ZIMMER BIOMET
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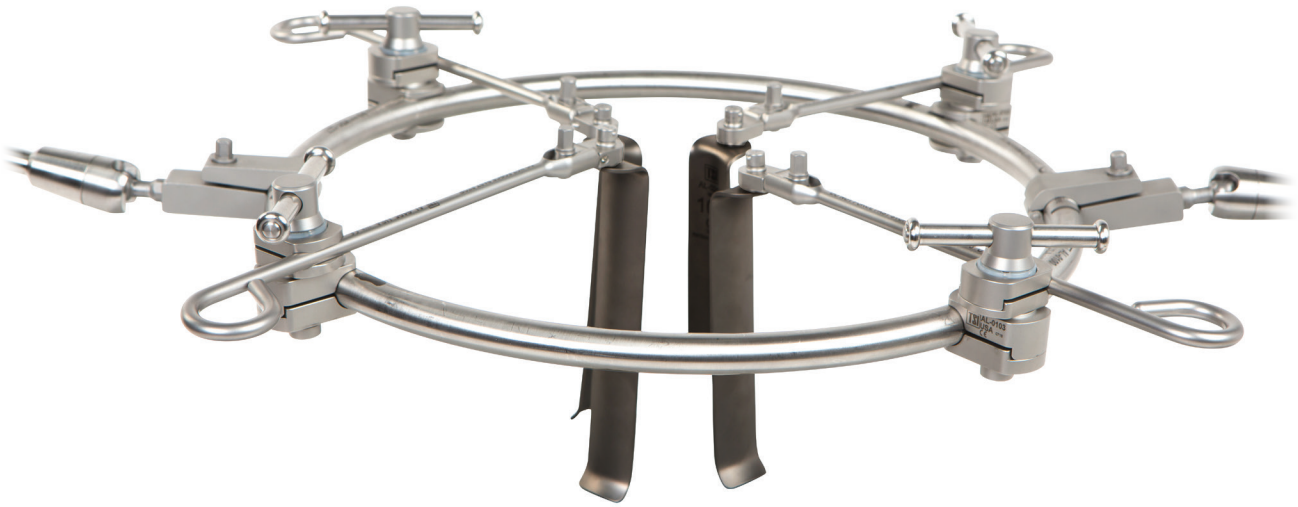
Zimmer Biomet Anterior Access Retractor System

User Guide



The Zimmer Biomet Anterior Access Retractor System is engineered to deliver state-of-the-art structural stability enabling surgeons to predictably retract critical vascular and retroperitoneal structures.

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

SYSTEM OVERVIEW

Two-Point Fixation

Articulating arms uniquely engineered for anterior lumbar surgery enable two-point fixation and structural stability essential to confidently and predictably retract delicate vasculature and retroperitoneal structures from the anterior lumbar column.

Secure connection using retractor ring

Secure Blade Connection

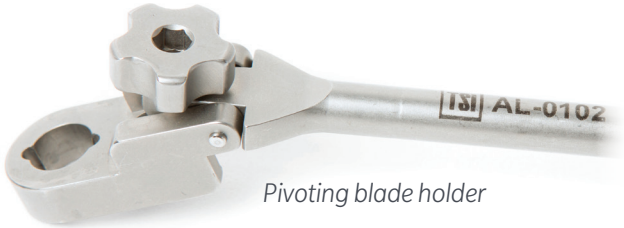
The ring clamps have been designed to prevent retractor blade migration from the intended deployment location. A secure connection with the retractor ring is established with ease enabling the surgeon to access the anterior lumbar spine with confidence while retracting critical vascular anatomical structures.

Tactile Adjustment of Blade Angulation

Angulation of retractor blades up to 30 degrees, in both positive and negative directions, allows surgeons to maximize exposure while maintaining miniaturization of the incision and compensating for patient's sacral anatomy relative to the L5 vertebral body.

Blade angulation

Step-wise blade angulation can also be achieved by combining a hex wrench and a pivoting blade holder for incremental exposure of the surgical field.



Pivoting blade holder

Fixed or Rotating Blade Engagement

The patented, double pin connector gives surgeons the freedom to choose - blades can be engaged in either a fixed or rotating position either to ensure retraction force or accommodate seamlessly to patient anatomical landmarks.

Fixed or rotating blades

USER-CENTERED DESIGN

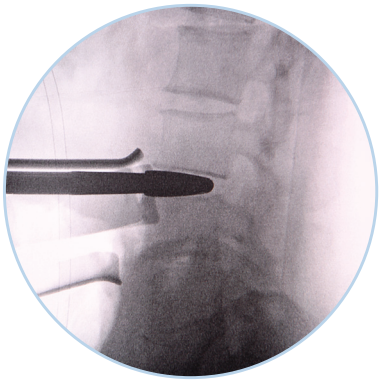
Low-Profile

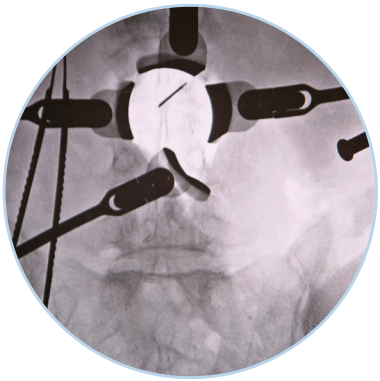
The retractor system assembly has a low-profile set-up, allowing unencumbered access to the patient. Thoughtfully engineered articulating arms when used in combination with the rotating table clamp, allow the surgeon to adapt the system to varying patient demands and multi-level surgery.

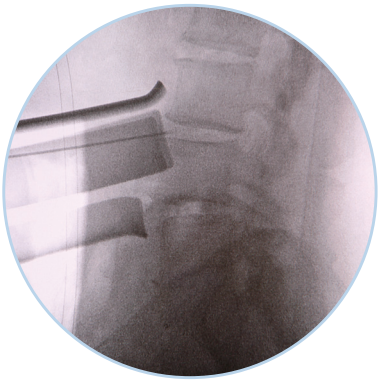
Ring clamp

Low-Impact

The intentional design of the ring clamp allows engagement onto the retractor ring with ease, preventing movement during surgery and undue strain on the surgeon's hands.







The blades are available in aluminum, allowing for optimal visualization of anatomical structures during intraoperative fluoroscopy. Spine surgeons can visualize end plate alignment, vertebrae, and intervertebral disc space with ease and without disruption of radiopaque instrumentation hindering the view of critical structures of the spine.

Varying patient anatomies demand a wide spectrum of retraction possibilities. Ranging from 60 to 200 mm in length and widths of 25 and 50 mm, the Zimmer Biomet Anterior Access System enables a comprehensive approach to surgical access.

Aluminum blade offering found in PCRRARETALUM

ZIMMER BIOMET ANTERIOR ACCESS RETRACTOR SYSTEM SETUP

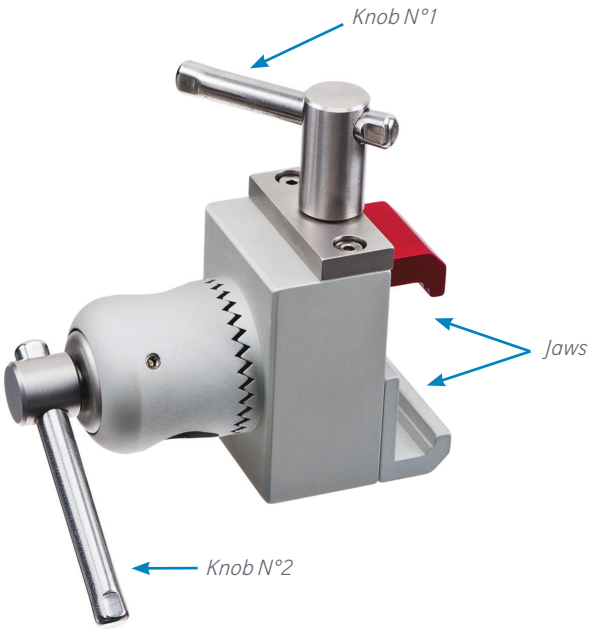


Figure 1
Rotating table clamp

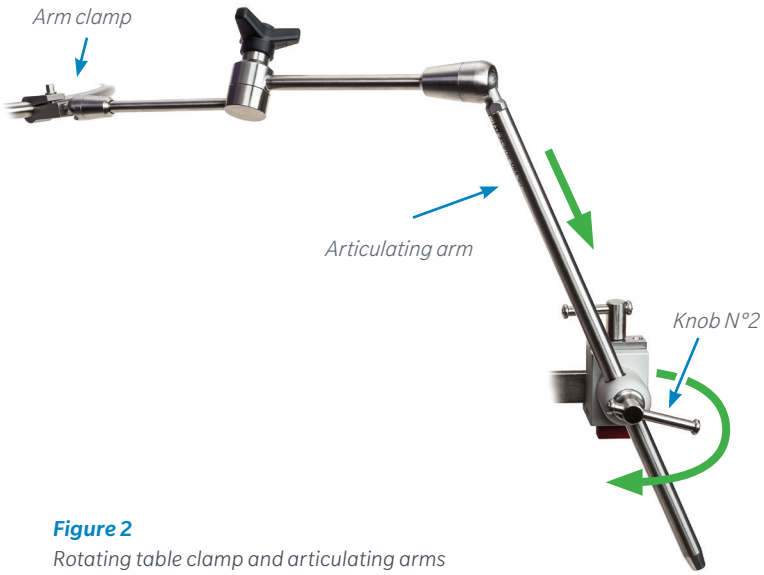


Figure 2
Rotating table clamp and articulating arms attached to operating table

ARTICULATING ARM ASSEMBLY

- Loosen knob N°1 of rotating table clamp.
- Attach rotating table clamp to surgical rail by the top and bottom jaws and tighten knob N°1 to secure the clamp at the desired location (Figure 1). Using the same method, attach the second rotating table clamp to the opposite side of the table.

  Note: *Table clamps should be attached to the table so that they are positioned as far caudally and cranially as possible while still allowing the arm clamp to attach to the retractor ring.*

- Insert an articulating arm into each of the rotating table clamp.
- Adjust the height of the articulating arm and lock its position by tightening knob N°2 of the rotating table clamp (Figure 2). Take care to position the articulating arm as low as possible to ensure it will not impede the surgeon's movements.

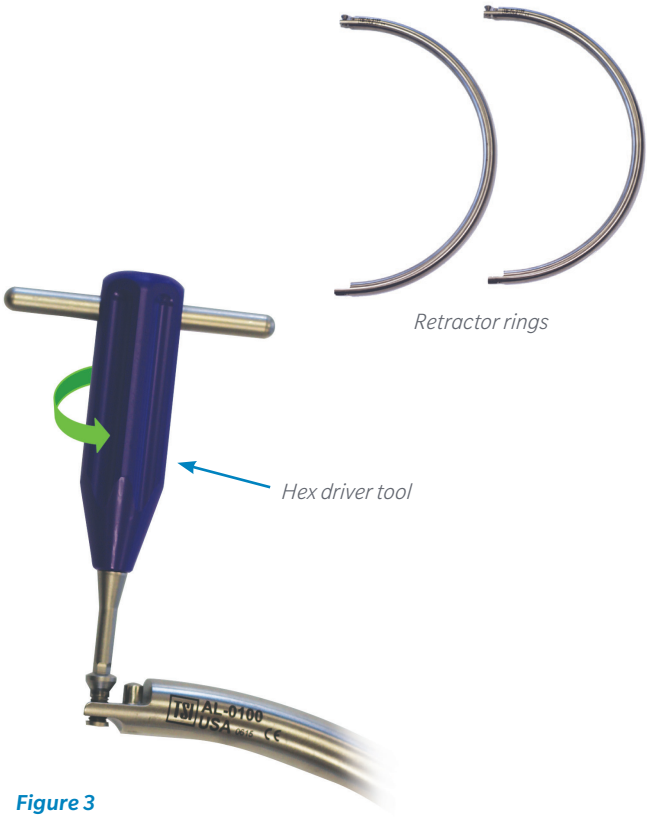


Figure 3
Retractor ring assembly

Figure 4
Assembled retractor ring

RETRACTOR RING ASSEMBLY

- The retractor ring consists of two ring segments. Loosen the screws on each ring segment using the hex driver tool (Figure 3).
- Assemble the retractor ring by pushing the two segments together. Use a flat surface to ensure that the screws and forks are properly aligned.
- Secure the assembly by tightening each screw on the retractor ring with the hex driver tool (Figure 4).
- Extension bars can be used to enlarge the operating space. Connect the extension bars on the ring segments and secure the assembly by tightening each screw on the retractor ring and on the bars with the hex driver tool (Figure 5).

