May 9, 2016

URGENT MEDICAL DEVICE FIELD CORRECTION
STATLOCK® IAB STABILIZATION DEVICE INSTRUCTIONS FOR USE

AFFECTED PART / PART NUMBER	PRODUCTS WHERE AFFECTED PART WAS USED	AFFECTED LOT NUMBERS
STATLOCK® IAB Stabilization Device Instructions for Use / Maquet Part Number 0065-00-0704	MEGA® 7.5Fr. 30cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0294-01)	All lot numbers from 3000001484 to 3000024495
	MEGA® 7.5Fr. 30cc Intra-Aortic Balloon Catheter with Insertion Kit, STATLOCK® & APA (PN 0684-00-0294-02)	
	MEGA® 7.5Fr. 40cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0295-01)	
	MEGA® 7.5Fr. 40cc Intra-Aortic Balloon Catheter with Insertion Kit, STATLOCK® & APA (PN 0684-00-0295-02)	
	MEGA® 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0296-01)	
	MEGA® 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit, STATLOCK® & APA (PN 0684-00-0296-02)	
	SENSATION PLUS® 7.5Fr. 40cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0568-01)	
	SENSATION PLUS® 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit (with Pressure Tubes) & STATLOCK® (no stylet wires) (PN 0684-00-0576-01)	

DISTRIBUTION DATES: December 5, 2014 to February 17, 2016

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

Dear Valued Customer,

The STATLOCK® IAB Stabilization Device, which is included in IAB catheter kits for MEGA® and SENSATION PLUS®, offers needle-free securement for intra-aortic balloon (IAB) catheters. Custom-engineered to fit Maquet's catheters, STATLOCK secures both the proximal and distal "suture" pads without the dangers of accidental needle stick or suture wound complications.

In the MEGA and SENSATION PLUS IAB Catheter Kits that were listed in the table on page 1, two STATLOCK Stabilization Devices for IAB are included in each of the catheter kits.

Identification of the issue with the STATLOCK IFU:

It was discovered during post-quarantine packaging on February 16, 2016 that the IFU for the STATLOCK Sheath Stabilization Device for Percutaneous Sheath Introducers (see Illustration 1, STATLOCK for PSI IFU on this page) was erroneously packaged with the MEGA and SENSATION PLUS IAB Catheter Kits, instead of the IFU for the STATLOCK Catheter Stabilization Device for IAB Catheters (see Illustration 2, STATLOCK for IAB IFU on this page).

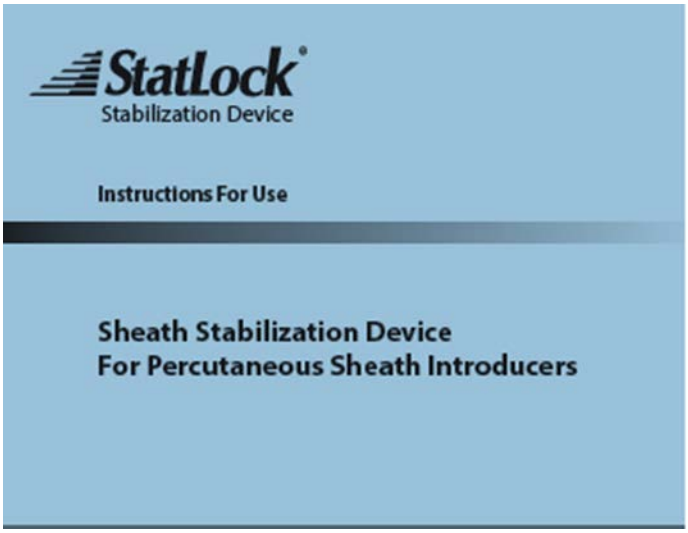

Illustration 1 - STATLOCK for PSI IFU (top of cover page)

