CENTRIC®

Plier Style Retractor

Surgical Technique

Life Spine®

STG-0081720, Rev. B

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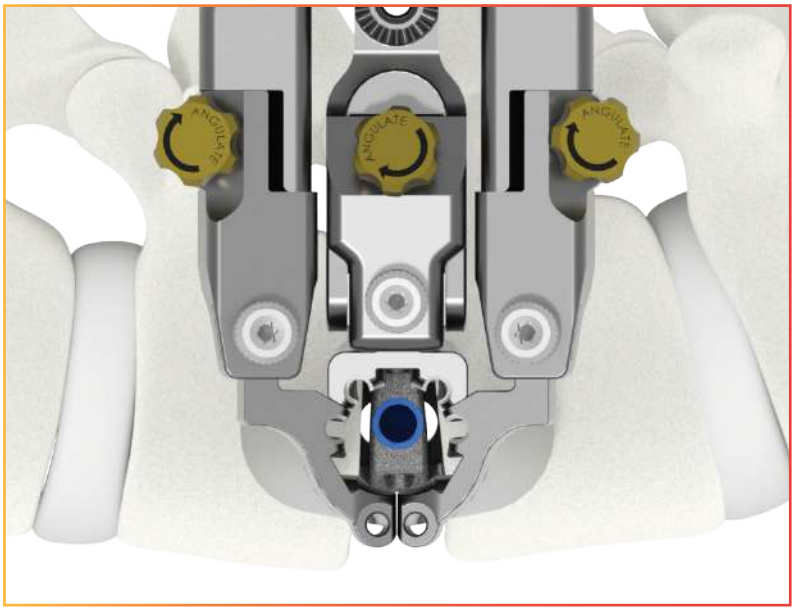
Features & Benefits

Lateral Access

The Centric Plier Style Retractor offers the surgeon complete and controlled tissue and muscle retraction. Versatility and flexibility allow the system to accommodate lateral approaches.



Controlled Distraction

- Independent blade angulation of 0° to 30° allowing an increase in distal exposure without enlarging the incision
- Adjustment of the center medial blade form 0 mm to 25 mm
- Blade length options from 9cm - 18cm

Ergonomic Design

- Removable handles help improve exposure & decrease difficulty when working around the iliac crest
- Multiple connections to the system's Table Arm
- Anodized black finish to minimize light reflection
- Simple set of instruments to make fine retractor adjustments in-situ.

Comprehensive

- Handheld fourth blade and bridge to improve tissue retraction
- Reusable and disposable lighting options provide superior in-situ visibility
- Complete offering of disposable components including dilator tubes, alligator clips, probes, guidewires, and blade extenders

Instrument Glossary

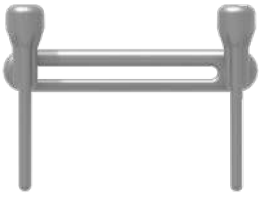
1/4 Square Ratcheting Palm Handle

Dilation Tube, Aluminum (1,2,3)

Retractor Blades (left, medial, right)

Blade Inserter/Remover

Fixation Pin Driver



Handheld Retractor Bridge

Blade Extender,
Installer/ Remover Insert

Long Blade Extender

Dilator Holder

Targeting Device

Instrument Glossary

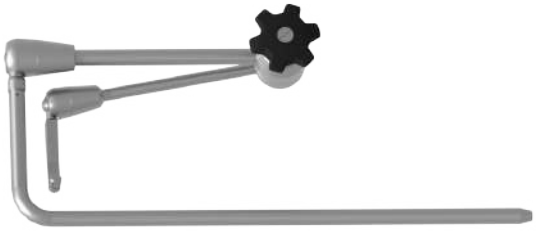
FluoroModulator

16cm Modified Handheld Retractor

1/4 Square Expansion Driver

Fixation Pin

Retractor Handles



Fixation Arm

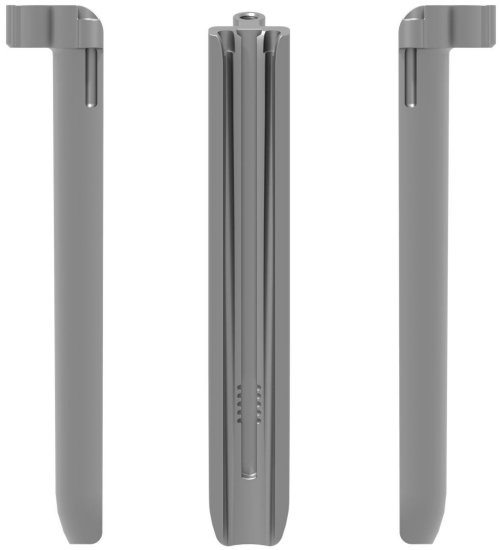
Blade Extender,
Installer/ Remover Insert

Long Blade Extender

Instrument Glossary

Blade Options

The Centric Plier Style Retractor System contains a wide range of retractor blades. A fourth blade bridge attachment comes standard in the set.



Range of Retractor Blades

	9cm	10cm	11cm	12cm	13cm	14cm	15cm	16cm	17cm	18cm
Medial Blade	O	X	X	X	X	X	X	X	O	O
Left Blade	O	X	X	X	X	X	X	X	O	O
Right Blade	O	X	X	X	X	X	X	X	O	O

*Modified handheld retractors are standard in the set in 16cm and 23cm lengths

X = Standard Set O = By Request

The Centric Plier Style Retractor System contains a wide range of retractor blades. A fourth blade bridge attachment comes standard in the set.

Comprehensive

The Centric Plier Style Retractor provides a comprehensive set of reusable and disposable instrumentation to meet surgical access requirements.

	Reusable	Disposable		Reusable	Disposable
Dilator Holder	X		Sounding Probe		X
Dilator Tube Sets	X	O	Alligator Clips		X
13" x 1.4mm K-wire		X	Fiberoptic Light Cables	X	X
Targeting Device	X		Blade Extenders		X
Neuromodulator	X		Fixation Pins (10cm - 16cm)	X	

X = Standard Set O = By Request

Surgical Technique

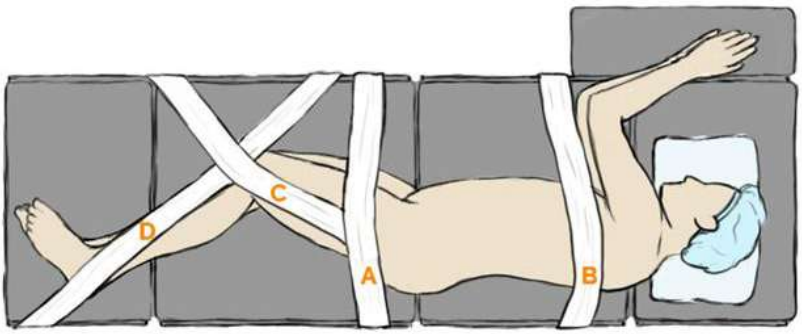
Patient Positioning

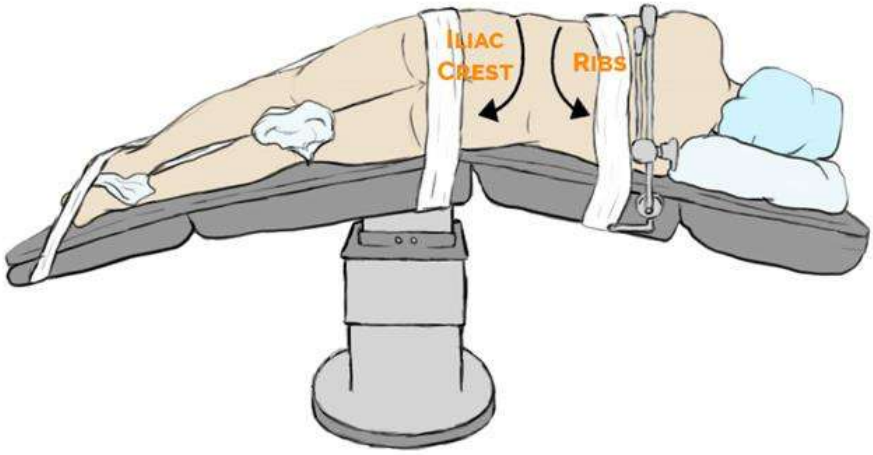
Rotate patient onto a flat Jackson table and identify approximate true Lateral and true AP positions.

Align the break of the bed between the patient's greater trochanter and the iliac crest. The back of the patient should be parallel with the table rails and should be straight up and down. Align the knees and ankles and place pillows between both for support. An axillary roll should be placed under the patient's chest with their arms out in front of them also supported with pillows. The patient's buttocks should be aligned. If shoulders and buttocks are not straight up and down, excessive bed tilting will be required to give the true A/P and Lateral images.

When taping the patient to the table, this order should be followed:

A. Over the greater trochanter and around the table
B. Over the thorax and around the table
C. From the greater trochanter to the knee, then to the table
D. From the table to the knee, past the ankle, then to the table





Once the patient is properly taped into position it is safe to break the table.

