GETINGE

[Month DD, 2019] **Via(INSERT METHOD)**

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE REMOVAL
MAQUET 7Fr., 7.5Fr. and 8Fr. REINFORCED INTRODUCER SETS

Product Code/REF Number:	**0684-00-0403-05 (7.5Fr)**		**0684-00-0403-06 (7Fr.),**	**0684-00-0403-10 (8Fr)**
Affected Lot Numbers:	3000040290	3000086802	3000051658	3000079612
	3000031711	3000079613	TLT	3000043101
	3000019781	3000053099	3000079614	3000036631
	3000014728	3000043100		3000015016
	TTQ			TTP
Distribution Dates:	November 8, 2014 to September 18, 2019			

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL USERS OF REINFORCED INTRODUCER SETS FOR MAQUET 7 Fr., 7.5 Fr. AND 8 Fr. INTRA-AORTIC BALLOON (IAB) WITHIN YOUR HOSPITAL OR FACILITY.

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

Dear Risk Manager,

Datascope / Maquet Getinge is initiating a voluntary Medical Device Recall – Removal of the Reinforced Introducer Sets for Maquet 7 Fr., 7.5 Fr.and 8 Fr. IAB (Intra Aortic Balloon) due to a potential breach in the Mylar side (clear plastic) of the pouch, which could compromise device sterility.

Identification of the issue:

During the execution of a remediation protocol for re-verification of packaging, Datascope / Maquet Getinge found a small slit on the Mylar side (clear plastic) of the pouch of one device. Imprints of the sharp corners of the polystyrene strip used in packaging were observed around the slit, which likely caused the breach in the pouch compromising the sterility of the device.

Risk to Health

Adequate packaging and packaging materials are essential to help preserve the sterility of medical devices. Improperly sterilized medical devices may pose a serious risk of patient infection,

including pyrogenic reaction, inflammatory response, and the possibility of a deadly infection. The probability of serious injury or illness occurring as a result of this potential issue is unlikely, however, likelihood is greater for immunocompromised patients.

To date, Datascope / Maquet Getinge has not received any complaints, nor have any adverse events been reported resulting in serious illness or injuries caused by the Reinforced Introducer Set for Maquet 7 Fr., 7.5 Fr. and 8 Fr. IABs (Intra Aortic Balloon) regarding this potential issue.

Actions to be taken:

Our records indicate that you have received an affected product related to this recall listed in the table on pages 1 and 4. Please follow the instructions below for the return of the product to the manufacturer.

Should you have any unused and unexpired affected Reinforced Introducer Sets, you are eligible for a credit.

- 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.
- Please contact your local Datascope / 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 Datascope / Maquet Getinge office in the spaces provided on the E Medical Device Removal Response Form on Page 4 of this letter, if you are returning products to Maquet /Datascope /Getinge.
- Please complete and sign the attached MEDICAL DEVICE REMOVAL RESPONSE FORM (page 4) to acknowledge that you have received this notification. Return the completed form to your local Datascope / 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 Datascope / 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,

_____

Rachana Patel
Specialist I, Regulatory Affairs and Field Action Compliance
USA Shared Services
GETINGE
45 Barbour Pond Drive
Wayne, NJ 07470 USA

[Month DD, YYYY]

MEDICAL DEVICE REMOVAL
RESPONSE FORM
MAQUET 7Fr., 7.5Fr and 8Fr REINFORCED INTRODUCER SETS

Product Code/REF Number:	**0684-00-0403-05 (7.5Fr)**		**0684-00-0403-06 (7Fr.),**	**0684-00-0403-10 (8Fr)**
Affected Lot Numbers:	3000040290	3000086802	3000051658	3000079612
	3000031711	3000079613	TLT	3000043101
	3000019781	3000053099	3000079614	3000036631
	3000014728	3000043100		3000015016
	TTQ			TTP
Distribution Dates:	November 8, 2014 to September 18, 2019			

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

If all affected product has been used or consumed, please check this box: ☐
Please, complete this form and return it to Getinge even if you do not have any 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 Datascope / Maquet Getinge office to request return authorization (RMA #) and shipping instructions.

Affected Lot Number and QTY Is Being Returned for Each Lot			**Getinge Returned RMA #:**

ACKNOWLEDGMENT (Please provide required information and signature below.):
By signing this form, I acknowledge that I have read and understood this Medical Device Recall - Removal Notice for the all affected product on page 1 and 4. I ensure that all users of the Reinforced Introducer Set for Maquet 7 Fr., 7.5 Fr. and 8 Fr. IABs (Intra Aortic Balloon) at this facility have been notified accordingly.

Signature/Date:_____ **Name:**_____

Hospital Name:_____ **Department:**_____

Title:_____ **Address, City and State:** _____

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