



**Phantom Series**  
XL3 Retractor System®  
ML-2014

USER GUIDE

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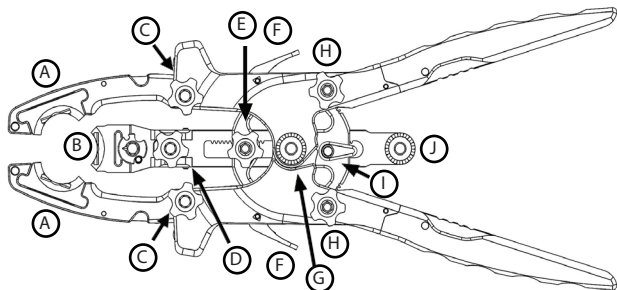
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# 1. Introduction

## Intended Use:

The XL3 Retractor System is intended to retract tissue for access to the lateral lumbar and thoracic spine.

## 2. Retractor Diagram



- A. **Caudal and Cephalic Blades**
- B. **Posterior Blade**
- C. **Caudal and Cephalic Blade Pivoting Knobs:** knob to control degree of pivot on the caudal and cephalic blades
- D. **Posterior Blade Pivoting Knob:** knob to control degree of pivot on the posterior blade
- E. **Incremental Retraction Knob for Posterior Blade:** knob to incrementally retract posterior blade
- F. **Caudal and Cephalic Blade Release Levers**
- G. **Arm Attachment Interface:** Attach arm or arm interface to retractor frame to enable posterior retraction
- H. **Incremental Retraction Knob for Caudal and Cephalic Blades:** knob to incrementally retract caudal and/or cephalic blades
- I. **Posterior Blade Release Lever**
- J. **Arm Attachment Interface:** attach arm or arm interface to center rack to enable anterior retraction

### 3. XL3 Retractor System Setup

#### 3.1 Prior to Use:

- Clean and sterilize all XL3 components according to General Cleaning and Sterilization Instructions.
- For instruments with moving parts, lubricate joints with a steam permeable, water soluble instrument lubricant prior to sterilization.
- For prepackaged sterile items, inspect each package prior to use and do not use if the package is damaged or sterility has been compromised.

#### *Surgical arm inspection before use:*

- Inspect entire assembly for damage.
- Hold arm assembly at column and turn central tightening knob clockwise.
- Check to make sure that arm is rigid at all three joints.
- Insert arm column into table clamp, turn column tightening lever clockwise and ensure that it holds.
- After the patient has been positioned on the OR table, attach the **Table Clamp** (ML-0021) to the OR table side rail.
- Loosen the knob of the **Table Clamp**. Attach the table clamp on the opposite side of the operating surgeon, positioned near the patient's arm pit, to the surgical rail

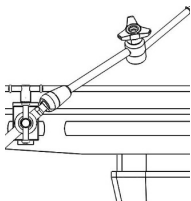


Figure 1  
Attach the table clamp to the OR table side rail

over the sterile drape, then tighten the clamp to the rail (Figure 1).

- Insert the **Articulating Arm (ML-0061)** or **Articulating Arm, Rack Clamp, Large (ML-0063)** into the table clamp. *Note: Place the arm away from the surgical incision site until it is needed to attach the XL3 Blade Retractor. Ensure it does not interfere with fluoroscopy C-Arm.*

### 3.2 Sequential Dilation:

- With the patient in the lateral position, locate the desired level of the disc to be operated, confirming with AP and Lateral imaging.
- Adjust the table as necessary to have the disc space vertical and not rotated.
- After a small incision is made, perform blunt dissection into retroperitoneal space and advance the initial **8 mm Dilator (ML-0446)** to the lateral aspect of the disc space. Use fluoroscopy to confirm position and advance a **K-wire** into the disc space to anchor the **8 mm Dilator (Figure 2)**. When inserting through the psoas muscle, slowly rotate the dilator 360° while conducting triggered EMG.

*Note: Pass the opposite end of the dilator clip cable to the Neuro-monitor. The dilator clip is compatible with any 1.5 mm DIN safety connector (i.e. Natus Endeavor™<sup>1</sup> or equivalent).*

- Image to confirm that the proper disc level has been accessed. Keep hands out of the radiation field by using the **Dilator Holder (ML-0056)**



**Figure 2**  
Insert 8 mm dilator and anchor with K-wire

<sup>1</sup>Endeavor IOM Systems is a trademark of Natus Medical Incorporated

or ML-0057) to hold each dilator for imaging.

*Note: The initial dilator is stainless steel and is radiopaque. Use fluoroscopic imaging to confirm placement of initial dilators. Subsequent dilators are aluminum and are radiolucent which allows the user to confirm that the initial dilator remains positioned on the disc space as desired.*

- Disconnect the dilator clip from the initial **8 mm Dilator** and attach clip to the **13 mm Dilator** (ML-0447).
- Slide the **13 mm Dilator** over the initial dilator and into the operative site. Rotating the dilator 360° through the psoas muscle while conducting triggered EMG.
- Repeat with subsequent **18 mm Dilator** (ML-0448) (Figure 3).



**Figure 3**  
Sequentially dilate by sliding one dilator over the previous dilator

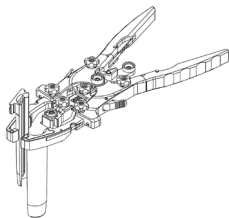
### 3.3 Selecting the Proper Length Blades:

- Once the **8 mm Dilator** has been successfully inserted, note the depth of the dilator, then select a blade length depth 10 mm longer than the dilator depth to allow for the retractor body to be just above the skin of the patient, e.g. for a dilator depth of 110 mm, select a blade length of 120 mm.

*Note: Each dilator has depth markings and may be used for blade selection. Identifying the blade needed after the initial dilator is inserted enables the user to assemble the retractor while the sequential dilation is completed.*

### 3.4 Assembly and Installation of Retractor:

- Attach the appropriate length



**Figure 4**  
Insert the caudal and cephalic blades

blades on the **XL3 Retractor**.

- Insert the caudal and cephalic blades by top loading them into the lateral slots on the retractor body until they click in place (Figure 4).
- The posterior blade is also top loading (Figure 6). Use the **Hex Driver Tool (ML-0505)**, to rotate the lock until it is in the open position, with the arrow pointing to the 'Release' text (Figure 5). Slide the retractor blade into its slot, then lock the blade in place by rotating the lock arrow toward the incision (or away from 'Release') using the **Hex Driver Tool** (Figure 6).
- Once the blades are installed, approximate the blade position by bringing the blades back to their neutral, start position (Figure 7).

*Note: When in its neutral, start position, the blades should form a complete circle at the base.*

- Slide the retractor blades around the **Black Introducer (ML-0518)**, then slide the retractor onto the **18 mm Dilator (Figure 8)**. The introducer will assist in placing the retractor smoothly over the **18 mm Dilator**. Once the blades are engaged over the **18 mm Dilator** the **Black Introducer** can be removed.

*Note: The black introducer is a reusable item and the use of this item is optional.*

### 3.5 Retraction:

- Slide the retractor and attached blades over the **18 mm Dilator** and into the surgical site (Figure 9).

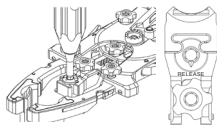


Figure 5  
Open posterior blade lock

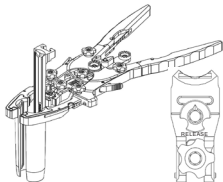


Figure 6  
Insert posterior blade

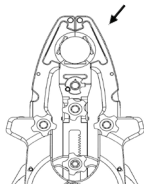


Figure 7  
Bring the blades back to their start position. The retractor will be in the smallest opening position.

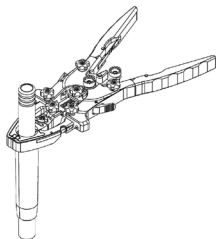


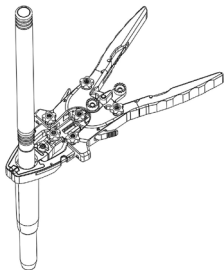
Figure 8  
Use the introducer to assist in placing the retractor body and blades into the wound

- Remove the **Dilators** and **K-wire**.

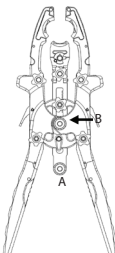
### 3.6 Attach Arm to the Retractor Frame:

The Phantom XL3 Lateral Access System includes either the **Articulating Arm** (ML-0061) or the **Articulating Arm, Rack Clamp, Large** (ML-0063) which is used in combination with the **Arm Interface** (ML-0902). Both options are used to hold the **Retractor** (ML-0905) in place during a procedure.