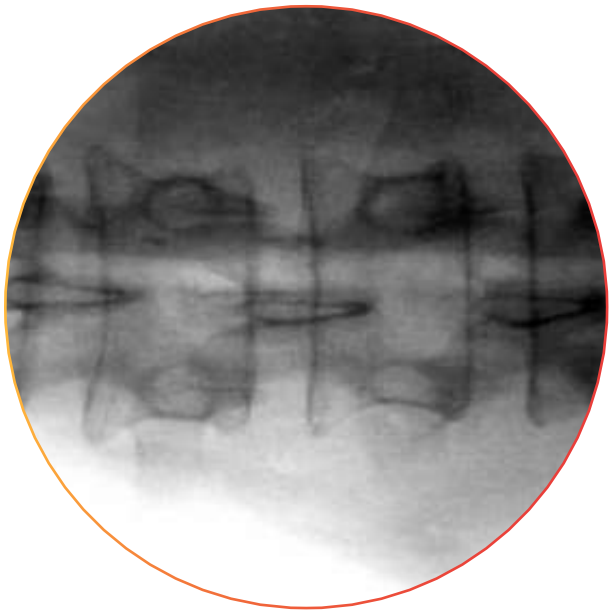
Note: It is ONLY necessary to break the table if the iliac crest is preventing access to the disc space. Breaking the bed causes undesirable tensioning of the psoas and lumbar plexus.

True A/P and Lateral Imaging

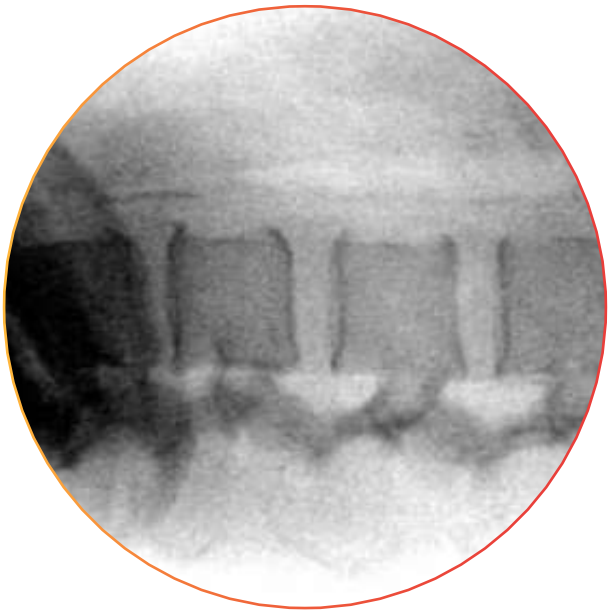
When obtaining the proper operative views, it is important NOT to adjust the C-Arm. Instead, use the table's moving capabilities. The c-arm's "wig-wag" function may be adjusted to match the angle of the disc space. This angle differs per the level of the spine.

True A/P: When finding the true A/P image, use the tilt function on the table. Look for the midline spinous process with symmetrical pedicles. This view is often called "Owl Eyes".

True Lateral: When finding the true Lateral image, use the Trendelenburg function on the table. Look for superimposed pedicles, linear endplates, and linear posterior cortex.



TRUE A/P VIEW



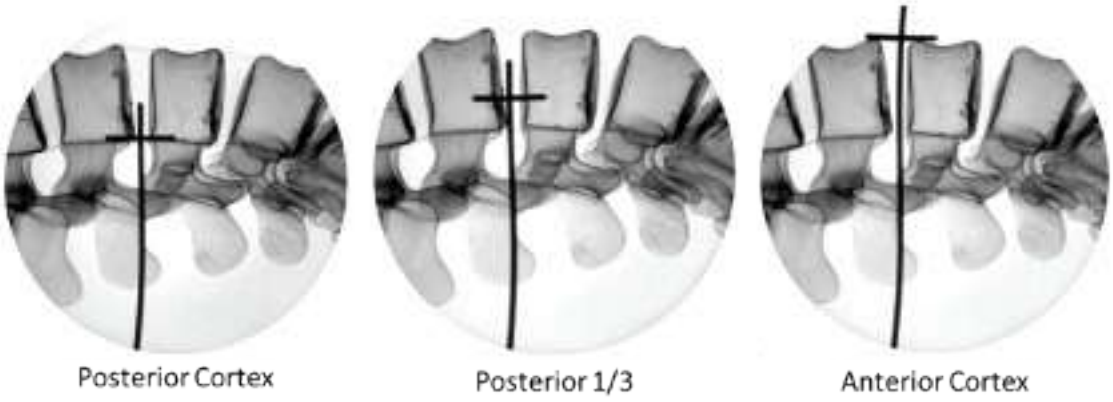
TRUE LATERAL VIEW

Note: For multi-level cases, it is often times necessary to readjust the table for proper imaging at every level.

Surgical Technique

Targeting and Incision

Target the appropriate operative level using the included targeting device. It is recommended to mark the skin where posterior cortex, posterior 1/3, and anterior cortex are found. Create an approximately 3cm horizontal, vertical, or oblique incision for dissection to the psoas.

