



**AMALGATOME® SD (ASD)- Action Required  
(Part number- X101789, 2-inch)  
ASD Surgical Skin Grafting and Debridement Blade**

**Part number and Lot impacted:**

- X101789, 2-inch, ASD Surgical Skin Grafting and Debridement Blade
- Lot # X-0000000000002

**What is the Issue:**

It was identified that the sterilization expiration date label on Lot # X-0000000000002 for Amalgatome SD, 2-inch Surgical Skin Grafting and Debridement Blade (part number- X101789) was incorrect. The date of June 25, 2019 (date of manufactured) was entered as the date of expiration, however product is acceptable for use. The correct date of expiration for this lot of excision rings is June 25, 2021 ((2) two years from the date of manufacturing).

**NOTE:** Documentation on Gamma sterilization for the lot affected is available upon request.

**Risk to health:**

There is no risk to health. The date of June 25, 2019 (date of manufactured) was entered as the date of expiration, however product is acceptable for use. The correct date of expiration for this lot of excision rings is June 25, 2021 ((2) two years from the date of manufacturing).

**How do you identify the lot?**

The lot number and part number are identified on the outside of the pouch and box. See boxed red area for reference below.





**What Actions are required by the customer?**

**Step 1:** Confirm that your stock of X101789 on hand.

**Step 2:** Please quarantine impacted excision rings and your Burn Account Manager will be contacting you regarding the relabeling of your product. The re-work will consist of new labels with the correct expiration date.

**Step 3:** Fill out Customer Response Card confirming that you have received and understood the communication and have verified the number of units and lot number based on our records. Upon completion email the card to [saigal@exsurco.com](mailto:saigal@exsurco.com).