30-05-2019

URGENT FIELD SAFETY NOTICE

Sensation Plus 7.5 Fr. 40cc Intra-Aortic Balloon Catheter with Accessories

Product Code/Part Number:	0684-00-0568-01
Affected Lot/Batch Numbers:	3000082472, 3000084069, 3000085231, 3000086994, 3000087688, 3000091205, 3000091206, 3000091828
Distribution Dates:	November 20, 2018 – February 27, 2019

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL SENSATION PLUS 7.5 Fr. 40 cc INTRA-AORTIC BALLOON CATHETER WITH ACCESSORIES USERS WITHIN YOUR HOSPITAL/FACILITY

IF YOU HAVE FURTHER DISTRIBUTED ANY OF THE AFFECTED PRODUCTS, FORWARD THIS INFORMATION TO THE RECEPIENT.

Dear Risk Manager,

Datascope/Getinge is initiating a voluntary Medical Device Recall for the Sensation Plus 7.5 Fr. 40cc Intra-Aortic Balloon (IAB) Catheter with Accessories due to the outer user carton having reversed manufacturing/expiration information resulting in the product showing as expired before being manufactured.

Identification of the Issue:
Datascope/Getinge received complaints that the IAB catheter kit outer carton label contained reversed product manufacturing / expiration information. The date of expiration printed on the label was the actual manufacture date and the manufacture date printed on the label was the expiration date. This showed the product as expired before it was manufactured.

There were no injuries or deaths reported related to the labeling error. There is limited risk to patients as the outcome is that the user would discard the kit as expired prior to using the kit, however a delay in therapy caused by this issue could be serious. In addition the inside pouch does have the correct manufacturing and expiration dates printed on the label.

Datascope/Getinge determined the cause of the issue to be human error that occurred during an update to the label design.

Actions to be taken by the end-user:
A review of our records indicates that you have received Sensation Plus 7.5 Fr. 40cc Intra-Aortic Balloon Catheter with Accessories kits having lot / batch numbers that are affected by this recall.

Please examine your inventory immediately to determine if you have the lot/batch numbers listed in this notice. If so, please remove the affected products from areas of use and follow the instructions below for the return of the product to the manufacture.

Should you have un-used affected product you are eligible for either a replacement or credit.

Affected product should be returned to Getinge per the following process:

1. **Please complete the Urgent Field Safety Response Form on page 3 to acknowledge that you have received this Urgent Field Safety Notice letter. Please fax or email the completed form to your local Maquet/Getinge office as instructed on the form.**

2. Call Datascope/Getinge Customer Support at +971 44470962 to request a return authorization (RA) and shipping instructions to return any affected product.

3. Pack the product to be returned and send as instructed with paperwork.

4. Complete the response form (page 3 of this letter) and include the RA number and quantity of returned product.

The voluntary recall only affects the lot/batch numbers listed on page 1; no other product lot/batch numbers that were delivered to you are affected.

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

URGENT: Even if you do not have the affected product, please complete the attached URGENT FIELD SAFETY NOTICE CUSTOMER RESPONSE FORM on page 3, to acknowledge that you have received the Sensation Plus 7.5 Fr. 40cc Intra-Aortic Balloon Catheter with Accessories URGENT FIELD SAFETY NOTICE. Please fax or email the completed Customer Response Form to Mubashir.javed@getinge.com

Thank you for your cooperation and immediate assistance.

Sincerely,

Sincerely,

Barb Smith
Sr. Regulatory Affairs Specialist
Regulatory Affairs and Field Action Compliance
Getinge Group – Field Actions USA Shared Services

30-05-2019

URGENT FIELD SAFETY NOTICE
CUSTOMER RESPONSE FORM
Sensation Plus 7.5 Fr. 40cc Intra-Aortic Balloon Catheter w/ Accessories

PRODUCT CATALOG NUMBER	0684-00-0568-01
AFFECTED LOT NUMBERS	3000082472, 3000084069, 3000085231, 3000086994, 3000087688, 3000091205, 3000091206, 3000091828
MANUFACTURING DATES	November 20, 2018 – February 27, 2019

Facility Name
Address
Address

PLEASE ENTER THE INFORMATION REQUESTED BELOW FOR THE Getinge URGENT FIELD SAFETY NOTICE FOR Sensation Plus 7.5 Fr. 40cc Intra-Aortic Balloon Catheter with Accessories.

If you do NOT currently have any affected product please check this box: [ ]

If you have affected product in your inventory, please return to Getinge per the instructions provided on page 2 of this letter and provide the return information below:

Affected Lot No.	Quantity Returned	Getinge RMA no.

ACKNOWLEDGEMENT: Please complete the form below by entering the required information, including signature and date, to acknowledge that you have reviewed and understand the Getinge Urgent Field Safety Notice and have notified all relevant users and staff in your facility

Print Name: _____

Signature: _____ Date: _____

Title: _____

Phone: _____

Hospital Name: _____

Address: _____

EMAIL TO: Mubashir.javed@getinge.com