Bound Tree
Your Partner In EMS
5000 Tuttle Crossing Blvd. Dublin, OH 43016 614.760.5000 www.boundtree.com

November 2, 2018

URGENT: MEDICAL DEVICE RECALL
CURAPLEX EPI-SAFE KIT

Dear Customer,

This **URGENT NOTICE OF RECALL** is to inform you of a product recall involving **all lots** of the **CURAPLEX EPI-SAFE KIT (Models 8600-01100, -01101, -01102, -01120)** manufactured by Bound Tree Medical, LLC.

This recall has been initiated because the Instructions for Use included in the Epi-Safe Kits for the Epi-Safe Syringe (and/or the Safety Lok Syringe in Model 8600-01120) recommend a midpoint dosage of epinephrine for children between 0 lbs. and 66 lbs. of 0.15mL **that has not been approved by FDA for children.** Reliance on the current IFU and/or use of the Epi-Safe Syringe as instructed may result in the administration of an inappropriate dosage of epinephrine to young children experiencing anaphylaxis, especially those under 33 lbs. Common side effects of epinephrine are short in duration and include anxiety, nervousness, headache, fear, palpitations, sweating, nausea and vomiting, pale skin, shortness of breath, dizziness, weakness or tremors

Accordingly, the current IFU in ALL Epi-Safe Kits are being replaced with the IFU developed by the epinephrine's manufacturer, Par Pharmaceutical. **A copy of the new IFU is included in the recall package you will be receiving at your shipping locations.** If you have Epi-Safe Kit Models 8600-01100, -01101, and/or -01102, we are also recalling the Epi-Safe Syringe and replacing it with a standard graduated sterile syringe.

Please return the attached Recall Response Form to Bound Tree Medical even if you have no Epi-Safe Kits on site.

If the kits affected in this recall were resold by you, notification of your customers may be enhanced by including a copy of this recall notification letter.

Please call Bound Tree Customer Service with any questions. Customer Service is available Monday through Friday, 8:00 a.m. - 8:00 p.m. EST, toll free at 1-800-533-0523.

Thank you.

Ayshia Conkright
Ayshia Conkright
Regulatory Affairs

INSTRUCTIONS FOR RECALL

Please take the following steps to open all of your existing Epi-Safe Kits, take out the Epi-Safe Syringe and Instructions for Use, and replace them with a new syringe and instructions provided in your Recall package, storing the refurbished kits in a provided Ziploc bag. More specifically, please:

1. **Quarantine all Epi-Safe Kits in your possession immediately.**

2. **Open your Recall Package and confirm that your Recall Package contains a quantity sufficient to do the exchange for all of your existing Epi-Safe Kits :**
    a. **NEW ITEMS TO ADD TO YOUR EXISTING KITS**
        i. **Standard sterilized syringe with graduated lines [Exel International Inc., Luer Slip Tip Tuberculin Syringe with Cap, 1mL] [for Kits 8600-01100, -01101, and/or -01102 only]**

ii. **Par Pharmaceutical IFU for ADRENALIN - epinephrine injection with appropriate dosage instructions**

b. **SHIPPING MATERIALS FOR RETURNING THE RECALL RESPONSE FORM**
   i. **Pre-Stamped envelope for mailing back the Recall Response Form enclosed**
   ii. **Contact Bound Tree Customer Service to receive a Return Mail Authorization (RMA) for sending back the Epi-Safe Syringes and IFUs if you have determined that you need to return the Recall Package and all Epi-Safe Kits in your possession. Customer Service is available Monday through Friday, 8:00 a.m. - 8:00 p.m. EST, toll free at 1-800-533-0523.**

c. **FOR STORAGE OF THE REFURBISHED KITS**
   i. **6" x 8" Plastic Zip-Lock Bag marked EPI-SAFE KIT STORAGE**

If any contents are missing from your Recall Package, contact Bound Tree Medical, LLC immediately.

