AsahiKASEI

ASAHI KASEI MEDICAL CO., LTD.

Asahi Kasei Medical Co., Ltd.
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Customer Information Letter

Product name: ASAHI APS™-H SERIES HEMODIAFILTER
Type of action: Customer Information
Date: May 9, 2017

Attention:
European Distributors and Customers

Details of affected devices:
Product name: ASAHI APS™-H SERIES HEMODIAFILTER
List of product codes and LOT No. involved:

Product code	LOT No.
APS-21H	UF4447

Reference number assigned by the manufacturer is T-170310.

Description of the issue

Asahi Kasei Medical Co., Ltd. received a complaint in Japan that patient's blood did not flow through some hollow fibers of the dialyzer. According to our investigation, it was confirmed that some hollow fibers were clogged with the urethane resin. Therefore, the effective surface area of a few dialyzers of the affected LOT may be decreased.

Based on our risk assessment, the decision was taken to inform the customers about the potential deficiency of performance of the products and ask you to inspect the stockpile and send back the affected products to your dealer or Asahi Kasei Medical Europe GmbH.

Distribution of this letter

Please forward this letter as well as the attached "Confirmation Letter" to your customer in case that you have delivered products of the affected LOT.

Actions to be taken by distributors and/or customers:

1. Please do not use the affected products.
2. Please inspect your stockpile and send back all affected products left to your distributor or Asahi Kasei Medical Europe GmbH.
3. Please inform your customers about the possibility of clogged hollow fibers of the dialyzers. Please request your customers to inspect their stockpile and send back all affected products left to you or Asahi Kasei Medical Europe GmbH.
4. Please complete the "Confirmation Letter" to confirm:
   a). The receipt of this letter,
   b). That you dispatched the products to your distributor or Asahi Kasei Medical Europe for disposal.
   c). That you have informed your corresponding customers.

Asahi Kasei Medical Co., Ltd sincerely apologizes for the inconvenience caused.

Contact person:

If you have any questions, please get in contact with your distributor or:

Asahi Kasei Medical Europe GmbH
Steffen Giebisch
Quality Management Representative
Herriotstrasse 1
60528 Frankfurt am Main
Germany
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Taiichi Yoneda
General Manager
Product Strategy Department (Dialysis)
Blood Purification Business Division
Asahi Kasei Medical Co., Ltd.

Confirmation Letter

Product name: ASAHI APS™-H SERIES HEMODIAFILTER

Following number of affected products are found.

Product Code	LOT No.	Total number of Products
APS-21H	UF4447	

We confirm that we have received the "Customer Information Letter" dated May 9, 2017 related to the above mentioned products.

We confirm that we inspected our stockpiles with regard to product code and LOT No. mentioned above. We have found and sent back the number of products documented above.

We confirm that we have informed all corresponding customers by forwarding the "Customer Information Letter" and this attachment.

Distributor Name:_____

Address: _____

Person in charge: _____

Telephone: _____

E-mail: _____

Date and signature:_____

Customer Name: _____

Address: _____

Person in charge: _____

Telephone: _____

E-mail: _____

Date and signature: _____

Please complete this "Confirmation Letter" and send it via Fax or E-mail to your distributor or Asahi Kasei Medical Europe GmbH:

Fax: _____

E-mail: _____

Thank you for your kind cooperation.