

TKR POSITIONERS

Latest Revision 12/24/2015

Instructions for use

800-0141 24" TKR

800-0171 30" TKR



Contents

1.0	Overview of components	3
2.0	General Information	3
3.0	General Specifications	3
4.0	Intended Use	3
5.0	Warnings	4
6.0	Instructions	5,6
7.0	CE Label	7
8.0	Explanation of Symbols	8

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Initial Release 11/17/2009



TKR 24"

800-0141

TKR 30"

800-0171

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1.0 Overview of Components

The TKR TRACK BALL SYSTEM 24" or 30" is a surgical accessory that allows the surgeon to position the operative leg during total knee replacement surgery.

2.0 General Information

- This product is not made with (NRL) Natural Rubber Latex
- This device supports a 500 lb proportional patient load (6'4" tall patient per 99% human body model)
- Product warranty covers the product from manufacturing defects for a period of 2 years.
- If damaged in shipping, please call Customer Service at (888) 724-8763 or 781 982-7000 to obtain a Return Material Authorization (RMA) number. For product warranty issues also contact Customer Service.
- This product is maintenance free, check the condition of the product each time before using it.
- Life of device is 5 years under normal use.
- Storage of device shall be between -4°F to $+86^{\circ}\text{F}$
- ***All components must be cleaned before and after use. See cleaning instructions on page 6 of this manual.***
- ***All components need to be Autoclaved or flash sterilized. See sterilization instructions on page 6 of this manual.***

3.0 General Specifications

Device Dimensions (maximum)

800-0171 30"

Length: 30" +/- 0.5"

Width: 8" +/- 0.5"

Height: 11" +/- 0.5"

Device Weight: 6 +/- 0.5 lbs

Single person installation.

800-0141 24"

Length: 24" +/-0.5"

Width: 8" +/-0.5"

Height: 11" +/- 0.5

Device Weight: 6 + 0.5 lbs

4.0 Intended Use

The intended use is to allow the surgeon to position the operative leg in multiple positions (extension, flexion, tilt and rotation) during total knee replacement surgery.

5.0 Product Use Warnings



WARNING!

The maximum load placed on the product may not exceed the appropriate proportion of a patient weighing 500 lbs. Restrictions result from the permissible overall load, among other things, of accessory rails when using operating tables with a low maximum load capacity. Be absolutely sure to follow the instructions for use for your Operating Table system.



WARNING!

Hazard resulting from incorrect use. Be absolutely sure to follow the instructions for use for your Operating Table system.



WARNING!

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

6.0 Instructions



Set Up and Use of the TKR Positioner

1. Drape the surgical table.
2. Attach the rail clamp to the rail (a). Then flip the locking lever (b) right or left to secure. **(DO NOT ATTACH OVER THE NOTCHES WITHIN THE SIDE RAIL).**
3. Slide the track system crossbar (c) into the rail clamp, approximately 2" from patient's heel. Securely tighten the track system crossbar by turning the rail clamp star knob to the right (d).
4. Slide the base plate (e) into the cross support bar (f) making sure its flush. Tighten the two star knobs (g) by turning to the right.
5. Slide the adjustable slide block (h) on to the track system. **WARNING! Only adjust the adjustable slide block lever when it is on the track.**
6. Place the adjustable boot ball (i) into the track system's adjustable slide block.
7. Line the boot with our sterile disposable boot liner #800-0146 (sold separately as a case of 12).
8. Prep and position patient, turn the slide block locking handle (j) right to lock into desired position.

6.0 Instructions

CLEANING INSTRUCTIONS

- Clean the 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
 - CamLoc Clamp
- 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
- 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

GRAVITY	EXPOSURE TIME AT 121° C (250° F)	EXPOSURE TIME AT 132° C (270° F)	EXPOSURE TIME AT 135° C (275° F)	DRYING TIME
Wrapped Instruments	30 Mins.	15 Mins.	-	15-30 Mins.
Unwrapped Nonporous Items	-	3 Mins.	3 Mins.	1 Min.

PRE-VACUUM	EXPOSURE TIME AT 121° C (250° F)	EXPOSURE TIME AT 132° C (270° F)	EXPOSURE TIME AT 135° C (275° F)	DRYING TIME
Wrapped Instruments	-	4 Mins.	3 Mins.	20-30 Mins.
Unwrapped Nonporous Items	-	3 Mins.	3 Mins.	N/A

7.0 CE Label

TKR 24"
800-0141
TKR 30"
800-0171



SERIAL # _____



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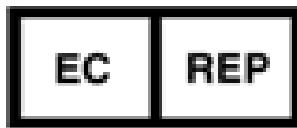


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EXPLANATION OF SYMBOLS



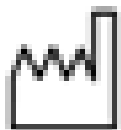
BATCH CODE / SERIAL NUMBER



AUTHORIZED REPRESENTATIVE
IN EUROPEAN COMMUNITY



MANUFACTURER



DATE OF MANUFACTURE



CONFORMITY MARK