June 28, 2023

NOTE: THIS NOTIFICATION HAS ALSO BEEN DIRECTED TO THE RISK MANAGER AT YOUR FACILITY

URGENT MEDICAL DEVICE REMOVAL
FSCA 2248146-06/12/2023-001-R

Datascope Sensation/Sensation Plus/MEGA/Linear IAB CATHETERS, Packaged Insertion Kits, & Reinforced Introducer Sets

Product Description:	Product Code/Part Number:	UDI Code:
PACKAGED INSERTION KIT - LINEAR 7.5 Fr. 25 cc IABs	D884-00-0019-12	10607567106632
PACKAGED INSERTION KIT - LINEAR 7.5 Fr. 34/40 cc IABs	D884-00-0019-13	10607567106649
PACKAGED INSERTION KIT - SENSATION 7 Fr. 34/40 cc IABs	D884-00-0019-16	10607567106724
PACKAGED INSERTION KIT - MEGA 8 Fr. 50 cc IAB	D884-00-0019-17	10607567107493
PACKAGED INSERTION KIT - MEGA 7.5 Fr. 30/40 cc IABs	D884-00-0019-21	10607567108025
PACKAGED INSERTION KIT - SENSATION PLUS 7.5 Fr. 40 cc IAB	D884-00-0019-22	10607567108612
PACKAGED INSERTION KIT - SENSATION PLUS 8 Fr. 50 cc IAB	D884-00-0019-23	10607567108599
SENSATION 7 Fr. 40cc IAB WITH ACCESSORIES, US ONLY	D684-00-0470-01U	10607567109558
SENSATION 7 Fr. 34cc IAB WITH ACCESSORIES, US ONLY	D684-00-0469-01U	10607567109541
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES, US ONLY	D684-00-0295-01U	10605767109596
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES APA, US ONLY	D684-00-0295-02U	10605767109602
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES, US ONLY	D684-00-0479-01U	10605767109503
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES, (APA) US ONLY	D684-00-0479-02U	10605767109510
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES, US ONLY	D684-00-0294-01U	10607567109572
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES APA, US ONLY	D684-00-0294-02U	10607567109589
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES, US ONLY	D684-00-0480-01U	10607567109527
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES, (APA) US ONLY	D684-00-0480-02U	10607567109534
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES, US ONLY	D684-00-0478-01U	10607567109480
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES (APA) US ONLY	D684-00-0478-02U	10607567109497
SENSATION PLUS 7.5Fr. 40cc WITH ACCESSORIES, US ONLY	D684-00-0568-01U	10607567109565
SENSATION PLUS 8Fr. 50cc IAB WITH ACCESSORIES, US ONLY	D684-00-0576-01U	10607567109633
MEGA 8Fr. 50cc IAB WITH ACCESSORIES, US ONLY	D684-00-0296-01U	10607567109619
MEGA 8Fr. 50cc IAB WITH ACCESSORIES, (APA) US ONLY	D684-00-0296-02U	10607567109626
REINFORCED INTRODUCER SET FOR LINEAR 7.5Fr. & MEGA 7.5Fr.	D684-00-0403-05	10607567106656
REINFORCED INTRODUCER SET FOR SENSATION 7Fr.	D684-00-0403-06	10607567106694
REINFORCED INTRODUCER SET FOR SENSATION PLUS & MEGA 8Fr.	D684-00-0403-10	10607567107943

Distributed Affected Lot Number:	**All**
Manufacturing Dates:	**IAB Kits: Since May 09, 2020** **Packaged Insertion Kits & Reinforced Introducer sets: Since May 31, 2018 - Present**
Distribution Dates:	**IAB Kits: Since May 09, 2020** **Packaged Insertion Kits & Reinforced Introducer sets: Since May 31, 2018 - Present**

Dear Customer,

Datascope Corp., a subsidiary of Getinge previously initiated a voluntary Medical Device Removal on June 23, 2023, via notification that was sent to the attention of Risk Manager at your facility, for Datascope/Getinge Sensation/Sensation Plus/MEGA/Linear IAB catheters, Packaged Insertion Kits & Reinforced Introducer Sets due to an issue that may impact patient safety when performing a sheathed IAB catheter insertion.

There have been Customer reports of the introducer dilator included within Datascope/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.

This notification is to inform you that Getinge will continue to distribute this product while we work to resolve the issue. However, this product may be affected by the same issue identified above.

Identification of the issue:

Datascope/Getinge has received ten (10) complaints over a three (3) year evaluation period since 2020; however, all ten (10) complaints were received from August 06, 2022 through May 29, 2023, reporting events in which during IAB catheter insertion, the introducer dilator fractures at the hub leaving the body of the introducer dilator housed within the sheath. Of the ten (10) events reported, there have been three (3) serious adverse events and one (1) patient death.

All reported events have been reviewed, and potentially impacted product lots have been identified. We are investigating the cause of this product defect.

Risk to Health:

If the introducer dilator fractures and remains within the sheath during IAB catheter sheath insertion, the introducer dilator/sheath assembly must be removed, and IAB insertion must be completed with another introducer dilator/sheath assembly. If the body of the introducer dilator dislodges 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.

In the event the patient is not eligible for sheathless insertion, or an appropriate alternate dilator/sheath assembly cannot be located, alternative means of providing hemodynamic support should be pursued based on the clinician's judgement.

Patients currently receiving therapy with an identified IAB catheter are not at risk for injury related to this issue.

User Actions to be taken now:

A review of our records indicates that you may have received Datascope/Getinge IAB catheters (containing the affected dilator/sheath assembly) and/or Packaged Insertion Kits & Reinforced Introducer Sets at your facility. Please examine your inventory immediately to determine if you have any impacted product.

To prevent patient injury, DO NOT USE the sheath or introducer dilator included in identified Datascope/GETINGE IAB insertion kits to perform a sheathed insertion. Further, do not use the provided Datascope/GETINGE sheath with an alternative dilator as the Datascope/GETINGE

sheath is designed to perform safely only with the accompanying introducer dilator. Doing so may cause patient injury.

Four options for Customers:

1. **Sheathed insertion may be performed with alternate dilator / sheath assemblies.**

In acknowledgement of the urgent need for counterpulsation therapy for your patients, until replacement Datascope introducer dilator/sheaths can be provided for the identified insertion kit(s), Datascope/Getinge suggests the following to permit safe sheathed insertion of Datascope/Getinge IAB catheters:

Sheathed IAB insertion may be completed using an alternate introducer dilator/sheath assembly with a wire-reinforced sheath. The wire-reinforced sheath must be:

- 10cm - 15.2cm in length
- One Fr (French) size larger in diameter than the provided Datascope/Getinge IAB sheath

To prevent reduced IAB integrity and performance, the sheath utilized needs to be large enough in diameter and the correct length. Additionally, a wire-reinforced sheath must be used to prevent kinking of the IAB catheter.

Alternate wire reinforced sheath selection:
To prevent damage to the Datascope/Getinge IAB catheter, it is advised that Customers utilize alternative introducer dilator/sheath assemblies with the following sized wire reinforced sheaths for each respective IAB catheter Fr size. **Please note that formal testing using alternate sheaths other than those supplied by Datascope/Getinge has not been conducted/validated.** It is anticipated, however, that a larger sized sheath will safely facilitate IAB insertion without impacting IAB performance.

	Alternate Wire Reinforced Sheath Sizing
7 Fr Datascope/Getinge IAB catheter:	8 Fr (length of 10 – 15.2 cm)
7.5 Fr Datascope/Getinge IAB catheter:	8 Fr (length of 10 - 15.2 cm)
8 Fr Datascope/Getinge IAB catheter:	9 Fr (length of 10 - 15.2 cm)

WARNINGS for SHEATHED INSERTION WITH ALTERNATE SHEATHS:

- Prior to inserting a Datascope/Getinge IAB catheter through an alternate sheath, confirm that the supplied 0.025 in guidewire is in place. Use of different sized guidewires may not permit safe delivery of the Datascope/Getinge IAB catheter and may compromise product performance.
- Should the sheath selected have a side port, set up a continuous flush line as directed per product guidelines.
- Proceed with IAB insertion as per current Datascope/Getinge IAB IFU instruction.

2. **If your facility currently uses sheathless insertion technique you may keep the IAB catheter and insertion kit to continue treatment with this technique.**

The IAB catheter may be inserted as per routine procedure if the patient has been

deemed appropriate for sheathless insertion by the clinician. The IAB catheter and remaining components of the IAB insertion kit, including the vessel dilator used for sheathless insertion, are not impacted by this notice. As a reminder, per the IFU the introduction of the IAB catheter using sheathless insertion is not recommended in patients with severe obesity, scarring of the groin or other contraindications to percutaneous insertion. Further, if you encounter difficulty while inserting the IAB catheter using sheathless insertion, please remove the IAB catheter and proceed with insertion with an appropriate alternate sized sheath as referenced above.

3. **Should you opt to proceed with sheathed insertion using the supplied introducer dilator and sheath, the following is advised.**

- Prior to use, carefully inspect the dilator for any kinks or fractures, especially near the hub. Dispose of product if kinks/fractures/other defects are observed.
- If a dilator fractures during insertion, do not attempt to remove the dilator separately from the sheath. Attempts to remove only the remaining dilator portion from the sheath may dislodge the dilator into the vessel and result in injury
- To remove the remaining dilator and sheath, clamp the dilator and sheath together
- Simultaneously pull the wire and dilator sheath assembly out of the vessel until the dilator has exited the vessel entirely
- The dilator/sheath assembly can then be taken off the wire
- Proceed with re-wiring as the site permits

4. **Return the Datascope/Getinge IAB catheter and insertion kit and/or the Packaged Insertion Kit & and Reinforced Introducer Set for credit**

If you have unused/unexpired affected catheters that you will be returning from your inventory, please note that given our current supply chain shortages we are offering a full credit for any affected IAB catheters. Please contact Datascope Getinge Customer Service at 888- 9GETUSA (888-943–8872) (option 2) between the hours of 8 AM and 6 PM Eastern Standard Time to request a return authorization number (RMA) and shipping instructions.

Please forward this information to all current and potential Datascope/Getinge IAB Catheter users within your hospital/facility.

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

Type of Action by the Company:
Datascope/Getinge has identified the issue with the introducer dilator and is working with the supplier towards a resolution.

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

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 using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/

- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

We apologize for any inconvenience this Medical Device Correction may cause. If you have any questions, please contact your Datascope/Getinge representative or call Datascope/Getinge Customer Service at 1-888-943-8872, options 2, Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This notification is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Jessica Minaya

Regulatory Affairs and Quality Compliance Field Actions

USA Shared Service