From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: Approval Letter for SwiveLock SP Suture Anchor (RC-2017-RN-00463-1) [SEC=UNCLASSIFIED]
Date: Tuesday, 18 April 2017 3:07:17 PM
Attachments: Approval Letter - RC-2017-RN-00463-1.pdf
Draft Customer Letter with TGA Amendments - RC-2017-RN-00463-1.docx

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Dear [redacted]

Please find attached a copy of the TGA's assessment for the proposed recall.

The text of the letter is acceptable **with the attached changes** and may be distributed to affected customers immediately.

Please forward a signed copy of the final letter to recalls@health.gov.au by 12:00pm, 21 April 2017.

Please confirm receipt of this email.

Kind regards,

Recalls and Case Management Section
Manufacturing Quality Branch

[redacted]
Email: recalls@health.gov.au

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

From: [redacted]device.com.au]
Sent: Wednesday, 5 April 2017 10:56 AM
Subject: Arthrex Recall Notification [SEC=No Protective Marking]

Dear TGA Recalls Coordinator,

My name is [redacted] at Device Technologies Australia.

Please be advised of a new recall that Device Technologies Australia has been notified by the manufacturer – Arthrex Inc.

Please find attached draft customer letter for the medical device recall of Arthrex SwiveLock Self-Punching Suture Anchor, ARTG number: 126657 and 164046.

In the interest of patient safety, we aim to mail out the letter by the end of today. Therefore we request TGA's feedback and any comments to be sent to us by 4pm today, 05 Apr 2017, in order to notify the customers as soon as possible.

I'll forward a copy of the Health and Hazard Evaluation as soon as it becomes available.

Please let me know if there's any further information required.

Kind Regards,

[redacted]

DEVICE TECHNOLOGIES

[redacted] | | **F** +61 2 9975 5711
[redacted] device.com.au | **W** www.device.com.au
A 1 Garigal Rd, Belrose, NSW 2085

Please consider the environment before printing this e-mail.

Australian Government

Department of Health
Therapeutic Goods Administration

Approval Letter

To: Device Technologies Australia Pty Ltd Attention: [redacted]

Phone: -

Sender: [redacted] Recalls Section Sender Phone: [redacted]

TGA ref #: RC-2017-RN-00463-1 Your ref #:

SwiveLock SP Suture Anchor

Product Codes: AR-2323BSLM, AR-2323PSLM, AR-2324BCM, AR-2324PSLM, AR-2600SBS-5, AR-2600SBS-7

Multiple Product and Batch Numbers

Subject: ARTG Numbers: 126657 and 164046 Date: 18/04/2017

MESSAGE:

Thank you for your notification of your proposed recall action for the above product.

Classification of the proposed recall action

The proposed recall action has been classified as follows:

Class of Recall:	**Class II**
Type of Recall:	**Medical Device Recall**
Recall Level:	**Hospital**
Reason for Recall:	**It has been determined that there is an issue with specific batches of the self-punching eyelet contained within the Arthrex SwiveLock SP Suture Anchor which may cause the eyelet to break on insertion in hard bone. Please note that there is no impact to the patient if the device has been implanted successfully.**
Product Distribution:	**9 hospitals, health providers and distributors in NSW, QLD, SA & VIC**

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@health.gov.au www.tga.gov.au

TGA Health Safety Regulation

Proposed Action:	**Device Technologies Australia (DTA) is requesting users to immediately discontinue use of the affected devices and to inform all relevant personnel at their facility of the recall notice. Users are further requested to quarantine their affected stock and return a completed Reply Fax Form, advising the quantity of affected stock. Users are advised that credit will be issued upon DTA's receipt of the returned items.**

The above information will be provided to appropriate Parties listed in Appendix IV and V of the Uniform Recall Procedure for Therapeutic Goods (URPTG). Additionally, this information will be published in the TGA's searchable recalls database, System for Australian Recall Actions (SARA) on the second day (excluding weekends) from the date of this approval.

Approval of the proposed recall action correspondence

The strategy for your recall action is acceptable.

The text of the letter is acceptable **with the changes in the attached document** and it may be distributed to affected customers immediately.

Please note:
1. **Addressees for Recall Action Letters** - Recall correspondence is to be addressed in accordance with Section G of the URPTG. In particular, where hospitals are involved, mail should be addressed to the "Chief Pharmacist" for medicines and to the "Chief Executive Officer" for device recalls. More targeted letters are acceptable as an adjunct to the recall action.

2. Dispatch of Recall Action Letters – Recall action letters are required to be dispatched to affected customers within 2 working days of receiving this approval. Recall envelopes as described in Section G of the URPTG must be used where mail distribution is the chosen method of communication. It is also acceptable to dispatch this notification electronically (facsimile or email) subject to the ability to confirm receipt. If the recall action letter is dispatched via email the subject line must reflect the appropriate title of the letter submitted, e.g. URGENT MEDICINE RECALL/URGENT RECALL FOR PRODUCT CORRECTION, followed by the name of the affected product. **Please advise the TGA if you are not able to initiate this recall within 2 working days.**

3. **Safety related recall actions** – For Class I and Class II recall actions (i.e. safety related recalls) you are also required under subsection (2) of Section 128 of the *Competition and Consumer Act 2010* to advise the Minister within 2 days after commencing the recall action. This can be done by completing and submitting the form on the next page to the ACCC.

Progress Reporting requirements

In accordance with the responsibilities of sponsors (Section H) of the URPTG, you are required to provide **reports on the progress of the recall action at or before two weeks and six weeks of the date of this correspondence**. A close out report on this matter is also expected at or before 3 months of the date of this correspondence.

Report type	2 week	6 week	Close out
Due Date	2 May 2017	30 May 2017	18 July 2017

The minimum information required for these reports is listed in Attachment 1 to this advice. If the information is available before the required time then it may be submitted earlier.

Should you require any additional advice or further assistance with the recall, do not hesitate to contact me using the above contact details

Yours sincerely

[redacted]
Recalls Section
Email: recalls@health.gov.au
(Signed electronically)

NOTIFICATION OF A SAFETY RELATED RECALL
(subsection (7) of Section 128 of the *Competition and Consumer Act 2010)*

Please fill in the blank spaces and send this form with any attachments by

FAX: (02) 6243 1073
or
EMAIL: recalls@accc.gov.au
or
POST:
To The Minister for Small Business
c/o: Australian Competition and Consumer Commission
GPO Box 3131
CANBERRA ACT 2601

Dear Minister

We _____ [Supplier name] are recalling the following affected products
[product name] _____
[batch/lot/serial no] _____
because [reason for recall]
_____
_____
___

The recall is being coordinated by the Therapeutic Goods Administration.

AND

[ ] Affected product has not been not been exported from Australia.
OR
[ ] Affected product has been exported from Australia to _____. A copy of the overseas notification letter is attached.

Yours faithfully

[Signature]

Name:

Date:

Australian Government

Department of Health

Therapeutic Goods Administration

Attachment 1: Reporting Requirements

Reports can be submitted to the Recalls Unit by
Email: recalls@health.gov.au
Facsimile: 02 6203 1451 or
Post: TGA Recalls Section, TGA, PO Box 100, Woden ACT 2606

Please include the relevant TGA Recall reference No. i.e. RC-XXXX-RN-XXXXX-X

2 WEEK REPORT REQUIREMENTS

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. e.g. the approved letter has been dispatched to all the customers previously provided to the TGA.	**[ ] YES**	**[ ] NO.** Please explain
2. Has a signed copy of the customer letter been provided to TGA Recalls?	**[ ] YES**	**[ ] NO.** Please provide a signed copy of the letter
3. Is the recall/corrective action progressing without major impediments? e.g The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain
4. Have the initial investigation findings changed the scope of the recall/correction e.g Additional units or products have not been identified with the same defect	**[ ] NO**	**[ ] YES.** Please advise
5. For any product exported from Australia, has the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia. Please list countries product has been exported to.	**[ ] YES** **[ ] No exports**	**[ ] NO.** Please explain

Attachment 1: Reporting Requirements

6 WEEK REPORT REQUIREMENTS

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% & detail attempts made to contact non-responding customers
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[ ] YES:** **[ ] No goods left to recall or correct**	**[ ] NO.** Please advise when this is expected to occur
3. Is the recall/corrective action progressing without major impediments? Eg The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain

CLOSE OUT REPORT REQUIREMENTS (by the agreed time)

1. (a) Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?*; or **(b) Correction - Have ALL units with customers been corrected (or have ALL customers been supplied with the correction?)** *A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.	**[ ] YES**	**[ ] NO.** Please explain & advise when this is expected to occur. Please provide a list of non responding customers.
2. What was the root cause of the defect that led to the recall/corrective action?	Please detail	
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	Please detail	
4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% & detail attempts made to contact remaining customers

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F 1800 999 323
W www.device.com.au

