SAB310, SAB314, SAB315, SAB316, SAB320
Ankle Block
Installation and User Guide
15094-001 REV M 2022-05-23

CE

INTRODUCTION

The Trulife Ankle Block is designed for the exoskeletal setup of various Trulife feet. Manufactured using high strength polyurethane foam surrounding a nylon core, the Ankle Block is lightweight and durable to withstand the forces imposed by dynamic response feet.

SELECTION

Product Code	Appropriate Foot Style	Foot Size Range	Max. Patient Weight	Max. Clearance (incl. foot)	Bolt Thread	Bolt Torque
Adult						
SAB310	SLF195/198	22-30 cm	300 lbs (136 kg)	6.1 in (15.5 cm)	M10	27Nm (20 ft-lbs)
SAB320	SNF160/163 SCH110/113	22-30 cm	325 lbs (102 kg)	6.1 in (15.5 cm)	M10	27Nm (20 ft-lbs)
Child's Play Energy						
SAB314	SEF132/144	13-15 cm	77 lbs (35 kg)	3.7 in (9.4 cm)	M8	16Nm (12 ft-lbs)
SAB315	SEF132/144	16-18 cm	99 lbs (45 kg)	4.1 in (10.4 cm)	M8	16Nm (12 ft-lbs)
SAB316	SEF132/144	19-21 cm	144 lbs (65 kg)	4.4 in (11.2 cm)	M8	16Nm (12 ft-lbs)

INDICATIONS

Lower-limb amputees to build a limb system.

FABRICATION

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

⚠ Never modify the exposed portion of the nylon core except to grind off the rotation control rib when necessary. Other modifications will void the warranty and can cause failure. Sanding or grinding of the foam surrounding the core is permitted only on the tops and sides, and only to a depth of 1/16" (2 mm).

⚠ Never cut down the embedded portion of the core. If you need a shorter connection, use the Trulife Laminating Core (SLC301, 302, 303) for Child's Play Energy Feet only.

⚠ Testing an unreinforced ankle block after shaping can cause failure.

The circular recess on the bottom of the ankle block must be placed posterior to the keel centerline as close as possible.

Before laminating, remove all dust from the shaped ankle block. For the SAB310, 314, 315, and 316 cover the exposed nylon core with a small poly bag and seal it with tape. For the SAB320, cover the exposed distal mounting surface with layers of PVA tape, Kemblo, or similar.

The lamination requires at least two layers of fiberglass-nylon stockinet. Ankles with circumferences smaller than 9" require an extra layer. Additional posterior reinforcement is recommended for heavy or high activity level patients.

⚠ Do not cut or nick the nylon core when trimming the laminate flush with the ankle block.

Trulife

Rotation control can be accomplished by either of two methods:

1. If rotational alignment is sufficient, make sure the central control rib engages the keel top as the foot mounting bolt is tightened.
2. If additional adjustment is required, grind down the rib. Mold a rib on the ankle block by placing a small amount of epoxy resin in the shallow recess. You may add fillers to the resin to make a paste.

Note: Do not contaminate the mounting threads. You may use a small amount of wax or clay to fill the groove in the keel top.

Carefully install the foot and adjust toe-out. After a trial period, if toe-out still requires adjustment, simply grind the epoxy out of the recess and repeat the rib molding procedure.

INSTALLATION AND USE
Use only metric bolts supplied or approved by Trulife. Use of unapproved bolts will void the warranty and can cause failure.

⚠ Apply Loctite 242 to bolt prior to assembly. Failure to do so may cause the bolt to seize when threading into insert.

The mounting bolt must engage the ankle block at least 7/8" (22 mm) for SAB310 and 320 installations [at least 5/8" (16 mm) for Child's Play Energy]. If the bolt is cut, deburr the cut end to avoid thread damage. Make sure you have a free running thread fit and that the bolt does not bottom out against the socket.

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

To maintain bolt tightness, apply three drops of Loctite 242 removable thread locking compound to the portion of the bolt that will engage the ankle block threads. Loctite requires several hours to cure completely.

Loctite: When adjusting alignment of bolts or screws that have been assembled with Loctite, the threads of the screw 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 values of the fasteners are set when retightening the fastener to the specified torque values.

Tighten the foot mounting bolt as specified in the selection table (M10 to 27Nm, M8 to 16Nm). A calibrated torque wrench and hex driver should be used.

⚠ Check the bolt periodically for loosening. Looseness of the bolt can lead to failure.

⚠ Do not install a wedge to adjust alignment.

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

CE

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.

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.

Trulife