

URGENT: MEDICAL DEVICE CORRECTION
Ceiling Lift Operator & Service Manual Updates

Date: October 5, 2022

RE: Tollos Cirrus 450, 600, 700 and 750 models, and Pinnacle 1000 Ceiling Lifts

Dear Healthcare Provider,

Tollos has received complaints of strap failure while using a Cirrus lift with the Infection Control (IC) strap. These reports concern only the IC strap and this correction notice applies only to Tollos Cirrus 450, 600, 700, 750, and Pinnacle 1000 model ceiling lifts equipped with the IC strap. This model number information is displayed on the decal affixed at the front of the unit.

If this IC strap fails during use, the patient may fall causing injury to them or the caregiver(s).

Following these reports, Tollos extensively tested several IC straps. Testing was also performed by an independent, third-party lab. The results of testing led to the following conclusions:

- There is no inherent defect or weakness in the IC strap.
- IC straps used for three years that were not damaged or excessively worn were as strong as new IC straps.
- Complaints most commonly occurred with IC straps that exhibited signs of excessive wear and/or damage.

Recognizing wear conditions and responding with appropriate service is key to avoiding serious injuries for patients or clinicians. For this reason, Tollos has updated our Ceiling Lift Operator's & Service Manuals to include the following instructions. In addition, Inspection Checklists in each manual have been updated to refer to this information.

Specific to lift straps, users should take the following steps to reduce risk:

- Immediately inspect all straps for signs of excessive wear or damage.
 - ▶ Refer to the pictures on the following pages as examples of wear/damage conditions requiring replacement.
- Discontinue use of any lifts with straps that show signs of excessive wear or damage.
- Service your facility's Pinnacle or Cirrus lift(s) by removing and replacing worn or damaged straps with new straps. Contact Tollos for assistance if needed.
- Educate staff to visually inspect the strap with each use, with instructions to not use lifts with visibly worn straps and to alert lift maintenance personnel of any concerns.
- As well as having staff inspect the belts before each use, it is recommended that maintenance or biomed staff (this function varies in different facilities) inspect straps on a regular basis as

determined by facility use but at least semi-annually.

All types of lifting straps, including IC straps, are prone to wear and require eventual replacement. Tollos recommends replacement of any straps showing signs of excessive wear or damage, or at 10,000 cycles, whichever occurs first.

Access complete Operator's & Service Manuals on the web at www.tollos.com/service-bulletins.

Any adverse events experienced with the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Tollos can be contacted by e-mail at service@tollos.com.

NOTE: If this device was distributed or sold to a third party, please forward this notification.

Please complete the enclosed response card and return to Tollos via the post-paid envelope. Thank you.

ILLUSTRATIONS

Illustrations 1-4 are examples of IC straps showing signs of normal wear and no structural damage. These straps are safe to continue to use as long as they have not exceeded 10,000 cycles. If the inspected straps are at 10,000 or more lift and lower cycles, then replace the straps.

NOTE: The images below were taken during service activities and the clasp is not shown in the correct position. The correct location of the clasp is just below the fold, shown with the red line on the picture furthest to the right.)