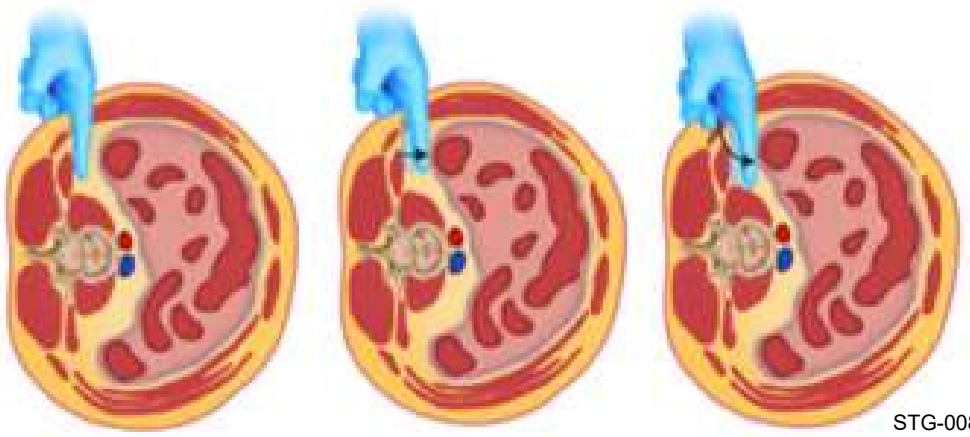


Access

Through the skin incision, dissect the subcutaneous layers until the abdominal musculature is reached. Use blunt dissector scissors to carefully spread the fibers of the oblique, internal oblique, and transversalis muscles until the retroperitoneal space is reached.

Note: Care should be taken to avoid perforation of the peritoneum.

Once inside the retroperitoneal space, use the index finger in a sweeping motion to release the peritoneum anteriorly. Once released use the same finger to palpate the psoas muscle or the anterior surface of the transverse and/or the anterior surface of the transverse process, verifying the proper position within the retroperitoneal space.



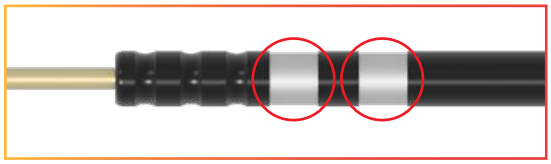
Dilation and Neuromonitoring

NOTE: Life Spine stresses the importance of neuromonitoring when performing lateral procedures. While the motor nerves of the lumbar plexus typically reside within the posterior 1/3 of the psoas muscles, their position may differ between patients.

Introduce the #1 Dilation Tube through the incision, using the inserted index finger to guide the Dilation Tube to the psoas muscle.

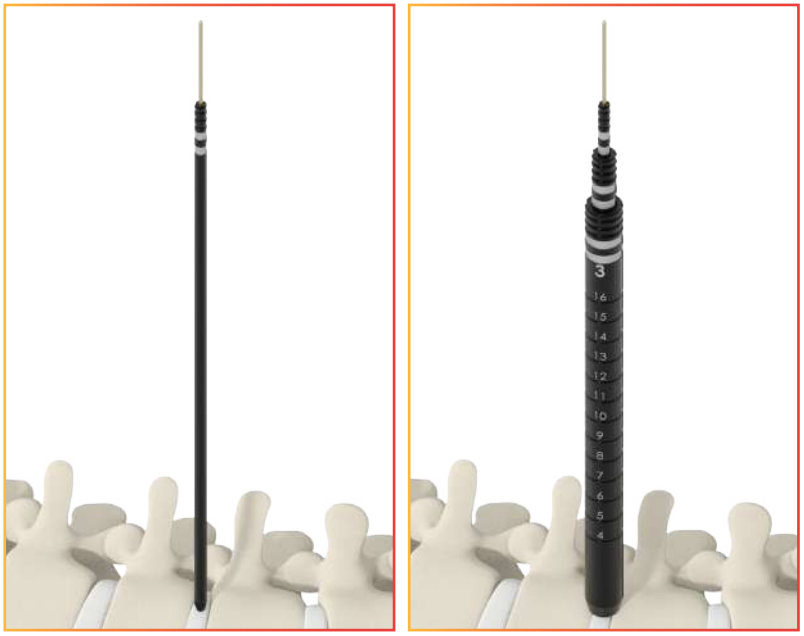
Once the #1 Dilation Tube has reached the lateral surface of the psoas, lateral fluoroscopy should be used to confirm its position before proceeding. The ideal docking location is the junction of the posterior 1/3 and anterior 2/3 of the disc space. Neuromonitoring should be used to identify the proximity of the lumbar plexus.

Attach the Alligator Clip to the proximal aspect of the Dilator #1. There are two silver bands identifying the clip attachment site. A vertical band on the proximal aspect of each dilator identifies the direction of neuromonitoring.



Using lateral fluoroscopy and neuromonitoring, pass the dilator through the psoas using a twisting motion to determine the relative proximity of the lumbar plexus. A lateral image should confirm that the Dilation Tube is approximately centered on and parallel with the disc space.

An A/P image will confirm that the Dilator is in the correct plane of and flush with the disc space. When the optimal position has been identified, secure the position by introducing a k-wire through #1 Dilation Tube and into the disc space.

