε στην πιλοτική οπή



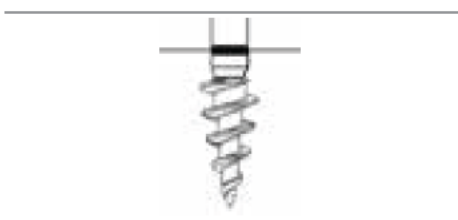
Μόλις φτάσετε την πιλοτική οπή , ρυθμίστε την τάση του ράμματος σύμφωνα με την προτίμηση του χειρουργού και χτυπήστε την πλαστική λαβή του εισαγωγέα μέχρι η άγκυρα να καθίσει σωστά. Το σωστό βάθος επιτυγχάνεται όταν το περιφερικό σημάδι φτάσει στο επίπεδο του οστού

- Ξεβιδώστε τον αναλώσιμο εισαγωγέα
- Ψηλαφίστε τον ιστό που στερεώνετε με τον αρθροσκοπικό ερευνητή για να βεβαιωθείτε ότι η επιδιόρθωση είναι σταθερή
- Κόψτε και απομακρύνετε τα ράμματα που περισσεύουν



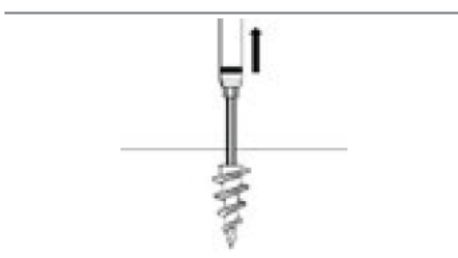
ΑΓΚΥΡΑ ΡΑΜΜΑΤΟΣ MECTALOCK TI

- Βρείτε την επιθυμητή θέση για την τοποθέτηση της άγκυρας MectaLock TI. Εισάγετε τον προφορτωμένο οδηγό με την άγκυρα MectaLock TI μέσω της κατάλληλης αρθροσκοπικής πύλης για να φτάσετε στην επιθυμητή θέση
- Απαλά χτυπήστε από πίσω τον αναλώσιμο εισαγωγέα για να τρυπήσει η άκρη της άγκυρας το οστό στο επιλεγμένο σημείο. Ενώ εφαρμόζετε μια απαλή αξονική πίεση στον εισαγωγέα, βιδώστε την άγκυρα μέσα στο οστό μέχρι το περιφερικό σημάδι πάνω στον εισαγωγέα να φτάσει στο επίπεδο του οστού



Ξεκουμπώστε τα ράμματα από την πλαστική λαβή και απαλά ξεκουμπώστε την άκρη του εισαγωγέα από την άγκυρα , τραβώντας τον εισαγωγέα έξω από την αρθροσκοπική πύλη

- Περάστε τα 2 ράμματα USP#2/EP#5 HS Fiber 39" UHMWPE μέσα από τους μαλακούς ιστούς σύμφωνα με την επιθυμητή μέθοδο και τεχνική του χειρουργού
- Ψηλαφίστε τον ιστό που στερεώνετε με τον αρθροσκοπικό ερευνητή για να βεβαιωθείτε ότι η επιδιόρθωση είναι σταθερή
- Κόψτε και απομακρύνετε τα ράμματα που περισσεύουν



11. ΜΕΤΕΓΧΕΙΡΗΤΙΚΗ ΦΡΟΝΤΙΔΑ ΚΑΙ ΠΑΡΑΚΟΛΟΥΨΗ

Ο γιατρός πρέπει να προειδοποιήσει τους ασθενείς να μειώσουν τις δραστηριότητές τους και να αποφύγουν τα υπερβολικά φορτία στο χειρουργημένο σκέλος . Επιπλέον, ο χειρουργός θα πρέπει να ενημερώσει τον ασθενή για τις προφυλάξεις που πρέπει να λαμβάνονται αναφορικά με ασκήσεις, θεραπείες και περιορισμούς των δραστηριοτήτων, τυχόν περιορισμούς που αναφέρονται στην ετικέτα αλλά και έκθεση σε μαγνητικά πεδία. Πρέπει να ενημερωθεί ο ασθενής ότι τα εμφυτεύματα μπορούν να επηρεάσουν τα αποτελέσματα αξονικής τομογραφίας (CT) ή σαρώσεις απεικόνισης μαγνητικού συντονισμού (MRI). Συνιστάται περιοδικός έλεγχος για να γίνει σύγκριση με την άμεση μετεγχειρητική κατάσταση και να προληφθούν σχετικές επιπλοκές. Υπερβολική φυσική δραστηριότητα και τραύματα του χειρουργημένου σκέλους μπορεί να προκαλέσουν αποτυχία του εμφυτεύματος. Αν προκύψει κάτι τέτοιο, είναι απαραίτητο να τεθεί ο ασθενής υπό επιτή

12. ΑΝΕΠΙΘΥΜΗΤΕΣ ΕΝΕΡΓΕΙΕΣ ΚΑΙ ΕΠΙΠΛΟΚΕΣ

Παρενέργειες που μπορούν να συμβούν κατά την επανασύνδεση των μαλακών ιστών στο οστό σε ορθοπαιδικές επεμβάσεις:

- Μόλυνση, εν τω βάθει και επιπολής
- Αλλεργίες ,μέτριες φλεγμονές και αντιδράσεις ξένου σώματος στο υλικό του εμφυτεύματος

Ορισμένες Ανεπιθύμητες Ενέργειες Μπορούν Εντέλει Να Οδηγήσουν Στο Θάνατο.

Οι Γενικές Επιπλοκές Περιλαμβάνουν:

- Φλεβική Θρόμβωση Με/Χωρίς Πνευμονική Εμβολή
- Καρδιαγγειακές Ή Πνευμονικές Διαταραχές
- Αιματώματα
- Συστημικές Αλλεργικές Αντιδράσει
- Συστημικός Πόνος

13. ΣΥΣΚΕΥΑΣΙΑ

Τα τμήματα του MectaLock Suture Anchors μηριαίων κουμπιών στερέωσης παρέχονται αποστειρωμένα σε συσκευασία μιας χρήσης. Για συστατικά μέρη που παραδίδονται στείρα, η μέθοδος αποστείρωσης υποδεικνύεται στην ετικέτα. Πρέπει να ελέγχεται η ημερομηνία λήξης στην ετικέτα αλλά και η ακεραιότητα της συσκευασίας ώστε να διασφαλίζεται ότι δεν έχει διακυβευτεί η στειρότητα των περιεχομένων. Αν η συσκευασία έχει υποστεί ζημιά ή έχει ανοιχτεί προηγουμένως, μην χρησιμοποιήσετε το συστατικό μέρος. Μην επαναποστειρώνετε.

14. ΦΥΛΑΞΗ

Οι συσκευασίες πρέπει να αποθηκεύονται σε δροσερό, στεγνό χώρο μακριά από το φως.

15. ΕΜΠΟΡΙΚΑ ΣΗΜΑΤΑ

Το Medacta είναι εμπορικό σήμα κατατεθέν της Medacta International SA, Castel San Pietro, Ελβετία.

Το αγγλικό κείμενο αποτελεί το κείμενο αναφοράς.

Τελευταία ενημέρωση: Ιούλιος 2020

s22

From: s22
Sent: Saturday, 28 August 2021 1:03 AM
To: s22
Cc: IRIS; s22@medacta.com.au; s22
Subject: R: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]
Attachments: TGA response (s41JA request for DIR 68783 & 68516).pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Dr s22

you will find here below the answers to your requests related to DIR 68783 and 68516:

1. Please provide a description of the adverse events and the rate for those events. Separate the events for Australia and the rest of the world and provide each in a percentage format. Provide a list of complaints and numbers for those similar complaints.
 This is the first event reported, no additional instrument breakages have been communicated considering both MectaLock PEEK Ø2.4 short and long drivers. In total, we have sold s47 short and long drivers (MectaLock PEEK Ø2.4).
2. In your detailed device analysis response dated 22 June 2021, it states "the laser welding failed, and the tip component has been detached from the main shaft of the inserter". Please provide details of your risk mitigation strategies in order to avoid the laser welding failure to ensure the device safety. You will find attached a dedicated rationale.

Do not hesitate to contact me if you have any issues.

Kind regards,

s22 s22 Regulatory Affairs Department s22@medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 Mob: s22 Fax: +41 91 696 60 66
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From: s22@Health.gov.au>
Sent: Friday, 30 July 2021 2:34 PM
To: s22@medacta.com.au>
Subject: s41JA request for DIR 68783 & 68516 [SEC=OFFICIAL]

Dear s22,

Good afternoon. Please find attached section 41JA request for DIR 68783 & 68516. Please note that the requested information must be provided within 20 working days from the date of this letter and no later than **30 August 2021**.
 Thanking you.

