

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

American Surgical Company, LLC Americot 20-01S (1/4" x 1/4")

Recall Date	Product Description	Recalling Firm	Recall Reason
11/1/2024	Americot 20-01S (1/4" x 1/4") or 6mm x 6mm: Neurological sponges for use in the protection of neural tissue during surgery. Ref: 20-01S ½ x ½ inches or 6mm x 6mm) Component: N/A	American Surgical Company, LLC	Product defect where the X-ray detectable barium strip (aka radio-opaque marker) becomes detached from the sponge (pattie). May delay surgical process as the surgeon may require extra time to remove the markers from the surgical field.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 10749915000039 Lot Number Expiration Date: 2023/03 AQ 2028/03/31; 2023/06 AP 2028/06/30; 2023/10 BO 2028/10/31; 2023/12 AY 2028/12/31; 2024/05 AE 2029/05/31; 2024/06 AQ 2029/06/30	5 boxes (200 sponges per box) were distributed in California	September and Prior

For additional information, please visit the [FDA Website](https://www.fda.gov).