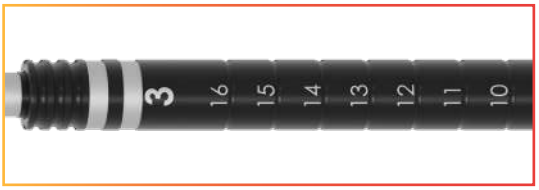


Once the k-wire is successfully inserted into the disc, remove the Alligator Clip from #1 Dilation Tube and introduce the #2 Dilation Tube over the first. Follow the same steps as #1 Dilation Tube: Attach the Alligator Clip and pass the #2 Dilation Tube through the psoas, twisting to determine the relative proximity of the lumbar plexus. Repeat the same process with #3 Dilation Tube. Keep all Dilation Tubes installed until retractor in place and fully locked.

Surgical Technique

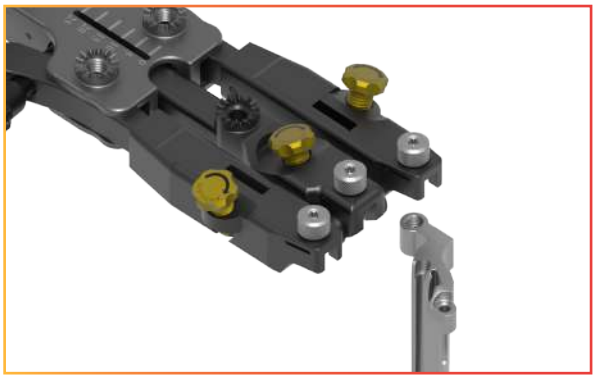
Blade Selection and Insertion

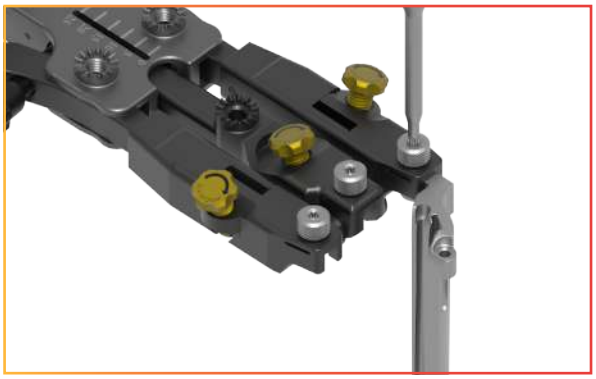
The #2 and #3 Dilation Tubes have depth measurements. Measure the point where the skin contacts the Dilation Tube and select the appropriate retractor blade.



Note: If the skin contact is between two depth measurements, select the longer blade length.

Load each blade into the respective arm from the bottom of the retractor's frame. Use your fingers to initially tighten the retractor blade locking mechanism, then tighten utilizing the Fixation Pin Driver. To remove a retractor blade, use the same method of installation.





The Centric Plier Style has removable retractor handles. To install, press the gold button on the handles and place onto the corresponding side of the retractor body.

Retractor Insertion

Once the retractor is assembled, align the central channel of the blades over #3 Dilation Tube with the retractor handles on the posterior side of the patient. Apply continual downward pressure on the retractor to pass the blades through the psoas. Twisting the retractor may also aid in passing through the psoas.

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Note: Maintaining downward pressure until the Table Arm is attached could help to mitigate tissue creep.

Note: Prior to placing the retractor, ensure that there is no expansion or toe on any blade. The distal tips of the retractor blades should be in contact with each other forming a circle.

A/P fluoroscopy may be used to confirm the proximity and alignment of the blades to the disc space.

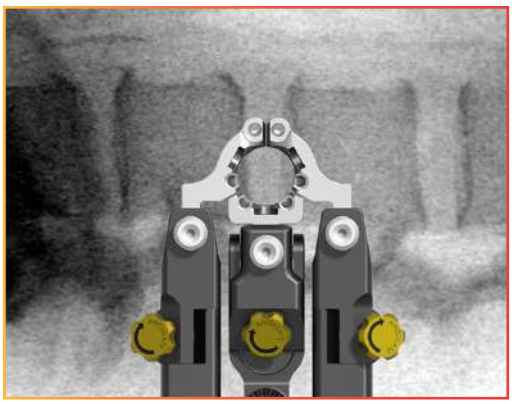
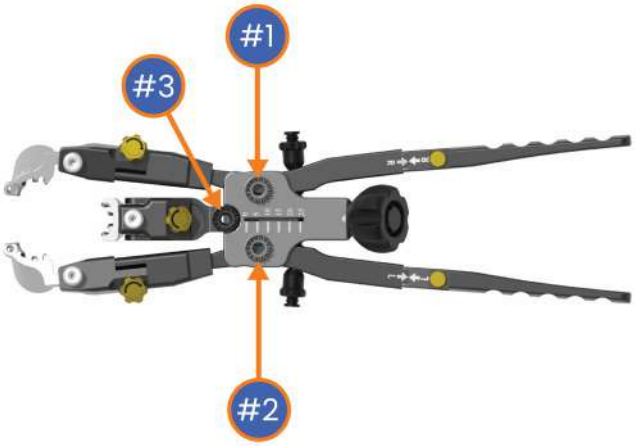


Table Arm Attachment

Attach the radial clamp to the OR bed-rail with the bed rail lock facing downward. Turn the bed rail lock clockwise until sufficiently tight against the rail. Confirm the Radial Clamp's Table Arm Lock is released and slide the Table Arm into the clamp. Orient the Table Arm at the desired height and position before locking the clamp.

