

INTRODUCTION


The M8-1.25 X 80 mm foot bolt kit is designed to be used with the Child's Play Energy Foot.

Product Code	Description	Torque Setting
SFB546	Child's Play Energy Foot Bolt Kit	31 Nm (23 ft-lbs, or as specified by adapter installation guide)


INDICATIONS


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


INSTALLATION AND USE

 The use of bolts not supplied by Trulife, or failure to follow instructions, may lead to structural failure of the components subjecting the user to a risk of serious personal injury and will void any warranties offered by Trulife.

The bolt may be cut to avoid any interference. Cut the bolt length as required to engage the full thread length of the mating adapter and deburr the cut end to avoid thread damage.

 Do not use the bolt if the threads are nicked or damaged during cutting.

 Do not install a lockwasher. The foot contains an internal stainless steel washer that does not require a lockwasher.

 Do not contaminate bolt or bolt clearance in keel with any type of adhesive, glue, or cement. To maintain bolt tightness, apply three drops of Loctite® 242 to the area of the bolt that will engage the threads of the fitting or nut. Check the bolt periodically for loosening. Looseness in any bolt may lead to failure.

Loctite: When adjusting alignment of bolts or screws that have been assembled with Loctite, the threads of the screw and screw hole should be cleaned free of any Loctite residue with a mild solvent such as alcohol. Then, reapply new Loctite to ensure the proper torque value of the fasteners are set when retightened.



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.

