



Instructions for Use

**TKR Positioner for Total Knee Replacement,
24" 800-0141**

**TKR Positioner for Total Knee Replacement,
30" 800-0171**

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Manufacturer
SchureMed (081001460)



Authorized Representative

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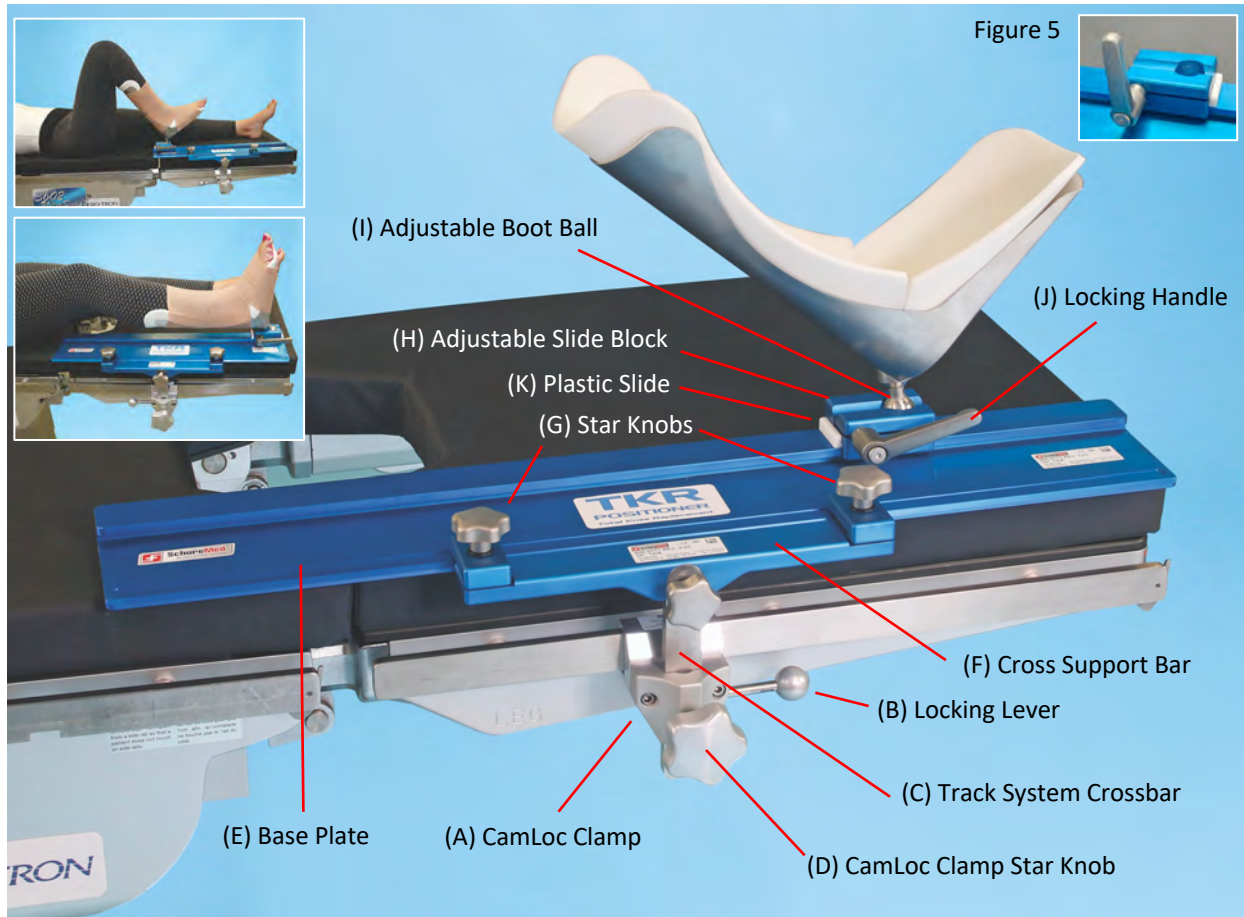
GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Device supports 500 lb. proportional patient load (6'4") tall patient per 99% human body model)*
- *Product warranty covers product from manufacturing defects for period of 2 years*
- *Product is maintenance-free, check product condition before next use*
- *Life of device is 3 years under normal use*
- *Store device between $-4^{\circ}F$ to $+86^{\circ}F$*
- *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.



Set Up and Use of TKR Positioner

1. Drape surgical table. Choose Standard CamLoc Clamp (sold separately) to use with 1-2 drapes or Large CamLoc Clamp for 3-5 drapes.
2. Attach (A) CamLoc Clamp to rail. Then flip (B) Locking Lever right or left to secure. **(DO NOT ATTACH OVER NOTCHES WITHIN SIDE RAIL).**
3. Slide (C) Track System Crossbar into CamLoc Clamp. Securely tighten Track System Crossbar by turning (D) CamLoc Clamp Star Knob clockwise.
4. Slide (E) Base Plate into (F) Cross Support Bar making sure its flush. Tighten two (G) Star Knobs by turning clockwise.
5. Insert Plastic Slide (K) within opening under Adjustable Slide Block (H), with notched side up. Make sure handle is rotated until it stops (do not tighten) before sliding on to Base Plate. Handle should be in 12:00 position (see Figure 5). Depress button and pull handle to adjust as needed. Slide on to track system while holding Plastic Slide up close to Adjustable Slide Block. **WARNING! Only adjust adjustable slide block lever when it is on track.**
6. Place (I) Adjustable Boot Ball into track system's Adjustable Slide Block.
7. Line boot with our Sterile Disposable Boot Liner 800-0146 (12/cs, sold separately)
8. Prep and position patient, turn (J) Slide Block Locking Handle right to lock into desired position

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.