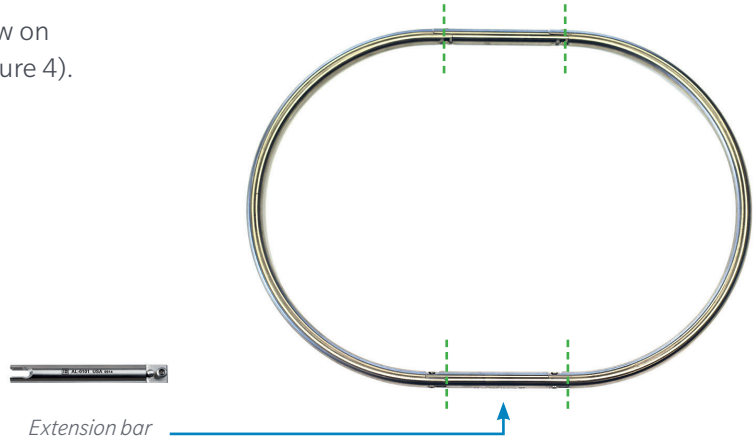


Figure 5

ZIMMER BIOMET ANTERIOR ACCESS RETRACTOR SYSTEM SETUP *(continued)*

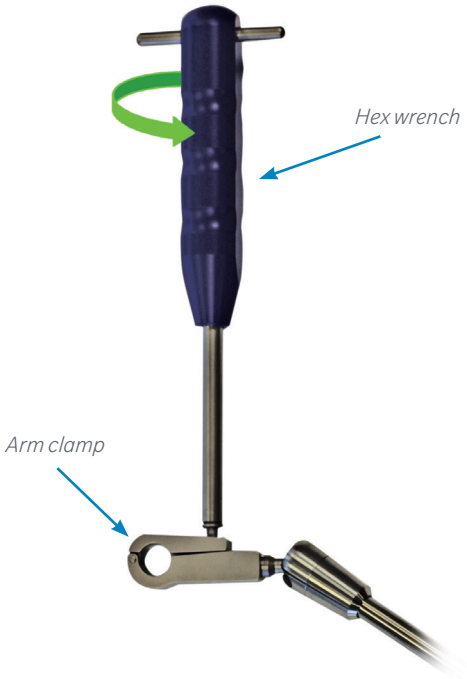


Figure 6

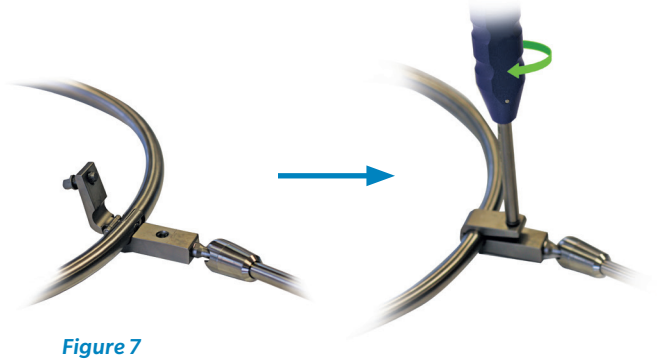


Figure 7

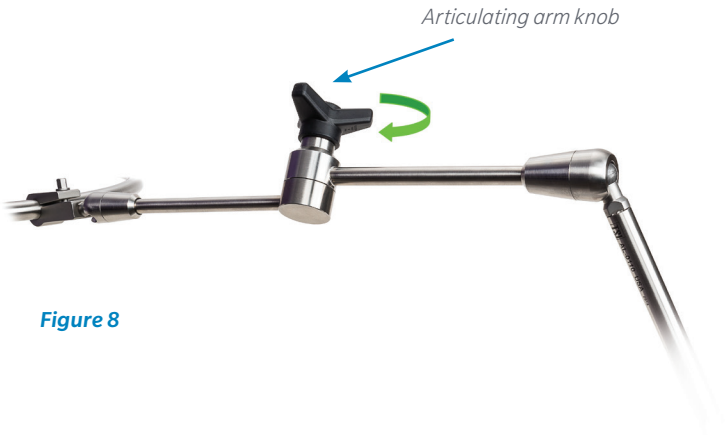


Figure 8

RETRACTOR RING TO ARTICULATING ARMS ASSEMBLY

- Using the hex wrench, unscrew the clamp of each articulating arm (Figure 6).
- Insert the retractor ring into the clamps and tighten clamps around the ring with the hex wrench where marked “Attach Rigid Arm Here” (Figure 7). This set-up position ensures structural stability of the combined articulating arm and ring construct.
- Adjust the two articulating arms to position the retractor ring as desired (Figure 8). To prevent movement of the retractor ring, ensure that the knobs of the articulating arms are completely tightened.

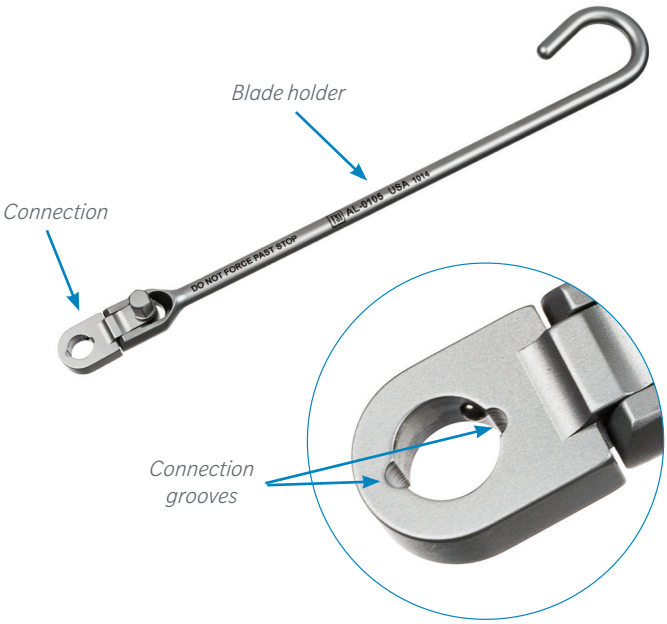


Figure 9

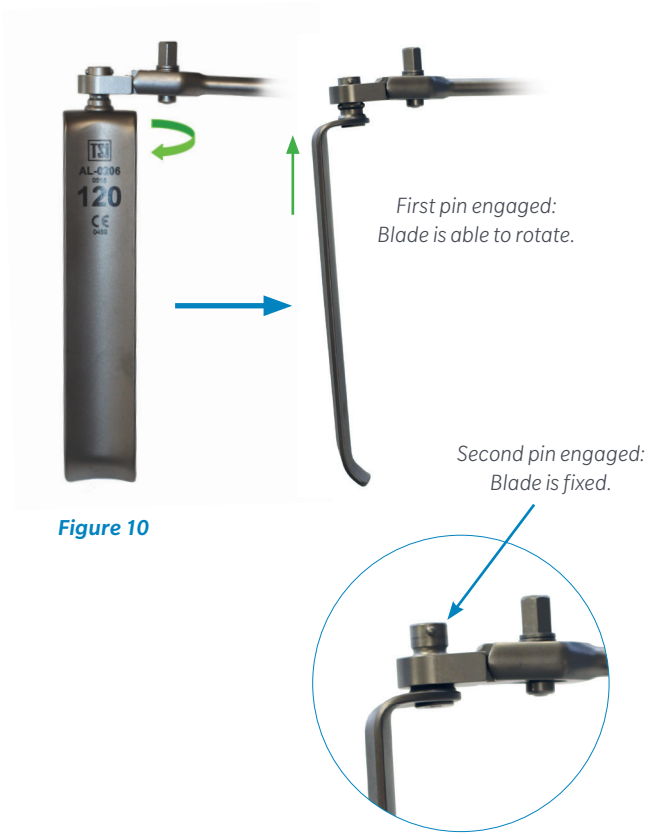


Figure 10

Figure 11

BLADE TO BLADE HOLDER ASSEMBLY

- Select the retractor blades to use. Up to 6 blades can be connected to the ring at the same time. Retractor blades have a dual pin connector.
- To attach the retractor blade to the blade holder, insert the blade through the blade holder connection so that the first pin of the connector can pass through the groove in the blade holder (Figure 9). When the first pin is engaged with the blade holder, the blade is attached and able to rotate (Figure 10).
- To obtain a fixed connection, align the second pin with the groove, and push the blade upward. When the second pin is engaged in the blade holder, the retractor blade will remain fixed (Figure 11).

ZIMMER BIOMET ANTERIOR ACCESS RETRACTOR SYSTEM SETUP *(continued)*

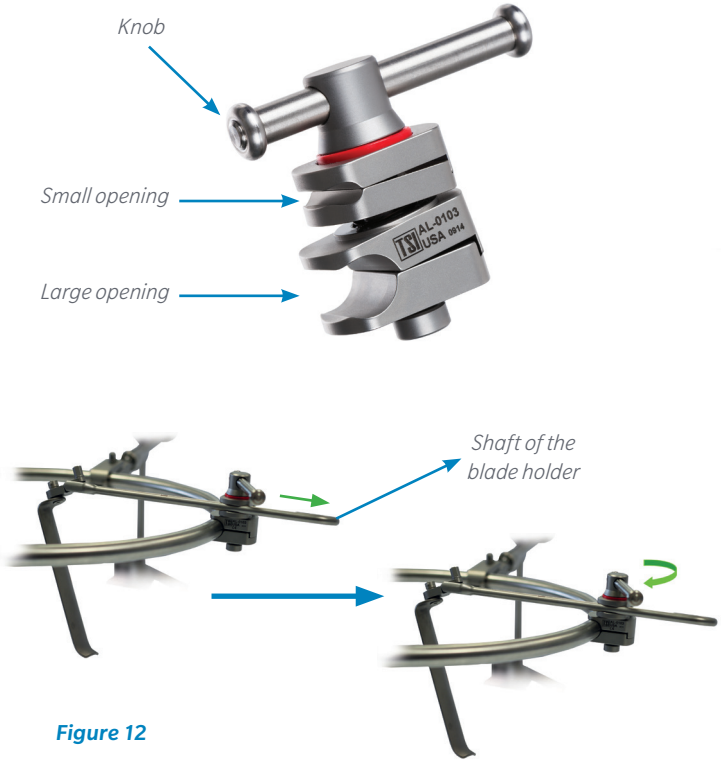


Figure 12

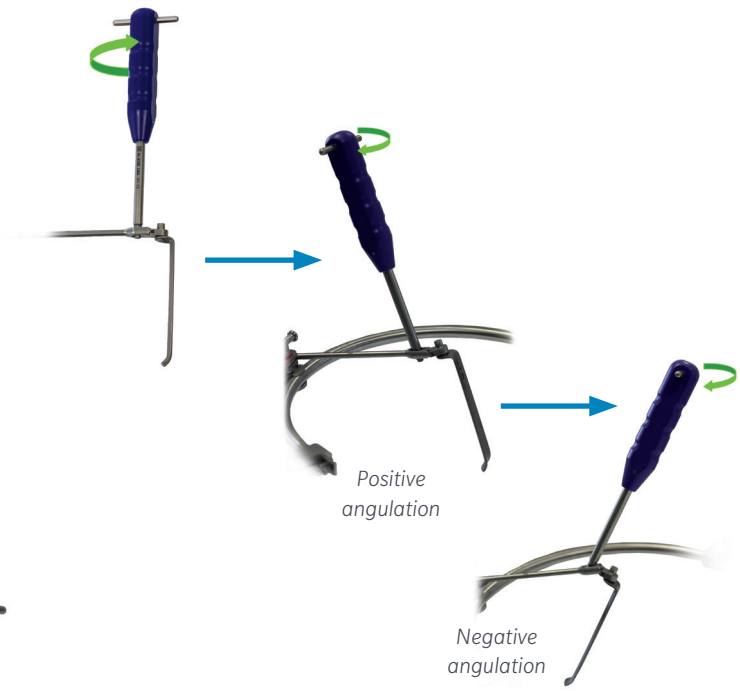


Figure 13

RETRACTOR BLADES TO RING ASSEMBLY

Blades can be positioned anywhere along the retractor ring.

- In order to attach ring clamp, loosen knob of the ring clamp and press the large opening onto the retractor ring, the clamp will snap onto the ring frame.
- Press the shaft of the blade holder into the small opening of the ring clamp to attach the two components.
- Adjust the assembly in the desired position. To lock the position tighten the knob of the ring clamp.
- To angulate the retractor blades use the hex wrench to loosen the swivel mechanism on the blade holder. Adjust the position of the blade by manipulating it by hand or using the hex wrench. Positive or negative angulation can be applied on retractor blades (Figure 13).
- To secure the blade, tighten the swivel mechanism with the hex wrench.

  Note: *It is only necessary to rotate the mechanism counter clockwise until the swivel mechanism moves freely. To avoid any damage to the mechanism, do not force screw mechanism past stop.*

