From: [redacted]
To: Recalls
Cc: [redacted]
Subject: RE: Copy of customer letter for Swivelock SP (RC-2017-RN-00463-1) [SEC=UNCLASSIFIED]
Date: Thursday, 20 April 2017 4:42:46 PM
Attachments: 294-AR0317_AU_Customer Letter_Final.pdf
Approval Letter for SwiveLock SP Suture Anchor (RC-2017-RN-00463-1) SEC... (588 KB).msg

Dear TGA Recalls Coordinator,

Please find attached final version of the letter we mailed out to the customers on 6 Apr 2017 in the interest of patient safety. We waited for TGA's response until 6 Apr 2017 as communicated in the initial notification (see attached). We would have been able to incorporate TGA's comments if we had received them earlier, however it is fortunate that the most important messages in the letter are agreed.

All of the affected customers have been informed and we have started collecting affected units back to our warehouse.

Please let me know if you have any further questions.

Kind Regards,

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From: [redacted] **On Behalf Of** Recalls
Sent: Thursday, 20 April 2017 10:17 AM
To: [redacted]@device.com.au>
Subject: Copy of customer letter for Swivelock SP (RC-2017-RN-00463-1) [SEC=UNCLASSIFIED]

Dear [redacted]

The approval letter email indicated that we required a copy of the final customer letter incorporating the TGA changes by 12:00pm, 21st of April.

This was my mistake, can you please provide us with this letter by 12:00pm today.

Kind regards,

Recalls and Case Management Section
Manufacturing Quality Branch

[redacted]
[redacted]
Email: recalls@health.gov.au

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