SEF132, SEF144
Child's Play ENERGY
Instructions and User Guide
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INTRODUCTION

The Child's Play Energy foot is a pediatric model of the Trulife Energy foot. Its sculpted cosmesis varies by size to reflect the natural appearance of a child's maturing foot. The combination of the cosmesis and the dynamic response composite keel offers shock absorption and a smooth rollover for a natural gait. The Child's Play Energy is appropriate for all lower limb pediatric amputees, including Symes, of all activity levels.

Product Code	Description	Sizes	Weight Limit
SEF132	Light	13–21 cm	65 kg / 144 lb
SEF144	Dark	13–21 cm	65 kg / 144 lb

Accessories

Model Number	Description	Sizes	Weight Limit
AAAK285	Foot Adapter	13–21 cm	65 kg / 144 lb
SFB546	Foot Bolt	13–21 cm	65 kg / 144 lb
SAB314	Ankle Block	13–15 cm	35 kg / 77 lb
SAB315	Ankle Block	16–18 cm	45 kg / 99 lb
SAB316	Ankle Block	19–21 cm	65 kg / 144 lb
SLC301	Laminating Core	13–15 cm	35 kg / 77 lb
SLC302	Laminating Core	16–18 cm	45 kg / 99 lb
SLC303	Laminating Core	19–21 cm	65 kg / 144 lb
SSY301	Symes Nut	13–15 cm	35 kg / 77 lb
SSY302	Symes Nut	16–18 cm	45 kg / 99 lb
SSY303	Symes Nut	19–21 cm	65 kg / 144 lb

LIMITATIONS

The Child's Play Energy cannot be used with R.O.L. rotators or other devices requiring modification of the keel.

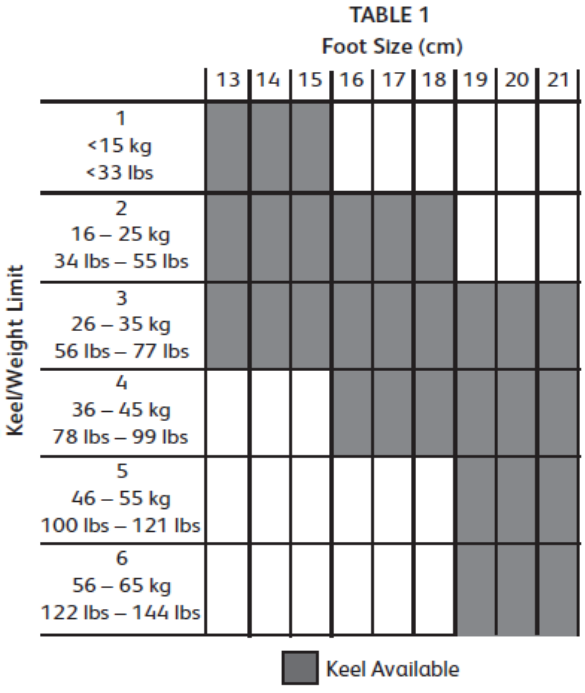
SELECTION

To determine which keel is appropriate for your patient, check TABLE 1 for keel availability by foot size. Please note that sizes 13–15 feet do not have split toe cosmesis.

Note: Choose the next higher keel level if your patient has a long BK limb, regularly carries heavy loads, or is at the upper limit for weight or activity level.

⚠ **Choosing a lower keel than what is suggested based on the above procedure and patient information will void the warranty and place your patient at risk. If your patient's weight and activity level exceeds the limits of these charts, please call Trulife for assistance.**

TABLE 1



INDICATIONS

The Child's Play Energy is designed for lower extremity amputees with low to high activity levels that weigh less, carried load included, than 65 kg (144 lbs).

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INSTALLATION AND USE

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

⚠

- Avoid strong solvents for cleaning the foot. Detergent based spray cleaners work well for routine cleaning of the foot.
- Never modify the 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.
- Use only bolts supplied or approved by Trulife. Use of unapproved bolts will void the warranty and can cause bolt failure.
- Do not install a lock washer. The Child's Play Energy contains a stainless steel internal washer that does not require a lock washer.
- Never reuse bolts. If you need to reinstall the foot (or attached component) for any reason, please call Trulife for a new bolt.
- Never install a wedge to adjust alignment.
- Do not contaminate bolt or bolt clearance in the keel with any type of adhesive, glue or cement.
- Take care to use the correct bolt. The Child's Play Energy can be installed with an 8 mm bolt (supplied).
- Make sure you have a free running thread fit and adequate thread engagement in the mating part. Incorrect bolt selection can cause thread damage, false indication of torque and bolt failure.
- To maintain bolt tightness, apply three drops of Loctite 242 removable thread locking compound to the portion of the bolt that will engage the threads of the fitting or nut. The thread locking compound will require several hours to cure fully.
- The bolt should be checked periodically for loosening. Looseness in any bolt may lead to failure.
- Tighten the foot bolt based on the mating component per TABLE 2. Use a calibrated torque wrench and hex head driver.

TABLE 2

Mating Component	Foot Bolt Torque
Foot Adapter/Symes Nut	31 Nm (23 ft-lbs or 276 in-lbs)
Ankle Block/Lamination Core	16 Nm (12 ft-lbs or 144 in-lbs)

ROTATION CONTROL
The keel of the Child's Play Energy is grooved to prevent rotation when used with other Child's Play components.

EXOSKELETAL INSTALLATIONS
The Child's Play Energy is designed to be used with the Child's Play Energy Ankle Block or Child's Play Laminating Core for exoskeletal construction. Standard foam ankle block lamination techniques should be used.

⚠**Avoid walking on an unreinforced ankle block after shaping.**

ALIGNMENT
The recommendations in this guide provide reliable starting points for static alignment of the Child's Play Energy. Since each patient is unique, final alignment may require additional adjustment.

To establish anterior/posterior placement of the foot, place the ankle bolt hole 3⁄8"–3⁄4" (10–19 mm) posterior to the midline of the socket (FIGURE 1). To establish medial/ lateral placement of the foot, center the ankle bolt hole on the midline of the socket.

⚠**Failure to follow the installation and use procedures set forth above may lead to structural failure of the components subjecting the user to a risk of serious personal injury.**

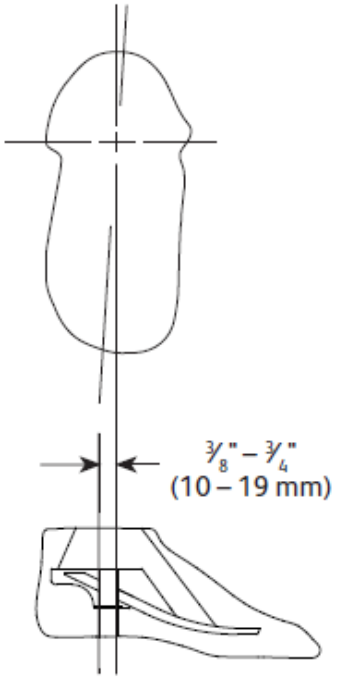

FIGURE 1: Bolthole alignment.

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/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.