19 December 2014

PRODUCT RECALL
MEDICAL DEVICE FIELD CORRECTION

NON-STERILE, NON-PATIENT USE DEMONSTRATION UNITS:

- **DEMONSTRATION SENSATION 7 Fr. 34cc and 40cc Intra-Aortic Balloon Catheter (IABC)**
- **DEMONSTRATION SENSATION PLUS 7.5 Fr. 40cc and 8 Fr. 50cc IABC**

USED FOR NON-CLINICAL DEMONSTRATION WITH THE FOLLOWING PRODUCTS:

- **CARDIOSAVE® Intra-Aortic Balloon Pump (IABP)**
- **CS300™ IABP (Also included are IABPs upgraded with a fiber-optic module)**

DISTRIBUTION DATES:

- **NON-STERILE, NON-PATIENT USE, DEMONSTRATION SENSATION & SENSATION PLUS IABC Units: October 2011- present**
- **CARDIOSAVE & CS300 IABPs: January 2007 - present**

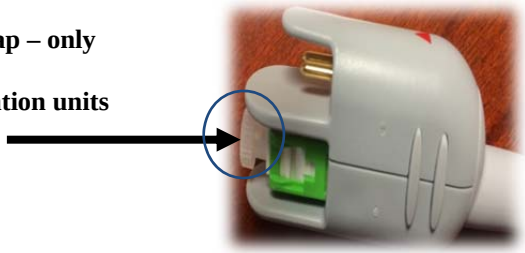
PLEASE FORWARD THIS INFORMATION TO ALL POTENTIAL INTRA-AORTIC BALLOON PUMP (IABP) USERS WITHIN YOUR INSTITUTION

Dear Risk Manager,

MAQUET makes available to our customers, a **non-sterile, non-patient use, demonstration** fiber-optic Intra-Aortic Balloon Catheter (IABC) for training purposes.

The purpose of this communication is to inform you that during the manufacture of our **non-sterile, non-patient use, demonstration** fiber-optic SENSATION and SENSATION PLUS IABCs, there is a protective Ferrule Cap (illustrated below) placed in the fiber-optic connection, which protects the optical fiber during manufacturing.

Ferrule Cap – only present on demonstration units



Identification of Issue:
During manufacturing of the sterile, for patient-use, SENSATION and SENSATION PLUS IABC products, the Ferrule Cap is removed from the fiber-optic connection at the time of final packaging.

We have become aware that during the packaging of some **non-sterile, non-patient use, demonstration,** fiber-optic SENSATION and SENSATION PLUS IABC units, the Ferrule Cap was not removed. If the fiber-optic connector on an affected **non-sterile, non-patient use, demonstration** unit is inserted into patient-use MAQUET CS300, CARDIOSAVE Intra-Aortic Balloon Pump (IABP) or IABPs upgraded with a fiber-optic module, the cap may become dislodged and remain in the fiber-optic receptacle of the pump.

The presence of a Ferrule Cap in the IABP fiber-optic receptacle will prevent insertion of a subsequent fiber-optic IABC. If this situation were to occur, an external transducer can be used to measure pressure.

NOTE: The sterile, for patient-use, SENSATION and SENSATION PLUS IABC products for commercial distribution are NOT affected by this issue.

Actions to be taken by IABP users:
We are asking that you inspect all your **non-sterile, non-patient use, demonstration** fiber-optic IABC inventory for the affected units. Please look for the **non-sterile, non-patient use, demonstration** fiber-optic IABC units in your training and education areas and **not** in your sterile product inventory.

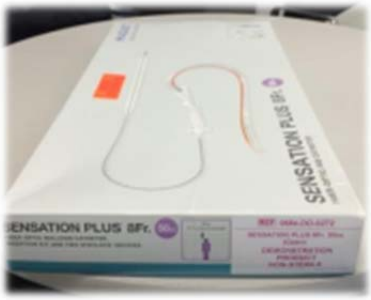
The **non-sterile, non-patient use, demonstration** part numbers listed below are only used by MAQUET and do not represent catalog numbers used by customers for purchasing purposes. There are two part numbers associated with each demonstration IABC. One part number is located on the outside of the demonstration box and a separate part number is located on the inner pouch which contains the non-sterile, non-patient use, demonstration IABC (see illustration below).

Both part numbers are included in the table below in the event that either only the demonstration box or only the inner pouch is available to inspect.

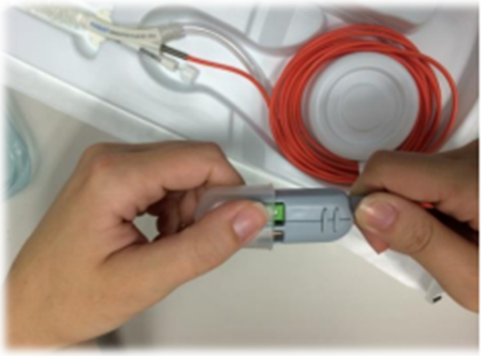
Sensation 7 Fr. 34cc IABC Demonstration Unit	**Sensation 7 Fr. 40cc IABC Demonstration Unit**	**Sensation Plus 7.5 Fr. 40cc IABC Demonstration Unit**	**Sensation Plus 8 Fr. 50cc IABC Demonstration Unit**	**Sensation Plus 8 Fr. 50cc IABC Demonstration Unit**
Inner Pouch	Inner Pouch	Inner Pouch	Inner Pouch	Inner Pouch
0684-DC-0433	0684-DC-0434	0684-DC-0567	0684-DC-0575	0684-DC-0271
0684-DO-0433	0684-DO-0434	0684-DO-0567	0684-DO-0575	0684-DO-0271
Demonstration Box	Demonstration Box	Demonstration Box	Demonstration Box	Demonstration Box
0684-DC-0469	0684-DC-0470	0684-DC-0568	0684-DC-0576	0684-DC-0272
0684-DO-0469	0684-DO-0470	0684-DO-0568	0684-DO-0576	0684-DO-0272

