



INTRODUCTION

The Trulife SACH with Pyramid is designed to provide amputees with more function and comfort than the average SACH. Its plastic keel has a rocker bottom to allow for easy rollover while maintaining a light weight. Most importantly, the Trulife SACH with Pyramid incorporates the beautiful Trulife LightFoot® cosmesis that you've come to expect from the Trulife line of prosthetic products. If a $\frac{3}{4}$ " (1.9cm) heel rise is needed, then the original Lifecast cosmesis is also available.

PRODUCT CODE	DESCRIPTION	HEEL RISE	WEIGHT LIMIT
SCH110	Lightfoot Foot Shell, Light	$\frac{3}{8}$ " (0.95 cm)	225 lbs/102 kg
SCH113	Lightfoot Foot Shell, Dark	$\frac{3}{8}$ " (0.95 cm)	225 lbs/102 kg
SCH120	Lifecast Foot Shell, Light	$\frac{3}{4}$ " (1.9 cm)	225 lbs/102 kg
SCH123	Lifecast Foot Shell, Dark	$\frac{3}{4}$ " (1.9 cm)	225 lbs/102 kg

APPLICATION

The Trulife SACH with Pyramid meets the requirements of all lower limb amputees with low to medium-low activity levels (see table below). The Trulife SACH with Pyramid is especially appropriate for new amputees, who initially require more rollover assistance during gait.

ACTIVITY LEVEL TABLE

LOW	Walking with aid
MED LOW	Limited walking
MED	Walking
MED HIGH	Jogging, light sports
HIGH	Running, basketball, farming, and other strenuous activities

LIMITATIONS

The Trulife SACH with Pyramid cannot be used with R.O.L. rotators or other devices requiring modification to the keel.

INSTALLATION AND USE

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

The Trulife SACH with Pyramid comes pre-assembled with a foot pyramid and foot bolt. Before installation, check the bolt for loosening, ensuring that the bolt is set to a torque value of 27 Nm (20 ft-lbs or 240 in-lbs).

Warning: Never modify the keel. It will void the warranty and can cause bolt or keel failure. If you must alter the form of the foot, be sure not to grind on the keel.

Warning: Never re-drill the mounting hole.

Warning: Use only bolts supplied by Trulife. Use of unapproved bolts will void the warranty and can cause bolt failure.





MAINTENANCE GUIDELINES

- Foot assembly should be inspected after first 30 days of use.
- Inspect entire prosthesis for wear during normal consultations.
- Periodically check the bolt for loosening. Retighten to 27Nm (20 ft-lbs or 240 in-lbs) if loose.

Warning: Looseness of foot bolt may lead to bolt failure.

ENDOSKELETAL INSTALLATIONS

When using the Trulife SACH with an Endoskeletal Cosmesis, remove the foot from the endoskeletal limb by loosening the foot bolt. Completely roughen the mounting surfaces of the foot and cosmesis. 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. Apply a thin layer of contact cement to each surface and allow it to dry. Apply a second layer of contact cement and also allow to dry. Match the two surfaces carefully and press them together tightly both on the outside and inside of the seam.

COLOR COATING

The Trulife SACH Foot is available in two color options: Light and Dark. Additional color coating may be applied as desired. Before applying color coating to the foot, remove any remaining mold release from the cosmesis with naphtha. Naphtha is recommended to improve the adhesion of color coatings, but alcohol can be used as well.

ALIGNMENT

The recommendations in this guide provide a reliable starting point for static alignment of the Trulife SACH with Pyramid. Since each patient is unique, final alignment may require additional adjustment.

BOLT HOLE ALIGNMENT

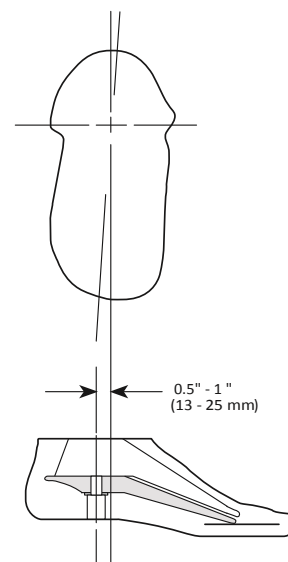
To establish anterior/posterior placement of the foot, place the ankle bolt hole 0.5"–1" (13–25 mm) posterior to the midline of the socket. To establish medial/lateral placement of the foot, position the ankle bolt hole 0.25" (6 mm) medial to the midline of the socket.

SOCKET FLEXION

Due to the flexibility of the forefoot and the preloading of the foot, suggested starting point is +3° of socket flexion for walking. The socket should also be adducted 5°. Foot motion should be smooth during the gait cycle, providing adequate toe resistance without active push off. The knee should not be forced into hyperextension during any phase of gait.

ABOVE KNEE ALIGNMENT

Use standard multiaxis foot alignment procedures when installing the Trulife SACH with Pyramid, but also place the pylon within 2° to 3° of posterior tilt. This will preload the keel and make the pylon vertical during midstance. If the knee becomes unstable, increase the toe lever by plantar flexing the foot or moving the knee center posterior of the TKA line.





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.

