

**URGENT MEDICAL DEVICE RECALL NOTICE****Name of Affected Products:** SCOUT MD™ Delivery System**Action Required:** Return Device(s) to Merit**Reason for Recall:**

Merit Medical Systems, Inc. is voluntarily recalling certain lots of the Merit SCOUT MD™ Delivery System (Scout MD) due to a manufacturing-related condition that may affect device performance. An internal review has identified that certain devices may experience difficulties deploying the device, which may result in the reflector not deploying as intended during use. Three lots are impacted in this recall as listed in the table below. Merit has chosen to remove the units from the market. Customers must immediately stop using or distributing the affected lots and return the affected products to Merit Medical.

**Risk to Health:**

According to Merit's evaluation of health hazards, use of the affected product may result in procedural delay, where a replacement device is needed to complete the procedure. Merit has received 5 complaints related to this issue. There have been no reports of patient harm or injury.

| <b>Catalog Numbers</b> | <b>Description</b>                              | <b>Lot Numbers</b> |
|------------------------|-------------------------------------------------|--------------------|
| MDS05A-01              | SCOUT MD™.Delivery System, Standard.16G.5.0 cm  | H3515477           |
| MDS10C-01              | SCOUT MD™.Delivery System, Standard.16G.10.0 cm | H3507794           |
| MDS05C-01              | SCOUT MD™.Delivery System, Standard.16G.5.0 cm  | H3507786           |

**Actions required of you:**

1. Immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility.
  - a. A picture of the SCOUT MD™ Delivery System is attached to help you identify the product (see image A).



Image A: SCOUT MD™ Delivery System labeling

2. Immediately discontinue the use of the affected lots of the SCOUT MD™ Delivery System.
3. Ensure that applicable personnel within your organization are made aware of this recall.
4. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities.
5. Please fill out, scan and email the completed Customer Response Form to Customer Service at [RESPONSE@merit.com](mailto:RESPONSE@merit.com) within 7 business days. All affected products shipped to you must be accounted for on the CRF.
6. Immediately return all affected lots in your possession to Merit, per the instructions in the attached CRF.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Web: MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

Phone: 1-800-FDA-1088 (1-800-332-1088)

Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at [RESPONSE@merit.com](mailto:RESPONSE@merit.com) or by phone at +1 (800) 356-3748 if you have any questions relating to this field action.

Merit Medical is committed to providing high-quality products to you and apologizes for any inconvenience this recall may cause.

Enclosure(s)