Kind regards,

Dr s22

Departmental Officer

Devices Post Market Monitoring

Medical Devices Surveillance Branch

Email: s22@health.gov.au

Telephone number s22

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.

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Event description

The patient underwent a labral repair s22 hip arthroscopy. Two MectaLock (J-Lock) PEEK anchors were used for refixing the labrum to the acetabulum with no visual issues. Then the surgeon sent to the agent a picture of an X-ray asking if the image in the X-ray was part of the anchor inserter handle. It appears that a part of the inserter handle has remained in the bone with the anchor. The patient underwent revision surgery to remove the broken part.

The event was reported to the manufacturer on 29 Jan 2021, but only after the revision surgery, which took place on s22, we were sure that the piece that remained in the patient was part of the Medacta device.

TGA question

In your detailed device analysis response dated 22 June 2021, it states “the laser welding failed, and the tip component has been detached from the main shaft of the inserter”. Please provide details of your risk mitigation strategies in order to avoid the laser welding failure to ensure the device safety.

Reply

The laser welding on the MectaLock inserter component is a technical specification associated to a critical process which is performed within the manufacturing process of the device. In particular, the residual failure risk associated to the welding is evaluated within the assembly process of the component as reported in the Risk analysis (Annex 2 of TF LI-SR-01, ITEM 1).

Item (per M07.26.xxxx)	Hazard (potential source of harm)	Harm (physical injury or damage to health of people, or damage to property or the environment)	Rationale for Probability of Harm	Severity of Harm	Probability of Harm	Residual Risk
B.02.3.10	Assembly process is not adequate to provide a safe and effective final product	Implant failure before the expected lifetime with consequent revision surgery. Another operation required with anaesthesia or septic risks	An adequate and controlled manufacturing process flow is implemented for the assembling of the “MectaLock PEEK Suture anchor” final product. (See Annex 20 of TF LI-SR-01). Validation activities and mechanical resistance tests are performed on products that are conform to all the specifications.	Very Serious	Very Low	Acceptable
B.02.3.10	Assembly process is not adequate to provide a safe and effective final product	Implant failure before the expected lifetime with consequent revision surgery. Another operation required with anaesthesia or septic risks	An adequate and controlled manufacturing process flow is implemented for the assembling of the “MectaLock PEEK Suture anchor” final product. (see Annex 20 of TF LI-SR-01). Validation activities and mechanical resistance tests are performed on products that are conform to all the specifications.	Very Serious	Very Low	Acceptable

As indicated within the manufacturing process flow of the device (FSR 0049, see extract below), the laser welding is one of the steps subject to a 100% Full Verification performed by the supplier and by Medacta, in order to verify that the specifications reported on the technical drawings are fully respected.

Analysis of Complaint 0172-21

4.3.6 SM Mectalock – Assembly (Cycle C0086)

Step #	Step Description	Planning Documents	Medacta / Supplier	Process FMEA	Qualification and Validation Documents	Deviation	Results	Other documents [e.g. rationales, additional information]
Start	Machining, laser marking, laser welding, cleaning of anchor inserter	SPC-01.009.000 rev.4	Maire-Didier	RA-01.009.000 rev.1	Full verification FVR-01.009.003	NONE	PASS	N/A

The supplier performs laser welding following a process that has been validated internally, defining specific technical parameters of the machines reported within the following Validation documents:

	IQ	OQ
Laser welding (internal MAIRE-DIDIER)	QI0016	QO/RQ00004

Moreover, Medacta performs inspections on the subject device according to a defined quality plan, specified within the inspection document CA51059. In particular, the laser welding is checked on 100% of the components in accordance with the internal procedure IC 08.55, which specifies the related acceptance criteria.

Design validation activities have been also carried out with final products to assess the required mechanical performance during all conditions of use and to confirm the safety and integrity of the device (reported in the Technical File Annex 8 of TF LI-SR-01, ITEM 1).

Conclusions

All necessary actions have been implemented to minimize any potential risk associated with the laser welding integrity. This is supported by design verification and validation activities which confirmed the effectiveness of the device during its intended use. The total residual risk of the whole system is therefore acceptable, with consideration of the individual risk and all risks from a cumulative perspective. It is therefore confirmed that the benefits, as correlated to the user needs, outweigh the collective and individual risks.

Description	Prepared by [CP]	Verified by [AQ]	Approved by [R]	Date
Reply to TGA question #2 – Complaint 0172-21	s22	s22	s22 	27 Aug 21

IRIS DIR Peer Review Procedure Checklist

DIR No.	68783	TRIM file No:	E21-259665
Lead investigator:	s22		
Review start date:	23/09/2021		

Instructions:

Save this document into the correct TRIM DIR number file

Complete **each** checklist question by ticking the appropriate checkbox.

Record any comments or requests to the investigator at the end of the document.

Return the review checklist and all files / documents / samples to the lead investigator

Discuss any comments with the lead investigator

Review of INITIAL requests to the sponsor / reporter

	Yes	No	NA
1.1 Are the questions asked or the information requested of the sponsor and/or reporter in line with the Team Meeting recommendations for the investigation?	☒	☐	☐
1.2 Are the questions asked or the information requested of the sponsor and/or reporter appropriate to the issue to be investigated?	☒	☐	☐
1.3 Can you suggest any additional information to request from the sponsor/reporter? If YES, list these in Review Comments section.	☐	☒	☐

Review of the Investigation

	Yes	No	NA
2.1 Has the investigator followed the appropriate WI for the level of investigation (see DPMMS WI 1.3 or 1.10)	☒	☐	☐
2.2 Are the administration details recorded on the DIR accurate for the device (eg ARTG number)?	☒	☐	☐
2.3 Have all relevant test results/reports, manufacturer/sponsor reports been included in the investigator's final outcomes/recommendation?	☒	☐	☐
2.4 Do the investigator's outcomes/recommendations address the issue as reported?	☒	☐	☐
2.5 Are the problems observed, Clinical signs and symptoms and health Impact consistent with the event clinical description?	☒	☐	☐
2.6 Are the Investigation findings, conclusions and OUTCOME decisions consistent with the investigation conducted?	☒	☐	☐

Review Comments

Comments/Recommendations:

- Correspondence and Chronology page has not been completed correctly. It should include a catalogue of all correspondence and evidence awkward (e.g. samples collected, and s41JAs sent/received).
- The evidence page has not been filled out correctly. This page should only be filled out between a team meeting and sending your questionnaire/RFI via DST. It gives us a snapshot of what you aim to complete in your investigation, including what potential EPs are in breach, and what questions you need answered. It is not an ongoing page that you continuously update as your investigation progresses, that is the purpose of the correspondence and chronology page.
- The investigation summary is great. However, I could not find any of the risk management analysis documents referenced within TRIM. Did you obtain this document? Or did you just fail to file it into TRIM?

Investigator's response:

Thanks for your valuable recommendations.

1. I have completed correspondence and chronology page putting the date and trim number for s41JA sent/received, IFU request/ received.
2. The evidence page has been filled based on your recommendation.
3. The risk management analysis document was not trimmed earlier and now I added into the trim container.

Reviewer Name: **S22**

Completion Date: 30 September 2021

Signature Signed Electronically

(Do not sign until the Review comment/recommendations have been agreed and finalised with the Investigator.)

s22

From: s22@Health.gov.au>
Sent: Wednesday, 6 October 2021 11:00 AM
To: s22
Subject: Reporter Completion Letter for DIR 68783 [SEC=OFFICIAL]
Attachments: [D21-3178893] DIR 68783_ Reporter_Complete_Letter.PDF

Dear MS s22

Good morning. Please find attached reporter completion letter for DIR 68783. Thanking you.

