



Medline International Germany GmbH
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URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

Kleve, October 04th, 2019

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

SECURITY INFORMATION of Medline MED-STOP Paediatric Fingertip

Medline reference: FSN-19/05
MoH reference:
Description: MED-STOP Paediatric Fingertip
Product Codes concerned: OR54916 – OR54926 - OR854VCP – ORNEX66VCP



Dear Customer,

This letter is to advise you that Medline Industries Inc, has issued a field safety notice on MED-STOP Paediatric Fingertip mentioned in the below table:

Product code	Description
OR54916	Soft suction liner 1000cc/ml with tubing and paediatric vacuum control
OR54926	Soft suction liner 1500cc/ml with tubing and paediatric vacuum control
OR854VCP	MED-STOP Paediatric, Fingertip, Manual Vacuum Control
ORNEX66VCP	MED-STOP Paediatric (fingertip with vacuum control) + ORNEX Tubing 6mmx1.80M, Non sterile

Issues:

An incident was reported to Medline during Paediatric MED-STOP use. A neonatal catheter with a small diameter was connected to the fingertip. The blue tip detached during catheter removal resulting in a delay of patient care.

Medline Industries Inc, would like to inform MED-STOP users that the blue tip is removable and could under certain conditions be detached.

To solve this potential issue, Medline has developed a new MED-STOP with a fixed blue tip. Its design will be shorter and more conical in order to be compatible with all Paediatric catheters. The new version of the MED-STOP will be available from January 2020.

Here is a diagram of the Paediatric MED-STOP with new tip





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Actions to be taken:

1. Read this Field Safety Notice carefully and communicate this notification to healthcare professionals in your facility.
2. Please complete and send back the enclosed acknowledgment form by either fax or email as soon as possible, but **not later than October 11th, 2019.**

The relevant competent authorities are informed of this safety notice.

We apologize for the inconvenience caused.

Yours Sincerely,
Kenneth Smith
International Quality and Regulatory Affairs Manager.

A handwritten signature in blue ink, appearing to read "Kenneth Smith", written over a faint blue line.

PS: This urgent safety information is only addressed to facilities that had received the concerned MED-STOP Paediatric Fingertip.



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**Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822
or send by email to: gmb-eu-ra-kleve@medline.com**

Medline reference: FSN-19/05

Please complete and send back the enclosed acknowledgment form by either fax or email to Medline as soon as possible, but no later than **October 11th, 2019**.

MED-STOP Paediatric Fingertip references concerned by this notification are:

Product code	Description
OR54916	Soft suction liner 1000cc/ml with tubing and paediatric vacuum control
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I have read and understood the security information provided by Medline and I acknowledge receipt of the FSN-19/05.

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

If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected products to other facilities, please distribute this notification to customers and confirm us that your customers have been notified.

Date: _____
Customer Number: _____
Name: _____
Position: _____
Facility: _____
Address: _____
City: _____
Telephone: _____
Fax: _____
Signature: _____