Urgent Recall and Field Safety Notice

American Surgical Company

March 31, 2016

Attention: American Surgical Company End-Users

Details on affected devices:

Catalog Number Description Lot Number Quantity Shipped

Description of the problem:

Sterile Packaging Integrity/Sterility Assurance

A failure in the sterile peel pouch has been discovered during a quality control inspection. This failure may result in a small tear in the pouch of the device leading to a potential compromised sterile barrier. A leak in the sterile barrier may allow contamination of the device increasing the risk of infection. After the failure was identified, a comprehensive investigation has shown an occurrence rate of less than 0.01% for the affected lots.

Action to be taken by the user:

Within 1 week of receipt of this letter, please return confirmation of receipt of this Field Safety Notice (Attachment 1).

Since you have purchased the lots under investigation, there may be affected devices in your inventory. You should address this by either selecting Action A or B:

Action A: Users should perform a check of the device before use and, as stated in the IFU, patties should not be used if in an open or damaged pouch. For the affected lots, special attention should be given to lower portion of the pouch where the Tyvek and clear film are sealed (please follow instructions in Attachment 2).

Action B: Place the affected lots in quarantine and contact American Surgical Company for an RMA and replacement.

All affected devices are eligible for replacement by ASC.

Within one month of the receipt of this letter, please return your confirmation of actions described in Field Safety Notice Completed (Attachment 3).

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Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

We thank you in advance for your cooperation and sincerely apologize for any inconvenience.

Contact Information:

American Surgical Company
45 Congress Street
Salem, MA 01970

Tel: 1-800-343-0060 Option 2
Fax: 781-595-5460
Email: CustomerService@AmericanSurgical.com

Attachment 1:

Confirmation of Receipt of Field Safety Notice

The undersigned person hereby confirms that _____
Organization Name

has received the Field Safety Notice from American Surgical Company dated March 31, 2016 regarding sterile packaging integrity/sterility assurance.

_____
Date

_____
Name

_____
Title

_____
Signature

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Attachment 2:

Follow these instructions to identify the devices that may have a compromised sterile barrier.

Please see Figure 1 for positive identification of the device.

Note identification of the part number, device description, and lot number highlighted.

Figure 1

Step 1:

The cause of the potentially compromised sterile barrier is a tear in the transparent film on the left or right sides near the bottom of the pouch where the film is sealed to the Tyvek. Please see Figure 2 for a specification of the area to inspect. Please see figure 3 for an example of what to inspect for.

Step 2:

The inspection should be carried out in a setting with good indirect light. If in doubt whether a specific device has a hole, please discard. Discarded devices should be quarantined to be returned to American Surgical Company. Information on discarded devices should be listed in Attachment 3 under "Quantity Returned".

Figure 2


Figure 3

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Attachment 3:

Confirmation of Field Safety Notice Completed

The undersigned person hereby confirms that _____
Organization Name

has completed the actions described in the Field Safety Notice from American Surgical Company dated March 31, 2016 regarding sterile packaging integrity/sterility assurance.

Catalog Number	Description	Lot Number	Quantity Shipped to	Quantity Exhausted	Quantity Inspected	Quantity Returned

_____
Date

_____
Name

_____
Title

_____
Signature

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