Urgent!

Field Safety Notice (FSN)

MAQUET
GETINGE GROUP

26. July 2017

FSCA Number:	2017-07-17
FSCA Title:	PLEGIOX Performance Not Always Achievable at High Flow Rates
Affected Product:	PLEGIOX Cardioplegia Heat Exchanger
Unique Device Identification (UDI Code):	04037691180038, 04037691302577, 04037691229591
Affected product details:	See table below
Description of the problem:	Dear valued PLEGIOX users, <u>Background:</u> 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. <u>Performance:</u> 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;

$$PF = (T_{bo} – T_{bin}) / (T_{wo} – T_{wi})$$

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:

The scope of this FSN encompasses all MAQUET Cardiopulmonary GmbH (MCP) product sets containing Cardioplegia Heat Exchanger (PLEGIOX) that may be susceptible to performance shortage when functioning at high flow rates.

According to our vigilance system, your stock has contained products affected by this action, and may still

have. Therefore, we urge you to take this FSN into considerations for all PLEGIOX produced within a period of two years to date.

PLEGIOX users shall be informed promptly whenever further corrective actions are taken in this regard.

Advice on action to be taken by the user:

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.

Referenced documents/attachments:

- Letter of Acknowledgement

Table: List of PLEGIOX Devices

#	Material no.	Description	Affected Lot
1	70103.2522	CHX 30#PLEGIOX Heat Exchanger	Manufactured after 2015.07.31 and before 2017.07.31
2	70103.6144	BO-CHX 30#PLEGIOX Heat Exchanger	
3	70103.4981	BE-CHX 30#PLEGIOX Heat Exchanger	

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.
- Please transfer this notice to other organizations on which the action has an impact and inform your personnel.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of this action.

Your understanding is much appreciated. Thank you for your continued support as we provide you with up-to-date information on the quality of our products. 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 shall be providing this notification to the necessary Regulatory Agencies.

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

Sincerely,

Managing Director [redacted]

Safety Officer [redacted]

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