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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.