



URGENT: FIELD SAFETY CORRECTIVE ACTION

Châteaubriant, Wednesday 6 June 2018.

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

SECURITY INFORMATION of Medline Sterile Procedure Trays (SPT) containing Getinge CEC Cannula

Medline reference: FSCA-18-05
Description: Medline SPT Packs
Product Codes concerned: HGGCV116, A and C and HGGCV118, A and B

Dear Customer,

Medline International France has been informed of the attached FSCA 2018-03-27 from the supplier Getinge concerning a potential risk of their CEC cannula. The Sterile Procedure Trays containing the components concerned by this Field Safety Corrective Action have been identified with a warning label informing you to remove the component and not to use it during the surgical procedure.

References and Lots Concerned

Tray Reference	Lots Concerned
HGGCV116, A and C	All Lots
HGGCV118, A and B	

Action:

Step 1:

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

Step 2:

Complete the acknowledgment form by either fax or email as soon as possible, but **not later than June 8th 2018** and indicate the quantity of Sterile Procedure Trays on stock, to receive the necessary "warning labels" to be put on each Sterile Procedure Tray.

Step 3:

Put the "warning labels" on each concerned Sterile Procedure Tray of your stock.

The "warning label" purpose is to inform healthcare professional not to use the cannula included in the Sterile Procedure Trays.

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

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

Step 4:

The Sterile Procedure Trays with its "warning label" can be released

Yours Sincerely,
Quality and Regulatory Affairs Dept.

Acknowledgement receipt to be faxed to the following: **xxxx
or email to **XXXXX****

Please complete this form with your option and return to Medline by either fax or email as soon as possible, but **not later than June 8th, 2018.**

Reference: FSCA-18-05

TRAYS CONCERNED - Please indicate the quantity in your stock:

REF	Quantity of Trays Quarantined by the customer
XXXXXXXXXX	

I have read and understood this Field Safety Corrective action and have distributed the information to all possibly impacted departments within my organization.

We have stock and ordered warning labels to be sent to below address in the quantity of quarantined trays

OR

We have NO trays left in our stock concerned by this Safety information

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

Date:

Name:

Position:

Facility:

Address:

Telephone:

Fax:

Signature: