SH2017-02 "PLEGIOX Cardioplegia Heat Exchanger"

28.08.2017

Dear customer,

In response to the Maquet Field Safety Correctiv Action "FSCA 2017-07-17" we hereby inform you on recommended actions concerning one component of our medical devices. A situation may arise with the PLEGIOX Cardioplegia Heat Exchanger H05134, H05175 and/or H06054 within your Extracorporeal Tubing Set by HMT Medizintechnik GmbH (HMT).
In the following you get the recommendation how you can proceed with PLEGIOX Cardioplegia Heat Exchanger. Please share this information with your customers.

Risk Assessment:

Background:

The PLEGIOX heat exchanger is used to set and maintain the temperature (for given flow rates and within the given temperature range) of blood cardioplegia and / or crystalloid cardioplegia solutions during extracorporeal circulation. The PLEGIOX heat exchanger consists of two liquid circulations strictly separated from each other by a separating barrier to separate both liquids from each other and to effect thermal transfer at the same time; the design of the PLEGIOX uses hollow fibers made of polyurethane. Hollow fibers serve as barrier separating the circulating liquids while effecting thermal transfer. The fluid to be tempered flows around the outside of these fibers. De-airing is ensured by a bubble trap with a filter integrated in the upper part of the PLEGIOX. An integrated bypass stopcock enables hot-shot to be performed.

Performance:

Performance factor (PF) characterizes the heat transfer performance of a heat exchanger; PF is calculated according the following formula and is a substantial marker of efficacy:

T_{in} = Temperature at cardioplegia inlet;
T_{bo} = Temperature at blood outlet;
T_{wo} = Temperature at water outlet;
T_{wi} = Temperature at water inlet;
$PF = (T_{bo} - T_{in}) / (T_{wo} - T_{wi})$

The heat exchanger performance is dependent on the transfer coefficient of the material, wall thickness of the separating medium, surface size, and flow conditions of the liquids. Performance factor varies over rate.
At lower blood/cardioplegia flows (up to 500 ml/min), a PF of around 0.85 to 0.90 can usually be achieved by modern devices on the market. The ideal PF of 1.0 is only theoretically possible.

Clinical Institutions basically select an appropriate cardioplegia heat exchanger for their procedures based on several selection criteria. One of these is the PF versus blood/cardioplegia flow characteristic.

Stimulus:

MAQUET Cardiopulmonary GmbH (MCP) internal investigations have revealed that the specification of the Performance Factor (PF) at flow rates of 1 liter per minute is not always maintained as defined in Instruction for Use (IFU). Deviations up to minus 20% were identified during in-house testing.
Based on above, MCP Post-Marketing Vigilance Program has monitored a fluctuance in performance at high rates that decreases the maximum performance factor of the PLEGIOX from the desired predefined values given in IFU.
As a proactive action, the decision has been taken to notify PLEGIOX users and clinicians that the desirable temperature value at cardioplegic flow rates higher than 500 ml per minute may either be not achieved or not maintained during the entire intervention.
It must however be emphasized that zero adverse event has been reported in relation to this insufficiency. All relevant competent authorities have been notified in this regard.

Recommended Action:

Performance instability is linked to flow rate increase. Average cardioplegia flows are however deemed as sufficient for clinical practice, thereby ensuring a safe use and reasonable performance of the PLEGIOX up to 500 ml per minute.

Review this Field Safety Notice and the recommended Actions.

- Assure that all customers/users receive notice of this issue.
- Confirm receipt of this Field Safety Notice by emailing or faxing the attached Customer Response Form to the email address or fax number indicated on the form.
- Please follow the instruction provided in this letter prior to going on cardiopulmonary bypass.
- Please review the original FSN "2017-07-17" from Maquet that you find in the attachment.

Kind regards

28.08.17
Date, Signature

Dr. Dominik Riester
Director Quality

28.08.2017, A. Assfalg
Date, Signature

Alexander Assfalg
Medical Devices Safety Officer

Field Safety Notice WHOLESALER REPLY FORM

Affected component: H05134, H05175 and H06054 Plegiox Heat Exchanger
Reference Number: SH2017-02
Effective Date: August 28, 2017
Action: Advisory

Please complete, sign and e-mail or fax this back:
To: Alexander Assfalg, Medical Devices Safety Officer,
HMT Medizintechnik GmbH
E-Mail/Telefax: Alexander.Assfalg@hmt-ffb.de / +49 8141 4003 60

Client number	
Client (Company) Name	
City	
Country	
By completion and return of this form, I am confirming receipt, reading and acting on this Safety Notice. We have ____ end user(s) to be contacted - (indicate the number of end users to be contacted). Affected sets are summarized in Addendum I.	
Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	