INSTRUMENTS

Retractor Ring PART NUMBER

AL-0100

Accessory Arm with Ring Clamp PART NUMBER

AL-0110

Extension Bar, 85 mm PART NUMBER

AL-0101

Blade Holder PART NUMBER

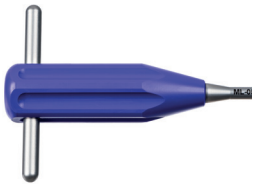
AL-0105

Hex Wrench PART NUMBER

AL-0106

Ring Clamp PART NUMBER

AL-0103



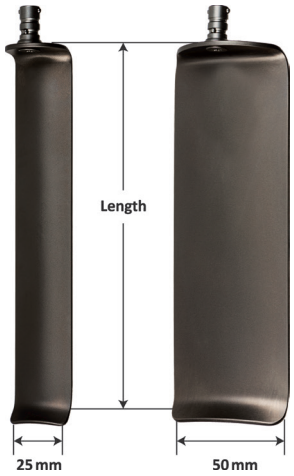
Hex Driver Tool PART NUMBER

ML-0505

Rotating Table Clamp for Accessory Arm PART NUMBER

ML-0021

INSTRUMENTS *(continued)*



ALIF Retractor Blades	PART NUMBER
25 x 60 mm, Gold	AL-0220
25 x 80 mm, Teal	AL-0222
25 x 100 mm, Brown	AL-0224
25 x 120 mm, Purple Splash	AL-0226
25 x 140 mm, Black	AL-0228
25 x 160 mm, Gray	AL-0230
25 x 180 mm, Blue Splash	AL-0232
25 x 200 mm, Gray Splash	AL-0234
50 x 60 mm, Gold	AL-0160
50 x 80 mm, Teal	AL-0162
50 x 100 mm, Brown	AL-0164
50 x 120 mm, Purple Splash	AL-0166
50 x 140 mm, Black	AL-0168
50 x 160 mm, Gray	AL-0170
50 x 180 mm, Blue Splash	AL-0172
50 x 200 mm, Gray Splash	AL-0174

ZIMMER BIOMET KIT CONTENTS

Anterior Access Retractor System Kit
Kit Number: PCRRARETINST

DESCRIPTION	QTY	PART NUMBER
Retractor Ring	1	AL-0100
Blade Holder	6	AL-0105
Accessory Arm with Ring Clamp	2	AL-0110
Hex Driver Tool	1	ML-0505

Anterior Access Retractor System Kit
Kit Number: PCRRARETALUM

DESCRIPTION	QTY	PART NUMBER
Extension Bar	2	AL-0101
Ring Clamp	6	AL-0103
Hex Wrench	2	AL-0106
Rotating Table Clamp for Articulating Arm	2	ML-0021
ALIF Retractor Blade, 25 x 60 mm, Gold	4	AL-0220
ALIF Retractor Blade, 25 x 80 mm, Teal	4	AL-0222
ALIF Retractor Blade, 25 x 100 mm, Brown	4	AL-0224
ALIF Retractor Blade, 25 x 120 mm, Purple Splash	4	AL-0226
ALIF Retractor Blade, 25 x 140 mm, Black	4	AL-0228
ALIF Retractor Blade, 25 x 160 mm, Gray	4	AL-0230
ALIF Retractor Blade, 25 x 180 mm, Blue Splash	4	AL-0232
ALIF Retractor Blade, 25 x 200 mm, Gray Splash	4	AL-0234
ALIF Retractor Blade, 50 x 60 mm, Gold	2	AL-0160
ALIF Retractor Blade, 50 x 80 mm, Teal	2	AL-0162
ALIF Retractor Blade, 50 x 100 mm, Brown	2	AL-0164
ALIF Retractor Blade, 50 x 120 mm, Purple Splash	2	AL-0166
ALIF Retractor Blade, 50 x 140 mm, Black	2	AL-0168
ALIF Retractor Blade, 50 x 160 mm, Gray	2	AL-0170
ALIF Retractor Blade, 50 x 180 mm, Blue Splash	2	AL-0172
ALIF Retractor Blade, 50 x 200 mm, Gray Splash	2	AL-0174

IMPORTANT INFORMATION ON THE ZIMMER BIOMET ANTERIOR ACCESS RETRACTOR SYSTEM

INTENDED USE

The Zimmer Biomet Anterior Access Retractor system is designed to retract muscle and tissue to expose the anterior lumbar spine.

GENERAL STERILIZATION AND CLEANING INSTRUCTIONS

Note:

- *The color of TSI's Titanium and Aluminum instruments may vary due to the anodizing process or alloy used. Shading or loss of color may also occur after sterilization. This is not a defect in the instrument or material and will not affect the performance of your high quality TSI instrument.*
- *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 1).*
- *Do not over turn the pivoting mechanism located on the retractor frames. Forcing the pivoting mechanism past stop may cause damage to the device (Figure 2).*

Figure 1

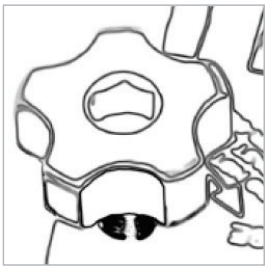


Figure 2

Reprocessing Instructions:

The following validated reprocessing steps should be used for reprocessing of TSI products. Other methods used for reprocessing of TSI devices shall be validated by the user prior to implementation.

Cleaning Instructions:

Point of Use:

1. Directly after use, remove coarse contamination from the instrument and keep the instrument moist for transit to the processing site. Prior to cleaning and sterilization do not use any fixing agents or hot water >104°F (>40°C) since this may lead to the fixation of residue and can interfere with the cleaning process.
2. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small components.
3. For suction tubes, draw sufficient volume of water through the suction tube using an available vacuum source, to provide adequate removal of all gross contaminants.
4. Perform cleaning as soon as is reasonably practical following use. Allowing instrumentation to dry with fluids and debris may result in staining, corrosion, and increased difficulty in the removal of contaminants.
5. During the transport of the instruments to the processing site, store contaminated instrument(s) securely in a closed container to avoid damage to the instrument and/or contamination of the environment.

