

From: [REDACTED]
To: [Recalls](#)
Cc: [REDACTED]
Subject: RE: Arthrex Recall Notification (RC-2017-RN-00463-1) [SEC=UNCLASSIFIED]
Date: Wednesday, 5 April 2017 12:25:28 PM
Attachments: [Master Customer List_Apr.xlsx](#)

Dear TGA Recalls Coordinator,

Thank you kindly for your response.

Please see below for details:

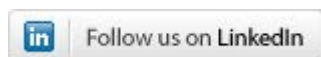
- Customer List (including name, state/territory and suburb)
[Please see attached customer list.](#)
- Export Status/overseas distribution from Australia (if applicable)
[Yes DTA has distributed to New Zealand, and we are working with Medsafe on this.](#)
- Intention for future supply (e.g. supply unaffected/corrected stock, product supply on hold, affected stock supplied with instructions, no future supply OR affected stock still supplied)
[Arthrex will supply stocks with a new design.](#)

Kind Regards,

[REDACTED]



[REDACTED]
device.com.au | [W www.device.com.au](http://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: Wednesday, 5 April 2017 11:09 AM
To: [REDACTED]@device.com.au>
Cc: [REDACTED]@device.com.au>
Subject: RE: Arthrex Recall Notification (RC-2017-RN-00463-1) [SEC=UNCLASSIFIED]

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.

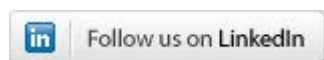
Please let me know if there's any further information required.

Kind Regards,



device.com.au | [W www.device.com.au](http://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.