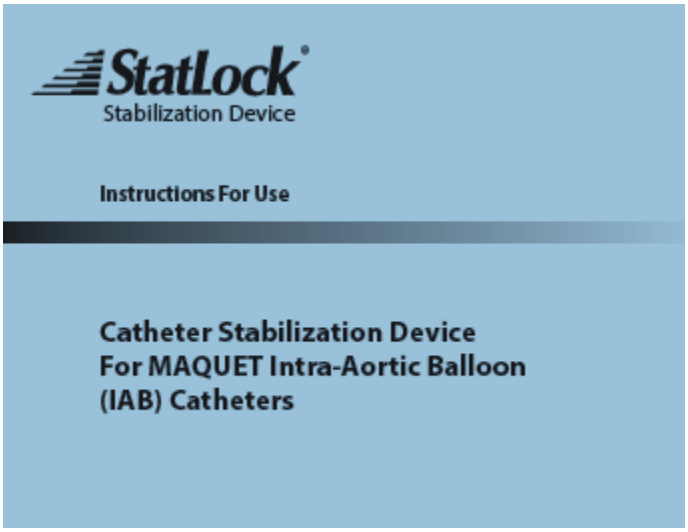

Illustration 2 - STATLOCK for IAB IFU (top of cover page)

It is important to note that the IFU for the STATLOCK for PSI references ties as part of the securing mechanism. However, there are no ties physically located in the STATLOCK for IAB which are included in the MEGA and SENSATION PLUS IAB Catheter Kits.

To date, there have been no reports of customer complaints that may be attributable to the STATLOCK IFU discrepancy.

Actions to be taken by MEGA and SENSATION PLUS IAB Catheter users:
Please check if any of the MEGA and SENSATION PLUS IAB Catheter Kits in your inventory was delivered within the distribution dates indicated in the table on page 1 and is affected by the field action. For any of the IAB catheter kits in your facility packaged with the incorrect STATLOCK for PSI IFU (see Illustration 1), prior to use remove the IFU from the package and dispose of it properly.

The replacement STATLOCK for IAB IFU will be available by the following options:

1) By visiting the Maquet website: www.Maquet.com/statlockIFU.

2) By scanning the QR code below using a mobile device equipped with a QR Reader application.

3) By contacting your local Maquet representative.

URGENT: Please complete the attached Field Correction Response Form on page 4 to acknowledge that you have received this recall notification and indicate that you have completed the steps outlined in this letter. Please return the completed form to MAQUET.

We apologize for any inconvenience this field correction may have caused.

Sincerely,

[redacted]

Regulatory Affairs and Field Action Compliance
Getinge Group
45 Barbour Pond Drive
Wayne, New Jersey 07470

May 9, 2016

MEDICAL DEVICE FIELD CORRECTION RESPONSE FORM
STATLOCK® IAB STABILIZATION DEVICE INSTRUCTIONS FOR USE
RETURN BY FAX OR EMAIL TO MAQUET

AFFECTED PART / PART NUMBER	PRODUCTS WHERE AFFECTED PART WAS USED	AFFECTED LOT NUMBERS
STATLOCK® IAB Stabilization Device Instructions for Use / Maquet Part Number 0065-00-0704	MEGA® 7.5Fr. 30cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0294-01)	All lot numbers from 3000001484 to 3000024495
	MEGA® 7.5Fr. 30cc Intra-Aortic Balloon Catheter with Insertion Kit, STATLOCK® & APA (PN 0684-00-0294-02)	
	MEGA® 7.5Fr. 40cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0295-01)	
	MEGA® 7.5Fr. 40cc Intra-Aortic Balloon Catheter with Insertion Kit, STATLOCK® & APA (PN 0684-00-0295-02)	
	MEGA® 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0296-01)	
	MEGA® 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit, STATLOCK® & APA (PN 0684-00-0296-02)	
	SENSATION PLUS® 7.5Fr. 40cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0568-01)	
	SENSATION PLUS® 8Fr. 50cc Intra-Aortic Balloon Catheter with Insertion Kit & STATLOCK® (PN 0684-00-0576-01)	

DISTRIBUTION DATES: December 5, 2014 to February 17, 2016

I acknowledge that I have read and understand the May 9, 2016 Medical Device Field Correction Letter for the MEGA and SENSATION PLUS IAB Catheter Kits. I confirm that all users of the MEGA and SENSATION PLUS IAB Catheter Kits at this facility have been notified accordingly.

I confirm that the incorrect IFU has been removed from the catheter kit package and disposed of properly. The correct IFU was obtained from Maquet (website/customer support).

Facility Representative Information:

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and Country:_____