There are three Table Arm attachment sites on the Centric Plier Style Retractor. When choosing where to attach the Table Arm, it is important to keep in mind the desired functionality of the Retractor.



Attachment Point #1 & #2 Retractor Body Connection: Attaching the Table Arm to either the left or right point will completely stabilize the retractor body and prevent any anterior/posterior movement of both the left and right blades. In this case, rotating the medial blade retraction knob will result in posterior movement of the medial blade.

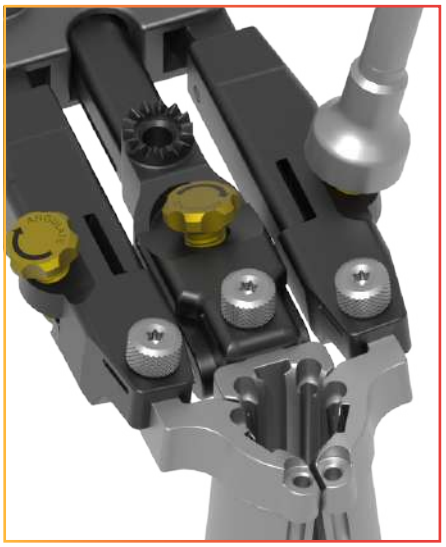
Attachment Point #3 Medial Arm Connection: Attaching the Table Arm to the medial arm of the retractor will stabilize the position of the medial blade. In this instance, engaging the posterior retractor knob will result in anterior movement of the left and right blades.

Once an attachment point has been selected, attach the table arm by rotating the lock clockwise until a secure fit has been established.

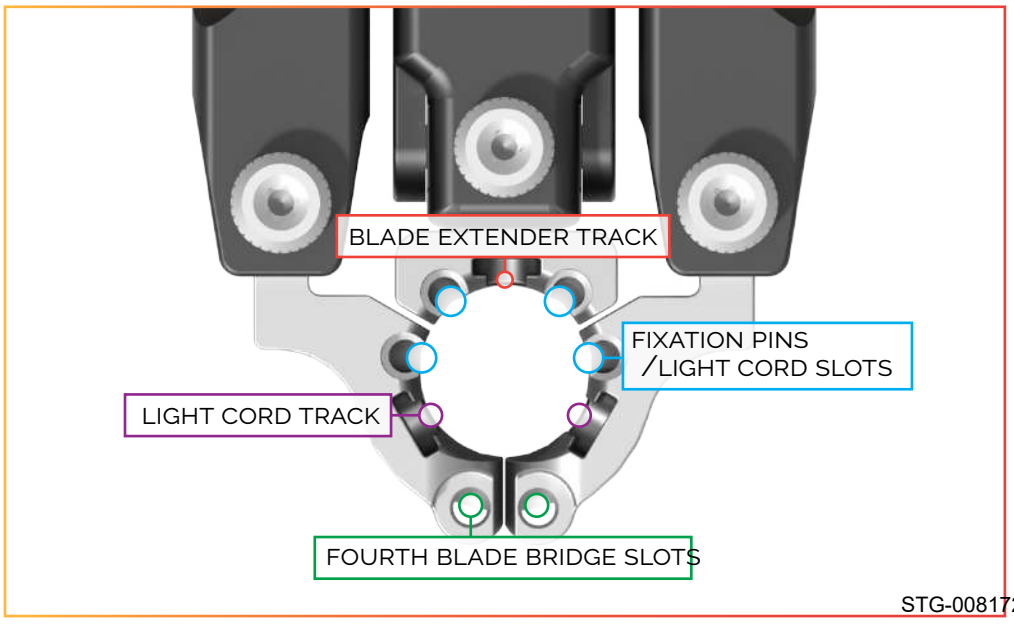
Surgical Technique

Retractor Expansion and Angulation

Retraction is gained by squeezing together the retractor handles for cephalic/caudal retraction, while turning the medial blade retractor knob for anterior to posterior retraction. Fine tune retraction can be gained for cephalic/caudal retraction with rotating the respective knob on the side of the retractor body using your fingers or the expansion driver. Angulation, or toe, can be achieved on all three blades independently. Utilizing the expansion driver, rotate the gold angulating knobs clockwise to achieve up to 30˚ of angulation.



