



INTRODUCTION

Trulife Energy is approved for use by all lower extremity amputees with low to medium activity levels. Its composite keel provides rollover assistance and stability. The Trulife Energy is available in a 9.5 mm • 3/8" heel rise and various cosmesis tones.

Product Code	Description	Heel Rise	Patient Weight*
SEF190	Trulife Energy, Caucasian	9.5 mm • 3/8"	136 kg • 300 lb
SEF193	Trulife Energy, Dark Brown	9.5 mm • 3/8"	136 kg • 300 lb

*For medium activity level

Selection

To optimize the selection and ensure amputee's safety, follow the two step procedure below to determine the appropriate category.

1. Locate the column that corresponds with the amputee's impact level.
2. Within the selected column, locate the amputee's weight.

Important Note: If the amputee has a long BK, carries heavy loads or will reach a higher activity level within a year, choose the next category higher.

Warning: Choosing a lower strength category than what is suggested based on the above procedure and patient data will void the warranty. If your patient's weight exceeds the limits of the chart please call Trulife Customer Service.

	Low	Medium-Low	Medium
Category	Walking with Aid	Limited Walking	Walking on Uneven Surfaces
4	101-136 kg 221-300 lb	101-136 kg 221-300 lb	101-136 kg 221-300 lb
3	81-100 kg 177-220 lb	81-100 kg 177-220 lb	81-100 kg 177-220 lb
2	61-80 kg 134-176 lb	61-80 kg 134-176 lb	61-80 kg 134-176 lb
1	<60 kg <132 lb	<60 kg <132 lb	<60 kg <132 lb

LIMITATIONS

The Trulife Energy Foot cannot be used with R.O.L rotators or other devices that require modification of the keel.

INSTALLATION AND USE

Recommended installation and use procedures must be followed for maximum safety and service life. The Trulife Energy comes pre-assembled with a Trulife spacer, foot pyramid and foot bolt.

Warning: Never re-drill the mounting hole.

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 modify the spacer. It will void the warranty and may cause failure.

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





Note: The Trulife spacer may be removed to increase clearance, add a Symes nut (SSY300), or use an Ankle Block (SAB320) . Simply cut the supplied bolt to length. Ensure a free running thread fit and adequate thread engagement in the mating part. Apply Loctite 242 and tighten to 59 Nm (44 ft-lbs) for foot adapter/Symes nut or 27 Nm (20 ft-lbs) for Ankle Block

Endoskeletal Installations

When using the Trulife Energy with a Trulife Endoskeletal Cosmesis, remove the foot from the endoskeletal limb. Completely rough the mounting surface 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 allow to dry. Match the two surfaces carefully and press them together tightly both on the outside and inside of the seam.

Color Coating

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 coating, but alcohol can be used as well.

Alignment

The recommendations in this guide provide reliable starting points for static alignment of the Trulife Energy. 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 13-25 mm (1/2"-1") posterior to the midline of the socket. To establish medial/lateral placement of the foot, position the ankle bolt hole 6 mm (1/4") medial to the midline of the socket.

Socket Flexion

Due to the flexibility of the forefoot and the required pre-loading of the foot, suggested starting points are +3° of socket flexion for the walking and -3° for running. The socket should also be adducted 5°. As the foot is moved into plantar flexion, the patient will be able to notice the level of push-off increase. As the level of push-off increases, the hyperextension moment of the knee at mid-stance also increases. You must therefore find a balance between the hyperextension moment at mid-stance and the level of push-off required. The knee should not be forced into hyperextension during any phase of gait.

Above Knee Alignment

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

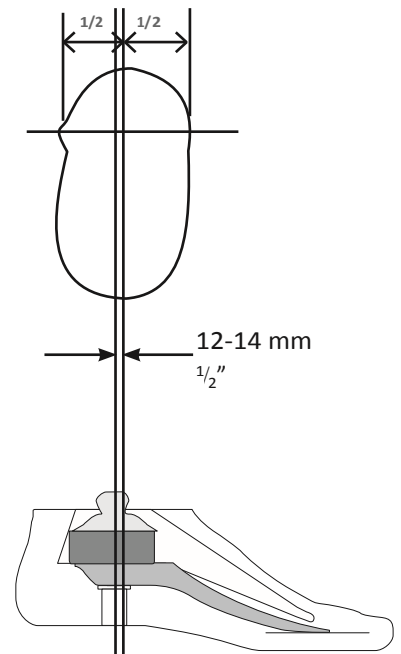


FIGURE 1. Alignment.

MAINTENANCE GUIDELINES

Foot assembly should be inspected after first 30 days of use.

- Inspect entire prosthesis for wear during normal consultations.
- Check the bolt for loosening every 6 months. Re-torque to 59 Nm (44 ft-lbs or 528 in-lbs) if loose.

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

**QUESTIONS**

Contact Customer Service at;

USA

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Email: info-usa@trulife.com

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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:

MDSS GmbH

Schiffgraben 41

30175 Hannover

Germany

Phone (+49)-511-6262 8630

FAX (+49) -511-6262 8633

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.