If you are in possession of any of the **non-sterile, non-patient use, demonstration** fiber-optic IABCs, we ask that you take the following steps:

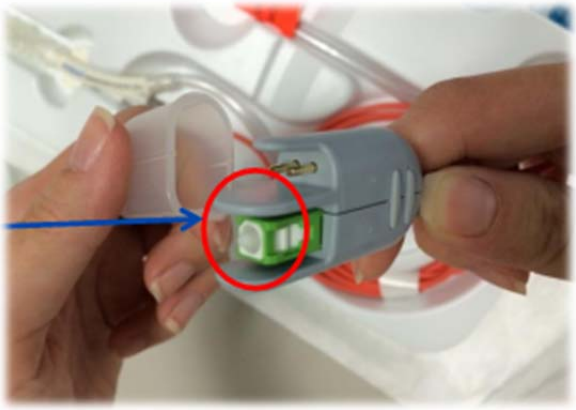
1. Remove the non-sterile, non-patient use, demonstration only fiber-optic IABC from the inner pouch.



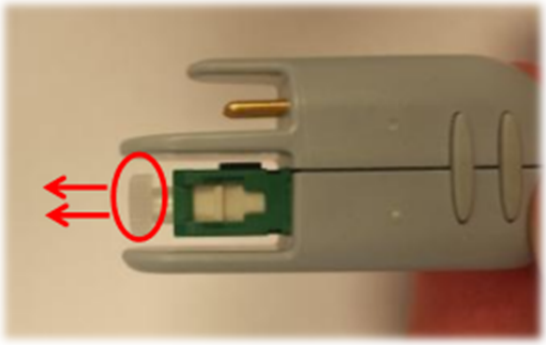
2. Remove the protective cap from the fiber-optic connector.



3. Visually inspect the fiber-optic connection and determine if the Ferrule Cap is present. If the cap is **not** present, go to step 5.



4. If the Ferrule Cap is present, remove the Ferrule Cap from the fiber-optic connector by gently pulling the cap straight *out of the fiber-optic connection* and discard.



5. Place the protective cap back on the connector and store the non-sterile, non-patient use, demonstration IABC back in the package. The non-sterile, non-patient fiber-optic IABC is now ready for your next demonstration.

In order to ensure that the Ferrule Cap has not become lodged in the fiber-optic receptacle of the IABP, the following steps must be completed.

Inspecting the CARDIOSAVE and CS300 IABPs for presence of the Ferrule Cap.

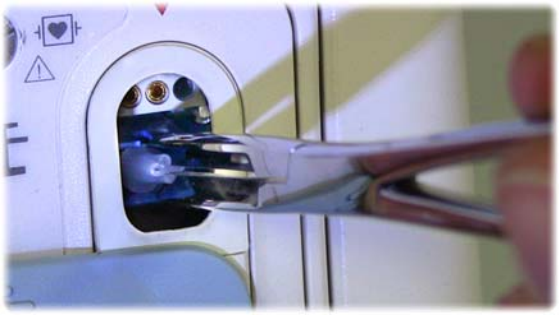
1. Open the door that covers the fiber-optic connector and visually inspect the connector and determine if the Ferrule Cap is present. If the cap is not present no further action is required.

Ferrule Cap present

Ferrule Cap not present

2. If the Ferrule Cap is present, carefully grab the Ferrule Cap with a pair of hemostats or other locking forceps.

3. Carefully pull the Ferrule Cap straight out of the fiber-optic connector.



Note: There is no risk of any harm to the user when removing the Ferrule Cap out of the fiber-optic connector on the IABP.

URGENT: Please complete the attached Field Correction Response Form on page 6 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 your local Maquet office.

We apologize for any inconvenience this may cause. For customers with technical questions please contact the Technical Support Department at your local Maquet office.

Sincerely,

Karen LeFevere

Karen LeFevere
Director of Regulatory Affairs and Field Action Compliance
MAQUET
45 Barbour Pond Drive
Wayne, New Jersey 07470

19 December 2014

Field Correction Response Form

NON-STERILE, NON-PATIENT USE DEMONSTRATION UNITS:

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USED FOR NON-CLINICAL DEMONSTRATION WITH THE FOLLOWING PRODUCTS:

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- **CS300™ IABP (Also included are IABPs upgraded with a fiber-optic module)**

I confirm that my institution has received and reviewed the 19 December 2014 Field Correction Letter and has completed the following steps outlined in this letter:

- Inspection **of non-sterile, non-patient use, demonstration** SENSATION and SENSATION PLUS IABC units for the presence of Ferrule Cap.
- Inspection of the CARDIOSAVE and CS300 IABPs for presence of the Ferrule Cap in the fiber-optic connector and removal of the cap if present.

Please complete this document and fax or email the completed document to your local Maquet office

Institution Name: _____

Institution Address: _____

Country: _____

Signature: _____ **Date:**_____

Print Name: _____

Title: _____