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URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: Merit Products Containing Plastic Syringes Manufactured by Jiangsu Shenli Medical Production Co Ltd.
Action Required: Device Modification (Over-Label) –Discard Affected Syringes

Merit Medical Systems, Inc. (Merit) is voluntarily conducting a recall of specific lots of Merit products containing plastic syringes manufactured by Jiangsu Shenli Medical Production Co Ltd. (Jiangsu Shenli). FDA has issued a Field Safety Communication[1] for syringes manufactured in China by Jiangsu Shenli. Merit received notice from our supplier indicating they have supplied Merit with syringes from Jiangsu Shenli who received a Warning Letter[2] that states that all but one size/type of their syringes lack sufficient FDA market authorization. In the Warning Letter, FDA also cited "growing evidence of potential harm" for Jiangsu Shenli syringes. FDA recommends in their Field Safety Communication that if continued use of these syringes is "absolutely necessary" until alternatives are available to "closely monitor for leaks, breakage, and other problems." Leaks or breakage may result in a delay in treatment.

Merit includes these syringes in multiple products representing various catalog numbers, which have been sent to you and are identified in the attached Customer Response Form (CRF). While this action is specifically targeting the Jiangsu Shenli syringes contained in Merit products, the remaining components are unaffected and suitable for use once you have completed the activities described in this letter.

Merit requests that you immediately stop using or distributing the products containing the affected syringes and place them in quarantine until they can be over labeled to inform the user to discard the affected syringes and secure new syringes at the point of use.

Actions required of you:

1. Please immediately determine if any of the products identified in the attached CRF are within your facility, quarantine them, and discontinue use and distribution.
2. Ensure that appropriate 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. Additional distribution details may be required by health authorities.
4. **Please follow the attached instructions for placing the recall labels on the products containing Jiangsu Shenli syringes, which inform the users to not use the affected syringes. If additional recall labels are needed, contact Customer Service at (801) 208-4381. Product may be returned to inventory once properly over-labeled.**

[1] https://www.fda.gov/medical-devices/safety-communications/update-evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication
[2] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jiangsu-shenli-medical-production-co-ltd-677753-03182024

5. **At the point of use, the Jiangsu Shenli syringes are to be discarded. Photographs of Jiangsu Shenli syringes are enclosed to assist in identification.**
6. **Post this "URGENT MEDICAL DEVICE RECALL NOTICE" and Jiangsu Shenli syringe photographs on or near the affected products.**
7. If replacement syringes are needed, contact Customer Service at (801) 208-4381 for recommended syringe suppliers.
8. Please fill out, scan and email the completed Customer Response Form to Customer Service at response@merit.com within seven (7) days.

Actions Being Taken by Merit Medical

Merit is taking actions to immediately transition away from Jiangsu Shenli syringes. In the interim, to avoid product shortages, we may ship product containing the Jiangsu Shenli syringes until we have completed the transition, in which case, those products will already have the recall label applied. Product you continue to receive without the recall label and not identified on your Customer Response Form do not include Jiangsu Shenli syringes.

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.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at (801) 208-4381 | Hours: 6 am to 6 pm MST | Mon-Fri.

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

Enclosure(s) (CRF, Recall Labels, Recall Label Instructions, Jiangsu Shenli Syringe Images)