



URGENT: FIELD SAFETY CORRECTIVE ACTION

Châteaubriant, July 17th 2018

For the attention of: the Pharmacist responsible for medical device vigilance and the Biomedical Engineering Department.

SECURITY INFORMATION of Medline Sterile Procedure Trays including «Applimed» cannula needle

Medline reference: FSCA – 18/10
Description: «Applimed» cannula needle straight with olive, 100mm, stainless steel, G18, diameter 1.19mm, included in Medline Sterile Procedure Trays
Product Codes concerned: See details in the Table 1 below

Dear Customer,

This letter is to advise you that Applimed has issued a field safety corrective action related to 1 lot of cannulas needles included in some Medline Sterile Procedure Trays.

This recall is due to an event reported to Applimed for which the olive was found detached from the cannula, during the surgery.

References and lot numbers of concerned Sterile Procedure Trays are mentioned in the Table 1 of the Acknowledgment Receipt form below.

For the remaining packs available on your stock, "warning stickers", to be placed on each Sterile Procedure Tray, will be provided.

Actions to be taken :

Could you please:

Step 1:

Urgently check your stock and promptly put on quarantine the concerned Sterile Procedure Trays listed in Table 1 (see: acknowledgement form).

Step 2:

Complete the acknowledgment form and return by either fax or email as soon as possible, but not later than August 17th, 2018 and indicate the quantity of Sterile Procedure Tray on stock, to receive the necessary "warning stickers" to be put on each Sterile Procedure Tray.

Step 3:

Put a "warning sticker" on each concerned Sterile Procedure Tray of your stock and release the labelled packs.

The "warning sticker" purpose is to inform healthcare professional not to use the Cannula needle included in the Sterile Procedure Trays.

During the surgical procedure, the cannula needle should be removed and discarded.

The other components in the Sterile Procedure Tray can be used safely.

For remaining packs available in Medline stock, a "warning sticker" will be put on each Sterile Procedure Tray. A conformed single sterile cannula needle will be send to you directly upon request.

Yours Sincerely,
Quality and Regulatory Affairs Dept.

Acknowledgement Receipt to be faxed to the following: +49 2821 7510 7822
or email to gmb-eu-ra-kleve@medline.com

Reference: FSCA-18/10

Could you please complete the acknowledgment form and send it back by either fax or email as soon as possible, but not later than August 17th 2018.

Table 1:

Sterile Procedure Trays concerned by this notification delivered to your hospital are listed in the below table. Please mention the quantity of packs available in your stock:

REFERENCE	LOT	Quantity in stock
xxxxxxxx		
xxxxxxxx		
xxxxxxxx		

Number of warning stickers and single sterile cannula needles required:

I have read and understand the instructions provided. I acknowledge receipt of the FSCA-18/10 by signing this document.

I acknowledge receipt of this notification no. FSCA-18/10; I confirm that our stock has been checked for Sterile Procedure Trays containing the concerned cannula needle. The cannula needle will be discarded before use of the Sterile Procedure Tray.

I also agree to further distribute and communicate this important information within my facility as required.

Date:

Name:

Position:

Facility:

Address:

Telephone:

Fax:

Signature: