

From: [REDACTED]
To: [REDACTED]
Subject: RE: 2 week report for Swivelock SP (RC-2017-RN-00463-1) [SEC=UNCLASSIFIED]
Date: Thursday, 11 May 2017 12:13:07 PM

Dear [REDACTED]

Thank you for the 2 week report for the SwiveLock SP Suture Anchor recall action.

Please note that the 6 week report is due on the 30th of May 2017.

I apologise for the delay in responding to your email.

Kind regards,

Recalls and Case Management Section
Manufacturing Quality Branch

[REDACTED]
[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: Thursday, 4 May 2017 2:44 PM
To: Recalls
Subject: 2 week report for Swivelock SP (RC-2017-RN-00463-1) [SEC=No Protective Marking]

Dear TGA Recalls Coordinator,

Please find attached 2 week report for Medical Device Recall TGA ref: RC-2017-RN-00463-1.

Please let me know if you have any further questions.

Kind Regards,

[REDACTED]



[REDACTED] | F +61 2 9975 5711

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: Thursday, 20 April 2017 4:43 PM
To: 'Recalls' <Recalls@health.gov.au>
Cc: [REDACTED] <[\[REDACTED\]@device.com.au](mailto:[REDACTED]@device.com.au)>
Subject: RE: Copy of customer letter for Swivelock SP (RC-2017-RN-00463-1)
[SEC=UNCLASSIFIED]

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,

[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: Thursday, 20 April 2017 10:17 AM
To: [REDACTED] <[\[REDACTED\]@device.com.au](mailto:[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

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



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