

URGENT MEDICAL DEVICE RECALL

Timely Response Required

REX (Recovery Exercise Trainer) Pressure Therapy System – USER MANUAL

Model Number: DVTREX-U and DVTREX -L

Scope of Recall: All Serial Numbers



March 2023

Dear Valued Customer:

A voluntary Field Correction is being initiated by Compass Health Brands for the USER MANUAL for the REX (Recovery Exercise Trainer) Pressure Therapy System.

Reason for Field Correction: Compass Health Brands has recently identified an error in the Introduction section of the user manual that indicates the device may be used for the prevention of deep vein thrombosis (DVT). This model of the compression system is not designed or FDA-cleared for this indication for use. To date, Compass Health Brands has received 0 customer complaints for this error, and 0 injuries.

RISK TO HEALTH:

If an end user uses this device with the intention of preventing DVT, the device may not be effective for this purpose which could result in user not receiving proper and effective treatment.

ACTIONS TO BE TAKEN BY THE CUSTOMER:

Immediately replace the current user manual included with the device with the attached, corrected version, and dispose of the current manual. Compass Health Brands will additionally mail you replacement user manuals in booklet format (which is the same format as the current user manual), if you prefer to use that as a replacement, instead.

REQUIRED ACTION:

1. Ensure all affected personnel are fully informed of this notice. Forward this notice to your Regulatory Compliance Manager, Purchasing Manager, Customer Service Manager and Field Technicians.
2. The USER MANUAL for the REX (Recovery Exercise Trainer) Pressure Therapy System requires replacement.
3. Dealer/distributor must replace the user manual for any units still in your possession.
 - You may use the attached replacement user manual or visit <https://compasshealthbrands.com/product-recall> to download a replacement user manual.
 - Additionally, you may contact Compass Health Brands at (800) 947-1728 or indicate on the attached reply form (Attachment A) to order a replacement user manual(s) in booklet format be mailed to you.
4. Dealer/distributor must complete and return the attached Distributor/Dealer Field Correction Response Form (Attachment A) to Compass Health Brands **within fifteen (15) calendar days of receipt** of this field correction notification confirming your acknowledgement.

Send completed form to Compass Health Brands via email at regulatory@compasshealthbrands.com. **YOU MUST** complete and return this form even if you do not have affected product on hand.
5. Dealer/distributor must notify their customers that have received the REX (Recovery Exercise Trainer) Pressure Therapy System (using the attached Consumer Notification form) to alert them to this recall and the requirement to replace the USER MANUAL.

This voluntary Field Correction notification is being conducted with the knowledge of the United States Food and Drug Administration (FDA) in accordance with U.S. regulations. Any complaints and/or adverse events experienced with the use of this product must be reported promptly to Compass Health Brands Customer Support at (800) 947-1728 Monday-Friday 8:00 am EST - 5:00 pm EST and/or to the FDA through its MedWatch program.

Compass Health Brands appreciates your immediate attention to this urgent matter – we apologize for the inconvenience this may cause.

Thank you,

Elizabeth Proctor
Director, Regulatory Compliance

ATTACHMENT A – DISTRIBUTOR/DEALER FIELD CORRECTION REPLY FORM – **RESPONSE REQUIRED**

USER MANUAL for the REX (Recovery Exercise Trainer) Pressure Therapy System
Model Number: DVTREX-U and DVTREX -L

March 2023

Complete and return this form to Compass Health Brands **within fifteen (15) calendar days of receipt** of this field correction notification confirming your acknowledgement. Send completed form to Compass Health Brands via email at regulatory@compasshealthbrands.com.

Please check ALL applicable boxes:

- ☐ I have received the letter and have notified my Regulatory Compliance Team.
- ☐ I have replaced the user manuals for all devices still in my possession.
- ☐ I have identified and notified all customers that purchased this product.

Check method of notification used: Mail _____; E-mail _____; Fax _____; Phone _____

- ☐ I have provided all customers that purchased this product with the updated USER MANUAL in electronic form.

How many User Manuals in booklet format would you like to have mailed to you? _____

How many devices have been sold to customers as of the date of this notification? _____

CUSTOMER CONTACT INFORMATION (PLEASE PRINT CLEARLY):

Name: _____ Title: _____

Address: _____ City: _____

State: _____ Zip Code: _____ Telephone #: _____

Email Address: _____

Signature: _____ Date: _____