Understand. Innovate. Deliver.™

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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: Read and Understand

Merit Medical Systems, Inc. (Merit) is voluntarily issuing this Medical Device Recall Notice pertaining to 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] which 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. Merit includes these syringes in multiple kits 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 our kits, the remaining kit components are unaffected and suitable for use once the activities described in this letter have been completed.

FDA Recommendations For Consumers, Health Care Providers And Facilities

As indicated in their Field Safety Communication, FDA recommends that until further notice and because of potential quality and performance issues, users immediately transition away from using plastic syringes manufactured by Jiangsu Shenli[3], unless use of these syringes is absolutely necessary until users can complete the transition to syringes that are not manufactured by Jiangsu Shenli. FDA also recommends that if users only have syringes manufactured by Jiangsu Shenli, then users should continue to use them as needed until they are able to use alternative syringes and closely monitor for leaks, breakage, and other problems. Leaks or breakage may result in a delay in treatment.

Actions Required of You

1. Immediately transition away from using plastic syringes manufactured by Jiangsu Shenli, unless use of these syringes is absolutely necessary until you can complete the transition. Merit Customer Service may be contacted for Merit replacement syringes or direction to alternative suppliers. Once you have secured an adequate supply of alternative syringes or Merit kits that do not contain Jiangsu

[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
[3] The scope of FDA's Field Safety Communication covers multiple syringe manufacturers, however, Merit only received and shipped syringes from Jiangsu Shenli. Please refer to the FDA's website for complete details.

Shenli syringes, please contact Merit Customer Service to arrange for return of your remaining affected Merit kits.

2. 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 be identified with a label indicating the syringes have been recalled (Figure 1). Product you continue to receive without the recall label and not identified on your Customer Response Form do not include Jiangsu Shenli syringes.

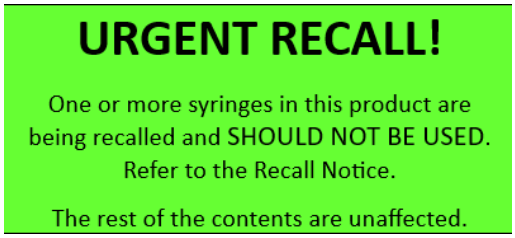

Figure 1

We are also requesting all of our direct customers (healthcare providers and facilities) to stop using and discard at the point of use the Jiangsu Shenli syringes packaged in our affected products unless absolutely necessary and that they over-label all existing product indicating not to use the Jiangsu Shenli syringes. The remaining kit components are suitable for use.

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 device safety notification may cause.

Enclosure: Customer Response Form