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COMPANY ANNOUNCEMENT

Urgent Medical Device Recall: Optimum Traction Device (O.T.D) Model number: EP – 800

Summary

Company Announcement Date:

February 27, 2024

Product Type:

Medical Devices

General Hospital & Personal Use

Reason for Announcement:

Possible failure of pole insert adhesive

Company Name:

Emergency Products and Research (EP+R)

Brand Name:

Emergency Products and Research Optimum Traction Device (O.T.D)

Product Description:

Extremity splint traction device

Company Announcement

Emergency Products and Research is announcing that it is conducting a voluntary recall of Optimum Traction Device (O.T.D) model EP – 800. The company initiated the recall after internal testing indicated a possible failure of the adhesive used to secure the pole insert may be inadequate, resulting in the device being unusable. To date, there have been no reports of adverse health consequences received. This recall is being made with the knowledge of the Food and Drug Administration and other relevant competent authorities.

Product Identification

The recall involves all Optimum Traction Devices (O.T.D), EP – 800 manufactured/shipped after September 1, 2023 containing a possible defective aluminum insert in the traction pole.

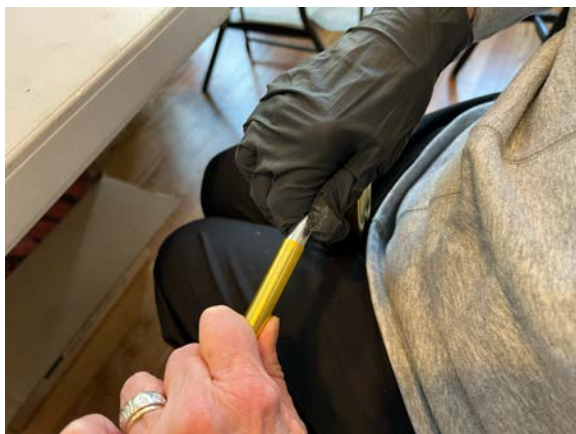
To help identify whether you have an affected traction splint that is subject to the recall, please inspect all splints received after September 1, 2023 for proper insert connection.

Figure 1



Ensure that all inserts are secured into the gold pole sections. The insert is silver in color; if the insert depicted in Figure 1 pulls out of the gold tube it is defective.

Figure 2



To check the insert simply hold the gold section in one hand and pull on the silver insert with your other hand to see if it is properly bonded and repeat for every section of the traction pole.

Remedy

All Optimum Traction Device (O.T.D) splints are now being manufactured with faster setting CA adhesive. In addition, the company initiated a more extensive simulated-use testing to ensure the revised adhesive is consistently reliable. Production and replacement of all recalled Optimum Traction Device (O.T.D) splints, model EP – 800 with the improved insert adhesive is currently underway.

Notifications Made

Concurrent with this press release, Emergency Products and Research (EP+R) is notifying all Optimum Traction Device (O.T.D) splint distributors and direct sales customers by email and direct mail. Each customer will receive instructions on how to arrange for a return of all affected products. Customers and distributors must return all unused affected products through their proper distribution channel.

If you purchased product directly from Emergency Products and Research (EP+R)

1. Immediately examine your inventory and set aside any product subject to recall pursuant to the identification instructions above.
2. Immediately discontinue use and/or distribution of any affected products.
3. If you received a recall information packet from Emergency Products and Research (EP+R), follow the instructions in that packet for return of the recalled product.

If you purchased product from a party other than Emergency Products and Research (EP+R):

1. Immediately examine your inventory and set aside any product subject to recall pursuant to the identification instructions above.
2. Immediately discontinue use and/or distribution of any affected products.
3. Contact the seller of the product and ask for instructions for return of all unused Optimum Traction Device (O.T.D) splint model, EP – 800 through that distributor.
4. If you do not have information on where you purchased the Optimum Traction Device (O.T.D) splint model, EP – 800 please contact the company using the information below.

Customers with questions may contact the company between the hours of **8:00 a.m. and 3:00 p.m. EST**

Emergency Products and Research (EP+R)

Phone Number +1 330 673 5003

Email EPRinfo@epandr.com

Website www.epandr.com

About Emergency Products and Research (EP+R)

For over three decades Emergency Products and Research (EP+R) has been a leader in the design, development and manufacturing of emergency medical products. Used by civilian EMS, military, and special forces around the world.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

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