SKF100, SKF101, SKF103, SKF200, SKF201, SKF203, SKF250, SKF251, SKF253, SKF300, SKF301, SKF303 SKF-KIT, SKF-REFURB-KIT, SKF-REFURB-KIT-01

Seattle Kinetic

Installation and User Guide

17772-001 REV L

CE

INTRODUCTION

The Seattle Kinetic system is a complete foot, ankle and pylon system suitable for K2 level end users up to 350 lbs. The Seattle Kinetic features a full length flexible keel, integrated multi-axis ankle, female proximal adapter and a 16" male pylon.

The Seattle Kinetic Light system is a complete foot/ankle system suitable for K2 level end users up to 350 lbs. The Seattle Kinetic Light features a full length flexible keel, an integrated multi-axis ankle, a male proximal adapter and a 16" female pylon. All categories of the Kinetic Light utilize a composite stirrup component that is lighter in weight than the steel version used in the Seattle Kinetic. Also, the foot shells of category 1 and 2 feet are constructed with a lighter weight, less dense, foam construction.

The Seattle Kinetic Edge has all the benefits of the Kinetic Light with the addition of a removable foot shell and more lively keel. Ideal for patients on the edge of advancing to a K3 product.

These products are designed to provide variable ankle stiffness, excellent ML compliance and plantar flexion in an aesthetically appealing Seattle Lightfoot shell. The Seattle Kinetic and Seattle Kinetic Light are compatible with the Seattle Endoskeletal cosmetic leg shells and are available in sizes 22 cm to 30 cm with three color options and five bumper durometer selections:

Product Code	Description	Patient Weight Limit
SKF100	Seattle Kinetic Light, Caucasian	160 kg / 350 lb
SKF101	Seattle Kinetic Light, Light Brown	160 kg / 350 lb
SKF103	Seattle Kinetic Light, Dark Brown	160 kg / 350 lb
SKF200	Seattle Kinetic Caucasian	160 kg / 350 lb
SKF201	Seattle Kinetic Light Brown	160 kg / 350 lb
SKF203	Seattle Kinetic Dark Brown	160 kg / 350 lb
SKF300	Seattle Kinetic Edge Caucasian	160 kg / 350 lb
SKF301	Seattle Kinetic Edge Light Brown	160 kg / 350 lb
SKF303	Seattle Kinetic Edge Dark Brown	160 kg / 350 lb
SKC300	Seattle Kinetic Edge Replacement Foot Shell, Caucasian	N/A
SKC301	Seattle Kinetic Edge Replacement Foot Shell, Light Brown	N/A
SKC303	Seattle Kinetic Edge Replacement Foot Shellc Dark Brown	N/A

Note: The Seattle Kinetic foot is also available as a foot/ankle System, without the 16" male bonded Pylon:

SKF250	Seattle Kinetic Caucasian	160 kg / 350 lb
SKF251	Seattle Kinetic Light Brown	160 kg / 350 lb
SKF253	Seattle Kinetic Dark Brown	160 kg / 350 lb

Trulife ORTHOTICS & PROSTHETICS

INSTALLATION AND USE

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

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

Warning: Never modify the keel or structural ankle components of the Seattle Kinetic or Seattle Kinetic Light.

Bumper Selection Instructions

To optimize selection, follow the three steps below to determine the appropriate bumper.
1. Locate the column associated with the amputee's foot length.
2. Locate the row corresponding to the amputee's weight.
3. The area where the column and row intersect lists the appropriate bumper firmness.

Important Note: If the amputee has a long BK, carries heavy loads or will reach a higher activity level within a year, choose the next category higher.

Warning: Choosing a lower rated bumper than what is suggested based on the above procedure and patient data will void the warranty. If your patient's weight exceeds the limits of the chart, please browse the catalog for other foot options or call Trulife Customer Service.

Foot Length	22	23	24	25	26	27	28	29	30
Weight									
137-160 kg 301-350 lb	-	-	-	-	5	5	5	5	5
101-136 kg 221-300 lb	-	-	4	4	4	4	4	4	4
81- 100 kg 177-220 lb	-	2	3	3	3	3	3	3	3
61-80 kg 133-176 lb	1	1	2	2	2	2	2	2	-
≤60 kg ≤132 lb	1	1	1	1	1	1	1	-	-

Seattle Kinetic Foot Installation:
1. Place the male bonded pylon into the foot pyramid receiver and tighten the four set screws to maintain the appropriate alignment.
2. To maintain set screw tightness, remove the set screws individually and apply Loctite 242® removable thread locking compound to the threads of each set screw and replace.
3. Using a 4 mm hex head driver and torque wrench, tighten the set screws to 15 Nm (11 ft-lbs or 133 in-lbs).

