
Urgent!
Field Safety Notice (FSN)



24. April 2018

FSCA Number: FSCA-2018-03-27

FSCA Title: Arterial Cannula – broken vent plug

Affected Product: All Arterial Cannulae and Customized Tubing Packs including the 3/8" Vent plug

Affected product details: See attached list (Annex I)

Description of the problem:

Dear valued colleagues and business partners,

An Arterial Cannula used for open heart surgery is normally equipped with a vent plug, which facilitates the de-airing of the cannula.

The vent plug of our Arterial Cannula consists of sintered polyethylene, therefore the structure of the vent plug is porous and gas-permeable. After the de-airing process is completed the customer has to separate the vent plug from the cannula to connect the extracorporeal circuit.

In some rare cases it has come to our attention that the vent plug broke during the separation from the Arterial Cannula.

Corrective Action:

Return immediately the affected products to your local Maquet representative.

Advice on action to be taken by the user:

- The scope of this FSN encompasses all Maquet Cardiopulmonary GmbH (MCP) products containing the 3/8" vent plug (SAP 70000.8256)
- According to our surveillance documentation, your current stock may include products affected by this action. Therefore, this action shall encounter all MCP purchased products including this 3/8" vent plug within a period of three years for non-coated Arterial Cannulae and within a period of two years for coated Arterial Cannulae to date.
- Fill and sign the attached Letter of Acknowledgement for customer and send it back to your local Maquet representative
- Return immediately the affected products to your local Maquet representative
- Please be aware, that due to the discontinuation of the Surgical Perfusion Catheters/ Cannulae product portfolio, we can currently not provide you a

replacement.

Referenced documents/attachments:

- Annex I: List of affected products (Country/ Region-specific)
- Annex II: List of all affected products
- Letter of Acknowledgement

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.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

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,

Managing Director

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Safety Officer

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