

FSCA-ref: 1721504-08/23/24-008R

23-AUG-2024

URGENT FIELD SAFETY NOTICE (FSN)**Product Recall****Name of Affected Products:** MONARCH® Inflation Device**Action Required:** Return Device(s) to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of MONARCH® Inflation Devices due to a packaging defect. Specifically, there may be a small hole in the Tyvek® sterile barrier of the device packaging. This issue affects the lots and part numbers identified in the attached table. Merit has not received any complaints or reports of patient harm or injury relating to this issue. According to Merit's evaluation of health hazard(s), **use of the affected product may result in exposure to pathogens/pyrogens which could lead to infection.**

Merit has chosen to remove the units from the market and requests that you immediately stop using or distributing the affected lots and return the units to Merit.

Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility, quarantine them, and discontinue use and distribution.
2. Ensure that applicable personnel within your organization are made aware of this field action.
3. 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.
4. Please fill out, scan, and email the completed CRF to Customer Service at RESPONSE-EMEA@merit.com within 7 calendar days. All affected product shipped to you must be accounted for on the CRF.
5. Please immediately return all affected lots in your possession to Merit per the instructions in the CRF.

Note, the relevant National Competent Authorities have been advised of this field action.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Customer Service at 0031 – 43 3588233.

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

Enclosure(s)