Important Customer Notice

Field Safety Notice Getinge Maquet Structural Heart Products Product Recall Datascope Sensation, Sensation Plus, Mega and Linear IAB Catheters

Category Tower 6
Contract Title Interventional Cardiology and Radiology
Field Safety Product Recall Notice FSCA 2249723-05/05/2023-008-C

ICN: 2180
Date: 26/06/2023

MHRA TBC
Recall Ref: 22

Alert:

- Datascope and Getinge has issued a precautionary recall of the Sensation Plus/ MEGA and Linear Intra-Aortic Balloon (IAB) catheter range due to an issue that may impact patient safety when performing a sheathed IAB catheter insertion.
- There have been customer reports of the introducer included within the Datascope and Getinge IAB insertion kits fracturing at the hub when attempting to remove the introducer dilator from the sheath, leaving the introducer dilator body housed within the sheath.
- During IAB catheter insertion should the introducer dilator fracture and remain within the sheath, the introducer dilator/sheath assembly must be removed, and IAB insertion must be completed with another introducer dilator/sheath assembly.
- Should the body of the introducer dilator dislodge partially or entirely from the sheath, surgical removal may be required. Damage to the femoral artery, descending aorta or embolization of the introducer dilator may result if the retained introducer dilator is not secured. Initiation of IAB therapy will be delayed until the introducer dilator and sheath are replaced, if a surgical intervention is required to retrieve the introducer dilator, or an alternative insertion site (contralateral femoral artery) is used to initiate therapy. In a worst-case scenario, this device failure may lead to death.

Products Affected:

- 10 of the affected products are listed on the eDirect service from NHS Supply Chain please refer to the product listing attachment.
- Please note due to ongoing supply issues, see ICN 1943 these products are currently suspended and we will update this Field Safety Notice when we have further information.

Next Steps:

- Read and follow the full instructions in the Field Safety Notice and share them with all users of the affected products.
- To prevent patient injury, it is advised to not use the sheath or introducer dilator included in identified Datascope and Getinge IAB insertion kits to perform a sheathed insertion. Further, do not use the provided Datascope and Geting sheath with an alternative dilator as the Datascope and Grtinge sheath is designed to perform safely only with the accompanying introducer dilator.
- Use of alternative dilators or sheaths may introduce patient injury. While Datascope and Getinge do not recommend the use of the sheath or introducer dilator, they understand that in the absence of alternative therapy options, clinicians may determine that withholding therapy may place the patient at greater risk.
- Please reference the options listed in the Field Safety Notice for further guidance,
- If you have unused/unexpired affected catheters that you will be returning from your inventory, please note that given the current supply chain shortages, Getinge is offering a full credit for any affected IAB catheters. Please contact your Datascope and Getinge representative to request a return authorization number (RMA) and shipping instructions. Also complete and return the Medical Device Removal Response Form to: iccomplaints.uki@getinge.com
- Where affected product/ lot numbers are being returned to the Supplier please also contact your local NHS Supply Chain Customer Service Advisor with full details to enable us to raise the appropriate credit on your behalf.
- Where potential alternatives are identified, Customers are advised to consult their own clinical experts to ensure suitability for your organisation's use of these products.
- If you have any further questions, please contact your local NHS Supply Chain Customer Service Advisor or Customer Relationship Manager.

Please be aware that in the event of a Field Safety Notice or Product Recall, we may need to provide manufacturers, UK responsible Persons and distributors with contact details of customers who have potentially received the affected stock. This is to help them to reconcile their stock and evidence to the regulators that all actions have been taken to ensure that the unused products have been removed from customers to prevent inadvertent use of faulty and potentially unsafe products.