

### Martins Arm Retractor System and Accessories

The reprocessing instructions provided in this document were developed in accordance with ISO 17664 and are compatible with healthcare facility practices described in ISO 15883 (washer-disinfectors) and ISO 17665 (moist heat sterilization).

#### 1. Device Description

The Martins Arm Retractor system is a manually adjustable surgical positioning device designed to hold and position retractors and other surgical instruments during procedures.

- Fixed Martins Table Clamp
- Rotatable Martins Table Clamp
- Martins Arm Retractor
- Quick-Connect Accessories

Rigid arms are available with straight or angled column configurations.

#### 2. Intended Use

The Martins Arm Retractor system is intended for use in sterile surgical environments to support and position surgical retractors and other instruments during procedures. The system is intended for use by trained healthcare professionals.

#### 3. Contraindications

This product should not be used for any purpose other than the intended use described in this IFU.

#### 4. Warnings

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Products are supplied non-sterile and must be cleaned and sterilized prior to use.
- Inspect instruments prior to each use for damage, wear, or malfunction.
- Do not force tightening knobs beyond their mechanical stop.
- Do not tighten the table clamp knob when the Martins Arm Retractor column is not fully inserted.
- The rail clamps are not insulated. Do not use the system when grounding a patient is unacceptable.
- If a device has been used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), the device must not be reused and should be permanently removed from service.

#### 5. Possible Adverse Effects

- Injury
- Infection
- Delay of surgical procedure

#### 6. Product Components and Operation

##### 6.1 Fixed Martins Table Clamp

Provides an attachment point to the operating table rail and secures the Martins Arm Retractor column.

1. Open the rail clamping knob until L-brackets fit over the rail.
2. Tighten the knob to secure the clamp.
3. Insert the retractor column.
4. Tighten the column clamping knob.

**Martins Arm Retractor System and Accessories****6.2 Rotatable Martins Table Clamp**

Allows full rotational positioning of the Martins Arm Retractor.

5. Open the rail clamp knob.
6. Position clamp over rail.
7. Tighten knob securely.
8. Insert column.
9. Adjust to desired angle.
10. Tighten column clamping knob.

**6.3 Quick-Connect Accessories**

Provides rapid connection of accessories to the distal end of the Martins Arm Retractor.

- Square Shaft Quick Connect
- Hex Shaft Quick Connect
- Tight Twist Hex Shaft
- Tight Twist Square Shaft

These connection systems are not interchangeable.

**6.4 Martins Arm Retractor**

Provides multi-axis positioning of surgical accessories.

11. Support distal end of the arm.
12. Loosen central knob counterclockwise.
13. Position accessory as required.
14. Tighten knob clockwise to lock position.

**7. Inspection Before Use**

- Inspect instruments for cracks or damage.
- Confirm joints lock securely.
- Verify column holds firmly in clamp.
- Check quick-connect collar locks securely.

**8. Reprocessing**

The following reprocessing instructions should be used for Martins products. Healthcare facilities are responsible for validating their reprocessing procedures according to institutional policies and applicable standards.

**Martins Arm Retractor System and Accessories****8.1 Cleaning**

- Remove gross contamination immediately after use.
- Keep instruments moist until cleaning begins.
- Do not use hot water above 40°C (104°F) before cleaning.

Supplies required:

- Ultrasonic cleaner
- Neutral pH enzymatic detergent
- Soft nylon cleaning brushes
- DI or RO water

**Manual Cleaning**

15. Rinse instrument for a minimum of 2 minutes.
16. Place instrument in ultrasonic cleaner with enzymatic detergent.
17. Sonicate for 10 minutes.
18. Transfer instrument to manual wash container.
19. Brush using nylon brush for a minimum of 1 minute.
20. Rinse for 2 minutes.
21. Dry with lint-free cloth.

**Automated Cleaning**

Automated cleaning may be performed using washer-disinfectors validated in accordance with ISO 15883.

- Wash at 60°C for 2 minutes
- Rinse at 60°C for 20 seconds
- Final rinse at 82°C for 2 minutes
- Forced air drying at 116°C for 9 minutes

Post Cleaning Inspection:

After cleaning, visually inspect each instrument to ensure all visible soil has been removed. If contamination remains, repeat cleaning steps.

**Martins Arm Retractor System and Accessories****8.2 Sterilization**

For instruments with moving parts, lubricate joints with a steam-permeable, water-soluble instrument lubricant prior to sterilization.

Instruments should be sterilized in the opened or unlocked position.

Use only FDA-cleared sterilization wrap validated for double wrapping.

Method	Temperature	Exposure Time	Dry Time
Gravity	121°C (250°F)	30 minutes	30 minutes
Pre-Vacuum (US)	132°C (270°F)	4 minutes	30 minutes
Pre-Vacuum (EU)	134°C (273°F)	3 minutes	20 minutes

Maximum sterilization temperature must not exceed 137°C (280°F).

**9. Storage**

- Store sterilized instruments in a clean and dry environment.
- Protect instruments from dust and mechanical damage.

**10. Limitations on Reprocessing**

Repeated reprocessing has minimal effect on stainless steel surgical instruments.

End of instrument life is determined by wear, damage, or loss of mechanical function resulting from use.

**11. Warranty**

Martins products are warranted to be free from defects in material and workmanship for five (5) years from the invoice date when used under normal conditions and for their intended purpose.

**12. Maintenance**

- Preventive maintenance is recommended every 2–3 years.
- Maintenance may include replacement of wear parts and instrument adjustment.