5TH August, 2022

**URGENT FIELD SAFETY NOTICE MEDICAL DEVICE REMOVAL**

**Insertion Kit for use with SENSATION PLUS 8Fr. 50cc IAB**
**SENSATION PLUS 8Fr. 50cc IAB Catheter**
**MEGA 8Fr. 50cc IAB Catheter**

| | |
|---|---|
| **UDI/ Part Numbers:** | **10607567107301 - 0684-00-0498-01 MEGA 8Fr. 50cc IAB Catheter**<br>**10607567108599 - 0884-00-0019-23 Insertion Kit for use with SENSATION PLUS 8F. 50cc IAB**<br>**10607567108605 - 0684-00-0576-01 SENSATION PLUS 8Fr. 50cc IAB Catheter**<br>**10607567109619 - 0684-00-0296-01U MEGA 8Fr. 50cc IAB Catheter**<br>**10607567109633 - 0684-00-0576-01U SENSATION PLUS 8Fr. 50cc IAB Catheter** |
| **Distributed Affected Lot Numbers:** | **3000166607 3000168086 3000169722 3000170709 3000171501 3000172352 3000172353 3000176574 3000176633 3000182611 3000183312 3000183313 3000184437 3000185680 3000186654 3000186655 3000196023 3000199196 3000199197 3000199198 3000200147 3000202083 3000213850 3000217952** |
| **Manufacturing Dates:** | **May 04, 2021 to January 31, 2022** |
| **Distribution Dates:** | **June 25, 2021 to April 05, 2022** |

Dear Customer,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Medical Device Removal for certain lots of 8Fr. 50cc IAB catheters and insertion kits due to an undersized vessel dilator included in the 8Fr. IAB insertion kit. During a sheathless insertion, the undersized inner diameter may result in the inability to insert the guidewire through the inner lumen of the dilator and the undersized outer diameter may reduce dilation of the vessel.

**Identification of the issue:**
Datascope Corp./Getinge was informed by the supplier of the vessel dilator that a single batch purchased from them did not conform to the required specifications for the product.

The intra-aortic balloon catheter and accessories are used to provide counterpulsation therapy in the aorta, whereby balloon inflation during diastole and deflation during systole increases blood supply to the heart muscle and decreases the work of the left ventricle.

**Risk To Health:**
The IAB catheter is designed for both a sheathed and sheathless insertion. This issue only applies to a sheathless insertion of the catheter when the vessel dilator is used. The IAB catheter can still be inserted as per the IFU without the vessel dilator if the Introducer Sheath and Introducer Dilator are used. Although, a sheathed insertion is much more common, it is important to recognize that a sheathless insertion could pose a risk to patients. Vessel dilation prior to catheter insertion is a common practice. Users are well versed in the process and the products commonly used to dilate vessels. The risks associated with insufficient dilation are well known.

A vessel dilator with an undersized outer diameter will not directly injure the vessel but may lack the full degree of dilation to facilitate an easier sheathless IAB insertion.

It is anticipated that an undersized vessel dilator still provides a fair amount of dilation. However, the most vulnerable of patients are those with smaller or compromised vessels for whom vessel dilation to the fullest 8Fr. is required for optimal IAB insertion. **This issue could result in a procedural delay, gas emboli, and vessel injury.**

To date, Datascope Corp./Getinge has not received any complaints or adverse events regarding this issue.

**Actions to be taken by the customer:**

- If difficulty is encountered while inserting the IAB catheter using a sheathless insertion technique, remove the IAB catheter and insert the supplied Introducer Sheath and Introducer Dilator over the guidewire. From that point, continue with the remainder of the instructions to insert the IAB catheter with the use of an introducer sheath per the IFU.

- Our records indicate that you have received a product from one or more of the lot numbers that are affected by this recall. Please examine your inventory immediately to determine if you have any of the product from the lots listed on page 1 and remove and quarantine any affected IAB.

- If you have affected catheters, please note that given our current supply chain shortages we are offering a full credit for any affected IAB catheters that are being returned from your inventory. Please contact your local Datascope Corp./Getinge Customer Service

- Please forward this information to all current and potential 8Fr. IAB device users within your hospital / facility.

- If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

- Please complete and sign the attached MEDICAL DEVICE REMOVAL - RESPONSE FORM (page 4) to acknowledge that you have received this notification, include any RMA number provided by Customer Service. Return the completed form to Datascope Corp./Getinge by e-mailing a scanned copy to **iccomplaints.uki@getinge.com**.

**Actions taken by Datascope Corp./Getinge:**

- Datascope Corp./Getinge has contacted the supplier and the issue has been resolved.

- You will be provided a credit for affected devices that are returned to Datascope Corp./Getinge.

This voluntary recall only affects the products listed on page 1; no other products are affected by this voluntary recall.

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your Datascope Corp./Getinge representative or office.

Sincerely,
Hari Rajendran
Regulatory Manager UKI

5th August 2022

# URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE - Removal RESPONSE FORM

**MEGA 8Fr. 50cc IAB Catheter**
**Insertion Kit for use with SENSATION PLUS 8F. 50cc IAB**
**SENSATION PLUS 8Fr. 50cc IAB Catheter**

**EMAIL TO: iccomplaints.uki@getinge.com**

**DISTRIBUTION DATES: June 25, 2021 to April 05, 2022**

Please acknowledge that you have read and understand this URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE - Removal RESPONSE FORM for the 8Fr IABs/Insertion Kits from Page 1 affected by this recall. Please ensure that all users of the 8Fr IAB Insertion Kits at this facility have been notified accordingly, and complete the entire form where applicable whether or not you have product to return.

| **Facility Representative Information:** | |
|---|---|
| Name | Title: |
| Department: | Phone: |
| Signature | Date: |
| Hospital Name | |
| Address, City and State | |

I **DO NOT HAVE** ANY AFFECTED PRODUCT: ☐ I **HAVE AFFECTED** PRODUCT: ☐

If you have affected product lot(s) to return please complete the table below:

| **Enter Lot** | **Quantity** | **RMA #** |
|---|---|---|
| | | |
| | | |
| | | |

**Return the completed form and EMAIL TO: iccomplaints.uki@getinge.com**

Getinge

45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com