Supplies and Equipment Needed for Cleaning:

- Ultrasonic Cleaner
- Pre-cleaning and Manual Cleaning enzymatic, pH Neutral Cleaner: such as Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner
- Soft Nylon Bristle Brush such as 3-1000 Integra Miltex Premium Grade Nylon Bristle Brush should be used for exterior surface cleaning. For internal cleaning, a brush size appropriate to the lumen inner diameter (ID) should be used. *For suctions a micro brush appropriate to lumen size, shall be used.
- Automated Cleaning enzymatic, pH Neutral Cleaner: such as Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner
- 60 ml Syringe with Needle
- Soft Bristled Brush (ex. M16)
- Tap, Deionized (DI), Reverse Osmosis (RO), or filtered water for processing

Cleaning:

***Automated cleaning is not suitable for instruments with long lumens, shafted lumen, ball joints, or braided cables (e.g. suction tubes, shim inserter tools, chordometers, articulating surgical arms, and flexible surgical arms), or scalp hook bands. Such instruments should only undergo manual cleaning.**

1. For both Manual and Automated Cleaning, all instruments, apart from the Articulating Arm, should be cleaned in the open or unlocked position.
   - Flexible Arms: Turn tightening knob counterclockwise to loosen the internal cable to enable movement of the surgical arm beads to allow water or detergent to flow between each link prior to placing arm in sonicator.
   - Suctions: Remove wire mandrel from suction tube lumen and process alongside suction tube.
   - Shim Inserter Tools: Disassemble. To disassemble hold the distal end of the device while turning the adjustment knob clockwise to remove the shaft and knob. Do not force the knob-the shaft should disengage freely.

- Chordometer: Turn the knob counterclockwise to loosen the measurement shaft.
- Articulating Arms: Turn tightening knob clockwise to tighten ball joint prior to placing arm in sonicator. The knob should be tightened enough to prevent manipulation of the arm.

2. An enzymatic, pH neutral cleaner is recommended.
   - Black coated and color anodized components may be negatively affected if aggressive cleaning mediums or appliances (e.g. extreme acidic/alkaline, abrasives) are used.
   - Exposure to chlorides or hydrogen peroxide may negatively affect the coating or colorization of the components.

For purposes of this IFU, the table below defines cold, luckewarm and hot water temperatures (per AAMI TIR12:2010).

Temperature Description	°Celsius	°Fahrenheit
Cold	<22°C	<72°F
Lukewarm	22°- 43°C	72°-110°F
Hot	>43°C	>110°F

Manual cleaning instructions:

1. Rinse each instrument individually with a steady stream of lukewarm tap water for a minimum of 2 minutes or until gross contaminants are removed.
   - For Suction Tubes, insert the supplied mandrel into the suction tube lumen to dislodge potentially trapped debris. Remove mandrel for further processing.
   - For Flex Arms, slide the surgical arm beads to allow water to flow between each link.
2. Place each instrument into a sonicator containing a solution of enzymatic, pH neutral detergent prepared according to the manufacturer's instructions, using lukewarm tap water. Sonicate for 10 minutes.
   - Ensure lumens are flushed to remove air bubbles prior to sonication.
3. In a manual wash container, prepare an enzymatic, pH neutral detergent wash solution, per detergent manufacturer's instructions, using lukewarm tap water.
4. Transfer each instrument from the sonicator to the manual wash container, and fully immerse in the cleaning solution prepared in Step 3.
5. While still submerged, using a soft nylon bristled brush, such as M16, brush each instrument for a minimum of 1 minute, to remove any visible contamination and debris, paying particular attention to hard-to-clean areas such as crevices and joints. Repeat the process until all visible contamination is removed.
   - For blades with lumens and shafted instruments with lumens (that are not suction tubes), use appropriately sized lumen brush to scrub the interior of lumen and soft bristled brush, such as M16, to brush the exterior of the lumen. Using a 60ml syringe, flush lumens with 25mL of cleaning solution, a minimum of 3 times, or until no soil is visible.
   - For Suction Tubes, insert the supplied mandrel into the suction tube lumen, or use appropriately sized lumen brush, to dislodge any trapped soil. Remove mandrel for further processing. Use appropriately sized lumen brush to scrub the interior of lumen and soft bristled brush, such as M16, to brush the exterior of the lumen. Using a 60ml syringe with needle, flush the lumen with 25ml of cleaning solution 3 times, or until the solution shows no evidence of contamination.
   - For Flex Arms, turn the tightening knob counterclockwise to loosen the internal cable to enable movement of the surgical arm beads to allow cleaning solution fluid to flow between each link.
   - For Shim Inserter Tools, use appropriately sized lumen brush to scrub the interior of lumen and soft bristled brush, such as M16, to brush the exterior of the lumen. Use a 60ml syringe with needle to flush the lumen with a minimum of 25ml of cleaning solution 3 times or until the solution runs clean and there is no evidence of contamination.
   - For Chordometers, use a 60ml syringe with needle to flush the lumen with a minimum of 25ml of cleaning solution 3 times or until the solution runs clean and there is no evidence of contamination.
6. Rinse each instrument with lukewarm tap water for a minimum of 2 minutes, or until no visible soil remains.
   - For items with lumens, using a 60ml syringe with needle, flush the lumen with 25ml of lukewarm water 3 times.
   - For Flex Arms, slide the surgical arm beads to allow water to flow between each link.
7. Dry each instrument using clean, absorbent, lint-free wipes, or pressurized air, to remove excess rinse water.

