June 7, 2019 via [INSERT METHOD]

URGENT FIELD SAFETY NOTICE
EXPANDED MEDICAL DEVICE REMOVAL
AXIUS Blower/Mister

Product Code/REF Number:	**CB-1000**
Affected Lot Numbers:	**96255605, 96255607, 96255608, 96255609, 96255611**
Expanded Affected Lot Numbers:	**96255614, 96255615, 96255616, 96255617, 96255618, 96255619, 96255620, 96255621, 96255622, 96255623**
Distribution Dates:	**September 10, 2018 to March 12, 2019**

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL AXIUS BLOWER MISTER USERS WITHIN YOUR HOSPITAL / FACILITY.

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

Dear Risk Manager,

On January 24, 2019 Maquet/Getinge issued an Urgent Medical Device Recall – Removal notification for a voluntary recall involving five lot numbers of the AXIUS Blower Mister. You may or may not have previously received the notification regarding the Axius Blower Mister due to failure of the device to emit carbon dioxide (CO_2) that may result in a procedural delay during off-pump coronary artery bypass (OPCAB).

Maquet/Getinge continually monitors performance of the AXIUS Blower Mister and has recently detected additional lots which may potentially be affected by the issue identified, and therefore Maquet/Getinge has expanded the scope of the recall to include these additional ten lot numbers.

The Axius Blower Mister permits both an adjustable flow of gas and a mist of saline intended to clear an anastomic site for improved visibility.

Identification of the issue:

Maquet/Getinge has received complaints for the Axius Blower Mister with some of the affected lot numbers listed above. The Axius Blower Mister was reported to have had no CO_2 flow, i.e. these devices did not output a mist, which is an indication that carbon dioxide (CO_2) did not flow through the device.

It is important to note, there have been no adverse events reported resulting in serious illness or injuries caused by the AXIUS Blower Mister issue.

Investigation by Maquet/Getinge has identified the cause to be due to a supplier manufacturing issue that may result in the affected lot numbers listed above of the AXIUS Blower Mister not to perform as intended. Maquet/Getinge is currently working with the supplier and has already implemented corrective measures.

Please stop using the affected lot numbers of the Axius Blower Mister listed above and follow the actions to be taken in this notification.

Actions to be taken:

Our records indicate that you have received the Axius Blower Mister having the lot numbers that are potentially affected by this expanded recall. Please refer to the complete list of affected lots on Page 1 of this letter.

Please examine your inventory immediately to determine if you have any of the affected Axius Blower Mister with the product codes and lot numbers listed on Page 1 of this letter. If you do have affected product, please follow the instructions below.

Should you have un-used affected product you are eligible for either a replacement or credit. If you are returning a full pack of 5 each, replacement of that full pack will be issued. For returns of incomplete packs, 4 each or less, a credit will be issued. Please contact your local Maquet/Getinge office to request a return authorization (RMA) and shipping instructions to return any affected product. Pack the product to be returned with the appropriate return documents and, using the shipping instructions provided, arrange for pickup with the designated delivery service provider.

Please also enter the lot numbers, quantity and RMA number provided by your local Maquet/Getinge office in the spaces provided on the Expanded Medical Device Removal Response Form on Page 4 of this letter, if you are returning products to Maquet/Getinge.

Please complete and sign the attached EXPANDED MEDICAL DEVICE REMOVAL RESPONSE FORM (page 4) to acknowledge that you have received this notification. Return the completed form to your local Maquet/Getinge office.

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 recall may cause. If you have any questions, please contact your local Maquet/Getinge representative or office.

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

Sincerely,

Allison Jean Kaplan
Specialist II, Regulatory Affairs and Field Action Compliance
USA Shared Services
GETINGE
45 Barbour Pond Drive
Wayne, NJ 07470 USA

June 7, 2019

EXPANDED MEDICAL DEVICE REMOVAL RESPONSE FORM

AXIUS Blower-Mister

PRODUCT CATALOG NUMBER	**CB-1000**
AFFECTED LOT NUMBERS	**96255605, 96255607, 96255608, 96255609, 96255611, 96255614, 96255615, 96255616, 96255617, 96255618, 96255619, 96255620, 96255621, 96255622, 96255623**
MANUFACTURING DATES	**September 10, 2018 to March 12, 2019**

ADD ACCOUNT#
[FACILITY NAME
SHIP TO ADDRESS
CITY, COUNTRY, POST CODE]

If all affected product has been used or consumed please check this 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 un-used affected product for return, please indicate the information required in the table below. Please contact your local Maquet/Getinge office to request return authorization (RMA #) and shipping instructions.

Affected Lot Number:	Quantity Being Returned:	Getinge RMA #:

ACKNOWLEDGMENT (Please provide required information and signature below.):
By signing this form, I acknowledge that I have read and understand this Urgent Field Safety Notice – Expanded Medical Device Removal for the AXIUS Blower Mister. I ensure that all users of the AXIUS Blower Mister at this facility have been notified accordingly.

Signature:_____ **Date:**_____

Name:_____ **Phone:**_____

Title:_____ **Department:**_____

Hospital Name:_____

Address, City and State: _____

Please return the completed form to your local Maquet/ Getinge office

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