Kind regards,

Dr s22

Departmental Officer

Devices Post Market Monitoring

Medical Devices Surveillance Branch

Email: s22@health.gov.au

Telephone number : s22

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

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Australian Government
Department of Health
Therapeutic Goods Administration

**Australian Medical Device
Incident Report Investigation Scheme**

MS **s22**
Quality and Risk Consultant
s22
s22
s22
Email: **s22**

File Reference: E21-259665
Sent by email

Dear MS **s22**

**DEVICE INCIDENT REPORT DIR 68783 - Medacta J-Lock PEEK Suture - Anchor, soft-tissue
implanted, non-biodegradable**

An investigation into the incident you reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any questions regarding this report please contact our team on **s22** or send an email to: IRIS@health.gov.au

Yours sincerely,
Signed electronically by

Dr **s22**

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

06/10/2021

Reporter Reference #: s22 ID 69823

Date of Adverse Event:

s22

Date of Report:

18/03/2021

ARTG #:

320484

Brand Name:

Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted,
non-biodegradable

Device Class:

Class IIb

Model #:

Serial #:

Software Version:

Batch #:

Ref 05.11.001

Lot #:

1954843

Manufacturer:

Medacta International SA

Sponsor:

Medacta Australia Pty Ltd

Unit A1 / 16 Mars Road

LANE COVE NSW 2066

Contact Name:

s22

Phone:

s22

Reporter:

Confidential: Yes

Date of Implant:

s22

Date of Explant:

Clinical Event Information:

Patient was admitted into surgery for right hip arthroscopy and femoral osteotomy and labral repair on the [redacted], Anchor introducer found retained in patient on surgeon appointment. Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon. Additional surgery required for removal of retained anchor introducer on s22

Patient Outcome/Consequences:

Additional surgery required for removal of retained anchor introducer on s22

Investigation Summary:

A review of the manufacturer's analysis shows that the welding failed due to the component being subjected to stress of excessive lateral bending. The manufacturer notes that it is not possible to identify a clear or specific root cause for the mode of failure. A review of the warnings and precautions section in the Instructions for Use (IFU) has shown that the breakage of the MectaLock Suture Anchor can occur if any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor. The review of the risk management analysis document shows that all necessary actions have been implemented to minimize any potential risk associated with the laser welding integrity. In addition, this is supported by design verification and validation activities which confirmed the effectiveness of the device during its intended use. The sponsor notes that this is an isolated event and a review of the IRIS database has shown that there is only one similar adverse event. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:

End of DIR 68783

From: s22
To: s22 @medacta.com.au
Subject: Sponsor Completion Letter for DIR 68783 [SEC=OFFICIAL]
Date: Wednesday, 6 October 2021 11:12:33 AM
Attachments: [D21-3178905] DIR 68783_Sponsor_Complete_Letter.PDF

Dear s22,

Good morning. Please find attached sponsor completion letter for DIR 68783. Thanking you.

Kind regards,

Dr s22
Departmental Officer
Devices Post Market Monitoring
Medical Devices Surveillance Branch
Email: s22 @health.gov.au
Telephone number : s22

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

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Australian Government
Department of Health
Therapeutic Goods Administration

**Australian Medical Device
Incident Report Investigation Scheme**

s22
Medacta Australia Pty Ltd
Unit A1 / 16 Mars Road
LANE COVE NSW 2066
Email: **s22**@medacta.com.au

File Reference: E21-259665
Sent by email

Dear **s22**

DEVICE INCIDENT REPORT DIR 68783 - ARTG # 320484 - Ligament anchor

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact our team on **s22** or

send an email to: IRIS@health.gov.au

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

06/10/2021

DIR 68783 - ARTG # 320484 - Ligament anchor

Reporter Reference #: s22 ID 69823

Date of Adverse Event:

s22

Date of Initial Report:

18/03/2021

ARTG #:

320484

Brand Name:

Medacta J-Lock PEEK Suture - Anchor, soft-tissue implanted,
non-biodegradable

Device Class:

Class IIb

Model #:

Serial #:

Software Version:

Batch #:

Ref 05.11.001

Lot #:

1954843

Manufacturer:

Medacta International SA [45296]

Sponsor:

Medacta Australia Pty Ltd [45972]

Unit A1 / 16 Mars Road

LANE COVE NSW 2066

Contact Name: s22

Phone: s22

Fax:

Email: s22@medacta.com.au

Reporter:

Confidential: Yes

Date of Implant:

s22

Date of Explant:

Clinical Event Information:

Patient was admitted into surgery for right hip arthroscopy and femoral osteotomy and labral repair on the [redacted], Anchor introducer found retained in patient on surgeon appointment.

Anchor introducer snapped off during surgery and not found until patient went for appointment with surgeon. Additional surgery required for removal of retained anchor introducer on s22

Patient Outcome/Consequences:

Additional surgery required for removal of retained anchor introducer on s22

Device Analysis Results:

Additional information received by Sponsor 03/06/2021

The component of the MectaLock PEEK inserter has been received and analysed. It's evident that the laser welding failed and the tip component has been detached from the main shaft of the inserter. The proximal portion of the analysed component was received scratched, most likely due to the extraction, therefore is not possible to perform a detailed microscopic analysis of the failure mode of the welding.

A deeper analysis on the safety of the device has been carried out by means of further mechanical investigation on equivalent devices sourced from the same production batch, as representative of the component object of this complaint. In particular, the welding between the shaft and the inserter tip has been subject to stress limit tests which confirmed the safety and reliability of the device under load conditions that are commonly expected during a surgery. Therefore, it's not possible to identify a clear or specific root cause for the mode of failure, unless an outstanding condition required a not foreseeable usage during the surgical procedure.

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Clinical Signs (Level 1)

Others

Health Impacts (Level 1)

Surgical Intervention

Type of Problem (Level 1)

Material Integrity Problem

Cause of Problem (Level 1)

No Findings Available

Outcome of Investigation

Reviewed, No Further Action Required

Clinical Signs (Level 2)

Insufficient Information

Health Impacts (Level 2)

Additional Surgery

Type of Problem (Level 2)

Break

Cause of Problem (Level 2)

Summary of Investigation:

A review of the manufacturer's analysis shows that the welding failed due to the component being subjected to stress of excessive lateral bending. The manufacturer notes that it is not possible to identify a clear or specific root cause for the mode of failure. A review of the warnings and precautions section in the Instructions for Use (IFU) has shown that the breakage of the MectaLock Suture Anchor can occur if any lateral loading is applied on the anchor/insertor while inserting the MectaLock anchor. The review of the risk management analysis document shows that all necessary actions have been implemented to minimize any potential risk associated with the laser welding integrity. In addition, this is supported by design verification and validation activities which confirmed the effectiveness of the device during its intended use. The sponsor notes that this is an isolated event and a review of the IRIS database has shown that there is only one similar adverse event. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:

End of DIR 68783

**Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring**

DIR : 46 - ID : 571181

Released by s22 on 28/09/2022 14:44:45

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
89036		1273-23	Final

ARTG: 320484	Document Container URL
--------------	--

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	12/07/2023
Date of Final Report:	Date of Initial TGA Action:	Reviewed by Team:	Date Response Received:
05/10/2023	12/07/2023		
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter consents to contact by sponsor:
16/10/2023	Healthcare Professional		N/A
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Sponsor		Trend data only	

Event Description for Website Publication:

The tip of the inserter was broken.

Clinical Event Information:

During anchor insertion, the surgeon felt like a lot of force was required to mallet into bone. Once the anchor was fully implanted, the introducer came away from the anchor immediately (without need for counterclockwise turns). The broken tip of the inserter was visible in the intraoperative xray.

It is feasible that, during the malleting phase, the anchor and the inserter were not fully axially aligned with the pilot hole and that the malleting was not fully axially aligned with the handle of the inserter. Slotted Aimer was not used. The tip was left inside the patient.

Suture fixation was adequate and surgeon used 2 more JLOCK anchors successfully following and 1 prior to the breakage. No revision surgery is planned.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	Alternative Person Phone:	Alternative Person Fax:	Alternative Person Email:

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> -> ;
Material Integrity Problem -> Break -> Material Fragmentation

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Musculoskeletal System -> ->

Health Impact

Recorded Health Impacts:

Change in Therapeutic Response -> Unexpected Therapeutic Effects ->

Patient Information

Sex:	Weight:	Age:
s22		s22 old
Patient Focused Corrective Action Taken:	Patient History:	
Patient Outcome/Consequences:	Additional Event Description:	

Describe any test (Lab, xray, etc.):

Additional Patients Added:

0

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For: Document 21

Submitting Reporter Section

Search Reporter By Surname:

Reporter Title:

Position:

Address 1:

Country:

Mobile:

Reporter #:

First Name:

Address 2:

Postcode:

Email:

Surname:

Company/Institution:

Town/Suburb:

Phone:

Last External Submission By:

Preferred Contact Method:

State:

Fax:

Initial Reporter Section

As Above?:

Search Reporter By Surname:

Title:

Position:

Address 1:

Postcode:

Mobile:

If No, fill out the following:

Initial Reporter #:

First Name:

Address 2:

Country:

Email:

Surname:

Company/Institution:

Town/Suburb:

Phone:

Allow the device company to contact you about the incident:

