Instructions for Use

REF **TKR Positioner, 24" (61 cm) 800-0141**

REF **TKR Positioner, 30" (76 cm) 800-0171**

Replacement Liners
TKR Boot Liners, 12/cs   800-0146

INTENDED USE
Intended use is to allow surgeon to position operative leg in multiple positions (extension, flexion, tilt, and rotation) during total knee replacement surgery. The intended users of this device are medical professionals within hospitals and surgery centers.
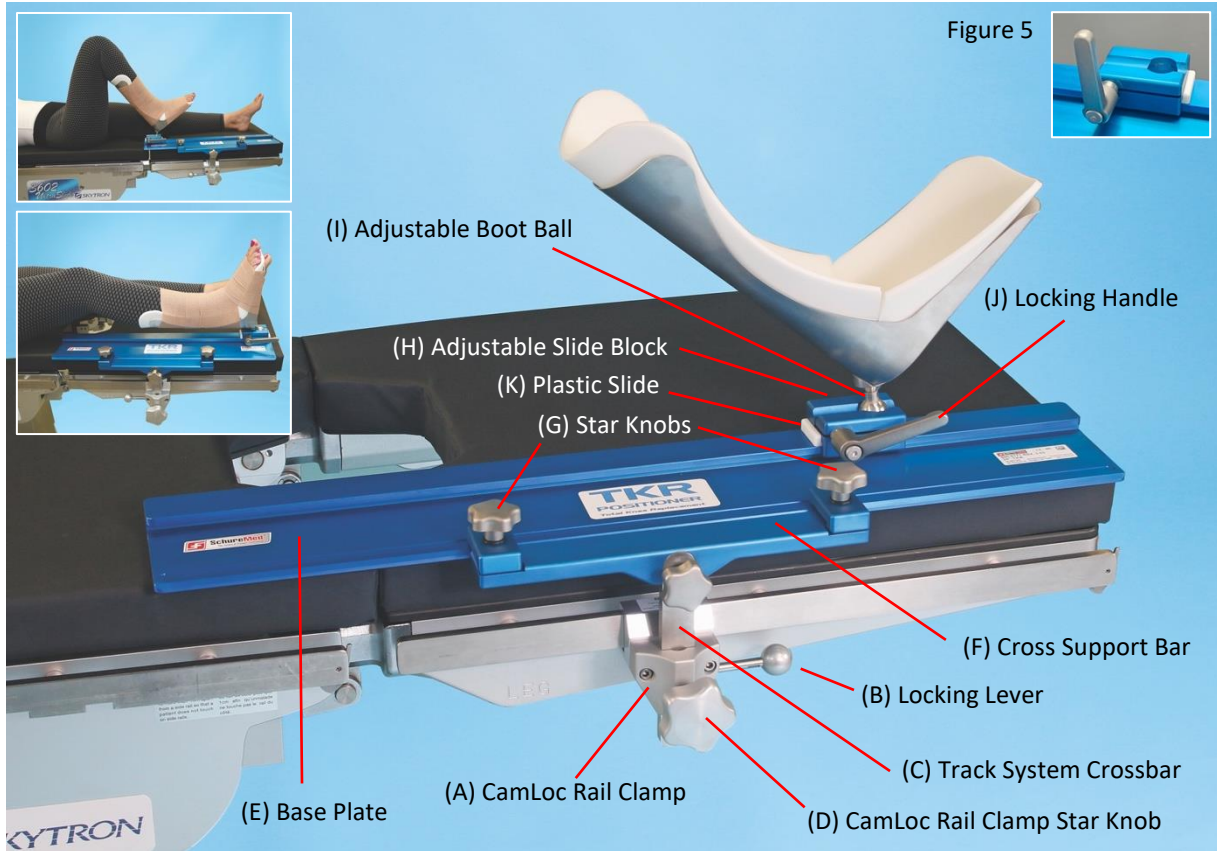
GENERAL INFORMATION
- *Product not made with Natural Rubber Latex*
- *Device supports 500 lbs. (227 kg) (proportional patient load 6'4" (193 cm) (tall patient per 99% human body model)*
- *Product warranty covers product from manufacturing defects for period of 2 years*
- *If damaged in shipping, call Customer Service at (888) 724-8763 or (781) 982-7000 to obtain Return Material Authorization number. For product warranty issues, contact Customer Service.*
- *Product is maintenance-free, check product condition before next use*
- *CE marked medical device according to MDR (EU) 2017/745*
- *Life of device is 5 years under normal use*
- *Store device between -4°F to +86°F (-20°C to +30°C)*
- *All components must be cleaned before and after use. See cleaning instructions on page 4 of this manual.*
- *All components need to be steam sterilized. See sterilization instructions on page 4-6 of this manual.*

INSTRUCTIONS
Become familiar with patient positioning device's features before use with patient. Always practice on a nurse, physician, or appropriate volunteer prior to using clinically.

