

From: [REDACTED]
To: [Recalls](#)
Cc: [REDACTED]
Subject: RE: RC-2017-RN-00463-1 - RE: Arthrex Recall Notification [SEC=UNCLASSIFIED]
Date: Friday, 7 April 2017 4:01:42 PM
Attachments: [HHE.pdf](#)

Dear TGA Recalls Co-ordinator,

My apologies for the delay.

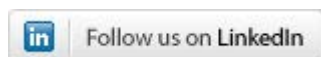
Please see attached HHE we have received from Arthrex.

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]

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.

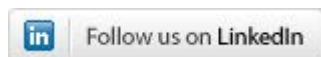
Please let me know if there's any further information required.

Kind Regards,

[REDACTED]



[REDACTED] | F +61 2 9975 5711
[REDACTED] [device.com.au](mailto:[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.

This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the system manager. This message contains confidential information and is intended only for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited.

"Important: This transmission is intended only for the use of the addressee and may

contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error please notify the system manager. This message contains confidential information and is intended only for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake and delete this e-mail from your system. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited.
