# URGENT: FIELD SAFETY NOTICE

## CONMED Corporation

## Infinity™ ACL Tibial Elbow and Tip Guides

March 25, 2021

CONMED Corporation is sending this communication to notify you of a product issue with the following catalog numbers. All lot codes of the Infinity™ ACL Tibial Elbow and Tip Guides manufactured from April 26, 2019, to August 6, 2020, are affected (Ref. Attachment I). This notification has been expanded to include procedural kits which contain affected Infinity™ ACL Tibial Elbow and Tip Guides and affected product which was shipped between October 20, 2020, and February 8, 2021.

| Catalog Number | Lot Codes | Device Name |
|---|---|---|
| KTE100 | See Attachment I | Infinity™ ACL Tibial Elbow Guide |
| KTT100 | See Attachment I | Infinity™ ACL Tibial Tip Guide |
| INFINITY_TRAY | See Attachment I | Procedural Kit - Canada |
| KIT_INFINITY_BASE | See Attachment I | Procedural Kit - Italy |

The Infinity™ ACL Tibial Elbow and Tip Guides are sold as reusable, nonsterile devices. CONMED has received complaints that the tips of the Infinity™ ACL Tibial Elbow and Tip Guides are potentially misaligned laterally which could affect the accuracy of the guide system. This condition could cause a delay in procedure and may require another device or alternate surgical method to be used. Surgeons who identify misalignment or incorrect position of the guide wire would correct this immediately by repositioning the guide wire; this action by the surgeon could prevent any potential negative effect. If a guide pin is not placed accurately during a procedure due to misalignment of the guide arm, this would be detected via endoscope and the channel location would be corrected or re-drilled. The surgeon may also opt to use a different device to re-drill the channel which could cause a minor delay in surgery. No patient or user injuries are likely to occur due to this defect. No injuries have been reported to date.

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 Infinity™ ACL Tibial Elbow and Tip Guides 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 October 1, 2019, and February 8, 2021.**

**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 those departments within your facility and all other facilities that may have received affected products from you. Please forward a copy of this notice to all facilities which may have affected products in their inventory. 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 unused devices from the affected lot codes still in their original intact cartons 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#: D221270**
**510K #: Exempt**

**Step 2b: If you HAVE inventory of any USED devices from the affected lot codes listed on Attachment I, you may return them using the following method:**

a) **Please clean, disinfect and sterilize the device the device following the directions for Cleaning, Disinfection, and Sterilization Information found in the Infinity™ Drill Guide System Instructions for Use, P000009343 (https://www.conmed.com/en/customer-service/catalogs-and-ifus) on pages 4-6 of the English language section or the appropriate translation.**
b) **Place the cleaned and sterilized device in a sterile wrap and insert this in a zip lock bag. Label the bag with the catalog number and lot code. Please mark the bag "Used Device."**
c) **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#: D221270**
**510K #: Exempt**

**Step 2c: 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: INFIN2020@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 **INFIN2020@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,

Patricia Cotter
Recall Coordinator

**ATTACHMENT I**
**PRODUCT LOT CODES**

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**Affected KTE100 and KTT100 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 |
|---|---|---|---|
| April 26, 2019 | 201926AB | August 6, 2020 | 202024AF |

Listing of affected catalog numbers and lot codes:

| Catalog Number | Lot Code |
|---|---|
| KTE100 | 201926AB |
| KTE100 | 201942AF |
| KTE100 | 201947AF |
| KTE100 | 202007AF |
| KTE100 | 202011AF |
| KTE100 | 202015AF |
| KTE100 | 202018AF |
| KTE100 | 202024AF |
| | |
| KTT100 | 201941AE |
| KTT100 | 201946AF |
| KTT100 | 202006AF |
| KTT100 | 202010AF |
| KTT100 | 202015AF |
| KTT100 | 202019AF |
| KTT100 | 202023AF |

