Urgent: Field Safety Notice
CONMED Corporation SRN US-MF-000012663
Universal Plus™ Laparoscopic Electrodes

May 7, 2022

Dear Risk/Purchasing Manager -

CONMED Corporation is sending this communication to notify you of reports related to the product numbers below. A specific range of lot codes of the Universal Plus™ Laparoscopic Electrodes devices are affected as defined in Attachment I.

Catalog No.	Lot Codes	Device Name
60-5272-027	See Attachment I	Spatula, 27cm, 5mm, 5/cs
60-5272-032	See Attachment I	Spatula, 32cm, 5mm, 5/cs
60-5272-127	See Attachment I	L-Hook, 27cm, 5mm, 5/cs
60-5272-132	See Attachment I	L-Hook, 32cm, 5mm, 5/cs
60-5272-227	See Attachment I	J-Hook, 27cm, 5mm, 5/cs
60-5272-232	See Attachment I	J-Hook, 32cm, 5mm, 5/cs
60-5272-927	See Attachment I	Needle, 27cm, 5mm, 5/cs
60-5272-932	See Attachment I	Needle, 32cm, 5mm, 5/cs
60-5274-027	See Attachment I	Spatula w/ Stealth ER, 27cm, 5mm, 5/cs
60-5274-032	See Attachment I	Spatula w/ Stealth ER, 32cm, 5mm, 5/cs
60-5274-044	See Attachment I	Spatula w/ Stealth ER, 44cm, 5mm, 5/cs
60-5274-127	See Attachment I	L-Hook w/ Stealth ER, 27cm, 5mm, 5/cs
60-5274-132	See Attachment I	L-Hook w/ Stealth ER 32cm, 5mm, 5/cs
60-5274-144	See Attachment I	L-Hook w/ Stealth ER, 44mm, 5mm, 5/cs
60-5274-227	See Attachment I	J-Hook w/ Stealth ER, 27cm, 5mm, 5/cs
60-5274-232	See Attachment I	J-Hook w/ Stealth ER, 32cm, 5mm, 5/cs
60-5274-244	See Attachment I	J-Hook w/ Stealth ER, 44cm, 5mm, 5/cs
60-5274-932	See Attachment I	Needle w/ Stealth ER, 32cm, 5mm, 5/cs
60-5274-944	See Attachment I	Needle w/ Stealth ER, 44cm, 5mm, 5/cs

The Universal Plus™ Laparoscopic Electrodes devices are sold as single use, sterile devices. The Laparoscopic Electrosurgical Blade is a single patient use electrosurgical blade with suction/irrigation capability for use in surgical endoscopic procedures. CONMED received reports that the tip of the electrode could detach during use. The reason for this detachment was a weak weld between the electrode tip and the metal shaft of the electrode. In most cases, the tip was easily retrieved by the surgical team during the surgery. If the tip detaches in the patient cavity and cannot be retrieved, there should be little to no potential consequences in leaving the electrode tip in the patient as the electrode tip is made of stainless steel. The surgeon should make a decision, based on the surgeon's own clinical experience and the patient's individual needs, regarding the manner and time spent in attempting to retriever the electrode tip. CONMED has received no reports of a detached tip not being retrieved and being left in the patient.

The weak weld was restricted to a specific manufacturing facility line and to a single welder. Based on this information, CONMED has decided to recall the devices listed above, by specific catalog number/lot code configuration per the product tables on Attachment I **to the user level**.
Therefore, do NOT use any Universal Plus™ Laparoscopic Electrodes with the catalog and lot codes on Attachment I. The affected lot codes are more fully described on Attachment I.

The affected products were distributed between August 27, 2019, and April 14, 2022.

Please adhere to the following protocol to manage this recall:
Step 1: Please review your inventory for any of the devices with the affected lot codes listed on Attachment I.
We ask that you contact all 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 2a: If you HAVE inventory of any of the devices from the affected lot codes 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#: D086621
510K #: K954056

Please do not return open or used devices.

Step 2b: 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: LAPELC2022@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 **+1 800-448-6506** (8:00am to 7:00pm EST Monday through Friday)**, fax to +1 315-624-3225, or** email **LAPELC2022@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 appropriate international competent authorities have been notified of this action.

Sincerely,

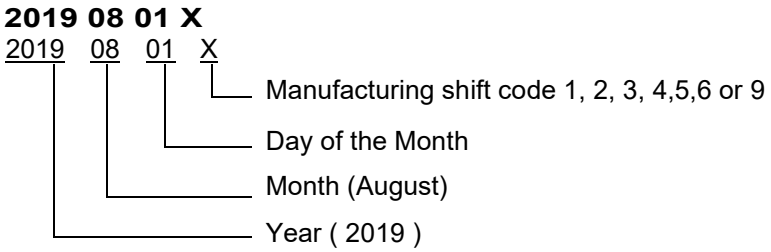
xxx

ATTACHMENT I
PRODUCT LOT CODES
Field Safety Notice

Affected catalog numbers and lot codes:
Lot codes for product manufactured to and including the dates listed below for each catalog number:

Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
August 1, 2019	20190801X	October 31, 2021	20211031X

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



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 affected inventory of the product to us.**
- □ **We are returning: (Complete table below and return form with affected product) for Credit Only (for distributors and healthcare facilities who purchase direct from CONMED)**

Catalog # being returned	Quantity per Box	Quantity of Eaches or boxes *(circle **boxes** or **Eaches** as applicable)*
60-5272-027	5/Box	
60-5272-032	5/Box	
60-5272-127	5/Box	
60-5272-132	5/Box	
60-5272-227	5/Box	
60-5272-232	5/Box	
60-5272-927	5/Box	
60-5272-932	5/Box	
60-5274-027	5/Box	
60-5274-032	5/Box	
60-5274-044	5/Box	
60-5274-127	5/Box	
60-5274-132	5/Box	
60-5274-144	5/Box	
60-5274-227	5/Box	
60-5274-232	5/Box	
60-5274-244	5/Box	
60-5274-932	5/Box	
60-5274-944	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 to ConMed Corporation.
It can be faxed to +1 315-624-3225, Attn: Field Action Support Team, or emailed to LAPELC2022@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:_____
_____