CE

INTRODUCTION

Trulife foot shells are some of the most durable and life-like looking foot shells in the industry. For increased strength and durability, Trulife molds a reinforced toe pad into each natural looking Trulife foot shell. All of Trulife's foot shells are available in two skin tones; light and dark.

Product Code	Description	Color
SFC190	Energy/Zumo Replacement Foot Shell	Light
SFC193	Energy/Zumo Replacement Foot Shell	Dark
SFC290	Solas/Triumph Replacement Foot Shell	Light
SFC293	Solas/Triumph Replacement Foot Shell	Dark
SKC300	Zenith/Kinetic Edge Replacement Foot Shell	Light
SKC303	Zenith/Kinetic Edge Replacement Foot Shell	Dark

INDICATIONS

Trulife foot shells are designed for lower extremity amputees who use Trulife prosthetic feet that require a foot shell.

REMOVAL AND INSTALLATION

Note: It may be advantageous to attach a pylon to the foot for added leverage.

Removing Foot from the Foot Shell

1. Insert the "removal end" of the shoe horn (short end with the hook) behind and under the heel of the foot (FIGURE1).
2. Push down on the shoe horn to lift foot from the cover.
3. Pull foot from shell (FIGURE 2).

FIGURE 1. Remove Foot Shell, Step 1

FIGURE 2. Remove Foot Shell, Step 2

Inserting Foot in to Foot Shell

1. Install a pylon onto the foot module.
2. If the foot includes a spectra sock, place the spectra-sock over the foot module.
3. Insert the toe of the foot module into the foot shell.
4. Place the long end of the shoe horn into the foot shell between the heel of the foot module and posterior end of the foot shell opening (FIGURE 3).
5. Push the shoe horn towards the anterior of the foot shell while applying downward pressure on the pylon until the foot module drops into the foot shell and engages the heel lock (FIGURE 4).
6. If the cover becomes "trapped" between the keel and the ankle, use a blunt screw driver to lift the cover over the ankle (FIGURE 5):
    a. Slide the screwdriver between cover and ankle.
    b. Work the screwdriver around the front of the ankle, using the opposite side of the keel as leverage if needed.

FIGURE 3. Insert foot in to shell, step 4

FIGURE 4. Insert foot in to shell, step 5

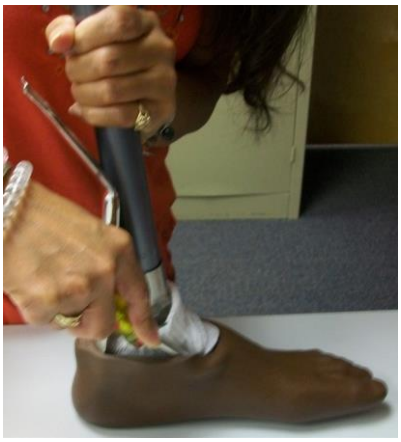

FIGURE 5. Insert foot in to shell, step 6

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.

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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.

Trulife