Retractor Blade Labeling



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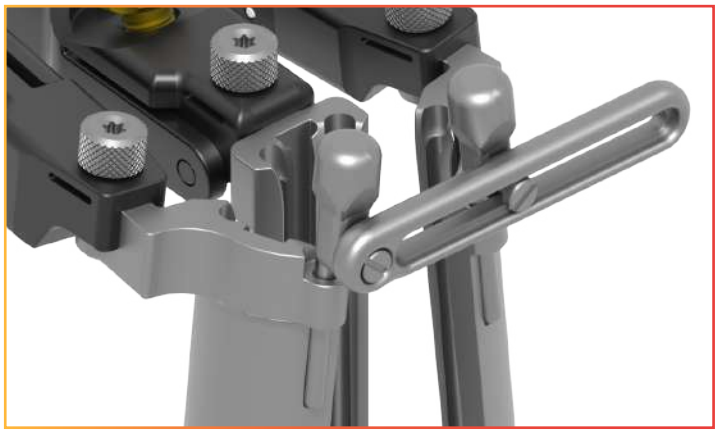
Optional Fourth Blade Attachment

Also included in the instrument set is a fourth blade. The fourth blade may be used in combination with the fourth blade bridge. Place the fourth blade bridge pins in the appropriate slots on the cephalad/caudal blades ensuring that the bridge is on the anterior side of the blades. The fourth blade may then be placed between the bridge and the incision, properly retracting the tissue.

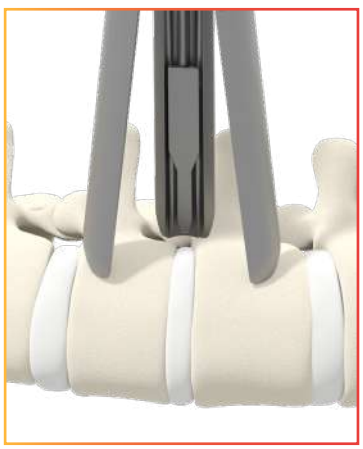


Optional Blade Fixation Pins

The cephalad and caudal blades have fixation pin tracks for additional stabilization to the retractor. The fixation pin will be screwed in using the fixation pin Blade Extender/Installer/Remover Insert.

Blade Extender Insertion

The system has the option for the use of Blade Extenders. Rotate the Blade Extender/Installer/Remover Insert clockwise onto the Blade Extender and place it down the respective track on the medial blade. Once the distal tip of the blade extender reaches the disc space, lightly mallet the Blade Extender/Installer/Remover Insert until maximum depth is achieved. Rotate the installer counterclockwise and pull straight out, ensuring the blade extender has not moved.



Fiberoptic Light Cables

The set comes standard with two options of fiberoptic light cables. The bifurcated light cable can be places down the fixation pin tracks, while the disposable light cable can be slid down the blade extender track.

LIFE SPINE®

CENTRIC® Plier Style Retractor System

Standard Product Insert

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Important Information on the CENTRIC Plier Style Retractor System
This IFU is intended to assist health care personnel in safe handling practices, effective reprocessing, and maintenance of all Life Spine, Inc's retractor systems and accessory families

PLEASE READ BEFORE USE
Failure to follow these instructions may render device unusable and may void warranties or service agreements

Description:
Instruments comprised of a variety of materials commonly used during orthopedic and neurosurgical procedures. All instruments abide by the available national and international standards and specifications for these devices. The instrument is fabricated and manufactured from the following:

1. Titanium
2. Stainless Steel

While most of the instruments found within this system are reusable, some instruments are marked as single use and should not be used for multiple procedures.

SCOPE:
This IFU provides recommended information for cleaning and sterilization of reusable surgical retractor systems and accessories* that are manufactured and/or distributed by Life Spine, Inc.
* Accessories refer to Life Spine retractor components such as adapters, wrenches, instrument cases, etc.

Indications for Use:
The CENTRIC Plier Style Retractor System is a manually operated device designed for use during surgical procedures of the spine.

Contraindications:
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Pregnancy.
5. Patients unwilling to cooperate with the post-operative instructions.
6. Patients with physical or mental conditions that would prohibit beneficial surgical outcomes.
7. Suspected or documented metal allergy or intolerance.
8. Use with components from other systems, unless otherwise specified.

Potential Adverse Events and Complications:
A listing of possible adverse events includes, but is not limited to:
1. Foreign body (allergic) reactions including metallosis, staining, tumor formation, and/or auto-immune disease.
2. Infection.
3. Dural tears.
4. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
5. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
6. Scar formation possibly causing neurological compromise around nerves and/or pain.
7. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
8. Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery
9. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
10. Change in mental status
11. Inability to perform the activities of daily living.
12. Paralysis
13. Death

Warnings, Cautions and Precautions:

WARNING: Whenever performing a surgery, care should be taken to avoid injury to the nerves, cauda equina and surrounding soft tissue.