3. **Replace the old syringes and instructions with the new:**
   a. **Note that it is easiest to do this one kit at a time so that you can keep track of how many syringes are in a given kit.**
   b. **Disassemble your Epi-Safe Kits by opening the clear plastic shrink wrap and remove (1) the Epi-Safe Syringe(s) [if applicable] and (2) the IFUs.**
   c. **Place the unrecalled contents from the Epi-Safe Kit (e.g., the vial of epinephrine, needle, alcohol wipes, etc.) into the 6" x 8" plastic zip-lock bag marked EPI-SAFE KIT STORAGE.**
   d. **Add one standard gradiated syringe(s) into the EPI-SAFE KIT STORAGE for every syringe that was previously in the Kit you are assembling.**
   e. **Add ONE new IFU into the EPI-SAFE KIT STORAGE bag.**
   f. **Seal your new Epi-Safe Kit and store pursuant to the new IFU.**

4. **Disposing the defective product:**
   a. **Dispose of the Epi-Safe Syringe and the original IFUs in adherence with your standard policies and procedures for disposal.**

5. **Complete the enclosed Recall Response Form and return to Bound Tree Medical, LLC as soon as possible. Returning the Recall Response Form is required even if you find that you have NO unopened Epi-Safe Kits in your possession.**

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RECALL RESPONSE FORM

PLEASE COMPLETE AND RETURN THIS RECALL RESPONSE FORM AS SOON AS POSSIBLE TO BOUND TREE MEDICAL, LLC BY EITHER EMAILING A PDF COPY TO REGULATORY@BOUNDTREE.COM OR VIA MAIL USING THE PRE-STAMPED ENVELOPE PROVIDED.

I have read and understand the Epi-Safe Kit recall notification November 2, 2018 letter.

Yes No

I have checked my stock and quarantined ALL inventory of Epi-Safe Kits in my possession.

Yes No **OR** I have checked my stock and have NO Epi-Safe Kits in my possession.

Indicate disposition of recalled product:

I have replaced _____Epi-Safe Syringes (if applicable)

I have replaced _____ IFU (if applicable)

After replacing my Epi-Safe Kits with the contents of my Recall Package, I have disposed _____ Epi-Safe Syringes and _____ Instructions for Use.
Indicate disposal methodology in the space provided or in an attachment if additional space is required.

_____

_____

OR

I have returned _____ Epi-Safe Kits because I am untrained in calculating a dosage based on weight and administering a drug via syringe (and/or my facility lacks the appropriately trained personnel) and would like a credit for the value of my Epi-Safe Kits.

I have stored the standard gradiated syringe [**Exel International Inc., Luer Slip Tip Tuberculin Syringe with Cap, 1mL**] (if applicable), the Par Pharmaceutical IFUs, and all other non-recalled contents of the Curapex Epi-Safe Kit within the 6" x 8" plastic zip lock bag provided to me and stored each new kit according to the Par Pharmaceutical IFUs.

Yes No **OR** Not applicable because I have NO Epi-Safe Kits in my possession.

Have ANY adverse events been reported to you in connection with the Epi-Safe Kit?

Yes No

If yes, please explain in the space below or in an attachment if additional space is required:

_____

_____

If you have further distributed the Epi-Safe kit to others, please attach contact information in the following format. Bound Tree Medical, LLC will directly contact all listed individuals/entities and provide them with further recall instructions. In the meantime, please send all listed individuals a copy of the recall notice to assist us in notifying others of the recall as quickly as possible.

NAME/ORGANIZATION	MAILING ADDRESS	PHONE NUMBER	E-MAIL ADDRESS

Please call Bound Tree Customer Service with any questions. Customer Service is available Monday through Friday, 8:00 a.m. - 8:00 p.m. EST, toll free at 1-800-533-0523.

Name (print)

E-Mail Address

Signature

Phone Number

Name of Organization and Title

Date