URGENT: FIELD SAFETY NOTICE

CONMED Corporation Hyfrecator® 2000 Electrosurgical Units

March 22, 2017

CONMED Corporation is sending this communication to notify you of a product issue with the following catalog numbers. Certain serial numbers of the Hyfrecator® 2000 Electrosurgical Units are affected.

Catalog Number	Device Name
7-900-100	HYFRECATOR 2000, 100V
7-900-115	HYFRECATOR 2000, 115V
7-900-220	HYFRECATOR 2000, 220V
7-900-230	HYFRECATOR 2000, 230V

The Hyfrecator® 2000 Electrosurgical Units are sold as non-sterile, reusable devices. A separate Accessory Package is included in each Hyfrecator® 2000 Electrosurgical Unit (ESU) carton. This Accessory Package contains 2 Sterile Handpiece Sheaths, P/N 7-796-19.
From December 2, 2015 to January 3, 2017, the Accessory Packages in the Hyfrecator® 2000 ESU cartons were packaged in error by the manufacturer with non-sterile P/N 7-796-19 Handpiece Sheaths in pouches that were labeled as "Sterile." This could cause an end user to use a nonsterile sheath as if it were sterile. CONMED has received no reports that this mislabeling has resulted in illness or injury.

This recall only concerns the Sterile Handpiece Sheaths, P/N 7-796-19, included in the Accessory Packages contained in the Hyfrecator® 2000 ESU cartons. There is no problem with the Hyfrecator® 2000 Electrosurgical Units or with cases of P/N 7-796-19 sold in cases as P/N 7-796-19BX or P/N 7-796-19CS.

The Hyfrecator® 2000 Electrosurgical Units were distributed between December 2, 2015, and January 3, 2017. Attachment I contains a detailed list of the affected serial numbers, as well as the affected lots of P/N 7-796-19, packaged with the affected Hyfrecator® 2000 Electrosurgical Units.

Based on this information, CONMED has decided to recall the devices listed above to the user level. **Therefore, please follow the steps below if you have received Hyfrecator® 2000 Electrosurgical Units (ESU) marked with any serial number in the range listed for the applicable catalog number on Attachment I.**

For Customers who have an *out-of-carton* Hyfrecator® 2000 ESU:

Step 1: Please review your inventory for any of the ESU's listed on Attachment I, by catalog number.
We ask that you contact all of those departments within your facility and any other facilities within your organization or any of your customers 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 an affected *out-of-carton* Hyfrecator® 2000 ESU (serial number listed on Attachment I), please check if you have any pouches of P/N 7-796-19 remaining in your possession which match the P/N 7-796-19 Sterile Handpiece Sheath lot number listed on the last page of Attachment I.

Step 3: If the sheath lots do match, please complete the business reply form (Attachment II) and return it with the sheaths 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#: D100199
510K #: K963088

Please do not return the Hyfrecator® 2000 Electrosurgical Unit or any used sheaths.
Preprinted labels are enclosed for your convenience.
Credit will be issued unless otherwise requested.

Step 4: If you DO NOT HAVE any affected sheaths to return, please complete the business reply form (Attachment II), indicating you have no sheaths and return by one of the means listed below:

1. **Email to: hyfr2000@conmed.com**
2. **Fax to: Field Action Support Team at +1 315-624-3225.**

Please note: If you have quantities of the Sterile Handpiece Sheath P/N 7-796-19, that were delivered pursuant to a separate order for P/N 7-796-19BX or P/N7-796-19CS, these devices are not suspect and do not to be returned to CONMED. However, CONMED will accept the return of such sheaths if they bear the same lot code as the recalled sheaths.

For Customers who have a Hyfrecator® 2000 ESU still in its *original sealed carton*:

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 or any of your customers 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 an *original sealed carton* containing a Hyfrecator® 2000 Electrosurgical Unit with a serial number listed on Attachment I, please complete the business reply form (Attachment II) and return it with the unit 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#: D048939
510K #: K970493

Please do not return any used or opened Hyfrecator® 2000 Electrosurgical Units.
Preprinted labels are enclosed for your convenience.
Replacement equivalent Hyfrecator® 2000 ESU's will be issued unless otherwise requested.

Step 3: If you DO NOT HAVE any affected Hyfrecator® 2000 ESU's 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: hyfr2000@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 **1-800-448-6506, fax to +1 315-624-3225, or** email **hyfr2000@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,

[redacted]

Patricia Cotter
Senior Specialist, Regulatory Affair

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)*
7-900-100	1/Case	
7-900-115	1/Case	
7-900-220	1/Case	
7-900-230	1/Case	
7-796-19	2/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 hyfr2000@conmed.com.

If you are returning product, include a copy of this completed form with the devices.

Return devices to: CONMED Corporation
RGA-RA-HYFR-2056
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:_____
SERVICOM MEDICAL (S) PTE LTD
Risk/Purchasing Manager
438B ALEXANDRA ROAD BLOCK B,08 03
ALEXANDRA TECHNOPARK, 119968
SINGAPORE