

## **Phantom Series** AL Retractor System AL-1000

USER GUIDE

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### 1. Introduction

### Intended Use:

The Phantom AL Retractor system is designed to retract muscle and tissue to expose the anterior lumbar spine.

### 2. Symbols & Laser Marking Glossary

Symbol	Meaning
ATTACH RIGID	Clamps located on articulating arms should be installed over the ring screw within the indicated space.
2	Ring screw should not exceed two counterclockwise rotations for disassembly. Do not force past stop.
	Caudal direction of retractor ring.
▼ 🗩	Cephalic direction of the retractor ring.

### 3. Phantom AL Retractor System Setup

### 3.1 Arm Assembly:

Loosen knob of Rotating Table
 Clamp (ML-0021). Attach table
 clamp to the surgical rail over the
 sterile drape by the top and bottom
 jaws. Tighten knob to secure clamp
 at the desired location. Using the
 same method, attach the second
 rotating table clamp to the opposite
 side of the table.

Note: Table clamps should be positioned so that one table clamp is positioned as far caudally while the other is positioned as far cranially as possible while still allowing the arm clamp to attach to the ring.

 Insert an Articulating Arm (AL-0110) into each of the Rotating Table Clamps. Position the Articulating Arm and Table Clamp so that they are angled as low as possible and will not impede the surgeon's movement (Figure One). Note: When lossening, do not force the knob of the articulating arm past the stop. Doing so could damage the ball joint and affect the rigidity of the articulating arm.

### 3.2 Retractor Ring Assembly:

- Clear enough space on a flat surface for assembly of the Retractor Ring (AL-0100). Each of the following Retractor Ring steps must be conducted on a flat surface to ensure that the screws and forks are properly aligned.
- The Retractor Ring consists of two ring segments. To loosen the screws,



Rotating Table Clamp and Articulating Arms attached to operating table turn the screws counterclockwise no more than two times on each ring segment using the **Hex Tool** (ML-0505). Assemble the **Retractor Ring** by pushing the two segments together.

Note: Connection points of the Retractor Ring should be brought to edge of flat surface to provide clearance for Hex Tool during assembly.

With the **Hex Tool**, tighten each screw on the **Retractor Ring** to secure the assembly (Figure Two & Figure Three).

Note: To prevent damage to the screws and forks on the connection points of the Retractor Ring, pull rings directly apart. Do not cant or twist the rings.

### 3.3 Retractor Ring to Articulating Arms Assembly:

- Using the Hex Wrench (AL-0106), unscrew the ring attachment of both Articulating Arms. Insert the Retractor Ring into the clamps and tighten the clamps around the ring where marked "Attach Rigid Arm Here" (Figure Four).
- Adjust the Articulating Arms to position the Retractor Ring in accordance with the markings that indicate the Caudal and Cephalic direction. To prevent movement of the Retractor Ring, ensure that the knob of the Articulating Arms are completely tightened.

Note: If a larger frame is desired, Phantom Extension Bars (AL-0101) may be attached to the Ring Segments (AL-0100) to create an ovular retractor ring.



#### Figure Two

Hex Tool tightening Retractor Ring assembly

Note: Do not force the screw past the stop. Excessive force may damage the assembly mechanism.



Figure Three Retractor Ring Assembly



#### Figure Four

Hex Wrench tightening the ring attachment around the Retractor Ring

Note: Ensure the hex wrench and screw are aligned with the threaded hole. Attempting to insert the screw at an angle may cause cross-threading.

### 3.4 Blade to Blade Holder Assembly:

- Retractor blades have a "dual fixation" connection which allows the blade to remain fixed or to rotate. To attach the **Retractor Blade** to the Retractor Blade Holder (AL-0105), insert the blade through the blade holder connection so that the first pin in the connector can pass through the groove in the blade holder.
- When the first pin is engaged with the Blade Holder, the Retractor Blade is attached and able to rotate.
- If a fixed connection is preferred, the second pin should be aligned with the groove, and the blade pushed upward. When the second pin is engaged in the Blade Holder, the Retractor Blade will remain fixed (Figure Five).

#### 3.5 Ring Clamp to Retractor Ring Assembly and Positioning:

Ring clamps (AL-0103) attach to any point of the ring. To attach, loosen knob of the Ring Clamp and press the larger of the two openings onto the ring frame; the clamps will snap onto the ring. Press the shaft of the Blade Holder into the smaller opening of the Ring Clamp to attach the two components. The Ring Clamp/Blade Holder Assembly can be freely adjusted



Dual fixation connection

until the knob of the clamp is tightened. Additional **Ring Clamps** and **Blade Holders** may be added to the **Retractor Ring** as desired. (Figure Six).

To angulate the **Retractor Blades**, use the **Hex Wrench** to loosen the swivel mechanism on the **Blade Holder** and manipulate the blade by hand to the desired position. To secure the blade, tighten the swivel mechanism with the **Hex Wrench** (Figure Seven).

> Note: it is only necessary to rotate the mechanism counterclockwise until the swivel mechanism moves freely. To avoid damage to mechanism, do not force screw mechanism past stop.

### 3.6 Lighting System Assembly:

- Loosen the small blue knob of Light Cable Flex Arm (HS-0305) and position jaws around the segment of either Articulating Arm that is closest to the Retractor Ring. Tighten small blue knob to affix the Light Cable Flex Arm to the Articulating Arm.
- Insert the bifurcated tip of the Light
  Cable (ML-0058 or ML-0048) into the light ports located at proximal end of the Light Cable Flex Arm. Ensure that the Light Cable is connected to the LED Light Source (ML-0051) and that the light source is plugged into a power source. Insert the Light Cable into the LED Light Source. Unsert the Light Cable into the LED Light Source to illuminate the operative site.



Figure Six Ring Clamp/Blade Holder Assembly attached to the Retractor Ring



Figure Seven Use Hex Wrench to loosen swivel mechanism  The Light Cable Flex Arm may be positioned as desired and readjusted as needed. Tighten the large blue knob to lock the arm into position (Figure Eight).

Note: Attaching the light cable flex arm to the ring segment may obstruct the surgeon's access. For optimal visualization, the Light Cable Flex Arm should be attached onto the Articulating Arm.

### 3.7 Disassembly:

- Completely loosen the Articulating Arm screws, do not over-loosen or force the screw past the stop.
- Disassemble the Retractor Ring by turning the screws counterclockwise twice with the Hex Tool.
- It is important that the Retractor Ring is disassembled by pulling the rings directly apart on a flat surface. Note: To prevent damage to the screws and forks on the connection points of the Retractor Ring, pull rings directly apart. Do not cant or twist the rings.



Figure Eight Full setup with Light Cable Flex Arm

# \land Warnings

- CAUTION: US Federal Law restricts this device to sale by or on the order of a physician
- 2. Product is intended to be used by trained surgeons
- 3. TSI components are for use with other TSI components unless otherwise specified by the manufacturer
- 4. End of life is normally determined by wear and damage due to use
- 5. Use of this instrument for any purpose, or in any matter other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all TSI metal products or fragments thereof can be located by means of fluoroscopic imaging
- To prevent damage to the screws and forks on the connection points of the Retractor Ring, assemble and disassemble ring on a flat surface
- 7. Products must be in unlocked position prior to sterilization
- For instruments with moving parts, lubricate joints with a steam-permeable, water soluble instrument lubricant prior to sterilization
- TSI light cables should only be used with the TSI light source (ML-0051)
- 10. The light source must remain off until the reusable light cable is inserted into the retractor blade(s)
- 11. Place the light source away from items that are flammable
- 12. Once the reusable light cable is connected to the light source, do not place the reusable light cable on drapes, sponges, or any flammable object
- Once the reusable light cable is connected to the light source, do not allow the reusable light cable to hang over the side of the sterile field
- 14. To verify that the proper amount of light output is achieved, hold single fiber optic end of light cable up to room light and look in bifurcated end to check for the percentage black dots seen (the black dots represent broken fibers in the bundle). If greater than fifty percent (50%) of the fibers are broken, the light cable may

need to be replaced

- 15. DO NOT FORCE ANY KNOBS PAST STOP
- 16. CJD (Creutzfeldt-Jakob Disease): Discard or destroy any product that comes in contact with or is exposed to patients with CJD, or anyone suspected of CJD. TSI does not provide any validated instructions to eliminate risk of cross-contamination
- 17. To maintain intended clamping capacity of the table clamp, do not tighten the rail clamping knob when the articulating arm column is not fully installed

#### 5. Product Information:

 End of life is normally determined by wear and damage due to use. Refer to the assembly instructions above to ensure that the products function as outlined.

#### 6. Contact Information:

For more information please contact: TeDan Surgical Innovations, LLC 12615 W. Airport Blvd, Suite #200 Sugar Land, TX 77478 Tel: 713-726-0886 Fax: 713-726-0846 email: info@tedansurgical.com