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FSCA-ref: 1721504-11/25/25-008R 25-NOV-2025

URGENT FIELD SAFETY NOTICE (FSN)
basixCOMPAK™ Inflation Device

1. Information on Affected Devices	
1.	1. Device Type(s)
	Single-use 20mL inflation syringe capable of producing a maximum pressure of 30 ATM/bars, fitted with a threaded plunger assembly with lock/release bar, a flexible high pressure extension tube, and a 3-way medium pressure stopcock.
1.	2. Commercial name(s)
	basixCOMPAK™
1.	3. Primary clinical purpose of device(s)
	Used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon.
1.	4. Device Model/Catalogue/part number(s)
	See attached part number table.

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	In rare instances, the handle may detach from the syringe during use due to an insufficient amount of adhesive on the handle. The lack of adhesive is not detectable prior to use. In a single instance, the detachment occurred concurrently with an adverse event. Product corrections are being implemented in newly manufactured lots.
2.	2. Hazard giving rise to the FSCA
	Detachment of the handle during use will result in residual contrast in the balloon and a delay in procedure while another syringe is used to aspirate the residual contrast. Although simulated use testing has not been able to replicate the failure, there has been a serious incident where it was reported that the balloon remained inflated after the handle detached.
2.	3. Probability of problem arising
	The global complaint rate for this hazard is 0.0009%.
2.	4. Predicted risk to patient/users
	Detachment of the handle during use will result in residual contrast in the balloon and a delay in procedure while another syringe is used to aspirate the residual contrast. In the worst-case scenario, the balloon may remain occlusive, which can lead to a rhythm disturbance.

	3. Type of Action to mitigate the risk	
3.	1. Action To Be Taken by the User ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Please read and understand the following: 1. Holding the cap and barrel together during use may effectively prevent detachment. 2. Visual indicators such as pressure drops on the gauge can alert users to potential failures. Refer to the product Instructions for Use. 3. Simulated use testing showed that handle separation results in flow restoration. 4. 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.	
3.	2. By when should the action be completed?	Immediately.
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes

	4. General Information	
4.	1. FSN Type	New
4.	2. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	3. List of attachments/appendices:	Part Number Table, Customer Response Form

	Transmission of this Field Safety Notice
	This notice needs to be passed to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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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