



IMPORTANT NOTE

These instructions are only general guidelines and may be altered by the Fitting Specialist according to each individual's needs or the specifications of the prescribing physician.

Any attempt at moving a patient in an acute and/or post-operative condition should be facilitated with help from support staff and all necessary precautions should be taken.

Treatment protocol may vary from institution to institution and the adherence of these requirements are the responsibility of the Fitting Specialist.

IMPORTANT REMINDER

- Before application of Orthosis, patient should be sure to wear a tight fitting, cotton T-shirt or stockinet as a buffer between the skin and the Orthosis. Wrinkles under the Orthosis can cause irritation and skin breakdown.
- The shell of the Orthosis can be cleaned with soap and warm water or rubbing alcohol. The Velcro adhered liners can be removed and washed with a gentle soap and water and air-dried.
- Follow 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.

BRACE APPLICATION INSTRUCTIONS

1. With the patients in a supine position with knees extended, palpate the waist indentation on the patient to demonstrate proper location of the orthosis.
2. Raise one arm over the patient's head on the side in which you will roll them.
3. Log-roll patient toward raised arm onto their side. Stand on the side to which you roll them supporting the patient as needed.
4. Place the posterior component into proper placement. Palpate waist indentations to align with the indentations of the orthosis.
5. Roll patient onto back. Place anterior component onto patient insuring that it aligns with the posterior component and waist indentation.
6. Start with tightening middle closures, followed with the bottom and top closures. Secure and tighten in original sequence.

Note: The Straps and Chafes on the XX-Large are moveable for adjustability and secured with screws. These screws will need to be tightened and occasionally checked for looseness. If necessary, add Loctite removable thread retaining compound to the threads of the screws to help prevent loosening.





QUESTIONS

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Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

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LIMITED WARRANTY

Trulife warrants that the PRODUCT will be free from defects in material and workmanship for the PRODUCT from the date of installation.

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 a PRODUCT has been modified/repared 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 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.

