



Instructions for Use

REF Wrist Tower 800-0135

INTENDED USE

Intended use is to provide traction and intra-operative positioning controlled by surgeon's preference during wrist surgery. The intended users of this device are medical professionals within hospitals and surgery centers.

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- Length: 14" +/- 0.5" (36 cm +/- 1 cm)
- Depth: 360° Rotation
- Height: 53" +/- 0.5" (135 cm +/- 1 cm) (extended), 34" +/- 0.5" (86 cm +/- 1 cm) (collapsed)
- Device Weight: 9.50 +/- 0.5 lbs. (4.3 +/- .22 kg)
- Attaches to surgical table rail using CamLoc Clamp (sold separately) where there are no notches
- Single-person installation

GENERAL INFORMATION

- Product not made with Natural Rubber Latex
- Device supports 500 lb. (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.
- 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)

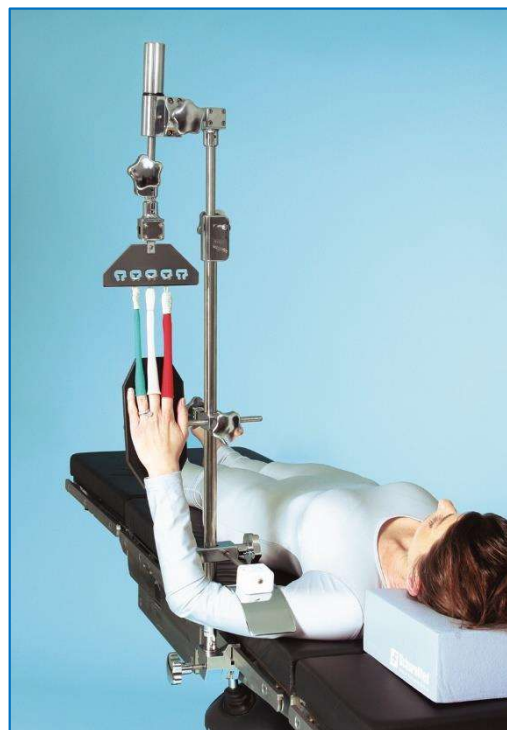
INSTRUCTIONS

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.

COMPONENT OVERVIEW

Wrist Tower is a device used during wrist surgery. Its function is to provide traction and intra-operative positioning controlled by surgeon's preference, during supine elbow surgery. A CamLoc Rail Clamp (sold separately) is required to attach Wrist Tower to surgical table where there is no notches.

- US: 0.375" x 1.125" (9.5 mm x 28.5 mm) PN# 800-0271
- Denyer: 0.242" x 1.5" (6 mm x 38 mm) PN# 800-0271-DEN
- Europe: 0.390" x 0.975" (10 mm x 25 mm) PN# 800-0271-EU



- *Eschmann (UK): 0.237" x 1.245" (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 1.1181" (10 mm x 30 mm) PN# 800-0271-SWISS*

