

Date: 24 September 2024

URGENT MEDICAL DEVICE FIELD SAFETY NOICE (FSN)

American Surgical Company, LLC
[REDACTED]

Dear Hospital, Purchasing Department, Operating Room Accounts and Distributors

Problem Description

- American Surgical Company (ASC) is issuing an Urgent Medical Device Field Safety Notice (FSN) to the users for the Americot 20-01S lots listed below. A product defect has been found where the X-ray detectable barium strip (aka radio-opaque marker) may become detached from the sponge (pattie). The affected products under FSN are the prescribed lots listed in the table below.

Lot Number	Expiration Date	UDI-DI
2023/03 AQ	2028/03/31	10749915000039
2023/06 AP	2028/06/30	10749915000039
2023/10 BO	2028/10/31	10749915000039
2023/12 AY	2028/12/31	10749915000039
2024/05 AE	2029/05/31	10749915000039
2024/06 AQ	2029/06/30	10749915000039

- American Surgical Company has replacement product available, therefore Americot 20-01S may be replaced without any disruption. Contact Customer Service for product replacement. The ASC Customer Service department can be reached at 1-800-343-0060 between the hours of 8:30 am and 5:00 pm Eastern Time, Monday through Friday.
- Other lots of this product are not subject to FSN as they were manufactured with a different manufacturing process – the defect was confirmed not to present itself in the other lots of products and the product can continue to be used.

Hazard Involved:

- Importantly, to date, ASC is not aware of any serious adverse events related to the possible defect.

Hazard to Patient: The detachment of the X-ray detectable barium strip from the sponge may delay surgical process as the surgeon may require extra time to remove the markers from the surgical field.

Mitigation: The fragment of the radio-opaque marker creates a strong signal under X-ray, which alerts the surgeon that there is foreign body in the surgical site.

Residual Risk: The surgical team is instructed to count and inspect all sponges before the surgical procedure and again after the surgical procedure prior to surgical closure. Americot 20-01S are supplied with notched holders to aid in final counting and inspection. If there is a question about counting or to the appearance of the barium strip, an x-ray image can be used to locate the sponge or barium strip fragments. In accordance with product instructions, the surgical team is to take 3 pictures using predetermined strength at 45°, 22.5°, and 0° angles anterior and posterior or the appropriate plane. Establish x-ray strength and time by prior testing on equipment that will be used.

Action to be taken by the customer:

- Effective immediately, American Surgical Company, LLC (ASC) requests your assistance. We ask that all lots listed in the table above within your inventory immediately be discontinued for use. We also ask the inventory to be quarantined, counted, and discarded.
- Report any complaint to ASC Customer Service 1-800-343-0060 or email: customerservice@americansurgical.com
- The product code and lot number can be found on the individual product pouch and carton.
- Please respond to this request by the deadline in the form below and return the completed form to customerservice@americansurgical.com or Fax: 1-781-595-5460 even if you do not have any inventory that remains.
- If you distribute this product, please forward them a copy of this communication and notify ASC Customer Service immediately.

Further information and support:

- For general questions regarding this communication, contact Customer Service at 800-343-0060 between the hours of 8:30 am and 5:00 pm Eastern Time, Monday through Friday.
- EU and UK regulatory authorities have been modified in regard to this FSN

We apologize for any inconvenience this may cause you and your staff.

Respectfully,



Field Safety Notice Customer Reply Form

1. FSN information	
FSN Reference number	<i>Pre-filled by ASC for Customer</i>
FSN Date	<i>Pre-filled by ASC for Customer</i>
Product/ Device name	Americot
Product Model Number	20-01S

Customer, please complete the following table:

Lot	A # Boxes Received	B # Boxes in Inventory	C = A-B # Boxes Used
2023/03 AQ	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>	<i>Customer to Complete</i>
2023/06 AP	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>	<i>Customer to Complete</i>
2023/10 BO	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>	<i>Customer to Complete</i>
2023/12 AY	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>	<i>Customer to Complete</i>
2024/05 AE	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>	<i>Customer to Complete</i>
2024/06 AQ	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>	<i>Customer to Complete</i>

2. Customer Details	
Account Number	<i>Pre-filled by ASC for Customer</i>
Customer Name	<i>Pre-filled by ASC for Customer</i>
Customer Address	<i>Pre-filled by ASC for Customer</i>
Department/Unit	<i>Pre-filled by ASC for Customer</i>
Shipping address if different to above	<i>Pre-filled by ASC for Customer</i>
Contact Name	<i>Pre-filled by ASC for Customer</i>
Title or Function	<i>Pre-filled by ASC for Customer</i>
Telephone number	<i>Pre-filled by ASC for Customer</i>
Email	<i>Pre-filled by ASC for Customer</i>

Customer, please complete the following table:

3. Customer Action		
Check		Please Initial and date.
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.	<i>Customer Initial and date</i>
<input type="checkbox"/>	I performed all actions requested by the FSN.	<i>Customer Initial and date</i>
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	<i>Customer Initial and date</i>
<input type="checkbox"/>	I have destroyed affected devices and completed the table below.	<i>Customer Initial and date</i>

Customer, please complete the following table:

Lot	Number Boxes Received	Number of Boxes Destroyed
2023/03 AQ	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>
2023/06 AP	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>
2023/10 BO	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>
2023/12 AY	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>
2024/05 AE	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>
2024/06 AQ	<i>Pre-filled by ASC for Customer</i>	<i>Customer to Complete</i>

Customer, please complete the following table:

Print Name	<i>Customer to Complete</i>
Title	<i>Customer to Complete</i>
Signature	<i>Customer to Complete</i>
Date	<i>Customer to Complete</i>

Return this signed form to American Surgical Company by: <i>(Deadline)</i>	
Email	Loredana.guseila@americansurgical.com
Customer Support	CustomerService@americansurgical.com
Postal Address	45 Congress St Suite 153 Salem, MA, 01970 USA
Fax	1-781-595-5460
Deadline for returning the customer reply form	<i>ASC to complete – two weeks from send date</i>