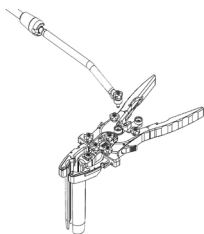
- Anterior retraction: To fix the posterior blade attach the **Articulating Arm** (ML-0061) or **Arm Interface** (ML-0902) to the starburst mounting point located on the back of the center blade (Figure 10A).
- Posterior retraction: To fix the retractor frame attach the **Articulating Arm** (ML-0061) or **Arm Interface** (ML-0902) to the center starburst (Figure 10B).
- Align the teeth of the starbursts on the distal end of the **Articulating Arm** (ML-0061) or **Arm Interface** (ML-0902) and on the desired fixation point on the **Retractor** frame, hand tighten and secure into place with the **Hex Driver Tool** (Figure 11).
- If using the **Arm Interface** (ML-0902), after ensuring that the **Arm Interface** has been secured onto the **Retractor** frame, bring the



**Figure 9**  
Slide retractor over dilators



**Figure 10**  
Attach the articulating arm to the retractor frame



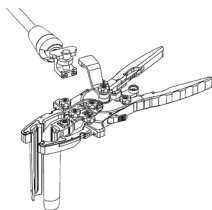
**Figure 11**  
Align teeth of the starbursts located on the articulating arm and retractor



**Articulating Arm, Rack Clamp, Large (ML-0063)** to the proximal end of the **Arm Interface** and secure the **Arm Rack Clamp** to the **Arm Interface**. (Figure 12)

- Adjust the **Articulating Arm (ML-0061)** or **Articulating Arm, Rack Clamp, Large (ML-0063)** as needed by loosening the central black knob and tightening it back into place when desired position is reached.

*Note: When loosening, 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.*



**Figure 12**  
Attach the Articulating Arm, Rack Clamp, Large (ML-0063) to the Arm Interface (ML-0902)

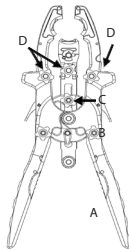
### 3.7 Position Retractor Blades:

- Press handles to increase bilateral retraction (Figure 13A).
- To increase retraction on an individual caudal or cephalic blade: use the **Hex Driver Tool** on the desired side's knob and turn, following the direction marked on the retractor (Figure 13B).
- To increase the retraction on the posterior blade: use the **Hex Driver Tool** on the center knob and turn clockwise (Figure 13C).
- To pivot the blades: use the **Hex Driver Tool** on the pivoting knobs and turn clockwise to toe out the blades up to 15° per side (Figure 13D).

*Note: One click is approximately 1.6 mm.*

*Note: The blades may be individually angulated to improve exposure without increasing tension at the skin.*

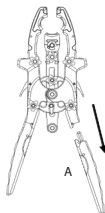
*Do not over turn the pivoting mechanism located*



**Figure 13**  
Position the retractor blades

on the retractor frames. Forcing the pivoting mechanism past stop may cause damage to the device.

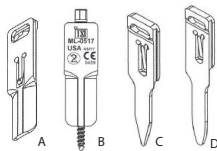
- Optional: Detach handles if desired. These handles may be removed at any point during the procedure by pushing the release button. (Figure 14A).



**Figure 14**  
Remove handles  
by pushing the  
release button.

### 3.8 Shim Installation:

- Shims may be used to help minimize muscle creep or to anchor the retractor (Figure 15):
  - Anchoring: Shim B, C, or D from Figure 15
  - Blade Extension: Shim A from Figure 15 (use with or without K-wire)



**Figure 15**

A: ML-0510, K-wire Shim  
B: ML-0514 or ML-0517, Screw Shim  
C: ML-0516, Spike Shim  
D: ML-0513, Blunt Spike Shim

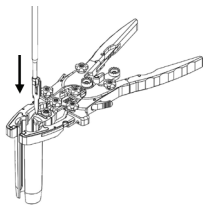
*Note: Lateral screw driver (ML-0515) should be used with screw shims (ML-0514 or ML-0517).*

- Attach appropriate shim to the **Shim Inserter Tool** (ML-0519). Turn the knob on the tool clockwise to lock the shim into place (Figure 16).  
*Note: All shims are compatible with any XL3 blade.*
- Slide the shim down the blade channel (Figure 17).
- When properly installed, the shim will engage with the ridges located at the base of the retractor blades.  
*Note: The Screw Shims (ML-0514 or ML-0517) do not engage with these features.*
- Turn the knob counter clockwise and disengage the **Shim Inserter Tool**.



