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1600 West Merit Parkway
South Jordan, UT 84095 USA
PHONE 801.253.1600
FAX 801.253.1688
merit.com

URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: EsophyX® Z+

Action Required: Sign and Return Customer Response Form

Merit Medical Systems, Inc. (Merit) is conducting a voluntary recall of the EsophyX® Z+ to update the Instructions for Use (IFU) to include additional warnings and precautions related to associated risks with device over-rotation and multiple deployments of fasteners.

The updated IFU now includes the following additions: (1) a warning to carefully consider placement location of fasteners to ensure appropriate and suitable plications are achieved; (2) Warning: Do not prematurely lock the helical retractor and to ensure the device has not been over rotated; and, (3) Warning: Do not deliver fasteners in the same location as previously deployed fasteners, as an adverse event such as fasteners breaking or pulling through tissue, or, in rare cases, perforation or pleural effusion may occur.

Risk to Health

Device over-rotation may result in tissue injury and minor bleeding. Deployment of multiple fasteners to the same location may result in tissue injury and unintended perforation.

As of 13-Mar-2025 Merit has received a total of 42 complaints related to this issue; a total of 5 of these complaints were MDR reportable with three (3) reports of patient harm or injury relating to this issue.

Affected Product

This recall affects all lots of catalog codes R2007 and R2275 of the EsophyX® Z+ within expiry. Merit's records indicate that you have received affected product.

As a result of this recall, Merit is referring you to an electronic copy of the updated IFU for the EsophyX® Z+. **Please note that you may continue to use product in inventory as you reference the new IFU and Merit training material. Additionally, all EsophyX® Z+ product ordered after February 10, 2025, will contain the updated IFU.**

Actions required of you:

1. Read and understand this communication and the updated IFU referenced in the attached poster.
2. **There is no need to return product to Merit.**

3. **Post the attached poster on or near the affected products so users are aware of the updated IFU.**
4. **Discard the current IFU with the product at point of use.**
5. Ensure that applicable personnel within your organization are made aware of this communication.
6. 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.
7. If you require paper IFUs, please contact RESPONSE@merit.com.
8. **Please fill out, scan and email the completed Customer Response Form to Customer Service at RESPONSE@merit.com within 7 calendar days**.
9. If you require additional product training regarding the IFU updates, please contact your Merit Sales Representative to schedule.

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 via email at RESPONSE@merit.com.

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

Sincerely,

Merit Medical Systems

Enclosure(s)