



URGENT: FIELD SAFETY NOTICE
CONMED Concept® HeatWave® Electrode

September 8, 2016

CONMED is sending this communication to notify you of a product issue with the Concept® HeatWave® Electrode **CS-023**. The affected lot codes are listed below and represent all product manufactured between September 1, 2011 and November 17, 2015:

Lot codes of Affected CS-023 Devices:

267221	301001	309889	318652	319649	325019
354759	334627	336041	341704	343927	349952
384294	354768	365239	369773	374480	378521
406137	385695	388538	392382	394178	396542
436808	413702	456341	423877	427704	433503
478513	451923	488101	464062	468012	471297
511327	482366	522335	494840	499981	505321
544240	515060	551152	527734	531802	536700
581072	550988	590037	557461	570449	574167
611804	588892	621304	597982	598682	605515
643396	619686	656909	629202	634911	643395
676005	654991	692617	667118	671471	674410
683144	695062	695063	297982		

CONMED has received complaints of damage to the electrode's shaft insulation which could result in burn marks on the shaft. If the shaft insulation is damaged in any way, it could increase the risk of patient burn. In no instance has it been reported to CONMED that this issue has resulted in illness or injury.

Based on this information, CONMED has decided to recall the devices listed above to the user level. These products were distributed between November 7, 2011, and July 11, 2016.

Therefore, please stop the use of these devices immediately.

Step 1: Please review your inventory for any of the devices listed above.

We ask that you contact all of those departments within your facility and any other facilities within your organization that may have received affected products. It is imperative that all end users of these devices receive this notice and respond immediately.



Step 2: If you HAVE ever received any of the devices listed above, please complete the Business Reply Form (Attachment I) and return it with the devices to:

**CONMED
NCR-51197
11155 Concept Blvd.
Largo, FL 33773 USA
Return via: UPS Account # W5Y261 (no charge to your facility)**

Please process a commercial invoice for the return to the United States referencing your purchase price as a value for Custom's purposes and note on the commercial invoice that the return is for evaluation purposes only. Please include the following information on the invoice, with the returned product:

**CONMED FDA Reg. # 1317214
MDL#: D220976
510K #: K991830**

Please do not return used devices.
Credit will be issued for the returned goods.

Step 3: If you DO NOT HAVE any affected devices to return, please complete the Business Reply Form (Attachment I), indicating you have no devices and return by one of the means listed below:

- 1. Email to: largheatwv@conmed.com**
- 2. Fax to: Field Action Support Team at +1 315-624-3225.**

If you have any questions or requests, please don't hesitate to contact the Field Action Support Team at +1 **800-535-8536**, fax to +1 **315-624-3225**, or email largheatwv@conmed.com.

CONMED is dedicated to providing safe and reliable products to our customers and their patients. We are committed to manufacturing product of the highest quality and sincerely apologize for any inconvenience this may cause you or your staff.

The US Food and Drug Administration has been notified of this action. In addition, the appropriate international competent authorities have also been notified.

Sincerely,

A handwritten signature in black ink that reads 'Patricia Cotter'.

Patricia Cotter
Senior Specialist, Regulatory Affairs



ATTACHMENT I
EFFECTIVENESS CHECK
FIELD SAFETY NOTICE
BUSINESS REPLY FORM

Please check all that apply:

- We DO NOT have any stock of the suspect lots.
- We have notified our accounts to return their stocks of the product to us.
- We are returning: (Complete table below)

Catalog # being returned	Quantity per Box	Quantity of Eaches or Boxes
CS-023	5/Box	

Have you received any reports of illness or injury related to this product? Yes___ No___
If yes-please document specific information. Include it when this form is returned. It can be: 1) faxed to +1 315-624-3225, Attn: Field Action Support Team, 2) mailed to CONMED, 525 French Rd., Utica NY 13502, Attn: Field Action Support Team, or 3) emailed to largheatwv@conmed.com

If you are returning product, include a copy of this completed form with the devices.
Charge shipping to: UPS Account # W5Y261

Return devices to: CONMED
NCR-51197
11155 Concept Blvd.
Largo, FL 33773 USA

Your Name: _____ Account # _____
(Please Print)

Signature: _____

Please complete at least one:

Phone: _____ Fax: _____ Email: _____

Distributor/Hospital: _____

Address: _____
