



Medline International Germany GmbH
 Wilhelm-Sinsteden-Straße 5 – 7
 D-47533 Kleve
 Tel: +49 (0) 2821 – 7510 – 0
 Fax: +49 (0) 2821 – 7510 – 7802

Regulatory Affairs
 Quality Department
 gmb-eu-ra-kleve@medline.com
 Tel: +49 (0) 2821 – 7510 – 7210
 Fax: +49 (0) 2821 – 7510 – 7822

www.medline.com/uk

Medline International Germany GmbH - Wilhelm-Sinsteden-Str. 5-7 - D-47533 Kleve

Kleve, June 2015

URGENT: VOLUNTARY RECALL
Medical Device Safety Advisory Notice

Object: Voluntary Recall of Surgical Clipper Charger base manufactured by Medline Industries, Inc.

Medline reference: FSCA-15-02 – Notice has been communicated to the French competent authority ANSM, responsible for the EU representative of Medline US, Medline Int. France SAS

Description: Medline Surgical Clipper Charger base

Products concerned: See details in the table below.

Dear Customer,

This letter is to advise you that Medline is recalling certain lots of the Medline Surgical Clipper Charger base. This Recall is being conducted due to a potential defective component on the circuit board causing the charger base to overheat that could result in a charger base malfunction.

Clipper charger base references and Lot numbers concerned by this notification:

REF	DESCRIPTION	LOT numbers
DYND70800UK*	SURGICAL CLIPPER & CHARGING BASE, UK	1,2,3,4,and 5
DYND70802UK	CHARGING BASE, UK	1,2,3,4,and 5

**recall applies to charging base component only*

Medline Surgical Clipper Charger Base





Advice on action to be taken by Medical Staff

1. Identify and discard any stock of the concerned charger base – Lot numbers 1,2,3,4 and 5. The Lot number can be found underneath the base of the Charger, see picture



2. If you do **not** have stock from the affected batch numbers, stated above, mark the according checkbox on the enclosed FSCA. Send the completed form to the following fax number: +49 2821 7510 7822 or email: gmb-eu-ra-kleve@medline.com
3. If you **do have** stock from the affected batch numbers, stated above, please stop using the chargers and discard them. Then mark the according checkbox on the enclosed FSCA, indicating the quantity. Provide the additional information requested and 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 FSCA form, Medline will arrange replacement of the discarded stock if necessary.

Please complete actions by 24th July 2015

Transmission of this Field Safety Corrective Action

This notice needs to be passed on to all recipients/users of this product within your organisation, in particular, the following:

All Wards
Risk Managers
Stores
Theatres

Yours Sincerely,

Quality and Regulatory Affairs Dept.



Acknowledgement receipt FSCA-15-02

To be faxed or emailed to RA Kleve: Fax +49 2821 7510 7822 or
E-Mail gmb-eu-ra-kleve@medline.com

Lot numbers of Surgical Clipper Charger bases concerned by this recall:

REFERENCE	DESCRIPTION	LOT numbers
DYND70800UK*	SURGICAL CLIPPER & CHARGING BASE, UK	1,2,3,4,and 5
DYND70802UK	CHARGING BASE, UK	1,2,3,4,and 5

**recall applies to charging base component only*

I, _____, acknowledge the receipt of the notification relative to the Recall FSCA-15-02.

I confirm that our stock has been checked and the following Surgical Clipper charger bases have been discarded.

REFERENCE	LOT	Quantity Discarded

I confirm that there are no Surgical Clipper Charger bases concerned by this recall in our stock.

Date:

Name:

Position:

Facility:

Address:

Customer number:

Telephone:

Fax:

Signature: