



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
AR-2324PSLM	PEEK SwiveLock SP Vented, 4.75mm x 24.5mm, Self-punching	10073992
AR-2600SBS-5	SpeedBridge Implant System with BioComposite SwiveLock 5.5mm x 24mm	10072597
		10074291
		10074288
		10076753
		10076852
		10081420
		10075965
10077252		
AR-2600SBS-7	AR-2600SBS-7 SpedBridge Implant System with PEEK SwiveLock Self-Punching	10084027
		10070003