WARNING: Safety precautions should be exercised when using electrical instruments to avoid user/patient shock, fire hazard or equipment damage.

CAUTION: Care should always be taken during use to avoid complications, such as neural injury.

PATIENT EDUCATION: It is important to provide preoperative instructions to patients, identifying potential risks and precautions for the intended surgery.

COMPATIBILITY: Life Spine's instruments and implants are not designed for use with components from other systems. Unless stated otherwise, Life Spine devices should not be combined with the components of other systems. Failure to do so may result in patient harm or instrument damage.

SINGLE USE: Reuse of single use devices that have been in contact with blood, bone, tissue, or bodily fluids may result in patient harm or injury. Risks associated with the reuse of single use devices include, but are not limited to, mechanical failure, material degradation and transmission of infectious agents. Resterilization of single use devices may result in instrument damage or decreased performance.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Preoperative Instructions:

1. The methods for use of the instruments are to be determined by the user's experience and training in the surgical procedures.
2. Instruments are not intended for use in any action other than that which is described in the technique guide. This includes, but is not limited to, such actions as hammering, prying and lifting.
3. The type of construct and surgical procedure should be determined prior to beginning the surgery. Adequate inventory should be identified prior to the surgery to verify that all necessary components are available during the time of the procedures.
4. Packages for both sterile and non-sterile components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used and should be returned to Life Spine.
5. Instruments should be carefully examined prior to use for functionality, excessive wear or damage. Damaged instruments should not be used as this increased the risk of malfunction and potential patient harm. The surgeon should be familiar with the various system components before use and should personally examine and assemble the device to verify that all parts and necessary instruments are present before the surgery begins.
6. Care should be used in the handling and storage of the system components. Standard hospital methods and practices should be used in instrument handling, cleaning after use and storage.
7. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
8. Surgical grade instrument lubrication should be applied to all moving components during the wash and sterilization cycle to ensure proper functionality.
9. Only patients that meet the criteria described in the indications should be selected.
10. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
11. Life Spine does not and cannot warrant the use of instruments nor any of the component parts upon which repairs have been made or attempted except as performed by Life Spine or an authorized Life Spine repair representative.

Operative Instructions:
1. Instructions of use should be carefully followed, as specified in the surgical technique guide.
2. At all times, extreme caution should be used around the spinal anatomy. Care should be taken to avoid unnecessary stress on the spinal area with the instrumentation.
3. When using the CENTRIC Plier Style Retractor for distraction, care should be taken to avoid damaging the pedicles or compromising the tap purchase.
4. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
5. Breakage, slippage, or misuse of the instruments or components may cause injury to the patient or the operative personnel. The physical characteristics required for many instruments do not permit them to be manufactured from implantable materials. If any broken fragments of instruments remain in the body of a patient, they could cause allergic reactions or infections. If an instrument breaks in surgery and fragments go into the patient, these pieces should be removed prior to closure and should not be implanted.

DO NOT IMPLANT THE INSTRUMENTS
The CENTRIC Plier Style Retractor utilizes fixation pins to fixate its blades to the vertebral bodies. These fixation pins, along with all instruments in this system, are not intended for surgical implantation.

Cleaning and Decontamination:

Precleaning:
Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Cleaning:
All instruments and trays must first be cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. A room temperature enzymatic cleaner bath (soak) or a solution of room temperature water and neutral pH detergent are effective in removing organic material from instruments. Use distilled (demineralized) water if possible. Instruments should be fully submerged for at least 10 minutes.

Instruments and trays must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Immerse instruments fully opened and flush all cannulas with room temperature water until rinse water runs clear. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments and trays. If there is any visual contamination, repeat the steps as necessary until the instruments and trays are visually clean. Rinse instruments and trays under running room temperature water for at least 1 minute to remove solutions.

If contamination is unable to be removed, return the instrument and/or tray to Life Spine in a sealed container clearly marked "contaminated."

Instruments and trays should never be exposed to cleaning agents containing any peroxides.
Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:
The CENTRIC Plier Style Retractor will be supplied clean and "NON_STERILE" and must be sterilized prior to use; moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2017 "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" according to the following validated cycle parameters: These products must be packaged in a FDA cleared wrap:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270°F(132°C)	4 Minutes	30 Minutes

The Sterility Assurance Level (SAL) is 1 x 10^{-6}, via the indicated methods.

No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Do not stack trays during sterilization. Use only sterile products in the operative field.

Always immediately re-sterilize all instruments and trays used in surgery. This process must be performed before handling or (if applicable) returning to Life Spine.

Product Complaints:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, LIFE SPINE. If any LIFE SPINE product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the local distributor should be notified immediately by telephone, fax or written correspondence.

When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

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13951 Quality Drive
Huntley, IL 60142
USA

Tel: 847-884-6117
Fax: 847-884-6118
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