**Figure 16**

Attach the selected shim to the shim inserter tool



**Figure 17**

Slide the shim down the blade channel

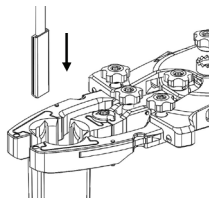
### 3.9 Light Cable Installation:

- Slide the shim tip of the **Light Cable** (ML-0068) into the shim channel of

the blade (Figure 18).

- 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. Turn on the light source to illuminate the operative site.

*Note: The light cables have a malleable cable that allows the user to lock each tip in place.*

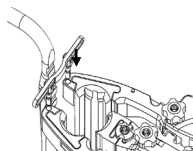


**Figure 18**  
Install the light cable

### 3.10 Optional 4th Blade Installation:

- If tissue creep occurs anteriorly, the **Ancillary 4th Blade** (ML-0904, ML-0906, ML-0907) may be used.
- Select the desired length of the **Ancillary 4th Blade** (ML-0904, ML-0906, ML-0907).
- Insert the **Ancillary 4th Blade** into the incision site, then retract.
- Once in desired position, insert the **Ancillary 4th Blade Cross Bar** (ML-0901) into the slots located on the distal tip of the **Retractor** frame (Figure 19).

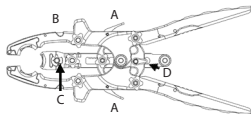
*Note: The concave side of the cross bar should be inserted into the retractor frame facing the anterior aspect of the patient allowing firm fixation of the 4th Blade. The grooves on the 4th blade are intended to prevent unintended movement caused from tissue creep.*



**Figure 19**  
Insert the ancillary 4th blade and cross bar

### 3.11 Disassembly:

- Release pressure from the tissue by pressing the release levers on the retractor to close the retractor blades (Figure 20A and 20D). Then, remove retractor from the surgical incision site.
- Push the release button to remove



**Figure 20**  
Disassemble the retractor

the caudal and cephalic blades (Figure 20B).

- To remove the posterior blade, use the **Hex Driver Tool** to turn the lock toward the 'Release' text (Figure 20C).
- Shims may be removed using the **Shim Inserter Tool**.
- **Phantom XL Insulated Dilators, K-wires, and Shims** are Single Use and must be discarded after use. Dispose of the Phantom XL Insulated Dilators, K-wires, and Shims (Single Use Only) in accordance with national regulations and approved hospital practices for surgical instrumentation disposal. Single Use Only: Reuse may compromise the structural integrity of the device and/or lead to device failure. Reuse also presents biological hazards associated with disease transmission and immune/allergy issues, some of which could cause severe illness or fatality.
- For instruments with moving parts, lubricate joints with a steam permeable, water soluble instrument lubricant prior to sterilization.



## Warnings:

1. CAUTION: US Federal Law restricts this device to sale by or on the order of a physician.
2. 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.
3. Product is intended to be used by trained surgeons.
4. TSI components are for use with other TSI components unless otherwise specified by the manufacturer.
5. Use of this instrument for any purpose, or in any manner other than those described 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.
6. Dispose of the Phantom XL Insulated Dilators, K-wires, and Shims (single-use only) in accordance with national regulations and approved hospital practices for surgical instrumentation disposal. Single Use Only: Reuse may compromise the structural integrity of the device and/or lead to device failure. Reuse also presents biological hazards associated with disease transmission and immune/allergy issues, some of which could cause severe illness or fatality.
7. 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.
8. TSI light cables should only be used with the TSI light source (ML-0051).
9. The light source must remain off until the reusable light cable is inserted into the retractor blade(s).
10. Place the light source away from items that are flammable.
11. 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.
12. 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.

13. 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.
14. Shims being used for anchoring should be based upon suitability of patient bone condition. Improper usage may lead to patient injury.

## **5. Product Information:**

1. 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:

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