Understand. Innovate. Deliver.™

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URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: HeartSpan® Transseptal Needles

Action Required: Return Device(s) to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of HeartSpan® Transseptal Needles because the labeled needle tip curvature may not match the actual needle tip curvature. The needles themselves have been manufactured according to their design specifications. This field action affects two (2) lot numbers and two (2) catalog numbers, as identified in the below table. The discrepancy is likely to be noticed by the clinician as the incorrect curvature of the needle is obvious and would not be used, resulting in user dissatisfaction. In the highly unlikely event that the incorrect needle is unknowingly used, an unintended anatomy puncture may occur, which is likely to require medical intervention.

Merit has not received any reports of patient harm or injury relating to this issue; however, Merit has received four (4) complaints involving 26 units.

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

Catalog Numbers	Lot Numbers
FND-019-01	E1913644
FND-019-02	E1913645

***Note:** The relevant National Competent Authorities will be notified of this Field Safety Corrective Action (FSCA).

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 Customer Response Form to Customer Service at RESPONSE-EMEA@merit.com within 10 business 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 attached CRF.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or 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)