KAWASUMI LABORATORIES, INC.
Shinagawa Intercity Tower B, 2-15-2, Konan,
Minato-ku, Tokyo, 108-6109, Japan
Phone: +81-3-5769-2664
Facsimile: +81-3-5769-2716

Urgent Field Safety Notice

Product name : A.V. Fistula Sets for Hemodialysis

FSCA Date : March 28, 2016

Type of action : Return of Medical Device to the Supplier

FSCA/FSN Nr.: 1603-E

Attention:

European Distributors and Users

Details of affected devices:

Product name: A. V. Fistula Sets for Hemodialysis

List of product codes and lot numbers involved:

Product code	Lot No.
AVFE1520CPLRG	150314I1
AVFE1620CPLRG	150313I1
AVF1525CLFG	150313I6
AVFE1625CPLFG	150313I8

Note: The products listed in the above table is referred "Products" hereinafter in this document.

Description of the problem:

KAWASUMI LABORATORIES, INC., is voluntarily recalling the Products because of investigations after a few clinicians have reported breakage of clamp on product.

The investigation result on the returned sample indicated that some portion of packed products has been excessively gamma irradiated during the sterilization process, resulting deterioration of plastic material. The reports from clinicians also suggest that the clamp breakage can be found once it is clamped manually and it was difficult to continue the treatment.

Currently, no health hazard has occurred during the usage of such products.

Transmission of this Field Safety Notice:

Please make sure that this Field Safety Notice has been passed on all the people who need to be aware within your organization and to any organization where the potentially affected Products have been transferred (if applicable).

Please transfer this notice to other organizations on which this action has an impact (if applicable).

Please maintain awareness on this notice and resulting action to ensure effectiveness of the corrective action (if applicable).

KAWASUMI LABORATORIES, INC., has informed the concerned Ministry of Health and/or authorities about the present FSCA through its European representative, Asahi Kasei Medical Europe GmbH.

Advice on action to be taken by distributors/users:

1. Do not use the Products.
2. Check your inventory and quarantine any potentially affected Products and inform your dealer or the EU authorized representative (Asahi Kasei Medical Europe GmbH) about the remaining quarantined inventory.
3. Please fill-in the Recall confirmation letter form to confirm the receipt of this field safety notice and that you have informed all necessary persons in your organization about this notice and that you have informed all your customers or other organizations who have received the affected Products from you.
4. Your dealer and/or Asahi Kasei Medical Europe GmbH will organize the removal of the quarantined Products.
5. For detailed procedure of this recall, your dealer or Asahi Kasei Medical Europe GmbH will contact you for further instructions.

KAWASUMI LABORATORIES, INC., sincerely apologize for the inconvenience caused by this action.

Contact reference person:

If you have any questions please make contact with your distributor or to

Asahi Kasei Medical Europe GmbH
Herriotstraße 1
60528 Frankfurt am Main
Germany
Tel: +49-(0)69-66371-500

Yoshihiro Shin,
General Manager, Product Safety Control Division
KAWASUMI LABORATORIES, INC.

Recall confirmation letter
Product name : A.V. Fistula Sets for Hemodialysis

Product code	Lot No.
AVFE1520CPLRG	150314I1
AVFE1620CPLRG	150313I1
AVF1525CLFG	150313I6
AVFE1625CPLFG	150313I8

The result of the inventory in our warehouse regarding the devices object of this Field Safety Notice is the following:

Product Code	Lot No	Total number of items in inventory

We/I confirm that we have received the Field Safety Notice FSN Nr. 1603-E dated March 28, 2016 related to the above mentioned items.

We confirm having informed all the persons in our organization who shall be aware of this information and as appropriate have informed those persons and organizations who have received the product from us.

We further confirm that we have organized the quarantining of the affected products and inform the inventory details of these goods to our supplier.

Supplier's name: _____

Address: _____

Person in charge: _____

Telephone: _____

E-mail: _____

Organisation name: _____

Address: _____

Division name: _____

Person in charge: _____

Telephone: _____

E-mail: _____

Date and signature: _____

Please complete the present form and send it via fax or e-mail to your supplier:

Fax: _____

E-mail: _____

Thank you for your kind cooperation.