DD Apr 2017
[redacted]
CHIEF EXECUTIVE OFFICER
HOSPITAL
ADDRESS
SUBURB STATE POSTCODEDevice

URGENT MEDICAL DEVICE RECALL
Arthrex SwiveLock® SP Suture Anchor
ARTG: 126657 & 164046 TGA Reference Number: ~~xxx~~RC-2017-RN-00463-1

Attention: Nurse Unit Managers~~, and~~ Surgeons, Health Providers and Distributors

Dear Customer,

Device Technologies Australia (DTA) in conjunction with the manufacturer, Arthrex Inc., is issuing this ~~voluntary~~ recall in relation to potential breakage associated with specific batches of Arthrex SwiveLocks® listed in **Appendix 1**. The Arthrex Part and Batch numbers in Appendix 1 are the only devices impacted by this recall.

Arthrex has recently determined that there is an issue with the self-punching eyelet contained within the Arthrex SwiveLock® SP Suture Anchor. This may cause the eyelet to break on insertion in hard bone.

There is no impact to the patient if the device has been implanted successfully.

Immediately discontinue use of these devices.

Actions Required:

In order to receive credit for the returned devices, please follow the following steps:

1. Ensure all relevant personnel at your facility are fully informed of this notice, including medical staff who use Arthrex SwiveLock® SP Suture Anchor.
2. Quarantine all affected stock listed in Appendix 1 remaining at your premises.
3. Complete and return the attached Reply Fax Form to acknowledge receipt of this notice and advise your quantity of affected stock.

A representative from DTA will ~~organize~~ organise pick-up of the affected products, and replacement at zero charge will be sent to you once we've received the returned items.

~~**Note:** There is no impact to the standard PEEK eyelet SwiveLock anchors and these are excellent replacements.~~

If any of the affected stock could have been transferred from your facility, please immediately let them know of this recall and forward this recall notice to them accordingly.

This action is being conducted following consultation with the Therapeutic Goods Administration.

Arthrex and Device Technologies remain committed to providing you the highest quality products and services. We ~~apologize~~ apologise for any inconvenience caused by this recall and thank you for your continued support.

For any further assistance or if you have any questions please contact our Product Manager, [redacted]

[redacted] Please include an Australian landline number.

Sincerely,

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[redacted]

Appendix 1

Part and Batch Numbers Subject to Recall

Product Code	Description	Batch Number
AR-2323BSLM	Bio-SwiveLock SP Vented, 5.5 mm x 24.5 mm, Self-Punching	10078259
AR-2323PSLM	PEEK SwiveLock SP Vented, 5.5 mm x 24.5 mm, Self-punching	10078258
AR-2324BCM	BioComposite SwiveLock SP Vented, 4.75 mm x 24.5 mm, Self-punching	10072425 10077133 10078077 10078340 10075792 10073992
AR-2324PSLM	PEEK SwiveLock SP Vented, 4.75 mm x 24.5 mm, Self-punching	10072597
AR-2600SBS-5	SpeedBridge Implant System with BioComposite SwiveLock 5.5 mm x 24 mm	10074291 10074288 10076753 10076852 10081420 10075965 10077252 10084027
AR-2600SBS-7	AR-2600SBS-7 SpedBridge Implant System with PEEK SwiveLock Self-Punching	10070003

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Reply Fax Form

[redacted]

Please complete and return to fax (02) 9975 5711

TO: [redacted]
Device Technologies

FAX: **02 9975 5711** **EMAIL:** [redacted]**evice.com.au**

SUBJECT: **URGENT MEDICAL DEVICE RECALL**
Arthrex SwiveLock® SP Suture Anchor

FROM: …… (Contact Name) ……

POSITION: ……

INSTITUTION: ……..

TELEPHONE: …… FAX: ……..

EMAIL: ……..

Please complete and return to Device Technologies immediately

I confirm receipt of the attached notification, have ensured all appropriate personnel are fully informed of the contents of this letter, and:

☐ Confirm the facility has no affected stock

☐ Quarantined all the affected stocks remaining, as per below:

Product Code	Batch Number	Quantity remaining (each)
AR-2323BSLM	10078259	
AR-2323PSLM	10078258	
AR-2324BCM	10072425	
	10077133	
	10078077	
	10078340	
	10075792	
	10073992	
AR-2324PSLM	10072597	
AR-2600SBS-5	10074291	
	10074288	
	10076753	
	10076852	
	10081420	
	10075965	
	10077252	
	10084027	
AR-2600SBS-7	10070003	

Signature: ……Date: ……

FAX THIS FORM TO: 02 9975 5711