

# 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:

Our records show that you may have purchased a REX (Recovery Exercise Trainer) Pressure Therapy System. 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 a replacement user

manual 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. The USER MANUAL for the REX (Recovery Exercise Trainer) Pressure Therapy System requires replacement.
  - Visit <https://compasshealthbrands.com/product-recall> to obtain a replacement user manual, or
  - Contact Compass Health Brands at (800) 947-1728 to order a replacement user manual in booklet format, or
  - Indicate on your Reply Form (attached) that you would like a replacement user manual.
2. Complete and return the attached Consumer Field Correction Response 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](mailto:regulatory@compasshealthbrands.com). Complete and return this form even if you do not have affected product on hand.

If you have transferred possession of this product to another individual/department/location, please notify them of this recall communication.

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 and recognizes the inconvenience this may cause.

Sincerely,  
Compass Health Brands

CONSUMER 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](mailto:regulatory@compasshealthbrands.com).

Number of REX (Recovery Exercise Trainer) Pressure Therapy Systems you own \_\_\_\_\_

Number of REX User Manuals in booklet form that you would like to have mailed to you: \_\_\_\_\_

I confirm that I have destroyed the original user manual that was packaged with my device and replaced it with the new user manual \_\_\_\_\_ YES \_\_\_\_\_ NO

**CUSTOMER CONTACT INFORMATION (PLEASE PRINT CLEARLY):**

Name: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_

State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ Country: \_\_\_\_\_ Telephone #: \_\_\_\_\_

Email Address: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_