

FIELD SAFETY NOTICE
2013-06-20

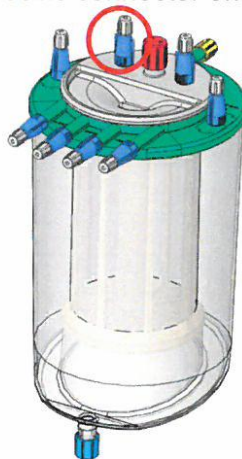
PLEASE FORWARD THIS INFORMATION TO ALL USERS AND BIOMEDICAL STAFF CONCERNED.

Subject **Cracks on Mounted Blue Reducer Cap on Top Cover on HC Reservoir**

Products affected: **Specific lots of all types of MAQUET HC Reservoirs and Tubing Sets including HC Reservoirs (see attached list for detail on lot numbers)**

Dear valued Customer,

It has come to the attention of MAQUET CardioPulmonary AG that specific lots of our Cardiotomy (HC) Reservoirs (see attached list of affected products) may potentially have cracked blue reducer caps on a specific connector on the reservoir cover.



Patient Risk:

No customer complaint has been reported to date. Internal testing has shown that the likelihood for the crack on the blue connector to affect the reservoir seal is extremely low. During set up of the reservoir, it is required within the Instructions for Use to check the integrity of the product (G-028, Item 70 000 4203). The cracked blue reducer cap would be detected at that time.

MAQUET'S Corrective Actions:

According to our records, you have received a MAQUET Cardiotomy reservoirs from the effected lots in your inventory. Therefore, we recommend that *prior to use*, you confirm the tightness of the Cardiotomy reservoir by checking the blue reducer cap marked on the drawing above for any cracks.

If the blue reducer cap has no visible cracks, use the device in accordance with the Instructions for Use. If the blue reducer cap appears to be cracked, please replace it with a single packed reducer which will be sent to your facility. The order number for the sterile blue reducer caps is 701046452.

Please complete and return the enclosed Letter of Acknowledgement latest July 26, 2013 to your local MAQUET representative to acknowledge receipt and understanding of this notification.

We apologize for any inconveniences this may cause. If you have questions or require additional information, please contact your local MAQUET representative or MAQUET Customer Service.

Yours sincerely
MAQUET Cardiopulmonary AG



Dr. Wolfgang Rencken
President/CEO



Arne Briest
Director
Quality Assurance

Attachment:
Letter of Acknowledgement Customer
List of affected products