SZN100, 103, 200, 203
TRULIFE ZENITH FOOT
Installation and User Guide

32042-001 REV C

CE

INTRODUCTION

The Trulife Zenith is a lightweight, multi-axial foot ankle system with an energetic, flexible toe loading response that automatically adjusts to variable walking and running speeds. The urethane bumper has four resistance options at heel strike for individualized patient fine-tuning. It offers smooth rollover to balance the transition from heel to toe. The Trulife Zenith comes with a removable 3/8" heel rise sandal toe foot shell with two available shades. There are two build height options to best meet patient requirements.

Product Code	Description	Sizes	Build Height	Weight Limit
SZN100	Light, Low Profile	22-30 cm	14.5 cm / 5.7 in	136 kg / 300 lb
SZN103	Dark, Low Profile	22-30 cm	14.5 cm / 5.7 in	136 kg / 300 lb
SZN200	Light	22-30 cm	17.8 cm / 7.0 in	136 kg / 300 lb
SZN203	Dark	22-30 cm	17.8 cm / 7.0 in	136 kg / 300 lb

ACCESSORIES

Model Number	Description	Sizes	Weight Limit
AAA200	Bonded Pylon	N/A	160 kg / 350 lb
SKC300	Foot Shell, Light	22-30 cm	160 kg / 350 lb
SKC303	Foot Shell, Dark	22-30 cm	160 kg / 350 lb

SELECTION

The Trulife Zenith foot has three 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.

Note: Choose the next higher category level if your patient has a long BK limb, regularly carries heavy loads, or is at the upper limit for weight or impact level.

Warning: Choosing a lower strength category than what is suggested based on the above procedure and patient information will void the warranty.

	Low Impact Level	Medium Impact Level	High Impact Level
Category	Walking on Uneven Surfaces	Light Sports	Running, Basketball
3	101-136 kg ● 221-300 lb	88-118 kg ● 193-260 lb	81-109 kg ● 179-240 lb
2	81-100 kg ● 177-220 lb	74-87 kg ● 162-192 lb	68-80 kg ● 150-176 lb
1	< 80 kg ● < 176 lb	< 73 kg ● < 161 lb	< 67 kg ● < 149 lb

INSTALLATION AND USE

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

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

In order to achieve better heel compression, move the socket slightly anterior to the recommended bench alignment.

HEEL ROD OPTION

In order to increase heel resistance and mid-stance stability Heel Rods are provided. Simply insert the desired Heel Rod in the hole of the main bumper. Secure with super glue if necessary.

Trulife

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.

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 Trulife Zenith outdoors.
- Rinse the Trulife Zenith thoroughly with fresh water after any contact with salt water, sand or other contaminates, and dry thoroughly.
- Discontinue use and consult your physician or prosthetist if the prosthesis causes pain or injures you in any way.

Warning: Failure to follow the installation and use procedure may lead to structural failure of the components, subjecting the user to risk of serious personal injury.

QUESTIONS

Contact Customer Service at;

USA
Tel: +1 800 492 1088
Fax: +1 800 245 3765
Email: info-usa@trulife.com

Canada
Tel: +1 800 267 2812
Fax: +1 613 392 4139
Email: infocanada@trulife.com

Visit Trulife online at www.trulife.com.

Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
Phone (+49) -511-6262 8630
FAX (+49) -511-6262 8633

LIMITED WARRANTY

Trulife warrants that the Trulife Zenith will be free from defects in material and workmanship for three (3) years for the foot and six (6) months for the foot shell from the date of installation.

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 Trulife Zenith 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 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 prosthetic 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 prosthesis 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.