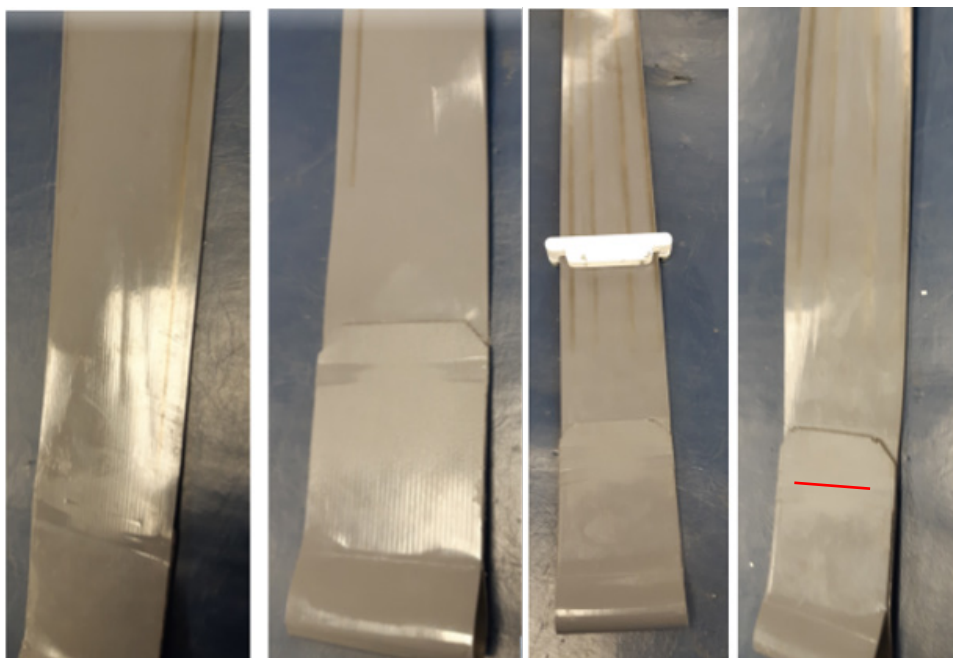


Illustration 1

Illustration 2

Illustration 3

Illustration 4

Illustration 5 is an example demonstrating wear to the point that the load bearing internal steel cables are showing. Replace any straps that are worn to this point.

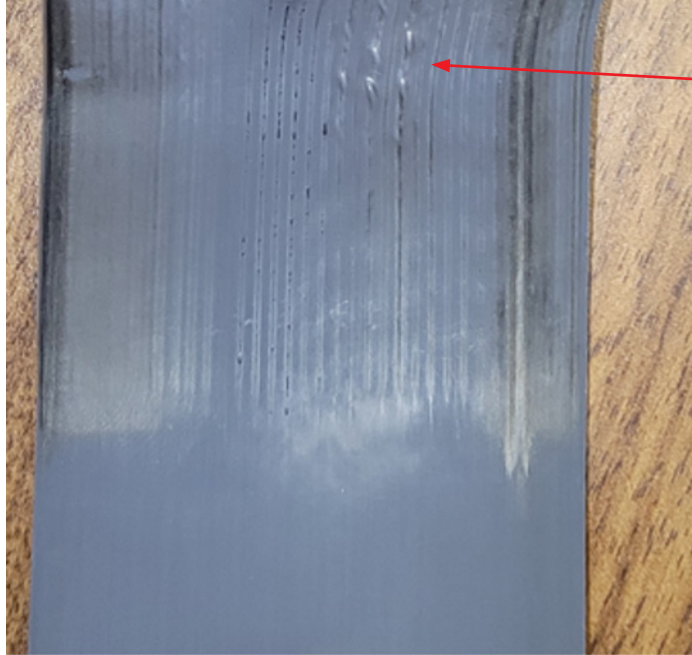


Illustration 5

Illustrations 6-8 demonstrate creasing. If creasing is deep, sometimes coupled with cracks, or if the strap has exceeded 10,000 cycles the strap must be replaced.



Illustration 6



Illustration 7



Illustration 8

Illustration 9 demonstrates physical damage. Do not use a lift with a damaged strap, and immediately replace any straps found to have physical damage.



Illustration 9

Illustrations 10 and 11 demonstrate a specific type of physical damage – damage to the edge of the strap. Replace any straps that have this type of damage. (Note that illustration 10 also demonstrates significant creasing.)

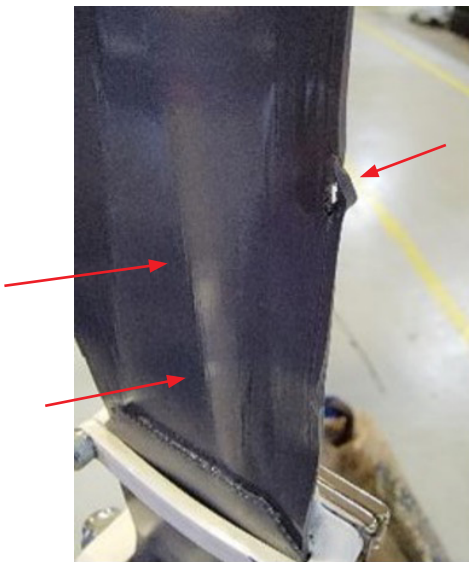


Illustration 10



Illustration 11

Illustrations 12-14 demonstrates the exterior appearance of a strap with severe damage to the load bearing steel cables internally. An x-ray of this strap is included to show the internal damage that corresponds to the exterior appearance. The close-up image of the opposite side shows the broken cable ends visible through the polyurethane covering. (Note, this strap also demonstrates severe creasing.)

