From: [redacted]
To: DL Recalls_Devices Group
Subject: Hospital Recall - Arthrex - SwiveLock SP Suture Anchor [SEC=UNCLASSIFIED]
Date: Friday, 21 April 2017 3:33:12 PM
Attachments: TGA Recall Notice - RC-2017-RN-00463-1.pdf

Please find attached a notice of a recall action. This may be further distributed as required.

The sponsor of the product is contacting the following customers. **Please do not pass on customer information to third parties**

NSW -

QLD -

SA -

VIC -

s 47(1)(b) [redacted]

Other relevant information: None

The attached information is being made available to you in accordance with section 61(7) of the *Therapeutic Goods Act 1989* for the purpose of alerting you to recall and other market actions conducted under the *Uniform Recall Procedure for Therapeutic Goods*. As the information may contain personal and commercially sensitive and confidential information, please safeguard the information and do not distribute this email to third parties.

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

Do you know all Recall Actions undertaken in Australia are on the System for Australian Recall Actions (SARA)? For further information, please refer to the TGA Website http://tga.gov.au/safety/sara.htm

Australian Government

Department of Health
Therapeutic Goods Administration

URGENT MEDICAL DEVICE RECALL*

LEVEL: Hospital

CLASS: Class II

REFERENCE: RC-2017-RN-00463-1

DATE AGREED: 18/04/2017

PRODUCT: **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 (see attached)

ARTG Numbers: 126657 & 164046

SPONSOR: Device Technologies Australia Pty Ltd

PHONE: 02 9972 8339 – Device Technologies

REASON: 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.

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 sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 9 hospitals, health providers and distributors in NSW, QLD, SA & VIC

Product export status: New Zealand

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm

Product affected by Recall action RC-2017-RN-00463-1

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