

Urgent: Medical Device Recall

Cardinal Health
15 Hampshire Street
Mansfield, MA 02048



CardinalHealth

cardinalhealth.com

December 27, 2018

Event-2018-01914

Dear Valued Customer:

Cardinal Health is voluntarily initiating a product recall of one lot of **Curity™ All Purpose Sponges** first distributed on 10/17/2018.

Product Code	Product Description	Lot Number
8044	Curity™ All Purpose Sponges, Non-woven, 4 Ply, 4" x 4" (10.2 cm x 10.2 cm)	18E190262

Reason for Recall:

This voluntary recall is being conducted because the product does not meet sterilization requirements. Customers can identify the affected product by referring to Attachment A. The potential harms of using this product non-sterilized are inflammation, cellulitis, infection and wound infection. Cardinal Health is not aware of any reports of injury or harm related to this issue.

Action Required:

1. **INSPECT** your inventory for the affected product code and lot number (see Attachment A)
2. **SEGREGATE and QUARANTINE** all on-hand product
3. **RETURN** the enclosed acknowledgment form via fax to 847-689-9101 or 614-652-9648, whether or not you have affected product, indicating the product code, lot and quantity of product you've quarantined or discarded.
4. **NOTIFY** any customers to whom you may have distributed, or forwarded product affected by this recall
5. **CONTACT** the appropriate Customer Service group to arrange for return and credit of any affected product:
 - Hospital—800-964-5227
 - Federal Government—800-444-1166
 - Distributor—800-635-6021
 - All other customers—888-444-5440

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We request that you contact Cardinal Health if you experienced quality problems or adverse events.

The FDA can be contacted to report any adverse events experienced with the use of these products:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or email) or call FDA 1-800-332-1088.

Urgent: Medical Device Recall

Cardinal Health
15 Hampshire Street
Mansfield, MA 02048



CardinalHealth

cardinalhealth.com

We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions, or desire special assistance relating to this product, please feel free to contact Cardinal Health at 800-292-9332. Your cooperation and compliance with the requests in this letter are appreciated.

Sincerely,

A handwritten signature in black ink that reads "Stephanie Shield".

Stephanie Shield
Director QRA, North America Medical Manufacturing

Urgent: Medical Device Recall

Cardinal Health
15 Hampshire Street
Mansfield, MA 02048



cardinalhealth.com

Attachment A

Figure 1. Example shipper carton displayed labeling for Product Code 8044 Lot Number 18E190262

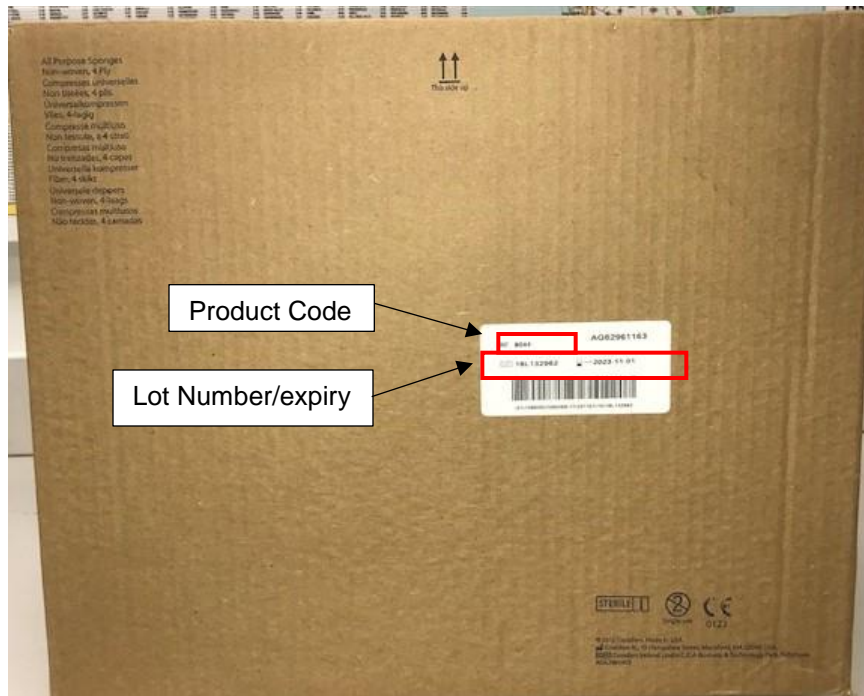


Figure 2. Example individual pouch labeling for Curity™ All Purpose Sponges Product Code 8044 Lot Number 18E190262

