From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: RC-2017-RN-00463-1 - RE: Arthrex Recall Notification [SEC=UNCLASSIFIED]
Date: Friday, 7 April 2017 3:33:11 PM

Dear [redacted]

Please provide the HHE for this issue as soon as possible.

Kind regards

[redacted]

[redacted]
Recalls and Case Management
Manufacturing Quality Branch

[redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
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

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