

TECHNICAL SERVICE BULLETIN

AMALGATOME[®] MD

(Model Numbers: X100457 Lot X-000000000159)

April 6, 2026

Dear Exsurco AMALGATOME MD Customer,

During an investigation it was found that Amalgatome MD Blades (X100457 - ASSY, BOX OF 5 AMALGATOME MD PKG) Lot X-000000000159 were determined based upon an internal investigation to be nonconforming to internal dimensional specifications. This may result in the blade not biting or shredding, uneven, inconsistent, or thin skin recovery during use of these blades.

This may not occur on every blade in this lot as this issue has been limited to one sub-lot which is approximately 44% of the blades potentially affected. To date Exsurco has received four (4) confirmed complaints related specifically to this lot and zero (0) reported injuries regarding the above listed matter.

The Amalgatome MD Split Thickness Tissue Recovery System is used for recovery of allograft skin on cadaveric donors. There is no risk of injury to the user due to this event. X100457 Lot X-159 Amalgatome MD do pose a risk to donor skin due to the risk of shredding, uneven, inconsistent, or thin recovery.

If you have received product that is impacted, a communication was sent to the contacts on file for the respective facility on 06 APR 2026. Exsurco has determined that the following methods may be used to verify the product received is X100457 - ASSY, BOX OF 5 AMALGATOME MD PKG Lot X-000000000159.

Identification of X100457 Lot X-159:

Step 1: Identify the 5-piece boxes by the printed information. Each box will have "AMALGATOME MD EXCISION RING BLADE X100457(BOX OF 5)" printed on the top. The applied label will indicate the Lot number is X-000000000159 and the sterilization expiration date is 2028/01. See example below.



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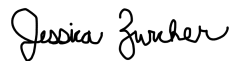
(Model Numbers: X100457 Lot X-000000000159)

Step 2: Fill out this Customer Response Card confirming that you have received and understood the communication and have verified the number of blade(s) currently on hand based on our records. Upon completion email the sheet to support@exsurco.com.

Step 3: A credit will be applied to the customer account for the full amount of purchased blades returned to Exsurco.

We are committed to providing our customers with quality products and services. Should you have any questions regarding this matter please contact me at (440) 370-4747 / email: jessiczurcher@exsurco.com

Sincerely,



Jessica Zurcher
Quality Assurance & Regulatory Affairs Manager