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URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: CorVocet™ Biopsy System

Action Required: Return Devices to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of the CorVocet™ Biopsy System due to a product defect resulting from incorrect assembly. This assembly error may occur when components are misaligned due to an issue with the manufacturing assembly equipment. In rare instances, the needle may eject from incorrectly assembled CorVocet™ biopsy devices when triggered outside the body, which results in the potential for a user or patient needle stick injury. The IFU includes the following precaution: "Never test the product by firing into the air. Damage may occur to the device and could result in patient and/or user injury."

Merit has not received any reports of user or patient harm or injury relating to this issue, however, as of the date of this letter, Merit has received five (5) related customer complaints. This recall affects 523 Merit lots and 50 Merit catalog numbers, as identified in the attached table. Please note that Merit has taken the necessary corrective actions so that all CorVocet™ biopsy product currently being shipped do not exhibit this issue.

Merit has chosen to remove the affected product from the market and requests that you immediately stop using or distributing the affected product and return it to Merit. Our records indicate you have received affected lots, as identified in the attached Customer Response Form.

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 or by phone at 0031 – 43 3588233 within seven (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 attached CRF.

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

If you have any questions concerning this communication, please don’t hesitate to contact your Merit Sales Representative or Merit Customer Service at RESPONSE-EMEA@merit.com or by phone 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)