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INTRODUCTION

The Solas is a multi-axial foot-ankle system that combines carbon composite S-shaped shank and split keel. It offers dynamic features such as heel strike shock absorption, smooth rollover, controlled plantar flexion, split keel stability and a balanced transition from heel to toe.

Product Code	Description	Weight Limit*
SLS490	Solas, Light	160 kg / 350 lb
SLS493	Solas, Dark	160 kg / 350 lb

* For medium impact level

Effective build height:	16.3cm (6.4”)
Height to top of pyramid:	18.3cm (7.1”)
Heel rise:	9.5mm (3/8”)

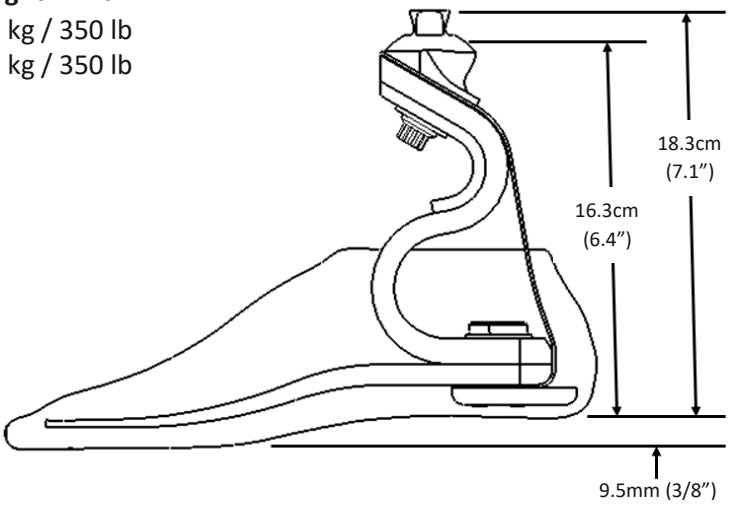

Figure 1: Solas dimensions

ACCESSORIES AND REPLACEMENT PARTS

Product Code	Description
SFC290	**Foot Shell, Light**
SFC293	**Foot Shell, Dark**
28584-003	**Replacement Spectra-Sock**

INDICATIONS

The Solas foot is intended for lower limb amputees, trans-tibial or higher, with a functional level of K3-K4.

APPLICATION

The Solas foot is appropriate for amputees with low to high impact levels. Recommended installation and use procedures must be followed for maximum safety and service life. Refer to the Selection Table below to determine the appropriate foot for your patient.

SELECTION

The Solas foot has four available category options. Each is designed and tested to support a specific weight and impact level combination.

To optimize the selection and ensure amputee’s safety, follow the two steps below to determine the appropriate category.

- Locate the column that corresponds with the amputee’s impact level.
- Within the selected column locate the amputee’s weight.

⚠ **If the amputee has a long BK, carries heavy loads or will reach a higher impact level within a year, choose the next category higher.**

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⚠ **Choosing a lower strength category than what is suggested based on the above procedure and patient data will void the warranty and place your patient at risk.**

Category	Foot Length (cm)	Low Impact Level	Medium Impact Level	High Impact Level
		Walking Uneven Surfaces	Light Sports	Running, Basketball
4	26-30	137-160 kg ● 301-350 lb	124-145 kg ● 271-320 lb	106-125 kg ● 232-274 lb
3	24-30	101-136 kg ● 221-300 lb	89-123 kg ● 194-270 lb	76-105 kg ● 166-231 lb
2	23-29	81-100 kg ● 177-220 lb	71-88 kg ● 155-193 lb	61-75 kg ● 133-165 lb
1	22-28	<80 kg ● <176 lb	<70 kg ● <154 lb	<60 kg ● <132 lb

INSTALLATION AND USE

The Solas is shipped with a Spectra sock pre-assembled into a foot shell.

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

Bench Alignment

- Bisect the medial side of the socket and drop a plumb line. This line should fall between 12–14 mm (1⁄2”) anterior to the center axis of the pylon.
- Bisect the posterior side of the socket and drop a plumb line. This line should bisect the center axis of the pylon or pass through the heel.

Dynamic Alignment Suggestions

To achieve more heel compression, move the socket slightly posterior to the recommended bench alignment.

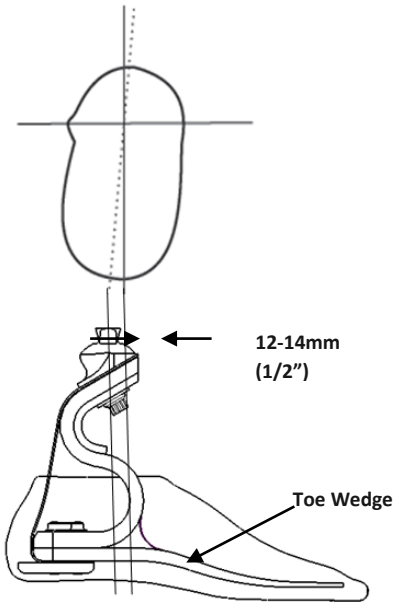

Figure 2: Solas bench alignment

Toe Wedge Options

To increase dorsiflexion resistance and mid-stance stability Toe Wedges are provided. Simply insert the desired Toe Wedge between the shank and keel as shown and tack with a drop of instant adhesive (super glue). Secure with additional adhesive if the evaluation is successful.

Finalize Foot and Cosmetic Cover

Follow assembly instructions and recommended fastener tightening torque of the mating modular adapter.
AAA adapter set screw torque setting is 15-18 Nm (11-13 ft-lbs).

MAINTENANCE GUIDELINES

- Foot assembly should be inspected after first 30 days of use.
- Inspect entire prosthesis for wear during normal consultations.
- Foot shell may require replacement if wear is excessive.
- Check screws periodically for loosening.

⚠ **Looseness in any screw may cause failure.**

- Check the pyramid bolt and the three keel bolts during each visit to verify correct torque setting:
    - Pyramid bolt = 88 Nm (65 ft-lbs) Use 7/16”, 12-point socket
    - Keel bolts = 20Nm (15 ft-lbs) Use 8mm socket

  If a bolt is loose:
  1. Remove the bolt.
  2. Clean the threads using a mild solvent such as alcohol.
  3. Apply Loctite 242 thread locker (or equiv.) to the fastener threads.
  4. Thread the bolt through the composite components and into the threaded part. Realign if necessary. Do not force the bolt.
  5. Tighten fastener to specified torque (listed above).

PATIENT USAGE GUIDELINES

⚠ Warnings and/or contraindications specified for the assembled prosthesis, include, but are not limited to:

- Patient must always wear shoes when using the Solas outdoors.
- Rinse the Solas thoroughly with fresh water after any contact with salt water, sand or other contaminates, and dry thoroughly. **Do not immerse foot in water.**
- Never disassemble the Solas, excluding procedures specifically referred to in the install guide.
- Discontinue use and consult your physician or prosthetist if the prosthesis causes pain or injures you in any way.
- Discontinue use and consult your prosthetist if any part of the prosthesis starts to make noise.
- Do not attempt to adjust or service the prosthesis except as advised by your prosthetist.
- Inform your prosthetist if you lose or gain a significant amount of weight.
- Have the prosthesis serviced at regular intervals specified by the prosthetist.
- Trulife’s feet are manufactured and tested for a particular weight and activity level. Use by an amputee, other than the one for whom it was originally manufactured, may be dangerous and will void any written or implied warranty.

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.

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