IMPORTANT INFORMATION ON THE ZIMMER BIOMET ANTERIOR ACCESS RETRACTOR SYSTEM (*continued*)

Automated cleaning instructions:

Use only washer/disinfector machines that have been validated in accordance with ISO 15883.

Suction Tubes, Shim Inserter Tools, Chordometers, Articulating Surgical Arms, Flexible Surgical Arms, and Scalp Hook Bands should not be cleaned using the Automated Method. These devices should be cleaned using the Manual Cleaning Process (detailed above).

1. Perform pre-cleaning to remove gross contaminants as follows:
   a. Rinse with running, lukewarm, DI, RO, or filtered water for a minimum of 1 minute for each instrument to remove gross contaminants.
   b. In a manual wash container, prepare an enzymatic, pH neutral detergent wash solution, per detergent manufacturer's instructions, using lukewarm tap water. Submerge and soak instruments in wash solution for a minimum of 1 minute.
   c. While still submerged, remove visible soil by scrubbing with a soft, nylon bristle brush for a minimum of 4 minutes or until no visible soil is observed.
   d. Use appropriately sized lumen brush to scrub the interior of lumen and soft bristled, nylon brush to brush the exterior of the lumen. Brush for a minimum of 1 minute, or until no soil is visible.
2. Rinse with running, lukewarm, DI, RO, or filtered water for a minimum of 1 minute for each instrument.
3. Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
   - Arrange instruments with curved surfaces and lumens facing downward to prevent pooling of water on the instrument.
4. Operate the washer/disinfector cycle according to the manufacturer's instructions.

Recommended minimal Automated washer/disinfector cycle parameters:

- Pre-wash rinse with cold tap water for 2 minutes.
- Heated wash at 140°F (60°C) for 2 minutes using an enzymatic, pH neutral cleaner such as Prolystica Ultra Concentrate Enzymatic Cleaner.
- Heated tap water rinse at 140°F (60°C) for 20 seconds.
- Heated deionized water rinse at 180°F (82°C) for 2 minutes.
- Forced air drying at 240°F (116°C) for 9 minutes.
- If any residual moisture is observed, wipe dry with absorbent, lint free cloth, or pressurized air for lumens.

Post Cleaning Inspection:

After cleaning, visually inspect each test article with the naked eye under normal lighting conditions to determine if all visible soil (e.g. blood protein substances and other debris) has been removed. If any soil is still visible, repeat cleaning steps.

SURGICAL ARM INSPECTION BEFORE USE:

Articulating Arms

1. Inspect entire assembly for damage.
2. Hold arm assembly at column and turn central tightening knob clockwise.
3. Check to make sure that arm is rigid at all three joints.
4. Insert arm column into table clamp, turn column tightening lever clockwise and ensure that it holds securely.

Flexible Arms

1. Inspect entire assembly for damage.
2. Turn the flex arm tightening knob clockwise and ensure the arm is sufficiently rigid for intended use.
3. When loosened, check cable between links for fraying. Normal use will eventually cause wear to the steel tensioning cable. If cable shows any frayed or broken wires, the flex arm needs to be replaced immediately.

STERILIZATION INSTRUCTIONS:

Lubricate:

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

Sterilize:

1. Instruments should be sterilized in the open or unlocked position. Central knob of articulating arms must be opened for sterilization.
2. Instruments should be sterilized by standard cycles using steam with established procedures.
3. We recommend the following sterilization temperature and time.

Gravity

The gravity displacement autoclave process is to sterilize the instruments at 250°F (121°C) for 30 minutes with a 150-minute dry time.

Prevacuum United States Standards

The prevacuum autoclave process is to sterilize the instruments at 270°F (132°C) for 4 minutes with a 30 minute dry time.

Prevacuum EU Standards

The prevacuum autoclave process used to sterilize instruments according to EU standards is at 273°F (134°C) for 18 minutes with a 20 minute dry time.

Autoclave temperatures should not surpass 280°F (137°C), as the handle, insulation or other non-metallic parts may be affected. (Note: The steam autoclave manufacturer may be contacted to confirm appropriate temperatures and sterilization times.)

Store

Instruments should be stored in a clean dry area with tip protectors. Please examine instrument prior to use for functionality and damage. When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrumentation disposal.

WARNING/PRECAUTIONS

***CAUTION**: US Federal law restricts this device to sale by or on the order of a physician.*

1. Product is intended to be used by trained surgeons.
2. TSI products are to be used only with the TSI retractor systems and may not be used with other manufacturer's products.
3. End of life is normally determined by wear and damage due to use.
4. Use of this instrument for any purpose, or in any manner 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 may be located by means of an X-Ray.
5. To prevent corrosion, instruments made of different alloys should be physically separated during cleaning and sterilization.
6. 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.
7. TSI light cables should only be used with the TSI light source (ML-0051).
8. The light source must remain off until the reusable light cable is inserted into the retractor blade(s).
9. Place the light source away from items that are flammable.
10. 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.
11. 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.
12. To verify that the proper amount of light output is achieved, hold single fiber optic end up to room light and look in bifurcated end (ML-0045 and ML-0048) or single end (ML-0047) 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.

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.*

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