MAQUET
GETINGE GROUP

July 7, 2014

SUPPLEMENT TO MARCH 21, 2014 RECALL NOTICE

PRODUCT RECALL
MEDICAL DEVICE FIELD CORRECTION

PRODUCT: MAQUET/Datascope System 98/98XT, CS100®/CS100i and CS300™ Intra-Aortic Balloon Pumps (IABP)

IABP	Model Numbers	
System 98	0998-00-0446-xx	0998-UC-0446-xx
System 98XT	0998-00-0479-xx	0998-UC-0479-xx
CS100i	0998-UC-0446Hxx	0998-UC-0479Hxx
CS100	0998-00-3013-xx	0998-UC-3013-xx
CS300	0998-00-3023-xx	0998-UC-3023-xx

Product Distribution Dates: January 17, 2003 – June 30, 2011

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

Dear Risk Manager,

On March 21, 2014, MAQUET notified you of our voluntary recall of specific Intra Aortic Balloon Pumps (IABP) manufactured by Datascope Corp between 2003 and 2011. Since the time of the announcement, MAQUET's Field Action Compliance Team has been monitoring the feedback we have received from our customers. This has prompted us to provide additional information regarding the recall and review actions to be taken by the IABP users during the time they are awaiting service of their affected IABP fan assembly. Therefore, the purpose of this letter is to supplement our March 21st Product Recall notice and provide you the most up-to-date information available.

Product Affected:

The Datascope Corp products included in the recall notice are the following specified systems that were manufactured between January 1, 2003 and June 30, 2011:

- 98/98XT
- CS100/CS100i
- CS300

These systems may contain an affected fan assembly that was inserted at the time of manufacturing or inserted during IABP maintenance.

Identification of Problem:

The fan assembly for specific System 98/98XT, CS100/CS100i and CS300 IABPs could potentially contain a misshapen retaining ring. This retaining ring could disengage within the fan assembly, causing the fan to stop rotating, which causes the power supply to overheat and the IABP to shut down without any visual or audible warning.

MAQUET is diligently working on scheduling an expedited replacement of the fan assembly with our customers.

Please note that units at your facility may have already been serviced for this field correction. However, we are notifying all customers originally affected with this supplemental information that Intra-Aortic Balloon Pumps involved in this field action that have not yet been serviced can remain in use if the IABP users take the following actions highlighted in this document:

Actions to be taken by IABP users:

Pursuant to the WARNINGS section of our Intra-Aortic Balloon Pump Operating/User Instructions, clinicians are instructed not to leave the patient unattended during Intra-Aortic Balloon Pump therapy.

In most cases, because patients in whom IABP therapy is being utilized are under close nursing supervision or in coronary/intensive care units, the likelihood that a sudden shutdown going unnoticed for more than a few minutes is very unlikely. In addition, most if not all, patients receiving IABP therapy have their arterial pressures monitored and these monitors are automatically set to alarm.

An additional hazard associated with a sudden shutdown is related to the static condition (no inflating or deflating) of the balloon during the interruption of therapy. It is important to note the following WARNING in the Intra-Aortic Balloon Pump Operating Instructions:

WARNING: The patient balloon should not remain inactive in the patient (i.e., no inflating or deflating) for more than 30 minutes, due to the potential for thrombus formation.

The Intra-Aortic Balloon Instructions for Use reiterates that a catheter should not remain inactive for more than 30 minutes. The following is taken directly from the Intra-Aortic Balloon (IAB) Instructions for Use, Manually Inflating and Deflating a Catheter.

MANUALLY INFLATING AND DEFLATING THE IAB CATHETER

PRECAUTION

- The IAB catheter should not remain inactive (i.e., not inflating and deflating) for more than 30 minutes because of the potential for thrombus formation.

To keep the IAB catheter active in the event of pump failure, manually inflate and deflate the IAB as follows:

WARNING

- Do not perform manual inflation of the IAB with the catheter extender tubing attached to the IAB catheter.

1. Detach the catheter extender from the IAB catheter's male luer fitting.
2. Attach the supplied three-way stopcock and syringe to the IAB catheter's male luer fitting.

WARNING

- NEVER INJECT AIR INTO THE INNER LUMEN (female luer hub).

3. Aspirate to assure blood is not returned through the extracorporeal tubing.

WARNING

- If you aspirate blood from the male luer fitting of the extracorporeal

tubing, immediate removal of the IAB catheter is indicated as damage may have occurred to the balloon membrane during insertion.
4. Inflate the IAB with 40cc air or helium and immediately aspirate.
Repeat every 5 minutes while the IAB is inactive.
5. Remove the three-way stopcock and syringe and reattach the IAB catheter's male luer fitting to the catheter extender and resume pumping.

In all cases where an affected pump is being used to support a patient, you should ensure that you have a back-up IABP unit immediately available. Should a sudden IABP shut-down occur, the following actions taken by the IABP user may differ depending on whether the patient would tolerate having IABP therapy discontinued versus a patient who is dependent on IABP:

1) **Patients that can tolerate having IABP therapy discontinued**
In addition to the instructions above regarding manually inflating and deflating a catheter for reduction of thrombus formation, thrombus formation can be further decreased by the concomitant use of anticoagulation therapy that patients on IABP therapy may be receiving. For patients who remain hemodynamically stable with or without the use of inotropic agents, qualified medical personnel can consider safe removal of the balloon catheter.

2) **Patients who are dependent on IABP therapy for hemodynamic support**
In the event of a pump failure, patients should be immediately transferred to a back-up IABP. Affected IABP's that have not been serviced **should not be utilized for patient transport via emergency medical services to another facility if a back-up unit is not available.**

If you do not have a back-up Intra-Aortic Balloon Pump, you may contact your Service Representative to arrange for a loaner Intra-Aortic Balloon Pump until your affected unit is serviced.

We apologize for any inconvenience this may cause. For customers with technical questions, please contact our Technical Support Department.

Sincerely,

Karen LeFevere

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Director of Regulatory Affairs and Field Action Compliance
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