

From: [REDACTED]
To: [Recalls](#)
Subject: RE: RC-2017-RN-00463-1 - RE: Arthrex Recall Notification [SEC=UNCLASSIFIED]
Date: Tuesday, 18 April 2017 11:07:32 AM

Dear TGA Recalls Co-ordinator,

I write to follow up with you if there's any update on this recall review?

Looking forward to your response.

Kind Regards,

[REDACTED]



[REDACTED]

[device.com.au](#) | [W www.device.com.au](#)
A 1 Garigal Rd, Belrose, NSW 2085



Please consider the environment before printing this e-mail.

From: [REDACTED]
Sent: Friday, 7 April 2017 4:02 PM
To: Recalls [REDACTED]
Cc: [REDACTED]@device.com.au> [REDACTED]
[REDACTED]@device.com.au>
Subject: RE: RC-2017-RN-00463-1 - RE: Arthrex Recall Notification [SEC=UNCLASSIFIED]

Dear TGA Recalls Co-ordinator,

My apologies for the delay.

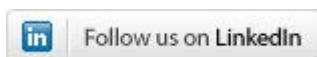
Please see attached HHE we have received from Arthrex.

Kind Regards,

[REDACTED]



[REDACTED] | F +61 2 9975 5711
[REDACTED] [device.com.au](#) | [W www.device.com.au](#)
A 1 Garigal Rd, Belrose, NSW 2085



Please consider the environment before printing this e-mail.

From: [REDACTED] **On Behalf Of** Recalls

Sent: Friday, 7 April 2017 3:33 PM

To: [REDACTED]@device.com.au>

Cc: [REDACTED]@device.com.au>

Subject: RC-2017-RN-00463-1 - RE: Arthrex Recall Notification [SEC=UNCLASSIFIED]

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]
Email: recalls@health.gov.au

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,



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