SUB-ASSEMBLY COMPONENTS

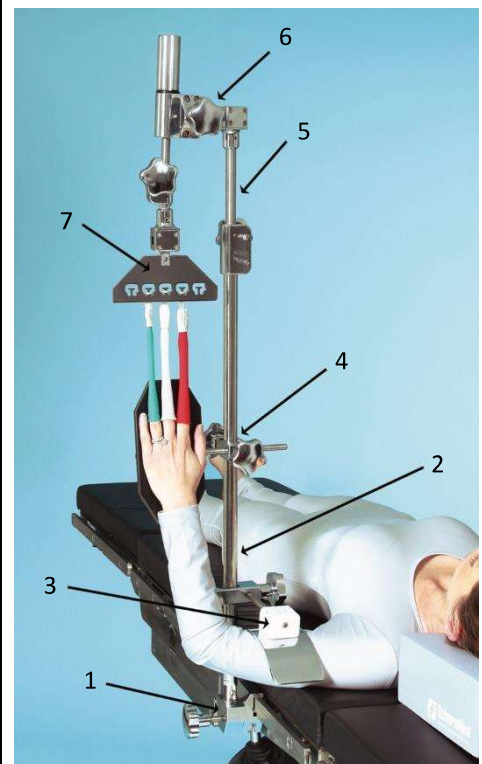


ATTACHING TO TABLE

Setup

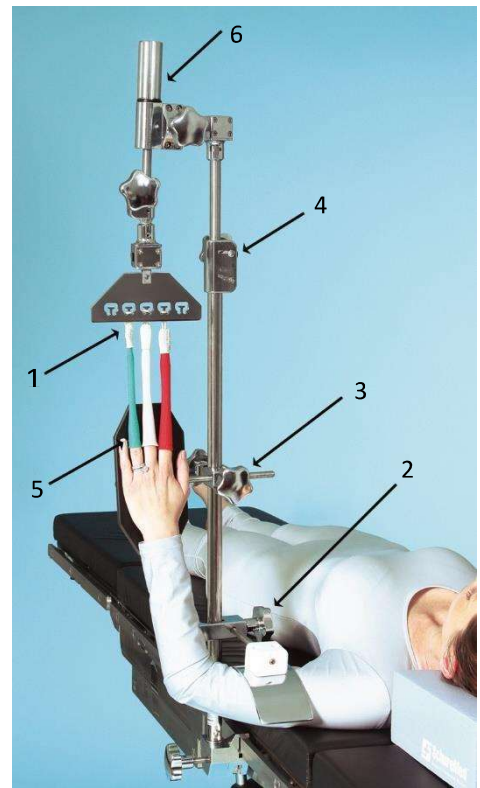
**Drape table prior to Setup*

1. *Attach CamLoc Rail Clamp drapes where there are no notches on side rail*
2. *Insert Lower Control Tube 790-0011 and it lock into clamp*
3. *Attach Counter Traction 790-0037*
4. *Attach Hand Support 790-0036*
5. *Attach Traction Support Bar 790-0014 and lock handle down tight*
6. *Plug in 790-0015 Traction System*
7. *Attach Schure Hand Positioner 790-0016*



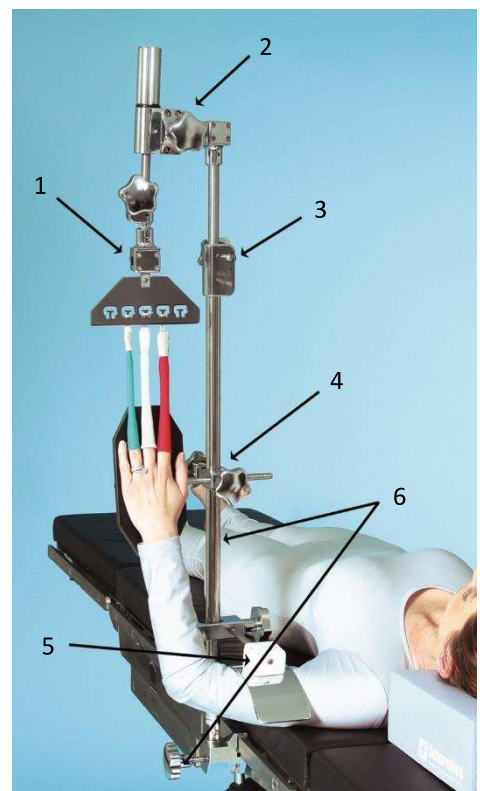
INSTRUCTIONS FOR USE

1. Insert (512-0015) Finger Traps into appropriate slot of (790-0016)
2. Adjust desired height of Counter Traction (790-0037) by unlocking handle, once at desired height, lock handle tight
3. Adjust desired height of Hand Support (790-0036) by unlocking handle, once at desired height, lock handle tight
4. Adjust height of (790-0014) by unlocking handle, once at desired height, lock handle tight
5. Insert appropriate fingers into finger traps (512-0015)
6. To adjust traction, turn knob right to tighten and left to loosen



TAKE DOWN

1. Remove Schure Hand Positioner 790-0016 by pulling plunger with one hand and using your other hand to remove Schure Hand Positioner
2. Loosen handle, unplug the Traction System 790-0015
3. Unlock handle, remove Traction Support Bar 790-0014
4. Unlock handle, remove Hand Support 790-0036
5. Unlock handle remove Counter Traction 790-0037
6. Loosen star knob on clamps, remove Lower Control Tube 790-0011
7. Unlock clamp, remove from side rail



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. (227 kg). Use care with low-maximum load capacity surgical tables that accessory rails are not overloaded.



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



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

CLEANING AND STERILIZATION INSTRUCTIONS

Cleaning Instructions

- Clean Wrist Tower 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 Wrist Tower into separate parts for cleaning: 790-0016, 790-0014, 790-0015, 790-0037, 790-0036, 790-0011 and CamLoc Rail 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), Center for Disease Control (CDC), National Center for Biotechnology Information (NCBI) and U.S. National Library of Medicine.*

Steam Sterilization

Pre-Vacuum Sterilization

Wrapped Instruments

Exposure Time at 132°C (270°F): 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: 081001460F0068EJ

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.
	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.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
	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.
	Medical Device	Indicates the item is a medical device.
	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.



Manufacturer

SchureMed (081001460)

452 Randolph Street, Abington, MA 02351 USA

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



Authorized Representative

Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands