

XX-Month-2023

URGENT Field Safety Notice -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	0884-00-0019-12	10607567106632
PACKAGED INSERTION KIT - LINEAR 7.5 Fr. 34/40 cc IABs	0884-00-0019-13	10607567106649
PACKAGED INSERTION KIT - SENSATION 7 Fr. 34/40 cc IABs	0884-00-0019-16	10607567106724
PACKAGED INSERTION KIT - MEGA 8 Fr. 50 cc IAB	0884-00-0019-17	10607567107493
PACKAGED INSERTION KIT - TRANS-RAY 7 Fr. 34/40 cc IABs	0884-00-0019-18	10607567107684
PACKAGED INSERTION KIT - MEGA 7.5 Fr. 30/40 cc IABs	0884-00-0019-21	10607567108025
PACKAGED INSERTION KIT - SENSATION PLUS 7.5 Fr. 40 cc IAB	0884-00-0019-22	10607567108612
PACKAGED INSERTION KIT - SENSATION PLUS 8 Fr. 50 cc IAB	0884-00-0019-23	10607567108599
PACKAGED INSERTION KIT - YAMATO PLUS-R 7.5 Fr. 30/35/40 cc IABs	0886-00-0019-25	10607567109657
PACKAGED INSERTION KIT - TRANS-RAY PLUS 7.5 Fr. 35/40 IABs	0884-00-0019-26	10607567111810
SENSATION 7 Fr. 34cc IAB WITH ACCESSORIES (CHINA)	0684-00-0469-01C	10607567109367
SENSATION 7 Fr. 34cc IAB WITH ACCESSORIES (INDIA)	0684-00-0469-07	10607567109732
SENSATION 7 Fr. 40cc IAB WITH ACCESSORIES (CHINA)	0684-00-0470-01C	10607567109374
SENSATION 7 Fr. 40cc IAB WITH ACCESSORIES (INDIA)	0684-00-0470-07	10607567109749
SENSATION 7 Fr. 40cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0470-09	10607567113135
SENSATION 7 Fr. 40cc IAB WITH ACCESSORIES	0684-00-0470-01	10607567106779
SENSATION 7 Fr. 34cc IAB WITH ACCESSORIES	0684-00-0469-01	10607567106755
SENSATION 7 Fr. 34cc IAB WITH ACCESSORIES, TURKEY	0684-00-0469-09	10607567113128
7FR. 34cc TRANS-RAY IAB WITH ACCESSORIES	0684-00-0545-01	10607567107656
TRANS-RAY 7FR. 40cc IAB WITH ACCESSORIES	0684-00-0546-01	00607567107663
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES	0684-00-0295-01	10607567107974
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES (APA)	0684-00-0295-02	10607567107981
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES (W/O STATLOCK)	0684-00-0295-03	10607567109404
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES (CHINA)	0684-00-0295-05	10607567109039
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES AND APA (CHINA)	0684-00-0295-06	10607567109046
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES W/O STATLOCK - INDIA	0684-00-0295-07	10607567111339
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES W/O STATLOCK (APA) - INDIA	0684-00-0295-08	10607567111346
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0295-09	10607567113241
MEGA 7.5Fr. 40cc IAB WITH ACCESSORIES (APA) (TURKEY)	0684-00-0295-10	10607567113258
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES	0684-00-0479-01	10605767106557
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES (APA)	0684-00-0479-02	10605767106540
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES (CHINA)	0684-00-0479-01C	10605767109329
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES (APA)(CHINA)	0684-00-0479-02C	10605767109336
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES (INDIA)	0684-00-0479-07	10605767109695
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES (APA) (INDIA)	0684-00-0479-08	10605767109701
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0479-09	10605767113180
LINEAR 7.5Fr. 34cc IAB WITH ACCESSORIES WITH APA (TURKEY)	0684-00-0479-10	10605767113142
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES	0684-00-0294-01	10607567107950
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES (APA)	0684-00-0294-02	10607567107967
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES (W/O STATLOCK)	0684-00-0294-03	10607567109398
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES (CHINA)	0684-00-0294-05	10607567109015
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES AND APA (CHINA)	0684-00-0294-06	10607567109022
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES W/O STATLOCK - INDIA	0684-00-0294-07	10607567111315
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES W/O STATLOCK (APA) – INDIA	0684-00-0294-08	10607567111322
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0294-09	10607567113227
MEGA 7.5Fr. 30cc IAB WITH ACCESSORIES (APA) (TURKEY)	0684-00-0294-10	10607567113234
LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES	0684-00-0480-01	10607567106564
LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES (APA)	0684-00-0480-02	10607567106571
LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES (CHINA)	0684-00-0480-01C	10607567109343
LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES (APA)(CHINA)	0684-00-0480-02C	10607567109350
LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES (INDIA)	0684-00-0480-07	10607567109718

LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES (APA)(INDIA)	0684-00-0480-08	10607567109725
LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0480-09	10607567113197
LINEAR 7.5Fr. 40cc IAB WITH ACCESSORIES WITH APA (TURKEY)	0684-00-0480-10	10607567113159
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES	0684-00-0478-01	10607567106526
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES (APA)	0684-00-0478-02	10607567106533
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES (CHINA)	0684-00-0478-01C	10607567109305
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES (APA) (CHINA)	0684-00-0478-02C	10607567109312
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES (INDIA)	0684-00-0478-07	10607567109671
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES (APA) (INDIA)	0684-00-0478-08	10607567109688
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0478-09	10607567113203
LINEAR 7.5Fr. 25cc IAB WITH ACCESSORIES WITH APA (TURKEY)	0684-00-0478-10	10607567113210
SENSATION PLUS 7.5Fr. 40cc WITH ACCESSORIES	0684-00-0568-01	10607567108063
SENSATION PLUS 7.5Fr. 40cc WITH ACCESSORIES (W/O STATLOCK)	0684-00-0568-03	10607567109428
SENSATION PLUS 7.5Fr. 40cc WITH ACCESSORIES (WITH PRESSURE TUBES, NO STYLET WIRE) (CHINA)	0684-00-0568-05	10607567109442
SENSATION PLUS 7.5Fr. 40cc WITH ACCESSORIES (TURKEY)	0684-00-0568-09	10607567113166
SENSATION PLUS 8Fr. 50cc IAB WITH ACCESSORIES	0684-00-0576-01	10607567108605
SENSATION PLUS 8Fr. 50cc IAB WITH ACCESSORIES (WITH PRESSURE TUBES, NO STYLET WIRE) (W/O STATLOCK)	0684-00-0576-03	10607567109435
SENSATION PLUS 8Fr. 50cc IAB WITH ACCESSORIES (WITH PRESSURE TUBES, NO STYLET WIRE)	0684-00-0576-05	10607567109381
SENSATION PLUS 8Fr. 50cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0576-09	10607567113173
MEGA 8Fr. 50cc IAB WITH STATLOCK	0684-00-0296-01	10607567108001
MEGA 8Fr. 50cc IAB WITH STATLOCK & APA	0684-00-0296-02	10607567108018
MEGA 8Fr. 50cc IAB WITH ACCESSORIES (W/O STATLOCK)	0684-00-0296-03	10607567109411
MEGA 8Fr. 50cc IAB WITH ACCESSORIES (TURKEY)	0684-00-0296-09	10607567113265
MEGA 8Fr. 50cc IAB WITH ACCESSORIES WITH APA (TURKEY)	0684-00-0296-10	10607567113272
MEGA 8Fr. 50cc IAB WITH ACCESSORIES (CHINA)	0684-00-0498-01	10607567107301
MEGA 8Fr. 50cc IAB WITH ACCESSORIES (INDIA)	0684-00-0498-07	10607567109756
MEGA 8Fr. 50cc IAB WITH ACCESSORIES (APA) (INDIA)	0684-00-0498-08	10607567109763
TRANS-RAY PLUS 7.5Fr 35cc IAB WITH ACCESSORIES	0684-00-0607	10607567111711
TRANS-RAY PLUS 7.5Fr 40cc IAB WITH ACCESSORIES	0684-00-0608	10607567111728
YAMATO PLUS-R 30cc IAB WITH ACCESSORIES AND RETRACTION KIT	0684-00-0559-01	10607567107585
YAMATO PLUS-R 30cc IAB WITH ACCESSORIES AND RETRACTION KIT (APA)	0684-00-0559-02	10607567107592
YAMATO PLUS-R 35cc IAB WITH ACCESSORIES AND RETRACTION KIT	0684-00-0560-01	10607567107608
YAMATO PLUS-R 35cc IAB WITH ACCESSORIES AND RETRACTION KIT (APA)	0684-00-0560-02	10607567107615
YAMATO PLUS-R 40cc IAB WITH ACCESSORIES AND RETRACTION KIT	0684-00-0561-01	10607567107622
YAMATO PLUS-R 40cc IAB WITH ACCESSORIES AND RETRACTION KIT (APA)	0684-00-0561-02	10607567107639
REINFORCED INTRODUCER SET FOR LINEAR 7.5Fr. & MEGA 7.5Fr.	0684-00-0403-05	10607567106656
REINFORCED INTRODUCER SET FOR SENSATION 7Fr.	0684-00-0403-06	10607567106694
REINFORCED INTRODUCER SET FOR SENSATION PLUS & MEGA 8Fr.	0684-00-0403-10	10607567107943

Distributed Affected Lot Number:	All
Manufacturing Dates:	IAB Kits: Since May 9th, 2020 Packaged Insertion Kits & Reinforced Introducer sets: Since May 31st 2018
Distribution Dates:	IAB Kits: Since May 9th, 2020 Packaged Insertion Kits & Reinforced Introducer sets: Since May 31st 2018

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge is initiating a voluntary Medical Device Field Safety Notice-Removal for Datascope/Getinge Sensation/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.

Identification of the issue:

Datascope/Getinge has received ten (10) complaints over a three (3) year period since 2020, 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/Gefinge suggests the following to permit safe sheathed insertion of Datascope/Gefinge 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/Gefinge 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/Gefinge 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/Gefinge has not been conducted/validated.** It is anticipated, however, that a larger sized sheath will safely facilitate IAB insertion without impacting IAB performance.

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

WARNINGS for SHEATHED INSERTION WITH ALTERNATE SHEATHS:

- Prior to inserting a Datascope/Gefinge 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/Gefinge 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/Gefinge 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.

- 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 refund

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 **[INSERT LOCAL SSU CUSTOMER SERVICE CONTACT HERE]** 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.

Please complete and sign the attached MEDICAL DEVICE Removal - RESPONSE FORM (page 7) 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 **[INSERT LOCAL SSU EMAIL HERE]** or by faxing the form to **[INSERT LOCAL SSU FAX NUMBER HERE]**.

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. New product will be distributed as soon as it is available.

This voluntary Field Safety Notification only affects the products listed on page 1 and 2; no other products are affected by this voluntary correction.

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your Maquet Cardiovascular, LLC /Getinge representative or office. [INSERT SSU CONTACT INFO]

Sincerely,

Specialist, Regulatory Affairs and Field Action Compliance
Datascope/Getinge

XX-Month-2023

**URGENT Field Safety Notice MEDICAL DEVICE REMOVAL -
Response Form**

FSCA 2248146-06/12/2023-001-R

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

DISTRIBUTION DATES: : IAB Kits was distributed after May 9, 2020

Packaged Insertion Kits and Reinforced Introducer sets after May 31, 2018

Insert Local Customer Info here

Please acknowledge that you have read and understand this Urgent Field Safety Notice for the Datascope Sensation/MEGA/Linear IAB Catheters from Page 1 affected by this recall. Please ensure that all users of the Datascope Sensation/MEGA/Linear IAB Catheters, Insertion Kits and Reinforced Introducer sets 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 by FAX to **[Insert Local SSU Fax Here]** or by EMAIL to **[Insert Local SSU email Here]**