Affected lot codes for Procedural Kits:

| Catalog Number | Lot Code |
|---|---|
| INFINITY_TRAY | 001 |
| INFINITY_TRAY | 005 |
| KIT_INFINITY_BASE | 1 |
| KIT_INFINITY_BASE | 2 |
| KIT_INFINITY_BASE | 3 |

**ATTACHMENT I**
**PRODUCT LOT CODES**

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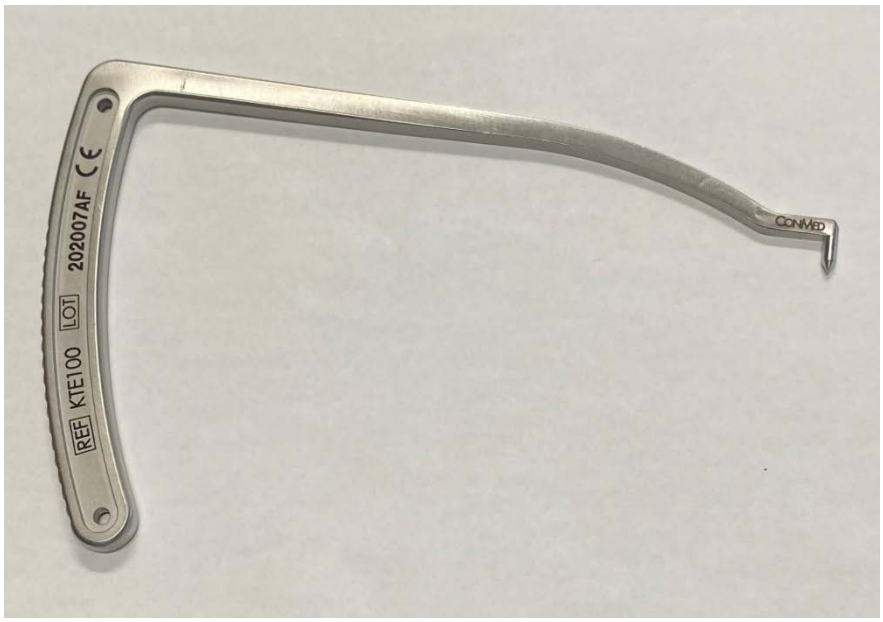
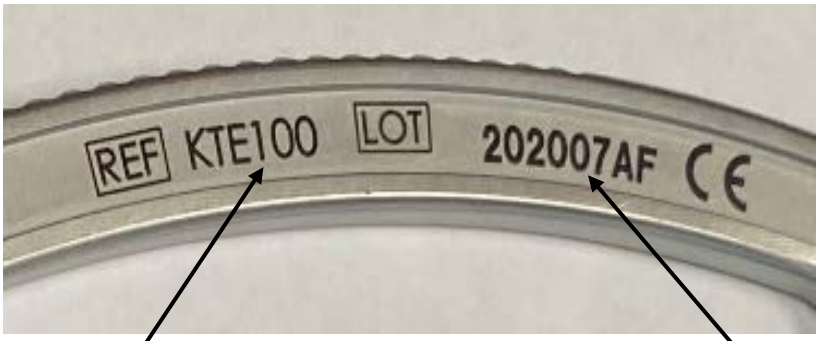
## How to locate the catalog number and lot codes on the Infinity ACL Guide Arms:

*Cat. No. KTE100 is shown in photo but the location of catalog number and lot code is the same for both Cat. No. KTE100 and KTT100.*



**ATTACHMENT II**
**EFFECTIVENESS CHECK**

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**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 (ONLY for distributors and healthcare facilities who purchase direct from CONMED)**
  **□ Replacement (for ALL healthcare facilities who purchase via a distributor)**

| Catalog # being returned | Quantity per Box | Quantity of eaches by lot code |
|---|---|---|
| KTE100 | 1/Box | |
| KTE100 | 1/Box | |
| KTT100 | 1/Box | |
| KTT100 | 1/Box | |
| INFINITY_TRAY | 1/Box | |
| KIT_INFINITY_BASE | 1/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 INFIN2020@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:_____
_____