



INTRODUCTION

The Trulife Endoskeletal Cosmesis offers high durability in a cost-effective, universal cosmesis shape for temporary or permanent patient application. Appropriate for use with the Lightfoot, Natural Foot and SACH Foot.

Product Code	Description	Height Accommodates	Foot Sizes
SEC201	Light	26 cm (10.25")	22–26 cm
SEC210	Dark	26 cm (10.25")	22–26 cm
SEC202	Light	39 cm (15.5")	26–29 cm
SEC211	Dark	39 cm (15.5")	26–29 cm

INDICATIONS

Lower-limb amputees to build a limb system.


INSTALLATION AND USE


Recommended installation and use procedures must be followed for maximum safety and service life.

The Endoskeletal Cosmesis can be sized and modified for the individual patient. Further ripping of partial cuts in the cosmetic cover can be prevented by notching the point where the cut ends using a leather punch. Cuts may also be reinforced by roughing up the surrounding area inside the cover and backing it with leather or Dacron.

The Endoskeletal Cosmesis can be glued directly to the foot.

1. Remove the foot from the endoskeletal limb by loosening the foot bolt.
2. Completely roughen the mounting surfaces of the foot and cosmesis.
3. Remove all foam particles from the abraded surfaces. If desired, apply small reference marks to the mounting surfaces to facilitate careful matching of the surfaces.
4. Apply a thin layer of contact cement to each surface and allow it to dry.
5. Apply a second layer of contact cement and allow to dry.
6. Match the two surfaces carefully and press them together tightly, both on the outside and inside of the seam.
7. If color coating is desired, remove any remaining mold release from the cover and foot with a solution of equal parts of naphtha and acetone. For best results, use a clean cotton cloth. The naphtha-acetone solution is recommended to improve the adhesion of color coatings, but alcohol can be used as well.
8. Push the limb pylon down through the cosmesis, matching the central rib on the adaptor with the keel top. Do not pull hard on the seam if the glue has not had a chance to dry thoroughly (usually at least 12 hours).

 **Avoid strong solvents (like methylene chloride) for cleaning the cosmesis. Detergent based spray cleaners work well for routine cleaning of the cosmesis.**

 **Never modify the foot keel. It will void the warranty and can cause bolt or keel failure. If you must alter the foam, be sure not to grind the keel. Never re-drill the mounting hole.**



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/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 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.

