[DAY/MONTH/YEAR]

URGENT: FIELD SAFETY NOTICE (RECALL/REMOVAL)
SENSATION PLUS® 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK®
Product Code/Part Number: 0684-00-0576-01
POTENTIAL LEAK OF BALLOON CATHETER TIP SEAL

Product Code/Part Number:	**0684-00-0576-01**
Affected Lot Number:	**3000043375**
Manufacturing Dates:	**October 13, 2016**
Distribution Dates:	**December 30, 2016 – February 23, 2017**

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL INTRA-AORTIC BALLOON (IAB) CATHETER USERS WITHIN YOUR HOSPITAL / FACILITY.

Dear Customer,

Maquet/Getinge is initiating a voluntary product removal involving one lot number of SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK. The SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter (IABC) with Insertion Kit & STATLOCK is used to provide counterpulsation therapy in the aorta when used with a compatible intra-aortic balloon pump.

Identification of the issue:

During internal pressure (leak) testing of the SENSATION PLUS 8Fr. 50cc, IABC, failures related to the tip seal leak were identified within the lot number listed above. This issue at the catheter tip seal could potentially cause a leak in the balloon and may lead to an interruption of therapy resulting in the need to replace the defective IABC with a new catheter. Such occurrences could cause momentary hemodynamic instability in the patient, or potential complications related to vessel bleeding related to replacement of the IAB catheter. To date, there have been no reports of serious injury.

It is important to note that the SENSATION PLUS IABC works in conjunction with the intra-aortic balloon pump that is designed to alarm should a balloon leak occur.

Actions to be taken by SENSATION PLUS IAB Catheter users:

Our records indicate that you have received the SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK having the lot number that is affected by this recall.

Please examine your inventory immediately to determine if you have any of the SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK with the lot number listed on page 1. If so, please remove the affected products, quarantine them and place in a secure location.

If you have affected SENSATION PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK, please contact your local Maquet/Getinge representative to request return authorization and shipping instructions to return any affected product. Pack the product to be returned with the appropriate return documents, using the shipping instructions provided.

On the attached FIELD SAFETY NOTICE (RECALL/REMOVAL) - RESPONSE FORM, Page 3 of this letter, enter the quantity and return authorization information in the space provided, if you are returning products to Maquet/Getinge.

Please complete and sign the response form to acknowledge that you have received this notification. Return the completed form to Maquet/Getinge by e-mailing a scanned copy to INSERT LOCAL SSU EMAIL ADDRESS or by faxing the form to INSERT LOCAL SSU FAX NUMBER.

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

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

We apologize for any inconvenience this Field Safety Notice may cause. If you have any questions, please contact your local Maquet/Getinge representative.

Sincerely,

_____

[NAME]
[TITLE]

[DAY/MONTH/YEAR]

URGENT: FIELD SAFETY NOTICE (RECALL/REMOVAL) - RESPONSE FORM
SENSATION PLUS® 8Fr. 50cc Intra-Aortic Balloon Catheter
with Insertion Kit & STATLOCK®
Product Code/Part Number: 0684-00-0576-01
Lot Number: 3000043375
FAX BACK TO: INSERT LOCAL SSU FAX NUMBER or
EMAIL TO: INSERT LOCAL SSU EMAIL ADDRESS

DISTRIBUTION DATES: December 30, 2016 – February 23, 2017

FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

If you do not have any affected product, please check the box: ☐

Please provide required information and signature below and return this form to Maquet/Getinge even if you do not have affected product.

If you have any affected product, please contact your local Maquet/Getinge representative to request return authorization and shipping instructions. Your local Maquet/Getinge representative can be reached at INSERT LOCAL SSU EMAIL ADDRESS or INSERT LOCAL SSU PHONE NUMBER.

Provide quantity of product being returned: _____
Enter return authorization information: _____

Please acknowledge that you have read and understand the [DAY/MONTH/YEAR] Medical Device Recall (Removal) Notice Letter for the SENSATION PLUS 8F, 50cc, IAB Catheter Kits. Please ensure that all users of the SENSATION PLUS 8F, 50cc, IAB Catheter Kits at this facility have been notified accordingly.

ACKNOWLEDGMENT (Provide required information and signature below.):

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

Return the completed form by FAX to INSERT LOCAL SSU FAX NUMBER or by EMAIL to INSERT LOCAL SSU EMAIL ADDRESS