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

800-0141 TKR, 24"

Length: 23.7" +/- 0.5" (602 mm +/- 12.7 mm)

Width: 7.5" +/- 0.5" (190.5 mm +/- 12.7 mm)

Height: 8.1" +/- 0.5" (205.7 mm +/- 12.7 mm)

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"

Length: 29.7" +/- 0.5" (754 mm +/- 12.7 mm)

Width: 7.5" +/- 0.5" (190.5 mm +/- 12.7 mm)

Height: 8.1" +/- 0.5" (205.7 mm +/- 12.7 mm)

Device Weight: 10 +/- 0.5 lbs. (4.5 kg +/- .22kg)

Gross Weight: 14.5 +/- 0.5 lbs. (6.5 kg +/- .22kg)

Single person installation.

COMPONENT OVERVIEW

TKR Positioner for Total Knee Replacement, 24" or 30", is a surgical accessory that allows surgeon to position operative leg during total knee replacement surgery.

800-0141-TRAY TKR Sterilization Tray, 24" (included with 800-0141 purchase)

800-0171-TRAY TKR Sterilization Tray, 30" (included with 800-0171 purchase)

Required Accessories: CamLoc Clamp and Sterile Disposable Boot Liners sold separately.

CamLoc 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

800-0146 Sterile Disposable 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



Product Use Warnings

WARNING!

Maximum load should not exceed appropriate proportion of a patient weighing 500 lbs. 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.

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

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

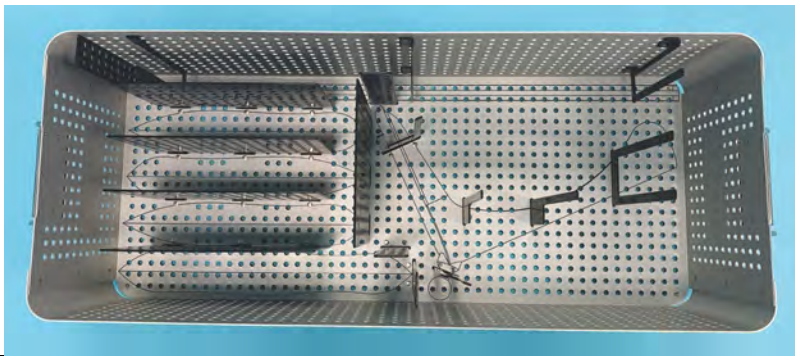
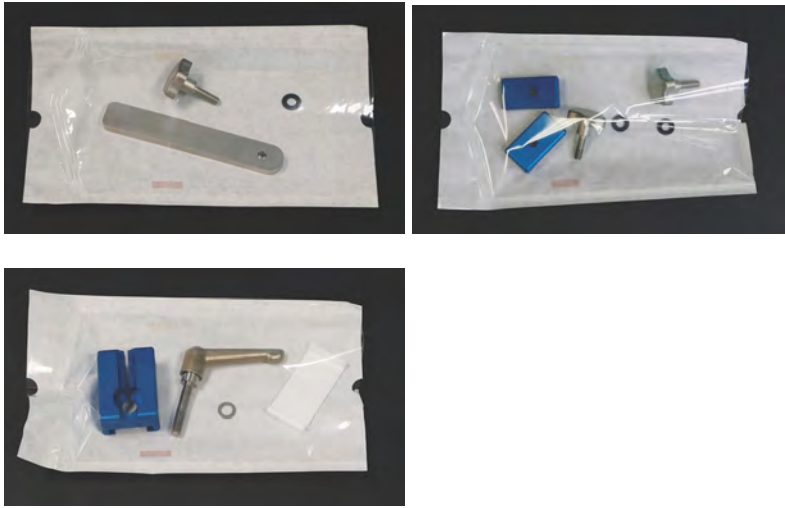


WASHER CLEANING

- Put through washer/decontaminator according to manufacturer’s instruction (Select cycle that does not include 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	
<p>Outside View</p> <p>24” Tray Dimensions: 26.5”L x 10.5”W x 6.75”D Weight: 7.9 lbs. (3.6 kg.)</p> <p>26” Tray Dimensions: 31.25”L x 10.5”W x 6.75”D Weight: 8.7 lbs. (3.9 kg.)</p>	

Sterilization Tray	
Inside View	
Component Placement in Pouches	
<p>7" x 12" Pouches</p> <p>Split parts evenly between 3 pouches.</p> <ul style="list-style-type: none"> • <i>Blade/Star Knobs</i> • <i>Handle/Ball Slide Block</i> • <i>Clamps and Handle</i> 	
<p>8" x 16" Pouch</p> <p>Mount Plate</p>	
Sterilization Tray Component Placement	
<p>Place following parts in the dedicated slots:</p> <ol style="list-style-type: none"> 1. <i>Place Base Plate upright (as shown)</i> 2. <i>Place TKR Boot within black outline for exact placement</i> 3. <i>Place pouches vertically in slots</i> 	

Steam Sterilization Procedure

Wrap using envelope method or accepted wrap method at your facility

Pre-Vacuum Wrapped Instruments

*Exposure Time at 132°C
(270°F): 4 minutes*

Drying Time: 40 minutes



Symbol Explanation



Date of Manufacture



Conformity Mark



Manufacturer



Batch Code/Serial Number



Authorized Representative
in European Community

IFU-800-0141 REV 3.05

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