

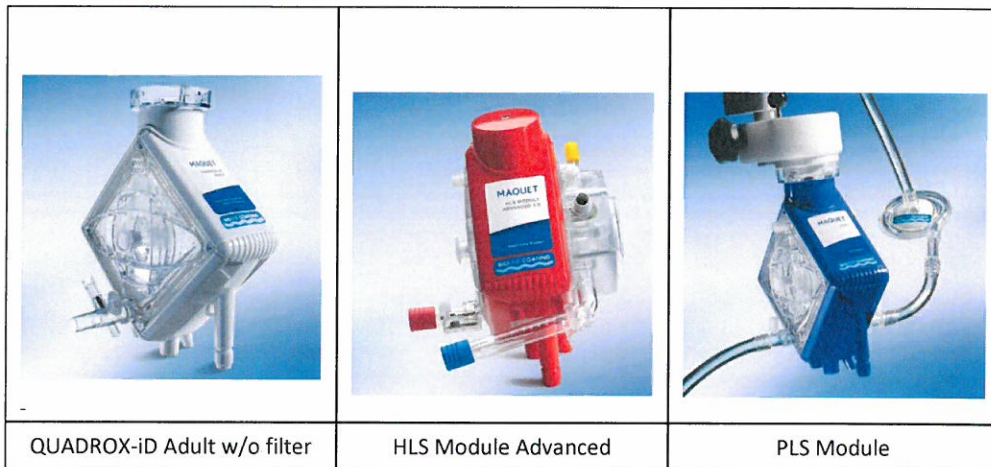
Urgent!
Field Safety Corrective Action (FSCA)

19. November 2015

FSCA Number: FSCA 2015-11-19

FSCA Title: Availability Information for improved Oxygenators

Affected Product: QUADROX-iD Adult/Small Adult
HLS Set Advanced / HIT Set Advanced
PLS Set / HIT Set PLS / HIT Set PLS Plus



Affected product details: See Listing in Text of Communication

Description of the problem:<Insert problem description>

In December 2014 Maquet Cardiopulmonary notified you via FSN 2014-12-11 of the increased incidence of blood leakage from the gas outlet connector of the Quadrox-iD Adult and Small Adult products, including the HLS and PLS Sets that contain related oxygenators of this product family. The increased leakage was due to a separation of a small number of the internal fibers from the polyurethane casting in the oxygenator. This separation resulted in the blood leakage that was the subject of the Field Safety Notice.

Since the release of this notification, we have been able to confirm the possible root cause that was described in the notification. Additionally, we have implemented and validated the necessary corrections that return the products to their original performance specifications. The correction necessary was the implementation of additional process controls during the production process of these fibers at our raw material supplier. The fibers produced under these increased process controls have now been delivered to Maquet Cardiopulmonary and used on the production of the finished oxygenator products.

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The following table shows the affected products as well as the production lots that contain 100% of the improved fibers.

Product Description	Product Order Number	Initial Lot Number
HMOD 70000-USA QUADROX-iD Adult without Filter	70105.3815	70104447
BEQ-HMOD 70000 iD Adult without Filter with BIOLINE Coating	70105.1992	
BEQ-HMOD 70000-USA QUADROX-iD Adult without Filter with BIOLINE Coating	70105.3824	70104440
BE-HMOD 70000 QUADROX-iD Adult without Filter with BIOLINE Coating	70104.1189	70104899
BE-HLS 5050 HLS Set Advanced 5.0 with BIOLINE Coating	70104.8127	70104520
BEQ-HLS 5050 USA HLS SET ADVANCED 5.0	701.052.797	
BEQ-HLS 5050-CA HLS SET ADVANCED 5.0	701.064.848	
BO-HLS 5050 USA#HIT SET ADVANCED 5.0	701052788	
BE-HLS 7050 HLS Set Advanced 7.0 with BIOLINE Coating	70104.7753	70100115
BEQ-HLS 7050 USA HLS Set Advanced	70105.2794	70104291
BO-HLS 7050 HIT Set Advanced 7.0 with SOFTLINE Coating	70104.9134	70102477
BEQ-HLS 7050-CA HLS SET ADVANCED 7.0 with BIOLINE Coating	70106.4847	
BO-HLS 7050 USA HIT SET ADVANCED 7.0 with SOFTLINE Coating	70105.2786	
BE-PLS 2050 PLS Set with BIOLINE Coating	70102.7818	70104119
BE-PLS 2051 PLS Set Plus with BIOLINE Coating	70105.0310	70102843
VKMOD 70000 Combination of QUADROX-iD Adult without Filter + Reservoir	70106.8085	
VKMOD 71000 Combination of QUADROX-iD Adult with Filter + Reservoir	70106.4762	
BO-VKMOD 71000 Combination of QUADROX-iD Adult with Filter + Reservoir SOFTLINE Coating	70106.6952	
BE-VKMOD 71000 Combination of QUADROX-iD Adult with Filter + Reservoir BIOLINE Coating	70106.7762	

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All product lot numbers beginning with the numbers above **and higher** contain only fibers that have been produced since the introduction of the additional process control measures that correct the leakage at the blood outlet connectors.

Based on our routine production and sterilization timelines, as well as our yearly planned production shut-down for clean room maintenance, you should already have begun to receive initial shipments of these (or higher) lot numbers.

Corrective Action:

Due to the added risks associated with the use of the oxygenators with increased leakage, we are now initiating a **REMOVAL** of all products with a lot number that is smaller than the lot numbers listed above.

Advice on action to be taken by the user:

1. Please conduct an inventory of all un-used products listed above.
2. Compare the Production lot number to the table above and initiate a product quarantine on all products that contain a numerical lot number smaller than the ones shown.
3. Contact your local Maquet Representative to request return of the affected lots.
4. A credit for the products will be issued upon receipt of the returned products.
5. Order any replacements per your normal product ordering process.

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.

Should you continue to see leakage, review the product lot number to determine its status in relation to this notification. Should you identify that this production lot number is a number that is listed above (or higher), please immediately report the event to us according to your local procedures and save the product for return to Maquet Cardiopulmonary for detailed investigation.

We apologize for any inconvenience this may cause you and are confident that the increased leakage previously seen has now been corrected. Thank you for your support of Maquet Cardiopulmonary during this issue.

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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

`sig,bio=1`

Safety Officer



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