DEVICE TECHNOLOGIES
DEVICE TECHNOLOGIES AUSTRALIA PTY LTD | ABN 40 058 091 973

HEAD OFFICE
1 Garigal Rd
Belrose NSW 2085
AUSTRALIA
P +61 2 9975 5755
F +61 2 9975 5711
E customers@device.com.au

Locked Bag 521
Frenchs Forest NSW 2086
AUSTRALIA
P 1300 DEVICE (338 423)
F 1800 999 323
W www.device.com.au

DD Apr 2017

CHIEF EXECUTIVE OFFICER
HOSPITAL
ADDRESS
SUBURB STATE POSTCODE

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

Attention: Nurse Unit Managers and Surgeons

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 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.

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 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]

Sincerely,
[redacted]

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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

Please complete and return to fax (02) 9975 5711

TO: [redacted]
Device Technologies

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

SUBJECT: **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