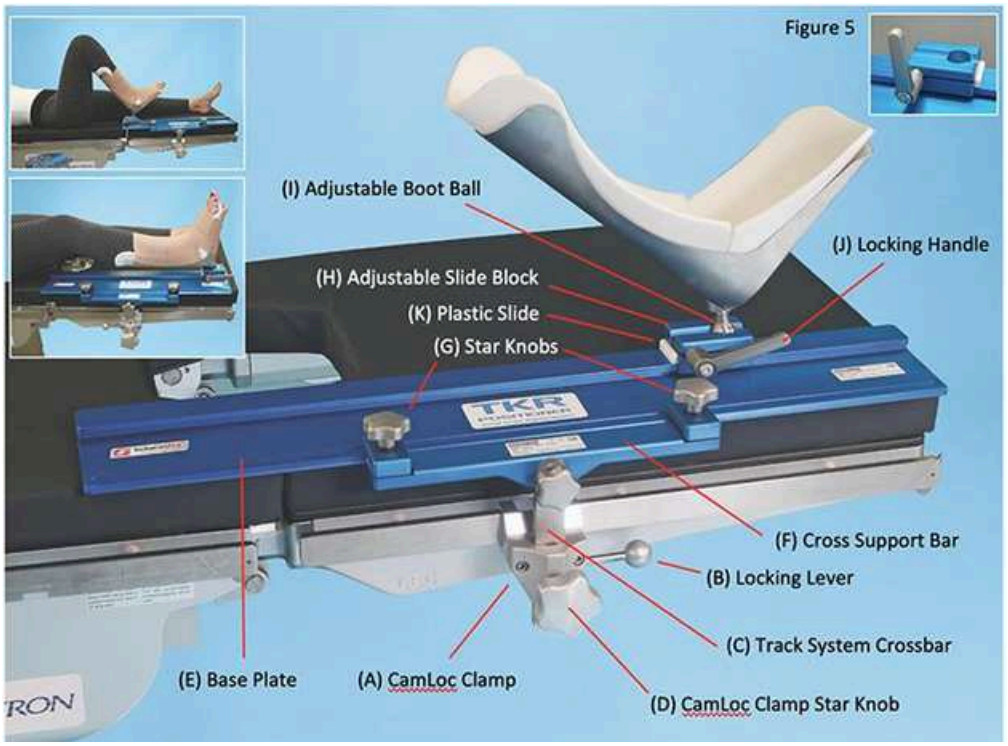
TKR POSITIONER, 24" & 30"

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 800-804-0333 to obtain Return Material Authorization number. For product warranty issues, contact Customer Service.
• CE marked medical device according to MDR (EU) 2017/745 • Product is maintenance-free, check product condition before next use
• Life of device is 3 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 below.
• All components need to be steam sterilized. See sterilization instructions below.

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 the 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 THE NOTCHES WITHIN THE 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). Single-person installation.

DSC-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)
Net Weight: 9 +/- 0.5 lbs. (4 kg +/- .22kg)? Gross Weight: 12.5 +/- 0.5 lbs. (5.6 kg +/- .22kg)

DSC-800-0171 TKR, 30” (760 mm)

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)

COMPONENT OVERVIEW

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

DSC-800-0141-TRAY TKR Sterilization Tray, 24” (61 cm) (included with 800-0141 purchase)
DSC-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# DSC-800-0271 or 800-0271-L

Denyer: 0.236” x 1.496” (6 mm x 38 mm) PN# DSC-800-0271-DEN
Europe: 0.394” x 0.984” (10 mm x 25 mm) PN# DSC-800-0271-EU
Eschmann (UK): 0.236” x 1.260” (6 mm x 32 mm) PN# DSC-800-0271-UK
Japan: 0.354” x 1.260” (9 mm x 32 mm) PN# DSC-800-0271-JPN
Swiss: 0.394” x 1.181” (10 mm x 30 mm) PN# DSC-800-0271-SWISS

Replacement Liners
DSC-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
- David Scott Company 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. (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.

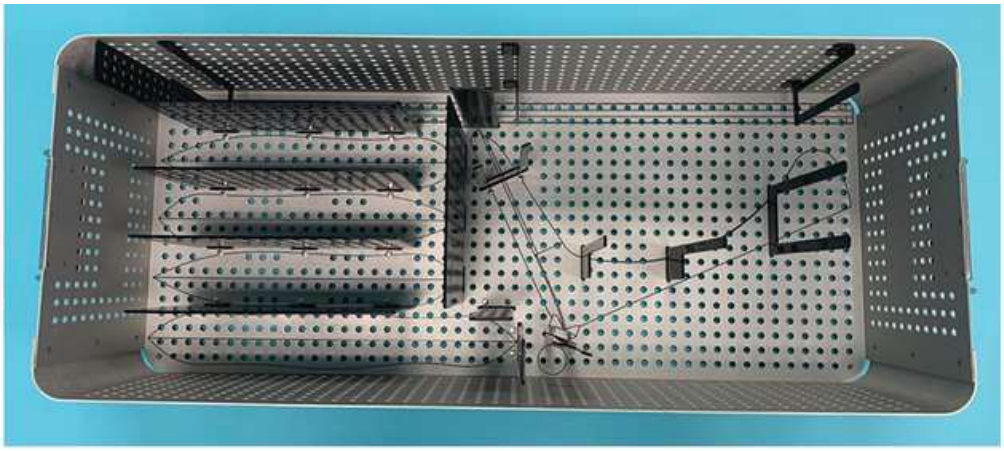
CLEANING

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 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.

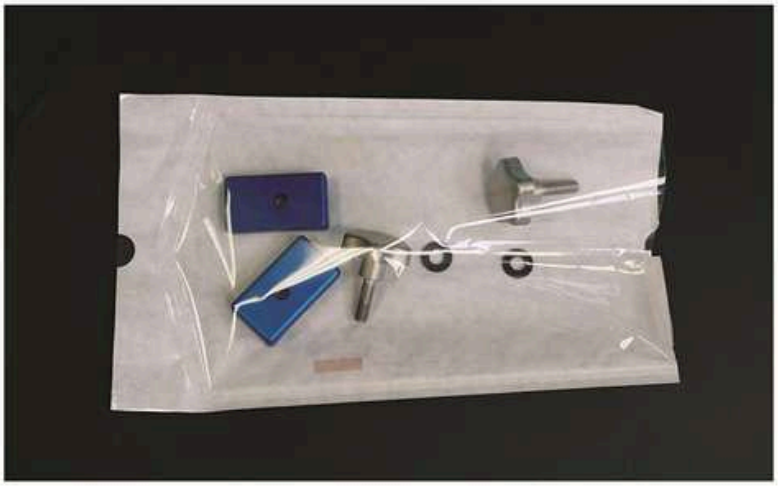
STEAM STERILIZATION



24” 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” 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)

COMPONENT PLACEMENT IN POUCHES



7" x 12" (18 cm x 31 cm) Pouches - Blade/Star Knobs, Handle/Ball Slide Block and Clamps/Handle

STERILIZATION TRAY COMPONENT PLACEMENT

Place following parts in dedicated slots:
1. Place Base Plate upright (as shown)
2. Place TKR Boot within black outline for exact placement
3. Place pouches 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.

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Basic UDI-DI: 081001460F0015DV

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