SFS240, 241, 242, 243, 244, 245
Foot Spacers
Installation and User Guide
15106-001 REV N 2022-05-23

CE

INTRODUCTION

Foot Spacers provide versatility during setup and fabrication of Child's Play Energy. They may be used either temporarily to permit easier access to alignment devices or permanently to allow setup on existing standard limb systems and to accommodate patient growth.

SELECTION

Spacers for use with Child's Play Energy (M8 Foot Bolt):

Model No.	Description	Height	Product Wt	Weight Limit
SFS240	Spacer for 13-15cm, ¼"	0.6 cm / 0.25 in	6.0 g / 0.2 oz	31 kg / 69 lb
SFS241	Spacer for 13-15cm, 1"	2.5 cm / 1.0 in	20.0 g / 0.7 oz	31 kg / 69 lb
SFS242	Spacer for 16-18cm, ¼"	0.6 cm / 0.25 in	9.0 g / 0.3 oz	41 kg / 89 lb
SFS243	Spacer for 16-18cm, 1"	2.5 cm / 1.0 in	28.0 g / 0.9 oz	41 kg / 89 lb
SFS244	Spacer for 19-21cm, ¼"	0.6 cm / 0.25 in	11.0 g / 0.3 oz	65 kg / 144 lb
SFS245	Spacer for 19-21cm, 1.2"	3.0 cm / 1.2 in	45.0 g / 1.5 oz	65 kg / 144 lb

INDICATIONS

Lower-limb amputees to build a limb system.

INSTALLATION AND USE

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

⚠ **Never modify the spacer. It will void the warranty and can cause failure. Never re-drill the mounting holes**.

- When using wood or foam ankle blocks, the distal end must be reinforced with two layers of laminate.
- Failure to reinforce the ankle block can result in bolt failure.
- The foot mounting bolt must fully engage the connecting ankle block or foot adaptor threads.
- You may stack up to two spacers.

⚠ **Do not stack more than two spacers in the definite setup.**

⚠ **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.**

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.