Note: The Seattle Kinetic female adapter uses GEOMET® coated set screws rather than the industry standard nickle plated or black oxide steel screws, which have a tendency to rust in increased humidity. You may notice that the coated screws, which have the same torque requirements, have a different "feel" when tightening.

- Use set screws supplied by Trulife. Use of unapproved fasteners will void the warranty and can lead to failure.
- Do not contaminate set screws with any type of paint, glue, or cement.
- Torque settings should be checked periodically. A loosely fastened bolt or set screw could lead to failure.

Seattle Kinetic Light and Seattle Kinetic Edge Foot Installation:

1. Connect proximal connecting components (pylon, clamp adapter, etc.) to the male proximal male pyramid feature of the foot as per typical modular component procedures.
2. Refer to the IFU's of the attached component for proper torque values and assembly procedures (typical set screw torque values for titanium and stainless steel 30mm female adapters are 15NM / 11Ft-lb).

Cosmetic Leg Shell Installation

1. After achieving the desired alignment of the prosthesis, disconnect the socket from the distal components.
2. Completely roughen the proximal surface of the foot and distal surface of the leg shell.
3. Remove all foam particles from the abraded surfaces.
4. If desired, apply small reference marks to the mounting surfaces to facilitate careful matching of the surfaces.
5. Apply a thin layer of contact cement to each surface and allow it to dry.
6. Apply a second layer of contact cement and allow it to dry.
7. Match the two surfaces carefully and press them together tightly both on the outside and inside of the seam.

Color Coating

If color coating is desired, remove any remaining mold release from the foot shell with naphtha before applying color. Naphtha is recommended to improve the adhesion of color coatings, but alcohol may be used as well.

Alignment Seattle Kinetic, Seattle Kinetic Light and Seattle Kinetic Edge

The recommendations in this guide provide reliable starting points for static bench alignment.

- To establish anterior/ posterior placement of the foot, ensure the pyramid receiver is 13mm(1/2")posterior to the mid-line of the socket (Illustration 1).
- To establish medial/lateral placement of the foot, position the pyramid center 6mm (1⁄4") medial to the midline of the socket.

Maintenance

Replacement of the bumper is recommended once a year (less often for low activity amputees) to maintain optimum performance of the Seattle Kinetic and Seattle Kinetic Light. Refer to the Seattle Kinetic Bumper Selection Chart located on page 2 of this install guide for the recommended replacement bumper.

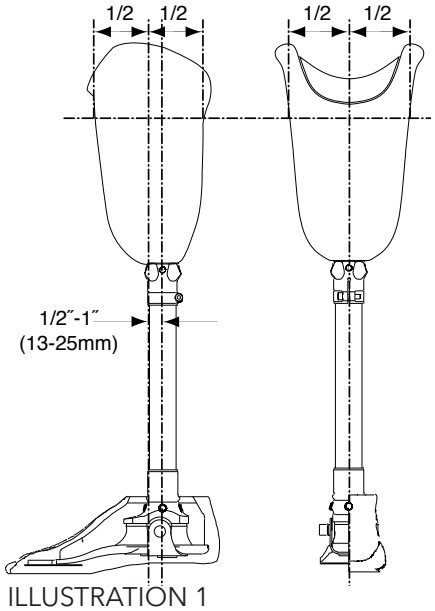

ILLUSTRATION 1

Seattle Kinetic, Seattle Kinetic Light and Seattle Kinetic Edge maintenance kits:

Product Code	Description	For use with:
SKF-KIT*	Seattle Kinetic Maintenance Tool Kit	All Kinetic Foot Models
SKF-REFURB-KIT	Seattle Kinetic Refurb Kit	SKF200, SKF201, SKF203, SKF250, SKF251, SKF253
SKF-REFURB-KIT-01	Seattle Kinetic Refurb Kit	SKF100, SKF101, SKF103, SKF300, SKF301, SKF303
SKF-BMP-1	Seattle Kinetic Soft Bumper	All Kinetic Foot Models
SKF-BMP-2	Seattle Kinetic Medium Bumper	All Kinetic Foot Models
SKF-BMP-3	Seattle Kinetic Firm Bumper	All Kinetic Foot Models
SKF-BMP-4	Seattle Kinetic X-Firm Bumper	All Kinetic Foot Models
SKF-BMP-5	Seattle Kinetic XX-Firm Bumper	All Kinetic Foot Models

* This kit is absolutely necessary for re-assembly of the Seattle Kinetic foot family. Without this tool, the axis shaft may not seat properly in the assembly leading to product failure.

FIGURE 1: SKF-KIT

SEATTLE KINETIC, SEATTLE KINETIC LIGHT AND SEATTLE KINETIC EDGE BUMPER CHANGING AND REFURBISHING INSTRUCTIONS

Note: Seattle Kinetic with serial number 6299 or below, utilize an older version bumper and pad. The instructions described below are still applicable. However, if a full rebuild is desired, a new bumper kit (SKF-BMP-{1, 2, 3, 4, 5}) is required.

Feet numbered 6300 or above are depicted in the following instructions:

Required Tools and Supplies:
- SKF-KIT (FIGURE 1.)
- SKF-REFURB-KIT (Seattle Kinetic Refurb Kit)
- SKF-REFURB-KIT-01 (Seattle Kinetic Light Refurb Kit)

Additional Tools (FIGURE 2.)
a. 4 mm hex key (quantity of 2)
b. Torque wrench with 4 mm hex driver
c. Mallet
d. Scrap piece of wood or plastic
e. Arbor press or bar clamp (not pictured)

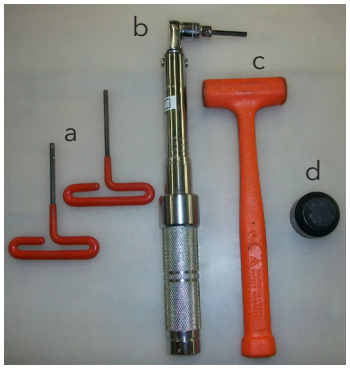

FIGURE 2: Additional tools needed

NOTE: the functional mechanisms of the Seattle Kinetic, Seattle Kinetic Light and Seattle Kinetic Edge are the same, except that the Seattle Kinetic uses a female upper bracket component and the Seattle Kinetic Light and Seattle Kinetic Edge use a male upper bracket component.

Disassembly:
1. Remove the two cosmetic plugs on either side of the foot.
   Note: For Seattle Kinetic Edge, remove foot shell. See install guide 17480-001 for foot shell removal instructions.

2. Using the two 4 mm hex wrenches, remove the button head screw and step washer from one side of the foot (FIGURE 3).

3. Lightly tap the mallet on the head of the hex key to lightly tap out the shaft (FIGURE 4).

4. Remove the internal components from the foot.

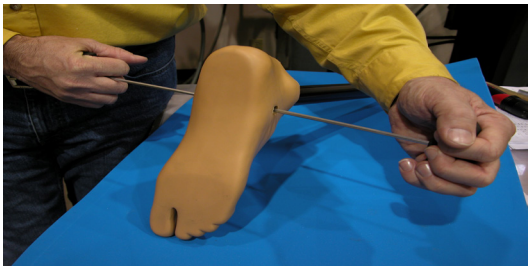

FIGURE 3: Loosening the shaft.

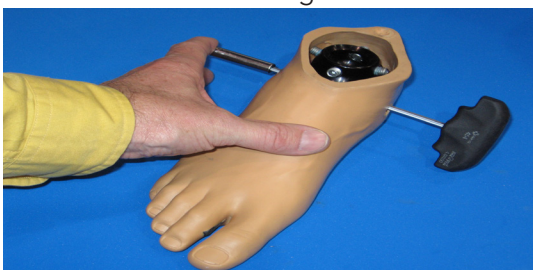

FIGURE 4: The shaft tapped out.

Assembly:

1. Coat the cylindrical part of the dorsi stop with white lithium grease, then insert it up through the distal pad and the bumper (FIGURE 5A, 5B, 5C).

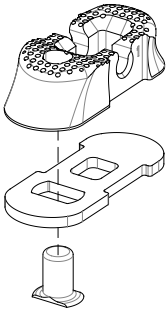

FIGURE 5A: Seattle Kinetic and Seattle Kinetic Edge - Dorsi stop inserted into pad spacer and bumper.

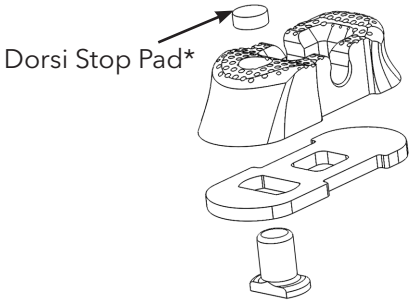

FIGURE 5B: Seattle Kinetic Edge - Dorsi stop inserted into pad spacer, bumper and dorsi stop pad
*This is a standard component of the Seattle Kinetic Edge (SKF300, SKF301, SKF303). When refurbishing all other Seattle Kinetic Foot feet, this component is optional.

FIGURE 5C: Dorsi stop inserted into pad spacer and bumper.

2. Insert the bumper assembly into the foot cavity, then coat the spherical delrin washers with white lithium grease and place them along the sides of the bumper (FIGURE 6). Orient the spherical surfaces of the washers so they are facing inward towards the bumper.

FIGURE 6: Inserting the Bumper assembly and Delrin washers inside the foot cavity.

3. Use a hex wrench to loosely align the bumper and components. Then, lubricate the proximal surfaces of the bumper with white lithium grease (FIGURE 7).

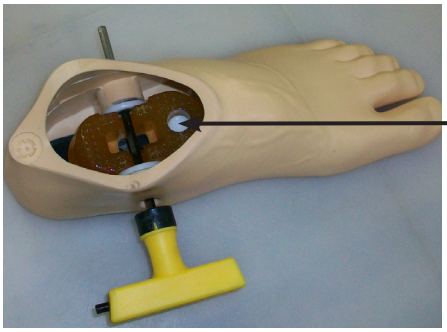

FIGURE 7: Loosely aligning the internal components.

4. Insert the hex shaft driver into the head of the shaft and thread the bullet onto the axis (FIGURE 8A and 8B).

FIGURE 8A: Insert hex shaft driver into shaft.

FIGURE 8B: Shaft attached to hex shaft driver with bullet threaded.

5. Place the upper bracket down on to the assembly through the cavity in the foot (FIGURE 9A, 9B).

Note: If the foot is undergoing a refurbish procedure, the bushing will need to be pressed into the distal end of the upper bracket prior to the upper bracket being inserted into the foot cavity.

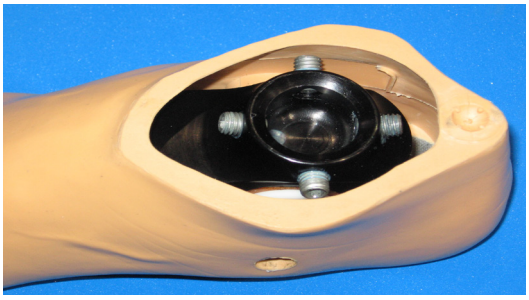

FIGURE 9A: Upper bracket inserted into foot cavity.

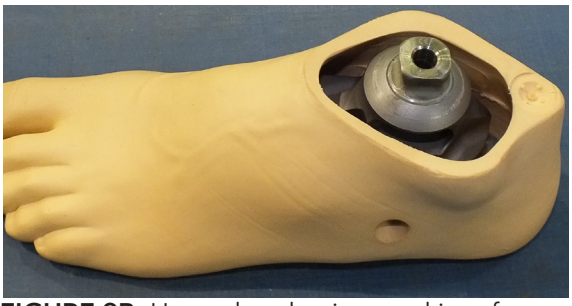

FIGURE 9B: Upper bracket inserted into foot cavity

6. Use the 4 mm hex wrench to generally align the holes of the assembly.
7. Compress the assembly with an arbor press or bar clamp until the holes appear to be aligned. Use a scrap piece of wood or plastic to prevent scratching the surface of the upper bracket (FIGURE 10).

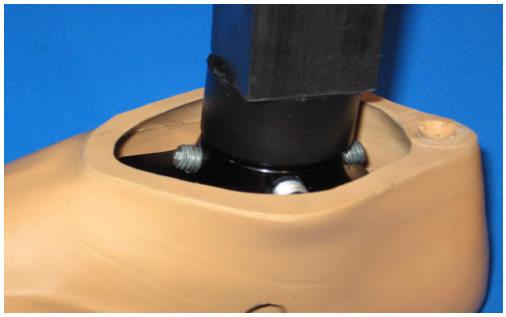

FIGURE 10: Upper bracket being compressed.

8. Lightly lubricate the bullet and axis with a coat of white lithium grease. With the assembly compressed, push the axis assembly through the ankle joint (FIGURE 11A, 11B), until the bullet begins to protrude from the opposite side. A light tap with a mallet might be necessary while maintaining a compressive force on the assembly.

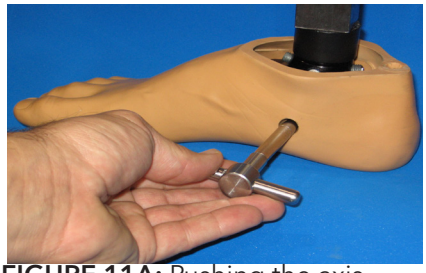

FIGURE 11A: Pushing the axis assembly through the ankle joint.

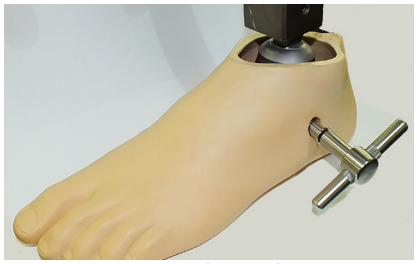

FIGURE 11B: Pushing the axis assembly through the ankle joint.

9. Place the tip of the protruding bullet into the shaft guide (FIGURE 12), and use your arbor press or bar clamp to drive the axis all the way until it is seated through the far side of the internal stirrup (FIGURE 13A, 13B).

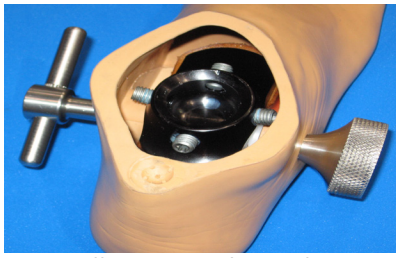

FIGURE 12: Bullet inserted into the shaft guide.

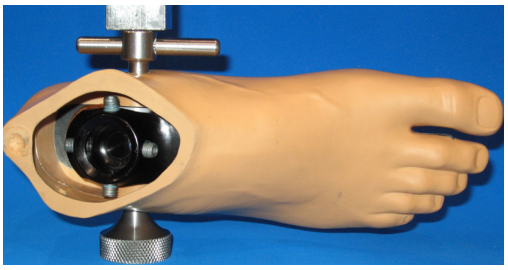

FIGURE 13A: Fully seating the axis.

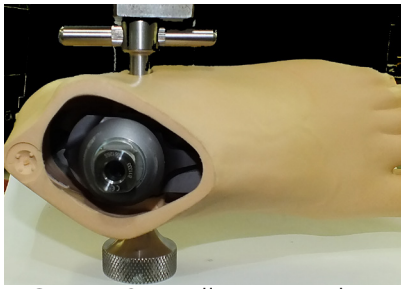

FIGURE 13B: Fully seating the axis.

10. Remove the bullet from the axis.

Note: The bullet should back out easily. If it doesn't, then the shaft was not pressed completely through the assembly. Repeat step 9 if necessary.

11. Install the M6 button head screw and washer into the axis. Use Loctite 242 on the threads (FIGURE 14).

Note: Ensure that the recess feature of the washer is oriented inward, towards the foot.

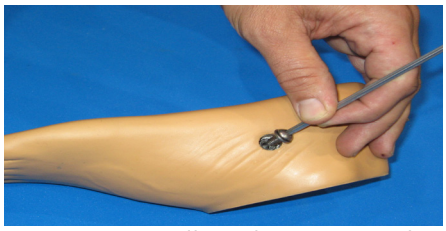

FIGURE 14: Installing the screw and washer.

12. Use a 4 mm hex wrench to hold the shaft and use a torque wrench to tighten the button head cap screw to 8 Nm (6 ft-lb).
13. Insert the cosmetic plugs back into the foot.

Note: For Seattle Kinetic Edge, install foot shell per install guide 17480-001.

CE

QUESTIONS

Contact Customer Service in the U.S. at 800-492-1088, or fax 800-245-3765
If calling from outside the U.S. or Canada, contact Customer Service at 517-787-1600, or fax 800-245-3765
Visit Trulife online at www.trulife.com

LIMITED WARRANTY

Trulife warrants that the Seattle Kinetic, Seattle Kinetic Light and Seattle Kinetic Edge will be free from defects in material and workmanship for two (2) years (one year 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 Seattle Kinetic or Seattle Kinetic Light or Seattle Kinetic Edge have 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.

Trulife
ORTHOTICS & PROSTHETICS