☐

Initial Reporter Confidential:

Preferred Contact Method:

State:

Fax:

Device Information Section

Product Exempt (Note: If not exempt, enter ARTG No):

Product Licence Category:

Brand Name:

Model #:

Purchase Date:

Date of Initial Procedure:

Search Device ARTG:

Device Class:

Initial Device Description:

Serial #:

Expiry Date:

Place of Implantation:

Device ARTG #:

GMDN / UMDN Code:

Usage of Device:

Batch #:

Date of Implant:

Reported Device Location:

Therapeutic Licence Type:

GMDN / UMDN Text:

Software Version:

Lot #:

Date of Explant:

Access Contact Title:

	§22	With Manufacturer	Document 21
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	19/07/2019	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:		Address 1:	
Medacta International SA		45296			
Address 2:		State/Province:		Country:	
Postcode:		Fax:		Email:	
Manufacturer Informed:		Contact Title:		Contact First Name:	
Yes		Mr.		§22	
Contact Surname:					
§22					

Supplier Information Section

Supplier Name:		Address 1:		Address 2:	
Town/Suburb:		Country:		Postcode:	
Phone:		Email:		Website:	
Supplier Informed:		Contact Title:		Contact First Name:	
Contact Surname:		Contact Fax:		Contact Email:	

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Event determined to be an isolated one	Team B (Iib, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:	
Notes for Team meeting:			
Outcomes from Team Meeting:			

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
16/10/2023	0 - Insufficient information to determine level of severity		Yes	§22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:

	No	Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		Isolated event		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			No	0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No	Isolated event			
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
45972	Medacta Australia Pty Ltd		45972
Attention To:	Address 1:	Address 2:	Town/Suburb:
	Unit A1 / 16 Mars Road		LANE COVE
State:	Postcode:	Phone:	Fax:
NSW	2066		

Email:

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Batch review performed on 5 July 2023
Lot 2227487: 75 items manufactured and released on 06-Feb-2023. Expiration date: 2027-Dec-12. No anomalies found related to the problem. To date, 16 items of the same lot have been sold with no similar reported event during the period of review.

Visual Inspection performed by R&D Project Manager

The breakage of the inserter occurred in correspondence to the change of section between the distal cylindrical portion and the thread, leaving the most distal pin (thread + cone) within the PEEK anchor. The breakage in this section suggests that the assembled inserter and anchor have been subjected to considerable lateral loads. As confirmed by the event report, the direction of insertion was not correspondant with the pilot hole axis, suggesting a misalignment between the inserter and the bone. Hammering the inserter in this configuration may result in an unforeseeable lateral hitting load condition, bringing to the weakest section breakage. A preliminary microscopic analysis of the broken section suggests an instantaneous failure, compatible with a hammering action, therefore excluding a cyclic load condition.
The constrained condition of the pilot hole prevented the anchor from failing (internally also supported by the metal pin) concentrating the loads on the interface section between the anchor and inserter.

Clinical Evaluation performed by Medical Affairs Department

While inserting an anchor in hip arthroscopy surgery, the surgeon reported the breakage of the introducer tip, after feeling hard insertion. As shown by the intraoperative X-ray at our disposal, the metallic tip of the instrument remained seated in the bone. Even though the material of the instrument is medical-grade stainless steel it does not belong to the series approved for long-term implantation and therefore we cannot guarantee that leaving the fragment in situ may not cause secondary problems. However, given that in this case the fragment is completely surrounded by bone, it is extremely unlikely that a secondary adverse effect would ever be triggered. Retrieving the fragment would undoubtedly be a very invasive procedure and therefore the surgeon has understandably decided to leave it in place.
It is difficult to determine the cause of this breakage, but the report indicates that the patient may have had sclerotic bone which made insertion difficult. With the information at hand, we cannot make a definitive conclusion.

Additional Details (use for tables):



Details of Similar Events:

MectaLock instruments 05.11.002 MectaLock PEEK Ø2.9 – Long driver Lot. 2227487: 1st case on the ref and lot.

Considering these and similar references, this is the 2nd case reported due to inserter breakage. However, the breakage of the previous complaint is different, it was a breakage at the welding point and lead to an additional surgery to remove the part. The occurrence rate is 0.26%.

Lot 2227487: 75 items manufactured and released on 06-Feb-2023. Expiration date: 2027-Dec-12. No anomalies found related to the problem. To date, 16 items of the same lot have been sold with no similar reported event during the period of review.

CAPA# Reference:

Risk Assessment

Frequency:

Severity:

Rating:

Type Cause and Outcome:

Number of Similar Events:

Expected Rate:

Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 16/10/2023

Reason for Level 1 Investigation

Details of Reasons

Reason for Level 1 Investigation

Focus of Level 2 Investigation

Details of Focus

Essential Principles					If 'Other' Selected					Document 21	

Sources of Evidence for Level 2

Details of Source											
Sources of Evidence				If 'Others' please specify here			Expected Sourcing Date			Date of Evidence Received	

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details										
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details					
Problem Observed (Level 1)		Problem Observed (Level 2)		Problem Observed (Level 3)	If 'Other' Selected
Material Integrity Problem		Break		Material Fragmentation	
Appropriate Term/Code Not Available				Foreign body left in patient	

Clinical signs symptoms and conditions

Details				
Level 1		Level 2		Level 3
Musculoskeletal System				

Health Impact

Details				
Level 1		Level 2		Level 3

Change in Therapeutic Response	Unexpected Therapeutic Effects		Document 21
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Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
Patient Sample Problem				

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Traced to User	Unintended Use Error Caused or Contributed to Event		

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR: 	Latest Investigation (DII) where this DIR is a Related DIR: 	Investigator: 	Peer Review: No	
Investigator's Notes: 	Summary Findings: No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.			Recall Number:

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered): 	Brand Name: 	Manufacturer Name: 	Device ARTG #: 	
--	----------------------------	-----------------------------------	-------------------------------	--

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click [N] to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
						Who sent the device to the TGA?:			Why does the TGA have the sample?:

Additional Patients

Click [N] to begin entering information.

Patient Details							
Sex:		Weight:		Age:			
Patient Focused Corrective Action Taken:				Patient History:			
Injured - Extent of Injury:		Was device directly linked to death?:		Was device directly linked to permanent disability?:		Consequence:	
Other Consequence:		Describe any test (Lab, xray, etc.):		Additional Event Description:		Medical Problem Device Used For:	

Additional Device Information

Where did you get this device from?:	How reliant is the affected person on correct/safe operation of this device?:
Any other relevant information to aid assessing/investigating the incident?:	

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:
Fax:	Email:		

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Town/Suburb:	State:	Postcode:	

Flow Details : DIR-REQ - Device Incident Request : 392939

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On /	Priority	Attach
392939	DIR-REQ		Closed	\$22	OPR Administration User	16/10/2023	Normal	0

Signature Details

Role	IRIS Investigator	
User	\$22	
Signed At	16/10/2023 16:02:33	
Comment		

From: s22@medacta.ch>
Sent: Thursday, 10 February 2022 10:18 PM
To: s22
Cc: IRIS; s22; s22; s22@medacta.com.au; s22; s22
Subject: R: RESPONSE OVERDUE RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]
Attachments: R: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/2021 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,
 I'm s22, s22 of Medacta International.
 I've personally followed the event involved in your communication and I would like to answer to the questions raised to Mr s22.
 As per the e-mail attached, the event and the incongruency between the DIR 68516 and DIR 68783 was reported to the Competent Authority in April 2021.
 As reported in your table, the event was communicated to the TGA by the sponsor as DIR 68516 and by the user as DIR 68783. They are related to the same event.
 The correct item involved in the event is the MectaLock PEEK Ø2.4 – Short driver reference 05.10.001 Lot. 1924147 that was wrongly reported by the user, as lot 1954843, in the DIR 68783.
 As per the above clarification, I would suggest to consider DIR 68783 as duplicate of the DIR 68516 that reports all the correct information related to this event.
 Do not hesitate to contact me if you have any issues.
 Kind regards,

s22 s22 <i>Regulatory Affairs Department</i> s22@medacta.ch www.medacta.ch	Medacta International SA Strada Regina CH-6874 Castel San Pietro Switzerland Pho: s22 Mob: s22 Fax: +41 91 696 60 66
---	--

Da: s22@health.gov.au>
Inviato: giovedì, 10 febbraio 2022 07:17
A: s22@medacta.com.au>
Cc: s22@medacta.com.au; s22@medacta.ch; s22@medacta.ch>
Oggetto: RE: RESPONSE OVERDUE RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]
 Dear s22,
 Thank you for your email along with the attachment. The lot number and date of implant is different in the 2 DIRs as shown in the table below:

DIR Number	Report type	Lot number	Model number	Date of Implant
68783	User	1954843	Unknown	s22
68516	Sponsor	1924147	05.10.001	s22

Please confirm if the DIR 68516 is a duplicate of DIR 68783 so we can make it a duplicate in our system? If these are 2 different incidents with 2 different devices the DIR 68516 will not be considered a duplicate.

