2018-11-12

FSCA Number: FSCA-2018-10-01

FSCA Title: Potential leakage at QUADROX-i Neonatal blood inlet connector

Affected Product:

- All variants and sets of QUADROX-i Neonatal which include the reducing screw adapter 1/4” x 3/16” (Ref.No. 70104.8593)
- All Custom Tubing Sets which contain a pre-connected reducing screw adapter 1/4” x 3/16” (Ref.No. 70104.5511) at the blood inlet connector of the QUADROX-i Neonatal Oxygenator

Affected product details: Following products are additionally affected by this FSCA:

- 70104.9158 HQV 51203 Neonatal Tubing Set
- 70106.7343 HQV 85503 Miniaturised Neonatal Pack,

Description of the problem:

Dear valued customers,

All variants and sets of QUADROX-i Neonatal Oxygenators are supplied with a separate reducing screw adapter 1/4” x 3/16”. It can be screwed onto the blood inlet and blood outlet connectors of the QUADROX-i Neonatal Oxygenator to reduce the port to size 3/16”.

Customized Tubing Sets that contain the QUADROX-i Neonatal Oxygenators in combination with a pre-connected reducing screw adapter 1/4” x 3/16” on the blood inlet connector of the oxygenator are also covered by this updated FSN.

Maquet Cardiopulmonary has received complaints in relation to leakage at the QUADROX-i Neonatal blood inlet connector.

Internal investigations have revealed that the leakage only occurs if the enclosed reducing screw adapter 1/4” x 3/16” is screwed onto the blood inlet connector of the QUADROX-i Neonatal Oxygenator.

The leakage occurs due to a non-conforming blood inlet connector that, in conjunction with the use of the screw reducing adapter 1/4” x 3/16”, does not result in a tight connector-adapter connection. The combination of the reducing screw adapter 1/4” x 3/16” with the blood outlet connector or the use of the blood inlet connector directly to tubing does not exhibit any leakage.

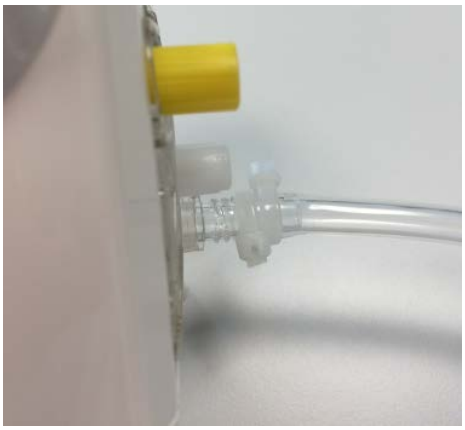
Using the QUADROX-i Neonatal Oxygenator in conjunction with the reducing screw adapter 1/4” x 3/16” can result in clinically relevant loss of prime before patient connection or blood loss during patient connection. Clinicians need to judge whether or not to replace the device, but device replacement is the mitigation of choice if leakage exceeds the clinically acceptable limit. Risks associated with device replacement during patient connection include but are not limited to interruption of cardiopulmonary bypass, blood loss and infection.

Maquet Cardiopulmonary thus recommends not using the adapter at the blood inlet connector of the QUADROX-i Neonatal Oxygenator. We also recommend to return any Customized Tubing Sets with a screw reducing adapter pre-attached to the blood inlet connector to Maquet Cardiopulmonary. If the use of the products is medically necessary, remove the pre-connected screw reducing adapter at the blood inlet connector of the customized tubing sets HQV 51203 and HQV 85503 and following the further instructions for an alternative method of tubing reduction below.

Using the device without the reducing screw adapter at all or using an alternative method of tubing reduction (see below) safely allows operators to set up and operate cardiopulmonary bypass without the potential necessity of device replacement in case of leakage. Maquet’s recommendation outweighs the risks associated with device use with the reducing screw adapter.

Maquet Cardiopulmonary has not received any complaints associated to serious injuries or deaths due to a leakage at the blood inlet connector.

Should you wish to reduce the blood inlet port to 3/16’’, we recommend connecting 1/4“ tubing to the inlet of the QUADROX-i Neonatal Oxygenator, reducing the 1/4“ tubing to 3/16“ using a standard tubing reducer. Two tie bands should be placed on all connections with the tie band heads oriented in a 180 degree configuration as shown below.



Corrective Action:

For Customized Tubing Sets with pre-attached reducing screw adapter; HQV 51203 and HQV 85503:

- Return to Maquet Cardiopulmonary any unused Customized Tubing Sets with pre-attached reducing screw adapter; HQV 51203 and HQV 85503.
- If medical necessary to use these Customized Tubing Sets, remove and do not use the **pre-connected** reducing screw adapter 1/4” x 3/16” (Ref. No. 70104.5511). Follow the further instructions to reduce the tubing using a standard tubing reducer.

For Tubing Sets with a reducing screw adapter packaged separately:

- Remove and do not use the **enclosed** reducing screw adapter 1/4” x 3/16” (Ref. No. 70104.8593)
- In case you also do not want to use this product with a standard tubing reducer, 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 containing the QUADROX-i Neonatal Oxygenator and the reducing screw adapter 1/4” x 3/16” (Ref. No. 70104.8593). It also encompasses all Custom Tubing Sets, which contain a pre-connected reducing screw adapter 1/4” x 3/16” (Ref. No. 70104.5511) on the blood inlet connector of the QUADROX-i Neonatal Oxygenator.

- Return any unused affected product to Maquet Cardiopulmonary.
- 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:

- 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

Approved / Geprüft	Signatory:	Signature / Unterschrift
UTC 2018-11-14, 13:38:34	Markus Medart (Geschäftsführung)	

Safety Officer

Approved / Geprüft	Signatory:	Signature / Unterschrift
UTC 2018-11-12, 15:11:58	Bernd Rakow (Regulatory Affairs)	

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