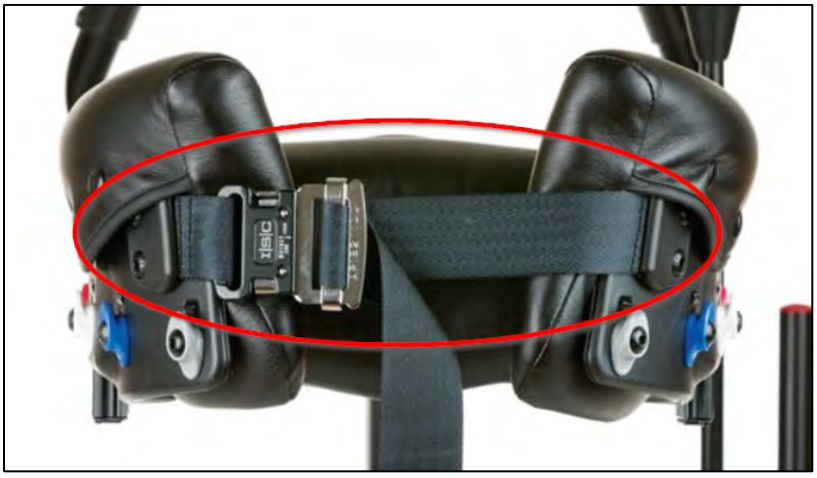
Rifton Equipment

URGENT: MEDICAL DEVICE CORRECTION

K310 & K320 Rifton TRAM
K660 E-Pacer

Dear Customer

Rifton Equipment is voluntarily recalling the body support strap from the Rifton TRAM and E-Pacer. The TRAM and the E-Pacer are transfer and mobility devices that can be used for seated transfers or as a support for standing or ambulation. The body support strap helps to secure the client in the body support system. Rifton Equipment has received complaints of fraying on the body support strap, presenting a risk of falling. **Serious injuries and/or deaths could occur due to the failure mode associated with this recall, with 15 complaints having been received for this failure mode (all of which were reported to FDA), including two which involved a concussion.**



The Body Support Strap

What is the reason for the recall?
The Body Support Strap is sewn at both ends to an aluminum stamping which is secured to the body support. Some of these stampings were manufactured with edges that are slightly sharper than normal, and over time these sharper edges can abrade the strap material, causing the strap to fray and eventually break.

Which products does this recall affect?
This recall affects some K310 and K320 TRAMs manufactured between July 4, 2012 and April 4, 2018, some K660 E-Pacers manufactured between June 12, 2017 and April 5, 2018, and all TRAMs and E-Pacers manufactured between March 6, 2019 and Nov 2, 2020. Our records indicate that you ordered the following TRAMs or E-Pacers which are subject to this recall:

[Product name] [Order date][Ship to name] [Ship to address] [ID Code] [Order number] [PO number] [Mark for]

Where is the ID Code?
The ID code can be found either under the horizontal mast, right below the “Rifton TRAM” or “E-Pacer” label, or for TRAMs ordered prior to November 2013, under the left leg:

What should I do now?

1. **Inspect your TRAM or E-Pacer**

Inspect your TRAM or E-Pacer by pulling down on the body support strap and checking, on both ends, to see if any fraying is visible. If no fraying is visible, you may temporarily continue to use the device until the replacement kit arrives. If fraying is visible on either end of the strap, please discontinue use of your TRAM or E-Pacer immediately until the body support is replaced.

An example of a fraying strap

2. **Contact Rifton**
   Contact Rifton at **888-473-8012** (9 to 5 EST, Monday – Friday) to confirm that you received notification of this recall. We will also need a contact name, phone number and email for the responsible person who will perform the replacement, and an address that we can send the replacement parts to.

Replacement Kit
The replacement is simple and should not take more than twenty minutes. The replacement kit contains:

- Body support assembly
- 2 Bolts, 2 nuts
- 1 Linkage arm
- 2 9/16" wrenches
- Replacement instructions
- Updated product manual
- Recall response letter

The person responsible for performing the replacement will need to remove and discard the old body support and install the new one with the tools and hardware provided. We will need confirmation from you when the replacement has been done.

I don't have the TRAM or E-Pacer anymore
If you have further distributed the TRAM or E-Pacer, please forward a copy of this notification email to the customer who received the device from you. Please also reply to this email to let us know that you do not have the product anymore, and provide us with contact information for the person who received the device from you.

More information?
Call us at **888-473-8012** (9 to 5 EST, Monday – Friday) if you have further questions regarding this recall.

Adverse Events
If you have experienced an adverse event related to the use of the TRAM or E-Pacer, you may report it to the FDA using the MedWatch Voluntary Consumer/Patient Report (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=consumer.reporting1).

Thanks for responding
Sincerely,

Rifton Equipment