Please provide the response by **COB 17 February 2022**.

Thanks & Regards,

s22
s22

Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone: s22

Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: s22@medacta.com.au>

Sent: Thursday, 13 January 2022 3:46 PM

To: s22@health.gov.au>

Cc: s22@medacta.com.au>; s22@medacta.ch>; s22

s22@medacta.ch>

Subject: RE: RESPONSE OVERDUE RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

A response to this enquiry was provided on 13/12/21. Please see attachment.

I will call shortly to clarify

Best regards

s22

From: s22

Sent: Thursday, 13 January 2022 3:29 PM

To: s22; s22

Cc: s22; s22; s22

Subject: RESPONSE OVERDUE RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]

Dear s22

A response to below information request is overdue.

Please provide a response to this request soon as possible, or further actions may be taken in the next step.

Kind regards,

s22

Departmental Officer

Devices Post Market Monitoring

Medical Devices Surveillance Branch

Phone: s22
 Email: s22 @health.gov.au

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia
www.tga.gov.au

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The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to them and their culture, and to all Elders both past and present.

 **Please consider the environment before printing this email.**

From: s22 @health.gov.au>

Sent: Tuesday, 7 December 2021 4:15 PM

To: s22 @medacta.com.au>

Cc: s22 @medacta.com.au>; s22 @medacta.ch>; s22 @medacta.ch>

Subject: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]

Dear s22

Thank you for your 2020-21 Annual Report submission.

I am reviewing your report.

A search in the IRIS database has revealed 2 DIRs (DIR 68783 and 68516) received for ARTG 320484 for the reporting period 1 July 2020 – 30 June 2021. I have noted only DIR 68516 is included within your annual report.

Action required by close of business 21 December 2021:

1. Please provide a justification on the discrepancy observed in DIR numbers for ARTG 320484.
2. Based on your answer to question 1, please advise if an amendment to reflect the correct adverse events (and their corresponding DIRs) number for ARTG 320484 is needed. If so, please provide the amended annual report.

Kind regards,

s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch

Phone: s22
 Email: s22 @health.gov.au

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia
www.tga.gov.au

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The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to them and their culture, and to all Elders both past and present.

 Please consider the environment before printing this email.

From: s22 [redacted] <[redacted]@medacta.com.au>

Sent: Tuesday, 28 September 2021 9:54 AM

To: IRIS <IRIS@health.gov.au>; IRIS <IRIS@health.gov.au>

Cc: s22 [redacted] <[redacted]@medacta.com.au>; s22 [redacted] <[redacted]@medacta.ch>; s22 [redacted]

s22 [redacted] <[redacted]@medacta.ch>

Subject: Medacta Australia Annual Report

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir/madam,

Please find attached the 2021 Annual report for Medacta Australia.

Should you require further information please do not hesitate to contact me .

Yours faithfully

s22 [redacted]

For and on behalf of Medacta Australia Pty Ltd

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s22

From: s22@medacta.com.au>
Sent: Thursday, 22 September 2022 8:33 PM
To: IRIS
Cc: s22; s22; s22; s22
Subject: Medacta Australia Annual Report
Attachments: 2022 Annual Report - Medacta Australia.xlsx

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir/Madam,

Please find attached the annual report of Medacta Australia Pty Ltd.

Please do not hesitate to contact me should you require further information

Kind Regards

s22

s22

s22

s22@medacta.com.au
www.medacta.com

Medacta Australia

Unit A1, 16 Mars Road
Lane Cove, NSW 2066
Australia

Pho: s22
Mob: s22
Fax: +612 9420 2578

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<https://www.mailguard.com.au>

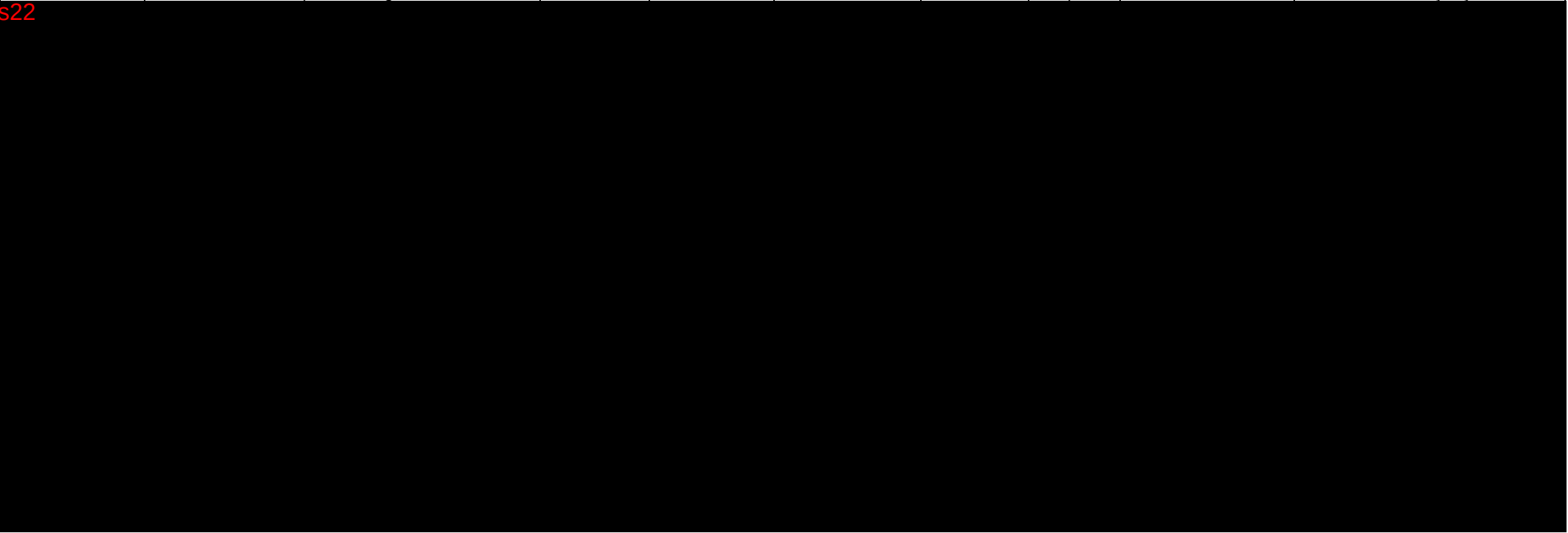
Class	Start Date	ARTG ID	Sponsor	Device Category	GMDN	Term	Intended Purpose	Sponsor ID	Address (line 1)	Address (line 2)	Town	State	Postcode	Manufacturer ID	Manufacturer Name
s22															
s22	19/07/2019	320484	Medacta Australia Pty Ltd	Non-active implantable devices	36174	Ligament anchor	The Meralock PEEK Suture anchors are intended for use in arthroscopic or open surgical approaches for fixation of su	45972	Unit 61 / 15 Mars Road		LANE COVE	NSW	2066	45296	Medacta International SA

ARTG Number	Product name (description)	Model Number (or Name)	Quantity supplied in Australia	Quantity supplied Worldwide (incl Australia)	Number of complaints (Aust / WW)	Number of Adverse Events (Aust / WW)	Comment relevant qualifications relating to data
Data from the 1st July 2020 to the 30th June 2021 - WW includes Australia							
320484	Ligament anchor	MectaLock PEEK Suture Anchors	S4 /		2/3	0/0	

ARTGNumber	Type of adverse events	Number Total (AU included)	Number AU	Percentage world Wide	Percentage in Australia	TGA DIR Number	Regulatory action	Comments
	(description and code)					if relevant	regulatory/corrective action/notification by the manufacturer	relevant qualifications relating to type of issue and actions

s22

ARTG Number	Type of complaint	Number Total (AU included)	Number AU	Percentage world Wide	Percentage in Australia	TGA DIR Number	Regulatory action	Comments
	(description and code)					if relevant	regulatory/corrective action/notification by the manufacturer	relevant qualifications relating to type of issue and actions
320484	Failure of press-fit	1	0	0.75%	0.00%	/	Nil	no related defect found
	Implant breakage	3	2	2.24%	3.77%	/	Nil	no related defect found



s22

From: s22 @health.gov.au>
Sent: Thursday, 10 February 2022 5:17 PM
To: s22
Cc: s22; s22; s22
Subject: RE: RESPONSE OVERDUE RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]
Attachments: RE: Review of Medacta Australia Annual Report - response due COB 21 Decem... (264 KB)

Dear s22

Thank you for your email along with the attachment. The lot number and date of implant is different in the 2 DIRs as shown in the table below:

DIR Number	Report type	Lot number	Model number	Date of Implant
68783	User	1954843	Unknown	s22
68516	Sponsor	1924147	05.10.001	s22

Please confirm if the DIR 68516 is a duplicate of DIR 68783 so we can make it a duplicate in our system? If these are 2 different incidents with 2 different devices the DIR 68516 will not be considered a duplicate.

