2019-02-18

FSCA Number: FSCA-2019-02-15

FSCA Title: Pre-Bypass Filter Labelling Integrity not ensured

Affected Product: All Pre-Bypass Filters used for Customized Tubing Packs Production (Ref.No. 701021039 – 1/2 x 3/8 – without vent, 701021040 - 1/2 x 3/8 – with vent, 701031084 – 3/8 x 3/8 without vent, 701031086 – 3/8 x 3/8 – with vent)

Affected product details: See attached list of distributed affected products (Annex I)

Description of the problem:

Dear valued customers,

The Pre-Bypass Filter is a product which is supplied integrated within heart lung machine tubing sets.

Maquet Cardiopulmonary has been informed that the printed information on the front and back side of the pre-bypass filter, showed incomplete print quality.

Internal investigations have revealed that the print on the filters had already been partially removed out of the packaging or it was also detected that the printing could be removed by touching with hands. The print does not necessarily come off during transport. Even if the print is still fully intact it could be an affected device. The print may be removed when touched without any solvent used.

Maquet Cardiopulmonary has not received any complaints for this issue. There have been no reports associated to serious injuries or death due to improper or delaminating print of the pre-bypass filter.

Should you wish to use the tubing set with a pre-bypass filter showing incomplete instructions or potentially delaminating print, we kindly request you to inform all clinical staff who use the product to follow the information and instructions that are normally printed on the Pre-Bypass-Filter:

“0.2 micron filter
For priming cardiopulmonary bypass circuits
Warning: not for use with cellular blood products. Follow instructions for use. Do not reuse.”

Using the pre-bypass filter not following the warning can result in flow obstruction, a replacement of the circuit and ultimately a delay in the surgery and potential cardio-pulmonary deterioration in an emergency situation.

Furthermore all clinical staff touching the Pre-Bypass Filter should exchange their sterile gloves after removal of the Pre-Bypass Filter from the primed circuit. This will reduce the potential risk of cross-contamination of erased ink into the blood stream or the surgical field of the patient.

Corrective Action:

- All clinical staff using these products should read and follow the information and instructions that are normally printed on the Pre-Bypass Filter, listed above
- All clinical staff touching the Pre-Bypass Filter needs to exchange their sterile gloves after removal of the Pre-Bypass Filter from the primed circuit
- In case you do not want to use the entire tubing set containing a potentially affected pre-bypass filter, please return the product to your local Getinge representative

Advice on action to be taken by the user:

- The scope of this FSN encompasses all Maquet Cardiopulmonary GmbH (MCP) products listed in Annex I containing a pre-bypass filter (Ref.No. 701021039 – 1/2 x 3/8 – without vent, 701021040 - 1/2 x 3/8 – with vent, 701031084 – 3/8 x 3/8 without vent, 701031086 – 3/8 x 3/8 – with vent)
- According to our surveillance documentation, your current stock may include products affected by this action.
- Please fill and sign the attached Letter of Acknowledgement for customer and send it back to your local Getinge representative

Referenced documents/attachments:

- Annex I: List of affected distributed products
- Letter of Acknowledgement Customer

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

i.A. Timothy J. Talcott 2019-02-18
Sr. Director of Quality Improvement Programs

Safety Officer

Approved / Geprüft	Signatory:	Signature / Unterschrift
UTC 2019-02-18, 14:48:58	Nursel Boelens (Director of Regulatory Affairs)	

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected distributed products per market

2019-02-18

This Annex I is considered as a supplementary attachment to the Field Safety Notice of FSCA-2019-02-15

FSCA Number: FSCA-2019-02-15

FSCA Title: Pre-Bypass Filter Labelling Integrity not ensured

Affected Product: All Customized Tubing Sets listed in this Annex I containing a pre-bypass filter (Ref.No. 701021039 – 1/2 x 3/8 – without vent, 701021040 - 1/2 x 3/8 – with vent, 701031084 – 3/8 x 3/8 without vent, 701031086 – 3/8 x 3/8 – with vent)

