Australian Government
Department of Health
Therapeutic Goods Administration

Close Out Minute

FINAL SUMMARY OF RECALL ACTION: RC-2017-RN-01125-1

Recall issue:

Product	Essure Permanent Birth Control Catalogue Number/Order Code: ESS305 All Batch Numbers ARTG Number: 174123
Problem	AMSL is advising that all lots of Essure are being removed due to a temporary suspension of the European EC certificate during the European certificate renewal process. Further, post-market information suggests that some patients may not be fully informed of possible device & procedure related complications, including changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of the device, allergy/hypersensitivity, or immune-type reactions.
Sponsor	Australasian Medical & Scientific Ltd
Recall Classification	Class II — Level: Hospital

Recall action:

Date recall agreed:	28/08/2017
2 week, 6 week and close out reports received:	☒ Yes ☐ No – Comments:
All customers contacted regarding the recall action:	☒ Yes ☐ No – Comments:
All identified affected units recovered or corrected:	☐ Yes ☒ No – Comments: 95% of customers have responded – 3 hospitals have been contacted on multiple occasions through email and phone call, yet they have not responded.

Additional requirements:

Responsible entity:	Bayer Healthcare LLC
Client number:	15634
Root cause:	Hazard alert ensued from a comprehensive review of data regarding ESSURE by Bayer (the manufacturer) which resulted in revision of the IFU and introduction of a PIB.

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Corrective/Preventative actions:	Commercial decision was made to withdraw the product from the Australian market. The IFU was updated to inform users who currently have this device implanted of the potential issues discussed in the Hazard Alert
Any additional comments:	None

Minute prepared by: [redacted] *(signed electronically)*
Date: 19/11/2018

This recall action has been reviewed and has now been completed in accordance with the requirements of the Uniform Recall Procedure for Therapeutic Goods:
☐ Yes ☐ No – Refer to Recall Coordinator / Relevant area of TGA for review - Comments:

Recalls Coordinator: [redacted] *(signed electronically)*
Date: 19/11/2018

IF REQUIRED - forward root cause and corrective actions to the following TGA staff if there are any concerns regarding the actions taken.

"Please review this information to make sure that there is ongoing compliance with legislative requirements or advise if any additional actions need to be undertaken from a regulatory context before this matter is closed on our database."

Select the appropriate area from the list below

Medical devices To: Device Vigilance & Monitoring, Comments (If Any): [redacted] MQB Comments (If Any): IVD's To: [redacted] IVD Assessment Comments (If Any): Device Vigilance & Monitoring,	Human tissue and cellular products (currently listed as medical devices) To: [redacted] Biological Science, SESPAB Comments (If Any): Device Vigilance & Monitoring, Comments (If Any): [redacted] Comments (If Any): AS REQUIRED:

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Comments (If Any): [redacted] Comments (If Any): Prescription Medicines OTC Medicines Listed & Complementary Medicines To: [redacted] MQB Comments (If Any):	Illegally supplied products [redacted] Director, Regulatory Compliance Unit Comments (If Any): Products tested by TGA laboratories [redacted] Comments (If Any):