Please provide the response by **COB 17 February 2022**.

Thanks & Regards,

s22
s22
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: s22 @medacta.com.au>
Sent: Thursday, 13 January 2022 3:46 PM
To: s22 @health.gov.au>
Cc: s22 @medacta.com.au>; s22 @medacta.ch>; s22 @medacta.ch>
Subject: RE: RESPONSE OVERDUE RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22
 A response to this enquiry was provided on 13/12/21. Please see attachment.
 I will call shortly to clarify
 Best regards
 s22

From: s22
Sent: Thursday, 13 January 2022 3:29 PM
To: s22 ; s22
Cc: s22 ; s22 ; s22
Subject: RESPONSE OVERDUE RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]

Dear s22
 A response to below information request is overdue.
 Please provide a response to this request soon as possible, or further actions may be taken in the next step.
 Kind regards,
 s22
 Departmental Officer
 Devices Post Market Monitoring
 Medical Devices Surveillance Branch

Phone: s22
 Email: s22 @health.gov.au

Therapeutic Goods Administration

Department of Health
 PO Box 100
 Woden ACT 2606 Australia

www.tga.gov.au

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The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to them and their culture, and to all Elders both past and present.

 Please consider the environment before printing this email.

From: s22 [REDACTED] <[REDACTED]@health.gov.au>

Sent: Tuesday, 7 December 2021 4:15 PM

To: s22 [REDACTED] <[REDACTED]@medacta.com.au>

Cc: s22 [REDACTED] <[REDACTED]@medacta.com.au>; s22 [REDACTED] <[REDACTED]@medacta.ch>; s22 [REDACTED] <[REDACTED]@medacta.ch>

Subject: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]

Dear s22 [REDACTED]

Thank you for your 2020-21 Annual Report submission.

I am reviewing your report.

A search in the IRIS database has revealed 2 DIRs (DIR 68783 and 68516) received for ARTG 320484 for the reporting period 1 July 2020 – 30 June 2021. I have noted only DIR 68516 is included within your annual report.

Action required **by close of business 21 December 2021**:

1. Please provide a justification on the discrepancy observed in DIR numbers for ARTG 320484.
2. Based on your answer to question 1, please advise if an amendment to reflect the correct adverse events (and their corresponding DIRs) number for ARTG 320484 is needed. If so, please provide the amended annual report.

Kind regards,

s22 [REDACTED]

Departmental Officer

Devices Post Market Monitoring

Medical Devices Surveillance Branch

Phone: s22 [REDACTED]

Email: s22 [REDACTED] <[REDACTED]@health.gov.au>

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

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 Please consider the environment before printing this email.

From: s22 [REDACTED] <[REDACTED]@medacta.com.au>

Sent: Tuesday, 28 September 2021 9:54 AM

To: IRIS <IRIS@health.gov.au>; IRIS <IRIS@health.gov.au>

Cc: s22 [REDACTED] <[REDACTED]@medacta.com.au>; s22 [REDACTED] <[REDACTED]@medacta.ch>; s22 [REDACTED] <[REDACTED]@medacta.ch>

Subject: Medacta Australia Annual Report

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir/madam,

Please find attached the 2021 Annual report for Medacta Australia.

Should you require further information please do not hesitate to contact me .

Yours faithfully

s22

For and on behalf of Medacta Australia Pty Ltd

s22 le

s22

s22 @medacta.com.au

www.medacta.com**Medacta Australia**

Unit A1, 16 Mars Road

Lane Cove, NSW 2066

Australia

Pho: s22

Mob: s22

Fax: +612 9420 2578

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s22

From: s22@medacta.com.au>
Sent: Monday, 13 December 2021 1:57 PM
To: s22
Cc: s22; s22; s22
Subject: RE: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]
Attachments: R: *Amended* DIR 68783 - Questionnaire Letter - Response due COB 27/04/20... (215 KB)

Dear Miss s22

1. DIR 68783 and 68516 refer to the same adverse event # 0172-21. In summary, we had originally reported the event as DIR 68516, and in parallel the TGA also received a notification from the hospital and registered the event as DIR 68783. Attempt to clarify the discrepancy had subsequently been made to the TGA by Medacta. (please see attached correspondence dated 26/4/21) On the TGA website DIR 68783 is the only available reference via the Medacta account.
2. Based on the response provided in point 1 above, Medacta do not propose any amendments to the annual report

Should further clarification be required, please do not hesitate to contact me

Thank you and best regards

s22

s22	Medacta Australia
s22	Unit A1, 16 Mars Road
	Lane Cove, NSW 2066
	Australia
s22@medacta.com.au	Pho: s22
www.medacta.com	Mob: s22
	Fax: +612 9420 2578

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From: s22
Sent: Tuesday, 7 December 2021 4:15 PM
To: s22
Cc: s22 ; s22 ; s22
Subject: Review of Medacta Australia Annual Report - response due COB 21 December 2021 [SEC=OFFICIAL]

Dear s22

Thank you for your 2020-21 Annual Report submission.
I am reviewing your report.

A search in the IRIS database has revealed 2 DIRs (DIR 68783 and 68516) received for ARTG 320484 for the reporting period 1 July 2020 – 30 June 2021. I have noted only DIR 68516 is included within your annual report.

Action required by close of business 21 December 2021:

1. Please provide a justification on the discrepancy observed in DIR numbers for ARTG 320484.
2. Based on your answer to question 1, please advise if an amendment to reflect the correct adverse events (and their corresponding DIRs) number for ARTG 320484 is needed. If so, please provide the amended annual report.

Kind regards,

s22
Departmental Officer
Devices Post Market Monitoring
Medical Devices Surveillance Branch

Phone: s22
Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.



This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to them and their culture, and to all Elders both past and present.

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From: s22 [REDACTED] <[REDACTED]@medacta.com.au>
Sent: Tuesday, 28 September 2021 9:54 AM
To: IRIS <IRIS@health.gov.au>; IRIS <IRIS@health.gov.au>
Cc: s22 [REDACTED] <[REDACTED]@medacta.com.au>; s22 [REDACTED] <[REDACTED]@medacta.ch>; s22 [REDACTED] <[REDACTED]@medacta.ch>
Subject: Medacta Australia Annual Report

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir/madam,

Please find attached the 2021 Annual report for Medacta Australia.

Should you require further information please do not hesitate to contact me .

Yours faithfully

s22 [REDACTED]
For and on behalf of Medacta Australia Pty Ltd

s22 [REDACTED]	Medacta Australia
s22 [REDACTED]	Unit A1, 16 Mars Road
	Lane Cove, NSW 2066
	Australia
s22 [REDACTED] <[REDACTED]@medacta.com.au>	Pho: s22 [REDACTED]
www.medacta.com	Mob: s22 [REDACTED]
	Fax: +612 9420 2578

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From: s22@medacta.com.au>
Sent: Tuesday, 28 September 2021 9:54 AM
To: IRIS; IRIS
Cc: s22; s22; s22
Subject: Medacta Australia Annual Report
Attachments: 2021 Annual Report - Medacta Australia.xlsx

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Dear Sir/madam,

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Should you require further information please do not hesitate to contact me .