800-0141

800-0171

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Figure 5

(I) Adjustable Boot Ball

(J) Locking Handle

(H) Adjustable Slide Block

(K) Plastic Slide

(G) Star Knobs

(F) Cross Support Bar

(B) Locking Lever

(C) Track System Crossbar

(A) CamLoc Rail Clamp

(E) Base Plate

(D) CamLoc Rail Clamp Star Knob

Set Up and Use of TKR Positioner

1. *Drape surgical table. Choose Standard CamLoc Rail Clamp (sold separately) to use with 1-2 drapes or Large CamLoc Rail Clamp for 3-5 drapes.*

2. *Attach CamLoc Rail Clamp (A) to rail. Then flip Locking Lever (B) right or left to secure.* ***(DO NOT ATTACH OVER NOTCHES WITHIN SIDE RAIL).***

3. *Slide Track System Crossbar (C) into CamLoc Rail Clamp (A). Securely tighten Track System Crossbar (C) by turning CamLoc Rail Clamp Star Knob (D) clockwise.*

4. *Slide Base Plate (E) into Cross Support Bar (F) making sure its flush. Tighten two Star Knobs (G) by turning clockwise.*

5. *Insert Plastic Slide (K) within opening under Adjustable Slide Block (H), with notched side up. Make sure Locking handle (J) is rotated until it stops (do not tighten) before sliding on to Base Plate (E). Locking Handle (J) should be in 12:00 position (see Figure 5). Depress button and pull Locking Handle (J) to adjust as needed. Slide on to track system while holding Plastic Slide (K) up close to Adjustable Slide Block (H).* ***WARNING! Only adjust adjustable slide block Locking Handle (J) lever when it is on track.***

6. *Place Adjustable Boot Ball (I) into track system's Adjustable Slide Block (H).*

7. *Line boot with our TKR Boot Liner 800-0146 (12/cs, sold separately)*

8. *Prep and position patient, turn Adjustable Slide Block Locking Handle (J) right to lock into desired position*

GENERAL SPECIFICATIONS
Device Dimensions (maximum)

800-0141 TKR, 24" (61 cm)
Length: 23.7"+/- 0.5" (61 cm +/- 1 cm)
Width: 7.5" +/- 0.5" (19 cm +/- 1 cm)
Height: 8.1" +/- 0.5" (20 cm +/- 1 cm)
Net Weight: 9 +/- 0.5 lbs. (4 kg +/- .22 kg)
Gross Weight: 12.5 +/- 0.5 lbs. (5.6 kg +/- .22 kg)

800-0171 TKR, 30" (76 cm)
Length: 29.7" +/- 0.5" (76 cm +/- 1 cm)
Width: 7.5" +/- 0.5" (19 cm +/- 1 cm)
Height: 8.1" +/- 0.5" (20 cm +/- 1 cm)
Device Weight: 10 +/- 0.5 lbs. (4.5 kg +/- .22 kg)
Gross Weight: 14.5 +/- 0.5 lbs. (6.5 kg +/- .22 kg)

Single-person installation.

COMPONENT OVERVIEW
TKR Positioner, 24" (61 cm) or 30" (76 cm), is a surgical accessory that allows surgeon to position operative leg during total knee replacement surgery.

800-0141-TRAY TKR Sterilization Tray, 24" (61 cm) (included with 800-0141 purchase)
800-0171-TRAY TKR Sterilization Tray, 30" (76 cm) (included with 800-0171 purchase)

Required Accessories: CamLoc Rail Clamp and TKR Boot Liners sold separately.

CamLoc Rail Clamp: 800-0271 For use with 1-2 drapes | **800-0271-L** For use with 3-5 drapes

US: *0.374" x 1.122" (9.5 mm x 28.5 mm) PN# 800-0271 or 800-0271-L*
Denyer: *0.236" x 1.496" (6 mm x 38 mm) PN# 800-0271-DEN*
Europe: *0.394" x 0.984" (10 mm x 25 mm) PN# 800-0271-EU*
Eschmann (UK): *0.236" x 1.260" (6 mm x 32 mm) PN# 800-0271-UK*
Japan: *0.354" x 1.260" (9 mm x 32 mm) PN# 800-0271-JPN*
Swiss: *0.394" x 1.181" (10 mm x 30 mm) PN# 800-0271-SWISS*

Replacement Liners*:* 800-0146 TKR Boot Liners, 12/cs

DISPOSAL
- **General** - *Prevent infection by cleaning and disinfecting product before disposal*
- **Packaging** - *Dispose packaging material via household waste according to national requirements*
- *SchureMed accepts back used or retired products - or dispose of product in accordance with national requirements*

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PRODUCT USE WARNINGS
WARNING!
Maximum load should not exceed appropriate proportion of a patient weighing 500 lbs. (227 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.

⚠

WARNING!
Hazards result from incorrect use. Strictly follow Instructions for Use with your Operating Table system.

⚠

WARNING! Only adjust adjustable slide block lever when it is on the track.

WARNING! *Do not reuse device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing*.

