

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Arthrex Recall Notification (RC-2017-RN-00463-1) [SEC=UNCLASSIFIED]
Date: Wednesday, 5 April 2017 11:08:59 AM

Dear [REDACTED]

Thank you for your email, this will be reviewed by the Recalls co-ordinator and you will be contacted in due course.

Please provide us with the following information:

- Customer List (including name, state/territory and suburb)
- Export Status/overseas distribution from Australia (if applicable)
- Intention for future supply (e.g. supply unaffected/corrected stock, product supply on hold, affected stock supplied with instructions, no future supply OR affected stock still supplied)

Kind regards,

Recalls and Case Management Section
Manufacturing Quality Branch

Phone: [REDACTED]
Fax: [REDACTED]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: [REDACTED]@device.com.au]
Sent: Wednesday, 5 April 2017 10:56 AM
To: Recalls
Cc: [REDACTED]
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,



|| F +61 2 9975 5711
device.com.au | W www.device.com.au
A 1 Garigal Rd, Belrose, NSW 2085



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