Yours faithfully

s22

For and on behalf of Medacta Australia Pty Ltd

s22

Medacta Australia

Unit A1, 16 Mars Road
Lane Cove, NSW 2066
Australia

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Pho: s22

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[illegible]

ARTGNumber	Product name (description)	Model Number (or Name)	Quantitysuppl iedinAustralia	Quantitysuppl iedWorldwide	Number of complaints	Number of Adverse Events	Comment
				(inclAustralia)	(Aust / WW)	(Aust / WW)	relevant qualifications relating to data
Datafromthe1stjuly2020tothe30thJune2021- WWincludesAustralia							
320484	Ligament anchor	MectaLock PEEK Suture Anchors	S4 /		0/6	1/1	

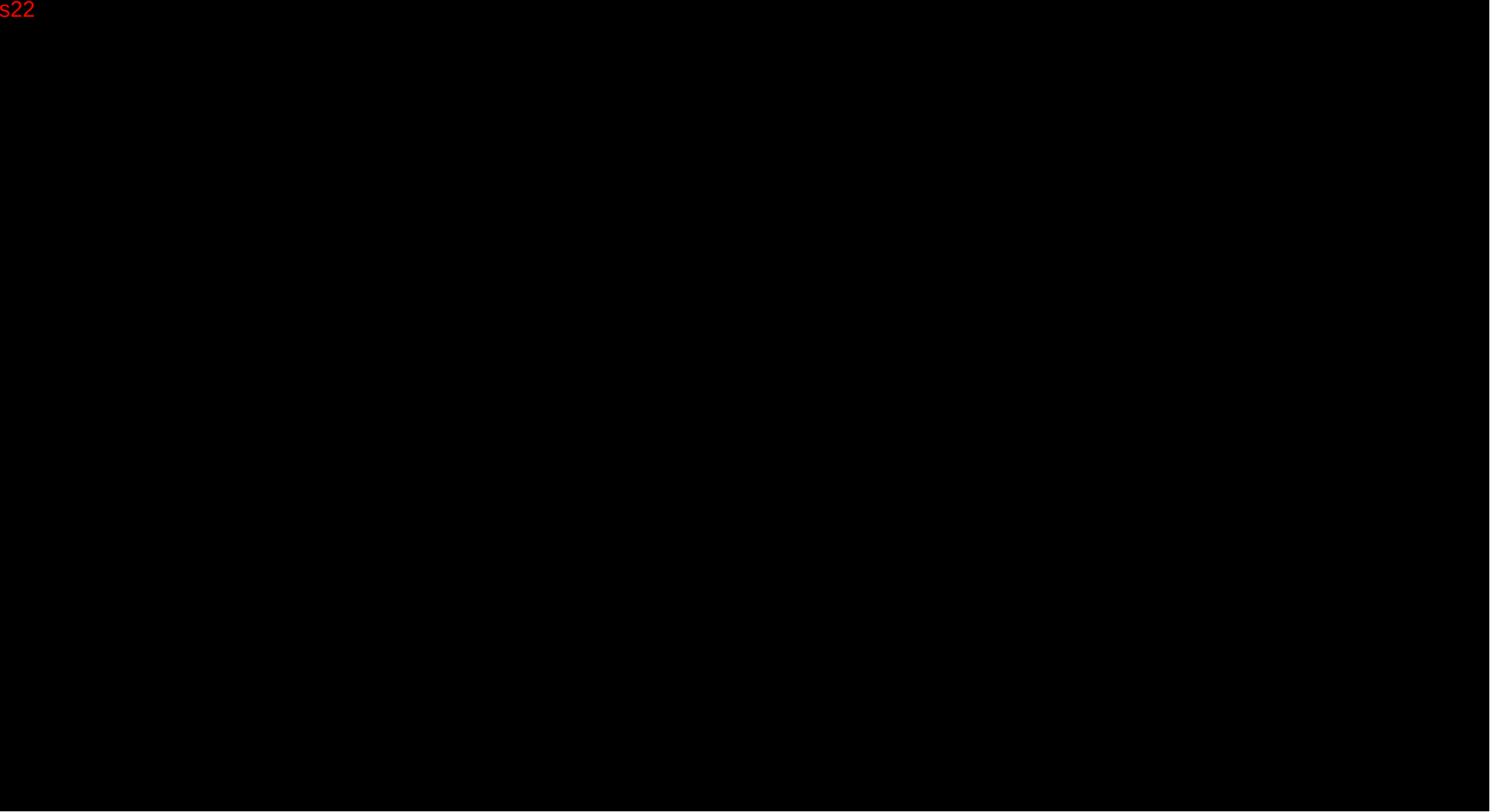
ARTGNumber	Type of adverse events	Number Total (AU included)	Number AU	Percentage world Wide	Percentage in Australia	TGA DIR Number	Regulatory action	Comments
	(description and code)					if relevant	regulatory/corrective action/notification by the manufacturer	relevant qualifications relating to type of issue and actions

s22

320484	<i>Instrument breakage</i>	<i>1</i>	<i>1</i>	<i>0.82%</i>	<i>1.43%</i>	<i>68516</i>	<i>Nil</i>	<i>no action - no trend observed</i>
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s22

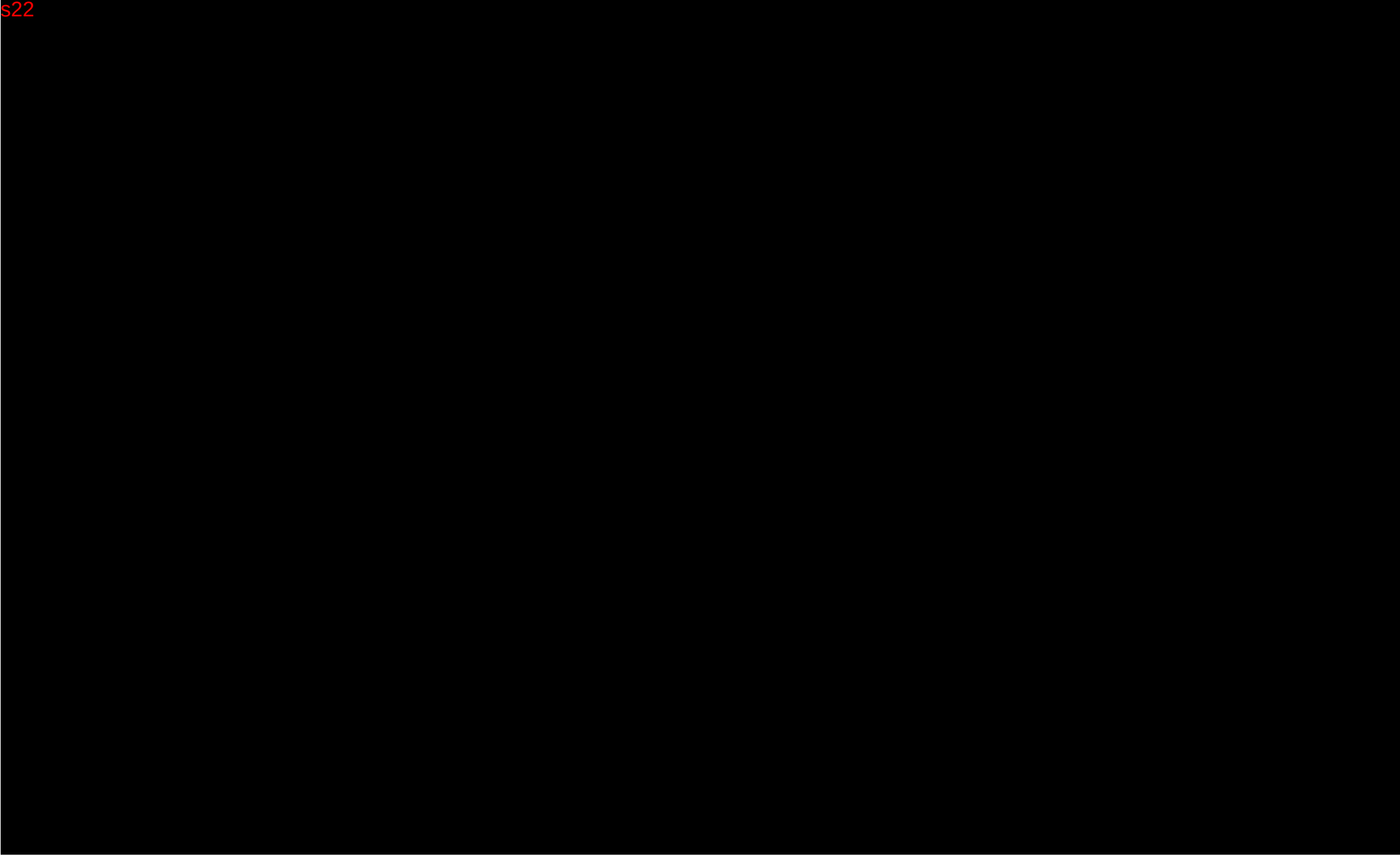
s22



ARTG Number	Type of complaint	Number Total (AU included)	Number AU	Percentage world Wide	Percentage in Australia	TGA DIR Number	Regulatory action	Comments
	(description and code)					if relevant	regulatory/corrective action/notification by the manufacturer	relevant qualifications relating to type of issue and actions
S22								
320484	Implant breakage	4	0	3.28%	0.00%	/	Nil	no related defect found
	Implant deformation	2	0	1.64%	0.00%	/	Nil	no related defect found

s22

s22



s22

From: s22@medacta.com.au>
Sent: Monday, 28 September 2020 11:17 AM
To: IRIS
Cc: s22; s22; s22
Subject: Medacta Australia 2020 Annual Report
Attachments: 2020 Annual Report - Medacta Australia.xlsx

REMINDER : Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir/madam,

Please find attached the 2020 Annual report for Medacta Australia Pty Ltd.

