UNDERSTAND. INNOVATE. DELIVER.

URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: basixCOMPAK™ Inflation Device

Action Required: Read and Understand

Merit Medical Systems, Inc. is voluntarily conducting a recall for the basixCOMPAK™ Inflation Device. In rare instances, the handle may detach from the syringe during use due to an insufficient amount of adhesive on the handle, a condition that is not detectable prior to use. Handle detachment during use will result in residual contrast in the balloon and procedural delay while another syringe is used to aspirate the residual contrast.

There has been a single incident where it was reported that the balloon remained inflated after the handle detached, which occurred concurrently with the patient experiencing an adverse event. Simulated use testing has not replicated this failure, specifically the balloon remaining inflated after handle detachment.

This notice is being sent out of an abundance of caution to ensure users are aware of this rare, potential issue. Product corrections are being implemented in newly manufactured lots.

Merit is issuing this notice to customers who have ordered the product in the past 3 years (see attached part number table). This notice is for your information and you are not required to return any product to Merit.

Actions required of you:

1. Please read and understand the following:
    a. Holding the cap and barrel together during use may effectively prevent detachment.
    b. Visual indicators such as pressure drops on the gauge can alert users to potential failures. Refer to the product Instructions for Use.
    c. Simulated use testing showed that handle separation results in flow restoration.
    d. Should the handle detach during use and the balloon not completely deflate, pull the handle out of the inflation syringe, disconnect the inflation syringe from the catheter, and use an alternate syringe to generate vacuum and aspirate residual contrast.
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.
4. Please fill out, scan, and email the completed Customer Response Form to Customer Service at RESPONSE@merit.com within seven (7) calendar days.

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 or via phone at +1 800 356 3748 | 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)

Part Number Table
basixCOMPAK™ Inflation Device

Catalog Code	Catalog Code
ENDO-AN2030/B	IN4915
IN4130/CNK	IN4916/A
IN4130/H	IN4917/A
IN4130/JPH	IN4918/A
IN4130/K	IN4919/A
IN4130/KRK	IS-30-A/B
IN4130/L	IS-30-B1/B
IN4130/T	K05-00761F
IN4230/JPH	K05-01717B
IN4230/K	K05-02080D
IN4330/CNK	K05-02090C
IN4330/K	K05-02221
IN4352/K	K05-02338
IN4430/K	K05-02470
IN4530/CNK	K05-02954
IN4530/K	K05-03094A
IN4530/T	K05T-00380C
IN4802/K	K05T-01674B
IN4802/T	K05T-01863
IN4852/K	K05T-01915
IN4901/A	K05T-01920F
IN4902/A	K05T-01955
IN4903/A	K05T-02138
IN4904/A	K05T-02138A
IN4905/A	K05T-02272G
IN4906/A	K05T-02272H
IN4907/A	K05T-02533
IN4908	K05T-03153
IN4909	K05T-03201
IN4910	K09-13203A
IN4911/A	K10T-05261
IN4912	K12T-04270A
IN4913/A	K12T-07956
IN4914/A	K12T-10922B

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