SSY300, 301, 302, 303
Symes Nut
Installation and User Guide
15107-001 REV L 2022-05-23

CE

INTRODUCTION
Designed for the LightFoot, Energy Foot and Child's Play Energy Foot, the Symes Nut provides for secure attachment to the socket and solid support for the keel. The Symes Nut is manufactured using an aluminum alloy with an abrasive etched finish for adhesion to the laminate.

SELECTION

Model No.	Description	Appropriate Foot Style	Weight Limit
SSY300	Symes Nut, Foot Size 22-30 cm	Lightfoot with Pyramid	136 kg • 300 lb
SSY301	Child's Play Symes Nut, Foot Size 13-15 cm	Child's Play Foot	35 kg • 77 lb
SSY302	Child's Play Symes Nut, Foot Size 16-18 cm	Child's Play Foot	45 kg • 99 lb
SSY303	Child's Play Symes Nut, Foot Size 19-21 cm	Child's Play Foot	65 kg • 144 lb

INDICATIONS
Lower-limb amputees to build a limb system.

INSTALLATION AND USE
Recommended fabrication, installation and use procedures must be followed for maximum safety and service life.

⚠ Never modify the Symes Nut. Modification will void the warranty and can cause failure.

The circular recess on the bottom of the Symes Nut must be placed posterior to the keel centerline as close as possible. Following bench alignment, the Symes Nut can be "tacked" in place with epoxy resin. Before test walking to confirm alignment, secure the Symes Nut to the socket using several layers of fiberglass casting tape as a temporary reinforcement. When satisfactory alignment has been achieved, remove the temporary fiberglass casting tape before applying the definitive lamination.

⚠ Testing an unreinforced Symes Nut can cause failure.

Lamination will require at least three layers of fiberglass. For Child's Play, use at least two layers. Additional posterior reinforcement is recommended for heavy or high activity level patients.

⚠ Use only metric bolts supplied by Trulife. Use of unapproved bolts will void the warranty and can cause failure.

The mounting bolt must engage the Symes Nut at least 11 mm (7/16") [for Child's Play, at least 16mm (5/8")]. If the bolt is cut, deburr the cut end to avoid thread damage. Make sure you have a free running thread fit, and the bolt does not bottom out against the socket.

⚠ Do not contaminate the bolt or thread insert with paint, adhesive, glue or cement.

To maintain bolt tightness, apply 3 drops of Loctite® 242 removable thread locking compound to the portion of the bolt that will engage the core threads. The thread locking compound will require several hours to cure completely.

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; this will ensure the proper torque value of the fasteners are set when retightened.

Torque the foot mounting bolt as specified in the foot installation guide. A torque wrench and hex head driver should be used.

⚠ Check the bolt periodically for loosening. Looseness in any bolt can cause failure.

⚠ Never install a wedge to adjust alignment.

ROTATION CONTROL
To control rotation, mold a rib on the Symes Nut using epoxy resin. Place a small amount of epoxy resin in the circular recess of the bottom of the Symes Nut. Fillers may be added to the resin to make a paste.

Note: Avoid contamination of the mounting threads. A small amount of wax or clay may be used to fill the keel top groove around the bolt hole. Carefully install the foot and adjust toe-out. Make sure the recess is oriented posterior to bolt hole. Allow the epoxy to cure. The foot may be removed if desired. If the toe-out requires adjustment after the trial period, simply grind the epoxy out of the recess and repeat the rib molding process.

Trulife

CE

⚠ 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.

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.

Trulife
3225 Woburn St. Suite 160
Bellingham, WA 98226
USA
Phone (+1) 360 697 5656
Email supportop@trulife.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

CH REP
MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau
Switzerland

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.

1 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.