Should you require further information please do not hesitate to contact me .

Yours faithfully

s22

s22

s22

s22@medacta.com.au
www.medacta.com

Medacta Australia
 Unit A1, 16 Mars Road
 Lane Cove, NSW 2066
 Australia
 Pho: s22
 Mob: s22
 Fax: +612 9420 2578

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[illegible]

Class IIb	19/07/2019	320484	Medacta Australia Pty Ltd	Non-active implantable devices	36174	Ligament anchor	The MectaLock PEEK Suture anchors are in	45972	Unit A1 / 16 Mars Road	LANE COVE NSW	2066	45296	Medacta International SA
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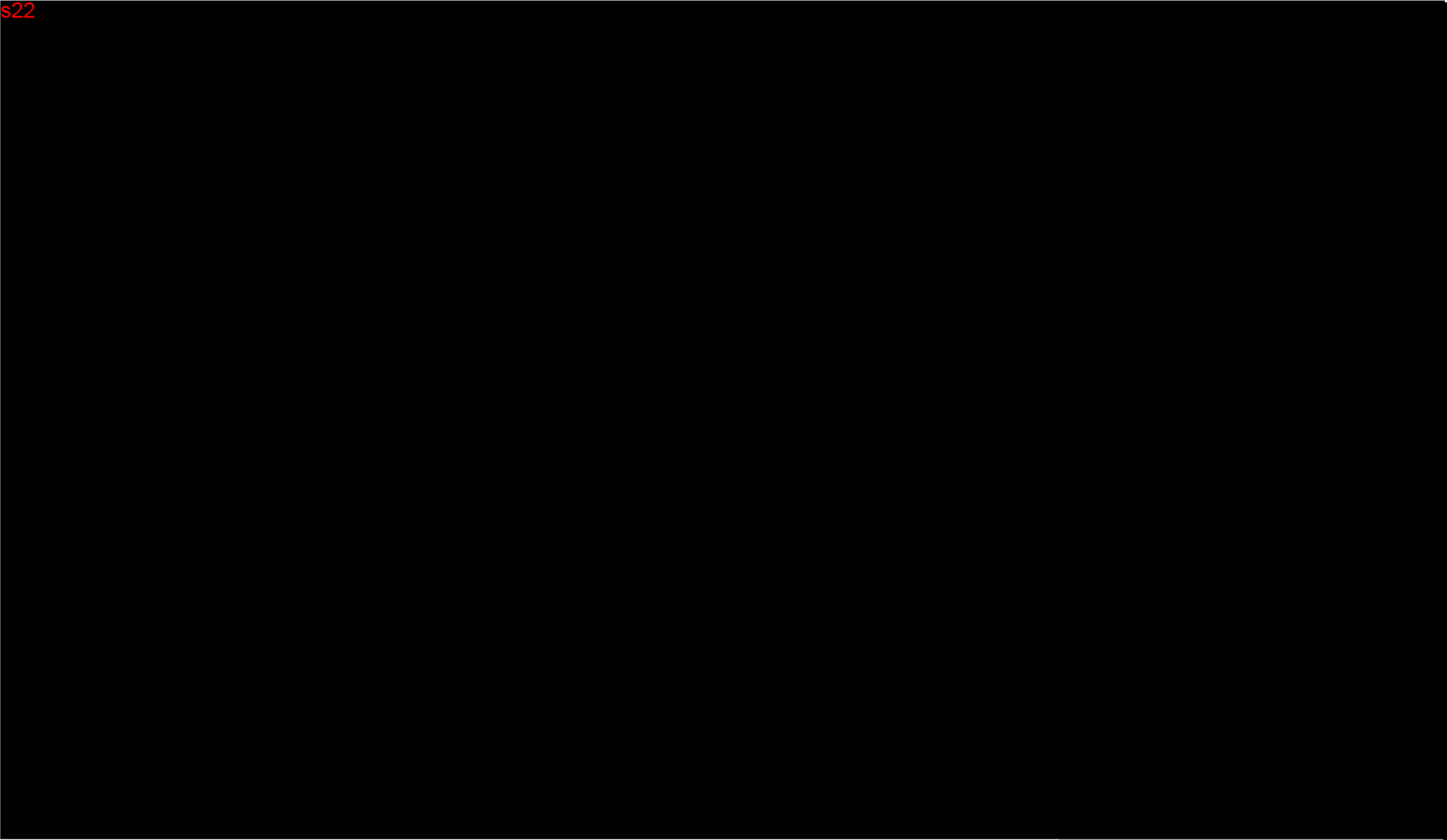
ARTG Number	Product name (description)	Model Number (or Name)	Quantity supplied in Australia	Quantity supplied Worldwide (incl Australia)	Number of complaints (Aust / WW)	Number of Adverse Events (Aust / WW)	Comment relevant qualifications relating to data
Data from the 1st July 2019 to the 30th June 2020 - WW includes Australia							
s22							
320484	Ligament anchor	MectaLock PEEK Suture Anchors	s4 /		0/4	0/0	
s22							

ARTG Number	Type of adverse events (description and code)	Number Total (AU included)	Number AU	Percentage world Wide	Percentage in Australia	TGA DIR Number if relevant	Regulatory action regulatory/correc tive action/notification by the manufacturer	Comments relevant qualifications relating to type of issue and actions
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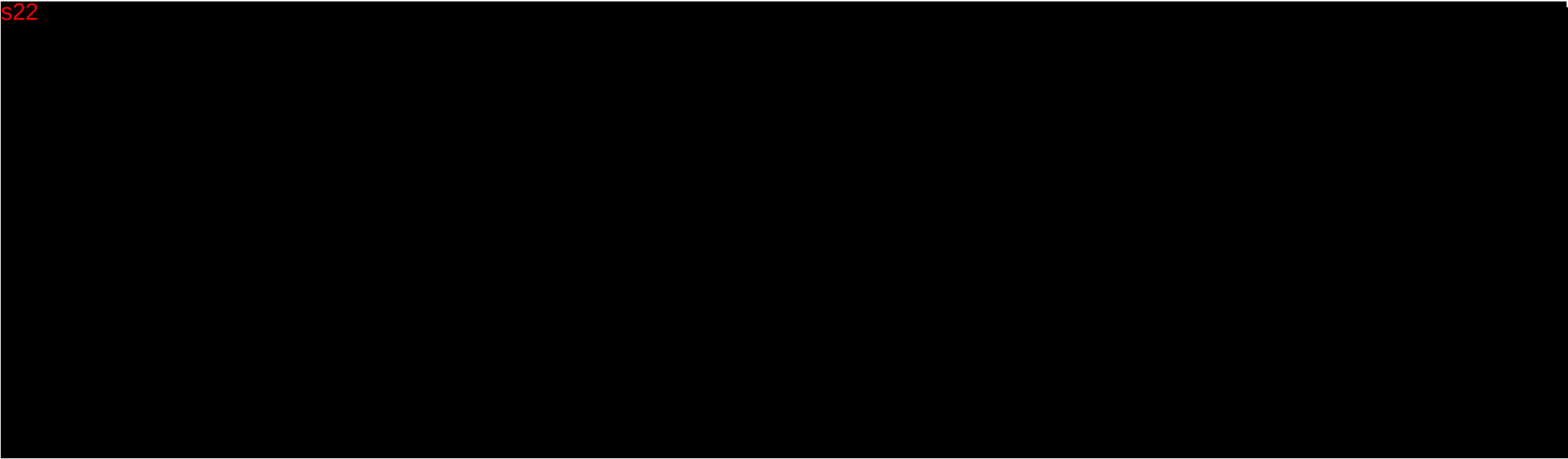
s22

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s22



s22



320484	Deformation	1	0	0.694%	0.000%	/	Nil	no related defect found
	Implant breakage	1	0	0.694%	0.000%	/	Nil	no related defect found
	Implant deformation	1	0	0.694%	0.000%	/	Nil	no related defect found
	Implants assembling	1	0	0.694%	0.000%	/	Nil	no related defect found