URGENT: FIELD SAFETY NOTICE

CONMED Corporation

Anchor Tissue Retrieval System™

March xx, 2019

CONMED Corporation is sending this communication to notify you of a product packaging discrepancy reported with the following catalog numbers. Certain lot codes of the Anchor Tissue Retrieval System™ devices are affected as defined in Attachment I**.**

Catalog Number	Lot Codes	Device Name
TRS100SB2	See Attachment I	Anchor Tissue Retrieval System™, 10 MM, 235 ML, (5/BX)
TRS175SB2	See Attachment I	Anchor Tissue Retrieval System™, 15 MM, 1550 ML (3/BX)
TRS190SB2	See Attachment I	Anchor Tissue Retrieval System™, 15 MM, 1850 ML (3/BX)
TRS-VATS-15	See Attachment I	Anchor Tissue Retrieval System™, VATS, 15 MM, 1550 ML (3/BX)
TRS-ROBO-8	See Attachment I	Anchor Tissue Retrieval System™, 8 MM, 125 ML (5/BX)
TRS-ROBO-12	See Attachment I	Anchor Tissue Retrieval System™, 12 MM, 300 ML (5/BX)

The Anchor Tissue Retrieval System™ devices are sold as single use, sterile devices. CONMED has received complaints that the individual device pouch had a void in its seal. CONMED's investigation has identified certain Anchor Tissue Retrieval System™ product with voids in the seal or a partial seal which sometimes results in an open channel. If this discrepancy goes unnoticed, it may compromise the sterility of the product. A possible infection may result from this discrepancy which would be temporary and reversible with antibiotic treatment. CONMED has received no reports that this seal discrepancy has resulted in illness or injury.

These seal discrepancies were localized to a specific manufacturing facility and sealing line. 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 Anchor Tissue Retrieval System™ with the catalog and lot codes on Attachment I unless listed as an Excluded Lot Code. The affected lot codes are more fully described on Attachment I.

The affected products were distributed between June 8, 2018, and February 28, 2019.

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 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 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#: D305162
510K #: K172940

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: TRS2019@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 **TRS2019@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. In addition, the US Food and Drug Administration has also been notified.

Sincerely,

Patricia Cotter
Senior Specialist, Regulatory Affairs

ATTACHMENT I
PRODUCT LOT CODES

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

Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
April 26, 2018	20180426X	February 15, 2019	20190215X

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

2014 10 01 X

2014 10 01 X

- X — Manufacturing shift code 1, 2, 3, 4,5,6 or 9
- 01 — Day of the Month
- 10 — Month (October)
- 2014 — Year (20**14**)

THE FOLLOWING LOT CODES ARE NOT INCLUDED IN THIS RECALL AND DO NOT NEED TO BE RETURNED:

Excluded Anchor Tissue Retrieval System™ Lot Codes -

1. All **alpha/numeric** lot codes (e.g. lots 68A8T or 19A8T)
2. All **numeric** lot codes ending with the number **"9"** (e.g. Lot code 201902159)
3. All excluded **numeric** lot codes listed in the tables below for each specific catalog number:

Excluded Lot Codes for Cat. Number TRS100SB2					
201805095	201806055	201809265	201810314	201811224	201812114
201805144	201806115	201809285	201811054	201811234	201812124
201805145	201807134	201810014	201811064	201811264	201812144
201805194	201807245	201810094	201811074	201811274	201812174
201805214	201808155	201810154	201811084	201811284	201812184
201805255	201808164	201810164	201811124	201811304	201812204
201805284	201808165	201810184	201811134	201812034	201812214
201805295	201808205	201810194	201811144	201812044	201901024
201805315	201808214	201810224	201811154	201812054	201901034
201806015	201808225	201810234	201811164	201812064	201901044
201806045	201808234	201810244	201811204	201812074	201901074
201806054	201809255	201810254	201811214	201812104	-----

ATTACHMENT I
PRODUCT LOT CODES

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Excluded Lot Codes for Cat. Number TRS175SB2				
201808025	201809215	201901164	201901184	201901224
201809205	201901154	201901174	201901214	----

Excluded Lot Codes for Cat. Number TRS190SB2		
201807114	201807275	----
201807175	201807304	----

Excluded Lot Codes for Cat. Number TRS-ROBO-12		
201901084	201901104	201901144
201901094	201901114	----

Excluded Lot Codes for Cat. Number TRS-ROBO-8		
201901244	201901284	----
201901254	201901294	----

Excluded Lot Code for Cat. Number TRS-VATS-15:	201808085

ATTACHMENT II
EFFECTIVENESS CHECK

URGENT: 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)**
  Check one: □ Credit (for distributors and healthcare facilities who purchase direct from CONMED)
  □ Replacement (for healthcare facilities who purchase via a distributor)

Catalog # being returned	Quantity per Box	Quantity of eaches or boxes *(circle **boxes** or **eaches** as applicable)*
TRS100SB2	5/Box	
TRS175SB2	3/Box	
TRS190SB2	3/Box	
TRS-ROBO-12	5/Box	
TRS-ROBO-8	5/Box	
TRS-VATS-15	3/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 TRS2019@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:_____
_____