Medline International Germany GmbH
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Regulatory Affairs
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www.medline.com/en

Address (if needed)

URGENT: FIELD SAFETY (CORRECTIVE ACTION) NOTICE

Medical Device Safety Advisory Notice

Kleve, January 10th, 2020

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

SECURITY INFORMATION of Medline Clipper Charger base with EU plug

Medline reference: **FSCA-19/09**
MoH reference:
Description: Medline Clipper Charger base with EU Plug
Product Codes concerned: See details in the **Table 1**

Dear Customer,

Medline Industries Inc is recalling certain lots of the Medline Surgical Clipper Charger bases fitted with EU mains plugs. This affects the charger bases only with grey power cables.

Issues:
This Recall is being conducted due to a potential defective component on the circuit board causing the EU charger base to overheat, which could result in a charger base malfunction.
This can cause a delay to surgical procedures.

Table 1:
Clipper charger base references and lot numbers concerned by this notification:

REFERENCE	DESCRIPTION	LOT numbers *less than* (with grey power cables)
DYND70800EU*	SURGICAL CLIPPER HANDLE & CHARGER BASE, EU PLUG	805**1707**XXXX
DYND70802EU	CHARGER BASE, EU PLUG	805**1707**XXXX

*****recall applies to charger base component only*

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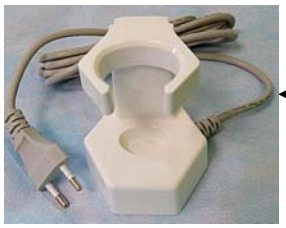
Medline Surgical Clipper Charger Base with grey power cable:

Lot Number on the base of the charger



Grey power cable

Actions to be taken:

- If you **do have** any in your stock or currently in use of the affected lot numbers, stated above, please:
  1. **Unplug the chargers once the clippers have been charged or not in use.**
  2. Complete the quantity of the replacement chargers required in the acknowledgement form page 3 and the additional information requested.
  3. Send the completed form to the following fax number: +49 2821 7510 7822 or email: gmb-eu-ra-kleve@medline.com
  4. On receipt of the completed acknowledgement form, Medline will arrange for the chargers to be replaced.
  5. The Clipper Charger bases with grey charging cable should be discarded once you have received the replacement chargers.

- If you do **not** have stock from the affected lot numbers, stated above, please:
  1. Mention '0' in the quantity to be replaced on the Acknowledgement form page 3.
  2. Send the completed form to the following fax number: +49 2821 7510 7822 or email: gmb-eu-ra-kleve@medline.com

Please complete actions by February 14th, 2020.

We apologize for the inconvenience caused.

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

PS: This urgent safety information is only addressed to facilities that had received the concerned affected products.

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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

Reference: FSCA-19/09

Could you please complete the acknowledgment form and send it back by either fax or email as soon as possible, but **not later than February 14th, 2020.**

Table 1:
Clipper charger base references and lot numbers (with grey charging cables) concerned by this notification:

REFERENCE	DESCRIPTION	LOT numbers *less than* (with grey power cables)
DYND70800EU*	SURGICAL CLIPPER HANDLE & CHARGER BASE, EU PLUG	805**1707**XXXX
DYND70802EU	CHARGER BASE, EU PLUG	805**1707**XXXX

*****recall applies to charger base component only*

☐ I have read and I acknowledge receipt of this notification nr FSCA-19/09 by signing this document. I confirm that our stock has been checked and I require replacement of charger bases.

Quantity to be replaced: _____

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: _____