HAND AND WASHER MACHINE CLEANING INSTRUCTIONS
- *Clean TKR Positioner thoroughly before using (before sterilization) and after each use*
- *Recommended cleaning products: (All solutions should be used in accordance with manufacturer's instructions)*
    - *Enzymatic neutral pH detergent solution*
    - *(Enzymatic cleaners are compatible with metal devices/instruments and are preferred)*
    - *Non-enzyme, hydrogen peroxide based solution*
    - *Coverage Plus NPD One Step Cleaner, Disinfectant & Deodorizer Concentrate*

- *Disassemble TKR Positioner into separate parts for cleaning:*
    - *Boot Ball*
    - *Mounting Plate with Clamp*
    - *Base Plate with Track*
    - *Slide Block with Handle*
    - *Plastic Slide*

HAND CLEANING
- *Scrub each piece with a soft, plastic scrub brush and a recommended cleaning solution (see above)*
- *Rinse all parts thoroughly to remove any chemical residue*
- *Wipe each part completely dry with a clean, lint-free cloth*
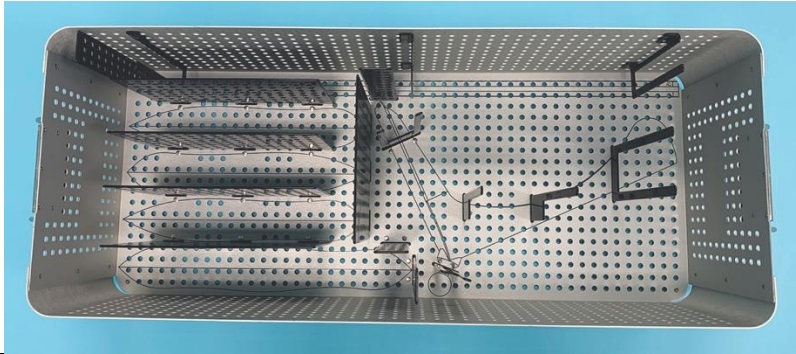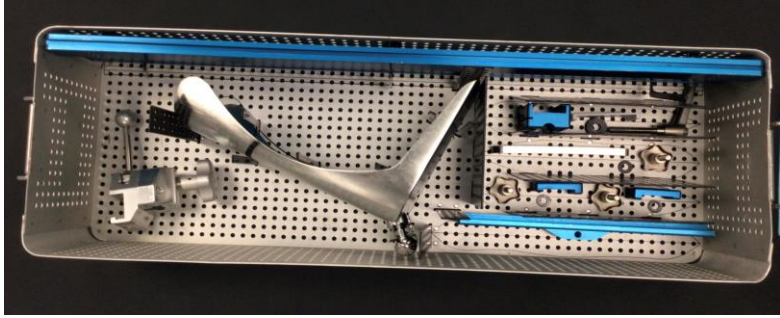
WASHER CLEANING
- *Put through washer/decontaminator according to manufacturer's instruction (Select cycle that does not included lubrication)*
- *Prepare for sterilization (device must be cleaned before sterilization)*
- *See sterilization instructions below*

*Based on information provided by the Healthcare Infection Control Practices Advisory Committee (HICPAC), the Center for Disease Control (CDC), the National Center for Biotechnology Information (NCBI) and the U.S. National Library of Medicine.

STEAM STERILIZATION

Sterilization Tray w/Lid

Outside View **24" (61 cm) Tray Dimensions:** 26.5"L x 10.5"W x 6.75"D (67 cm x 27 cm x 17 cm) Weight: 7.9 lbs. (3.6 kg) **30" (75 cm) Tray Dimensions:** 31.25"L x 10.5"W x 6.75"D (79 cm x 27 cm x 17 cm) Weight: 8.7 lbs. (3.9 kg)	

Sterilization Tray	
Inside View	

Sterilization Tray Component Placement	
Place following parts in the dedicated slots: 1. *Place Base Plate upright (as shown)* 2. *Place TKR Boot within black outline for exact placement* 3. *Place parts vertically in slots*	

Steam Sterilization Procedure	
Wrap using envelope method or accepted wrap method at your facility **Pre-Vacuum** *Wrapped Instruments* *Exposure Time at 270°F: (132°C) 4 minutes* *Drying Time: 40 minutes*	

USER NOTICE
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

UDI   Basic UDI-DI: 081001460F0015DV

eIFU Language Versions

To download and print the Instructions for Use, please go to http://www.schuremed.com/schuremed-eifu.

Symbol Glossary

Symbol	Title	Symbol Description
	Manufacturer	Indicates the medical device manufacturer.
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the european community.
	Use-by Date	Indicates the date after which the medical device is not to be used.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
SN	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
⚠	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
MD	Medical Device	Indicates the item is a medical device.
UDI	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
CE	CE Marking	European Conformity.
Ⓧ	Single Patient Use	Indicates the item is a single patient use medical device.

Manufacturer

SchureMed (081001460)
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Toll Free (888) 724-8763 | **Ph** (781) 982-7000 | **Fax** (781) 982-7001 | **orders@schuremed.com**

CE MD

EC REP **Authorized Representative**
Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands