



INTRODUCTION

The Zumo is approved for use by all K3 activity users. Its composite keel provides rollover assistance and stability. The Zumo is available in a 9.5mm • 3/8" heel rise with two color options.

Product Code	Description	Heel Rise	Patient Weight	Foot Sizes
SZM450	Light	9.5mm • 3/8"	205 kg / 450 lb	25-30 cm
SZM453	Dark	9.5mm • 3/8"	205 kg / 450 lb	25-30 cm

INDICATIONS

The Zumo is designed for lower extremity amputees with a medium activity level that weigh (carried load included) 205 kg or less.

INSTALLATION AND USE

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

The Zumo comes pre-assembled with a foot spacer, foot pyramid and foot bolt.

⚠ Never modify the keel. It will void the warranty and can cause bolt or keel failure. If you must alter the form of the foot, be sure not to grind on the keel.

⚠ Never re-drill the mounting hole.

⚠ Never modify the spacer. It will void the warranty and may cause failure.

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

Bolt Hole Alignment

To establish anterior/posterior placement of the foot, place the ankle bolt hole 12-14 mm (1/2") posterior to the midline of the socket. To establish medial/lateral placement of the foot, position the ankle bolt hole in line with the midline of the proximal socket.

Above Knee Alignment

Use standard foot alignment procedures when installing the Zumo.

MAINTENANCE GUIDELINES

- Foot assembly should be inspected after first 30 days of use.
- Inspect entire prosthesis for wear during normal consultations.
- Periodically check the bolt for loosening. Retighten to 59Nm (44 ft-lbs) if loose.

⚠ Looseness of foot bolt may lead to bolt failure and place the patient at risk of injury.

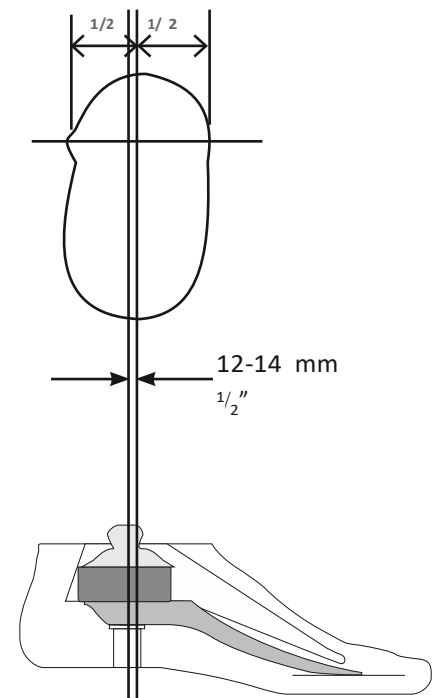
STORAGE AND USE

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/repared 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.

