CE

APPLICATION, INSTALLATION AND USE

The following instructions describe the process to install replacement straps that include a tension buckle. Recommended application, installation and use procedures must be followed for maximum safety and service life.

Figure 1: Tension Buckle and Quick Release Buckle

- Remove the simple chafe using a Philips screw driver keeping the barrel nut in place
- Place the provided barrel next to the one left in place
- Attach the tension buckle to the two barrel nuts using removable Loctite 242/243 to the threads of the two provided 8-32 X 3/8 flat head screws
- Attach the quick release buckle from the old strap to the new strap and adjust strap length to patient and cut off excess
- Use the provided alligator tab to secure the strap end in place
- Once strap tension is established there should not be any need for adjustments

Attention

- Follow the physician's and the fitting specialist's instructions for length of brace wear.
- Follow physician's and the fitting specialist's instructions for activities that are acceptable while wearing the orthosis.
- Physician's orders should supersede all protocol.

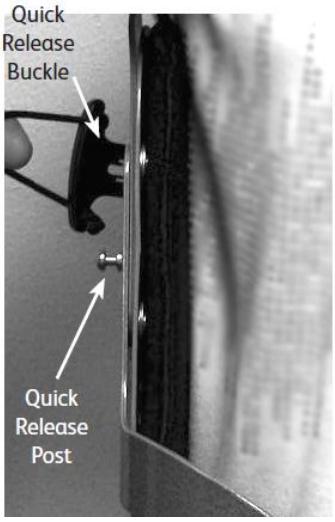

Figure 2: Buckle over Post

INSTALLATION AND USE

- Always wear a tight fitting undershirt as a buffer under the orthosis.
- Ensure the Tension buckle (FIGURE 1) is in the open position and the quick release buckle is unattached from the quick release post.
- While lying down, gently log-roll onto the back pad and strap without any bending or twisting of your spine. Insert your thumb into rope of quick release buckle (FIGURE 2) and pull buckle up and over quick release post. You may need assistance for this procedure.
- Close Tension buckle on opposite side.

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STORAGE AND USE
There are no identified restrictions on the temperature of storage and use.

DISPOSAL
There are no hazardous materials in the device. Comply with local and national laws and regulations.

LEGAL INFORMATION
MD The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.

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LIMITED WARRANTY
Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.

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