Affected Timeframe: The affected products listed below have been sold in the timeframe between 2018-03-22 and 2019-02-13

List of affected distributed products

Country	Material No.	Material Description	Lot No.	Qty.
AU	701063962	HQV 46352#Pre-connected Pump Pack	92246830	60
BG	701073116	H 124300#During CPB on pump	92270056	1
CA	701072923	HQV 94500#Cabaret de pompe Chicoutimi	92267058	12
CA	701072923	HQV 94500#Cabaret de pompe Chicoutimi	92266985	24
CA	701066295	H 56111u#Heart Lung Perfusion Kit	92267589	1
CA	701068175	BEQ-HQV 46904# HL Pack With HL 20	92267194	5
CA	701063761	BO-HQV 55004#OHI Perfusion Pack	92246216	42
CA	701068177	BO-HQV 46904#HL Pack With HL 20	92247616	2
DE	701072618	BO-HQV 0612#HLM-Set 1/4"x3/8"MHH with	92269809	6
DE	701035069	HQV 1509-1#Quadrox Komplettset "offen"	92253702	2
DE	701073545	HQV 126200u#HLM Komplettset Adult	92272699	1

DE	701045092	HQV 0200-1#Quadrox Komplett - Set	92247179	7
DE	701070947	BO-HQV 112800#Quadrox Komplett-Set	92243296	83
FR	701048185	BE-HQV 21607#Pack Circulatory Circuit	92247343	12
FR	701050391	BO-HQV 7600#Quadrox-i Complete	92246075	5
FR	701045404	HQV 7404 Quadrox "I" Pack with RotaFlow	92269963	7
IT	701027377	H 51800#HL - Set	92256574	20
IT	701048826	BO-H 87200#Adult set	92253732	20
IT	701073546	H 25400u#Circuito CEC Adulto without	92272694	3
IT	701027693	HQV 29201#Circuito CEC Adulto	92247267	10
IT	701056660	BO-HQV 36203#Circuito CEC Adulto	92247769	10
IT	701027693	HQV 29201#Circuito CEC Adulto	92248188	5
NL	701068281	BE-HQV 30533#MECC System	92241815	20
NO	701072147	BE-HQV 30103-2#Adult Pack	92247666	74
NO	701018472	BE-HQV 25900#Complete Pack, closed	92269893	5
NO	701018472	BE-HQV 25900#Complete Pack, closed	92238977	100
ES	701064022	HQV 100500#Set Circulacion Extracorporea	92245486	5
SE	701073538	HQV 101702u#Adult Tubing Pack	92271450	1
CH	701070485	BO-HQV 21715#CP C.E.C. Adulto	92246442	4
CH	701070485	BO-HQV 21715#CP C.E.C. Adulto	92246443	10
TR	701065790	BE-HQV 82356#MECC System	92248477	28
UK	701053616	HQV 3900#Adult Perfusion Pack	92247360	75

UK	701053616	HQV 3900#Adult Perfusion Pack	92258289	19
UK	701026914	HQV 51100#Adult Pre-connected Pack	92244888	60
UK	701053616	HQV 3900#Adult Perfusion Pack	92244660	36
UK	701026914	HQV 51100#Adult Pre-connected Pack	92262182	20
UK	701026914	HQV 51100#Adult Pre-connected Pack	92262119	10
UK	701053616	HQV 3900#Adult Perfusion Pack	92260838	30
UK	701053616	HQV 3900#Adult Perfusion Pack	92244957	76
UK	701026914	HQV 51100#Adult Pre-connected Pack	92260823	15
UK	701026914	HQV 51100#Adult Pre-connected Pack	92244603	65
UK	701053616	HQV 3900#Adult Perfusion Pack	92242911	30

Please note: SSUs are called to actively find out whether the listed devices have been forwarded or sold into any other country. That country where the unit is currently located is also an affected country. Please send any information about forwarding and selling to other countries to: FSCA.cp@getinge.com.

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

For follow up actions, please contact us on FSCA.cp@getinge.com.

Sincerely,

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY