



Medline International Germany GmbH  
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[www.medline.com/de](http://www.medline.com/de)

## **URGENT: FIELD SAFETY CORRECTIVE ACTION**

### **Medical Device Safety Advisory Notice and Product Recall**

Kleve, November 12<sup>th</sup>, 2019

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

#### **SECURITY INFORMATION of Medline Clipper Charger base with UK plug**

**Medline reference:** FSCA – 19/07  
**MoH reference:**  
**Description:** Medline Clipper Charger base with UK Plug  
**Product Codes concerned:** See details in the **Table 1**

Dear Customer,

This letter is to advise you that Medline is recalling certain lots of the Medline Surgical Clipper Charger bases fitted with UK mains plugs. This Recall is being conducted due to a potential defective component on the circuit board causing the UK 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 <i>less than -</i>
DYND70800UK*	SURGICAL CLIPPER HANDLE & CHARGER BASE, UK PLUG	8051705XXXX
DYND70802UK	CHARGER BASE, UK PLUG	8051602XXXX

*\*recall applies to charger base component only*

#### **Medline Surgical Clipper Charger Base**



Lot Number on the base of the charger





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**Actions to be taken:**

- If you **do have** any in 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 (Annex I) and the additional information requested. Send the completed form to the following fax number: +49 2821 7510 7822 or email: [gmb-eu-ra-kleve@medline.com](mailto:gmb-eu-ra-kleve@medline.com)
  3. On receipt of the completed acknowledgement form, Medline will arrange for the chargers to be replaced.
  4. The Clipper Charger bases 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. Write '0' in the quantity to be replaced on the Acknowledgement form (Annex I).
  2. Send the completed form to the following fax number: +49 2821 7510 7822 or email: [gmb-eu-ra-kleve@medline.com](mailto:gmb-eu-ra-kleve@medline.com)

**Please complete actions by 6<sup>th</sup> December, 2019**

The relevant competent authorities are informed of this safety notice.

We apologize for the inconvenience caused.

Yours Sincerely,  
Kenneth Smith  
Senior 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 Clipper chargers.



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**Annex I**

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

**Reference: FSCA-19/07**

Could you please complete the acknowledgment form and send it back by either fax or email as soon as possible, but **not later than December 6<sup>th</sup>, 2019**.

I acknowledge receipt of this notification nr FSCA-19/07; I confirm that our stock has been checked and I require replacement charger bases.

**QUANTITY TO BE REPLACED:** \_\_\_\_\_

I have read and understand the instructions provided. I acknowledge receipt of the FSCA-19/07 by signing this document.

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: \_\_\_\_\_

