Urgent

Field Safety Notice

MAQUET
GETINGE GROUP

Please forward this information to all users and biomedical staff concerned.

Venous Bubble Trap VBT 160 and Custom Tubing Sets containing the Venous Bubble Trap VBT 160

FSCA tracking number: 2014-08-06

Type of action: product removal

August 6, 2014

ATTENTION: ALL USERS OF THE BELOW MENTIONED PRODUCTS

Details on affected devices:

The following list of products are affected by this Field Safety Notice

- **Venous Bubble Trap; VBT 160 (Sterile Single Product)**
- **Venous Bubble Trap; VBT 160 U (Unsterile Single Product)**
- **Custom Tubing Sets containing the VBT 160; BE/BEQ-VBT (BIOLINE Coating)**
- **Custom Tubing Sets containing the VBT 160; BO-VBT (SOFTLINE Coating)**

The affected products and lot numbers are included in that attached list.

Description of the problem:

We have confirmed complaints from several customers that reported that during use, the VBT draws air into the system. We have confirmed the customer reports with our internal investigations and determined that a manufacturing defect in the production of the bubble trap is responsible for the intrusion of air into the system during use.

As the main function of the VBT is to remove air from the system during use, we consider this defect to propose an unacceptable increased level of risk for the patient. If unaddressed, this could result in air entering the circulatory system of the patient and causing severe injury and the possibility of death.

Maquet Cardiopulmonary has received no reports that the defect present in the VBT has resulted in a serious injury or death to any patient.

Advice on action to be taken by the user:

You are receiving this communication because our distribution records indicate that you have received one or more of the affected products/lot numbers. We are requesting that you immediately take the following action:

For the Unsterile Product:

- Product used for demonstration or non-clinical teaching purposes can continue to be used with the knowledge of this product defect.
- These products **MUST NOT** be sterilized for use in any clinical means.

For Sterile Single Products:

- Please quarantine and stop use of all affected products
- Please indicate on the enclosed acknowledgment the quantity of affected products that you have in your inventory.
- If you indicate the quantity of single sterile product in your inventory, we will automatically send you replacement Sterile Product from another manufacture.
- Contact your local Maquet Representative for instructions on return of the defective products

For Custom Tubing Sets that contain a Maquet VBT 160:

- Please quarantine and stop use of the affected products.
- Contact your local Maquet Representative for instructions concerning the return of the affected products.

There is the potential that this action results in serious difficulty regarding medically necessary procedures. If this is the situation at your institution, you may declare the medical necessity and continue to use the Custom Tubing Sets containing the VBT under the following circumstances:

- You acknowledge this communication and provide the return acknowledgement indicating that this causes a medical necessity in your facility.
- You agree to physically remove the affected VBT from your tubing set by cutting the VBT out of the set prior to use.
- Once the VBT is removed from the Tubing Set, you need to incorporate additional controls or components that provide an equivalent level of patient protection. This can be done with a replacement VBT (from another source) or other components depending on your clinical use of the custom tubing set.

If you require a replacement VBT for use, Maquet Cardiopulmonary will provide you with a sterile VBT (from Terumo) at your request. Please indicate on your letter of acknowledgement how many replacement VBTs you require.

Instructions for removing the Maquet VBT and for the incorporation of the replacement VBT will be provided with the replacement VBT shipment.

Until this manufacturing defect is resolved, Maquet will no longer be building STubing sets with the Maquet Venous Bubble Trap. Instead we will be providing a sterile Venous Bubble Trap from another manufacturer in addition to the Custom Tubing set (that no longer has a Maquet VBT included.

Once the issue is resolved, we will return to the manufacture of Custom Tubing Sets containing a Maquet VBT 160.

Transmission of the Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Maquet representative.

Sincerely,

Hartmut Schmidt
President and CEO

Michael Campbell
Medical Product Safety Officer
Director of Regulatory Affairs

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