

INITIAL ASSESSMENT FORM – RECALLS AND NON RECALL ACTIONS

RECALLS REFERENCE NUMBER RC-2017-RN-00463-1

PRODUCT name:	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
ARTG Number(s):	126657 & 164046
Sponsor/Supplier:	Device Technologies Australia Pty Ltd
Approval Area:	MEDDEV

PROBLEM Description	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.
Distribution of affected product:	9 hospitals, health providers and distributors in NSW, QLD, SA & VIC

Hazard Category:	Class II
Hazard description:	The issue may lead to 1) changes in surgical procedure (to retrieve broken pieces) and invariably leading to extended surgical duration and/ or 2) broken pieces being retained in patient (causing soft tissue irritation or articular damage)
Likelihood*	Possible
Overall Risk*	Moderate
Any related recall actions?	None for this particular recall action in the past 2 years

Proposed ACTION (supplied product)	-RECALL Device Technologies Australia (DTA) is advising users to inform all relevant personnel at their facility of the recall notice, quarantine their affected stock and return a completed Reply Fax Form, advising quantity of affected stock. Users are further advised that credit will be issued upon DTA's receipt of the returned items.
Level of action	Hospital
All end users identifiable?	YES – Direct supply by sponsor
Notification method	Mail – Email/Fax – Phone –
End user action(s)	-Return Product - -Read correspondence
Patient follow up?	NO
Sponsor action(s)	-Swap out goods -confirm receipt of correspondence
Future SUPPLY	-Supply unaffected or corrected stock (newly designed device will be supplied)

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Expected CLOSE OUT date	Not expected to take more than 3 months - <i>remedial action has been identified</i>
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Does the action meet any of the criteria for clinical advice:	<input type="checkbox"/> All IVD recalls <input type="checkbox"/> All hazard alerts <input type="checkbox"/> When there are questions about the “workaround” proposed by the sponsor <input type="checkbox"/> When the clinical implications are unclear in relation to deficiency identified <input type="checkbox"/> Any recalls that would require a web statement (i.e., hazard alert, consumer level recalls , vaccine recalls and recalls that have wider health implications) <input type="checkbox"/> Yes – send to clinical delegate for advice <input checked="" type="checkbox"/> No – Recall Coordinator to sign off
<i>Clinical Delegate advice</i>	<p><i>I consider the hazard classification to be appropriate. (If NO, provide reasoning and suggested classification in COMMENTS section below)</i> <i>YES / NO</i></p> <p><i>I consider the proposed action to be appropriate. (If NO, provide reasoning and suggested change/s in COMMENTS section below)</i> <i>YES / NO</i></p> <p><i>I consider the proposed correspondence to be appropriate. (If NO, provide reasoning in the COMMENTS section below and suggested amendments to the draft customer letter using tracked changes)</i> <i>YES / NO</i></p> <p><i>Signed: Dr FirstName LastName <signed electronically></i> <i>Date: Insert</i></p>
<i>Recall Coordinator Sign off</i>	<p><i>Agree with the hazard assessment?</i> <i>YES</i></p> <p><i>Agree with proposed action & correspondence?</i> <i>YES</i></p> <p><i>Signed: [REDACTED] <signed electronically></i> <i>Date: 18 Apr 2017</i></p>

Comments

Classification system.

Class I – Class I defects are potentially life-threatening or could cause a serious risk to health.

Class II – Class II defects could cause illness or mistreatment, but are not Class I.

Class III – Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

*Overall risk table

	Class III	Class II	Class I
Unlikely	Low	Low	Moderate
Possible	Low	Moderate	High
Likely	Moderate	High	High