URGENT: FIELD SAFETY NOTICE

CONMED Corporation CORE® Suction Irrigation Handpieces

5 July, 2016

CONMED Corporation is sending this communication to notify you of a product issue with the following catalog numbers. Certain lot codes of the CORE® Suction Irrigation Handpieces are affected**.**

Catalog Number	Device Name
CD8185	Handpiece, 5mm x 32cm Length Probe, Single Solution Bags
CD8190	Handpiece, 5mm x 32cm Length Probe, Single Solution or Dual Bags
CD8200	Handpiece Y-Tubing set, 5mm x 32cm Length, Probe Single Solution or Dual Bags
CD8300	Handpiece without Probe, Single Solution Bags
CD8302	Handpiece without Probe, Single Solution or Dual Bags
CD8400	Trumpet Handpiece with 5mm x 32cm Length Probe
CD8450	Trumpet Handpiece only

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The CORE® Suction Irrigation Handpieces are sold as sterile, single use devices. CONMED has identified certain CORE® Suction Irrigation product with creases in the packaging seal which sometimes result in an open channel. These channels may compromise sterility of the product. In no instance has it been reported to CONMED that a compromise in the sterile barrier has resulted in illness or injury.

Based on this information, CONMED has decided to recall the devices listed above and specifically on on Attachment I to the user level. **Therefore, do NOT use any** CORE® **Suction Irrigation Handpieces manufactured between June 9, 2011 and March 8, 2016.** The affected lot codes are more fully described on page 3.

The products were distributed between July 27, 2011, and June 20, 2016.

Step 1: Please review your inventory for any of the devices listed on Attachment I.

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 on Attachment I please complete the business reply form (Attachment II) and return it with the devices to:**

CONMED Corporation
525 French Road
Utica, NY 13502 USA
Attn: Ed Kovac
Return via: UPS Account # W5Y243 *(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#: D097491
510K #: K926477

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 II), indicating you have no devices and return by one of the means listed below:

1. **Email to: coresihp@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 **315-624-3237, fax to +1 315-624-3225,** or email **coresihp@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 and the have been notified of this action. In addition, the appropriate international competent authorities have also been notified.

Sincerely,

Patricia Cotter
Senior Specialist, Regulatory Affairs

ATTACHMENT I
PRODUCT CODES
FIELD SAFETY NOTICE

Affected lot codes for ALL catalog numbers listed:

Lot codes for product manufactured to and including the dates listed below:

Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
June 9, 2011	110609X	March 8, 2016	20160308X

Lot codes on boxes and packaging contain a lot code in the following form:

2014 10 01 X
2014 10 01 X
Or 14

- Manufacturing shift code 1, 2, 3, 4,5,6 or 9
- Day of the Month
- Month (October)
- Year (20**14**)

ATTACHMENT II
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 Case	Quantity of eaches or cases *(circle cases or eaches as applicable)*
CD8185	10/Case	
CD8190	10/Case	
CD8200	10/Case	
CD8300	10/Case	
CD8302	10/Case	
CD8400	20/Case	
CD8450	20/Case	

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 to ConMed Corporation.
It can be faxed to +1 315-624-3225, Attn: Field Action Support Team, mailed to CONMED, 525 French Rd., Utica NY 13502, Attn: Field Action Support Team, or emailed to coresihp@conmed.com.

If you are returning product, include a copy of this completed form with the devices.
Return devices to: CONMED Corporation
RGA-
525 French Road
Utica, NY 13502 USA
Attn: Ed Kovac
Return via: UPS Account # W5Y243

Your Name: _____ Account #_____
(Please Print)
Signature:_____
Please complete at least one:
Phone:_____ Fax:_____Email:_____
Distributor/Hospital :_____
Address:_____
_____