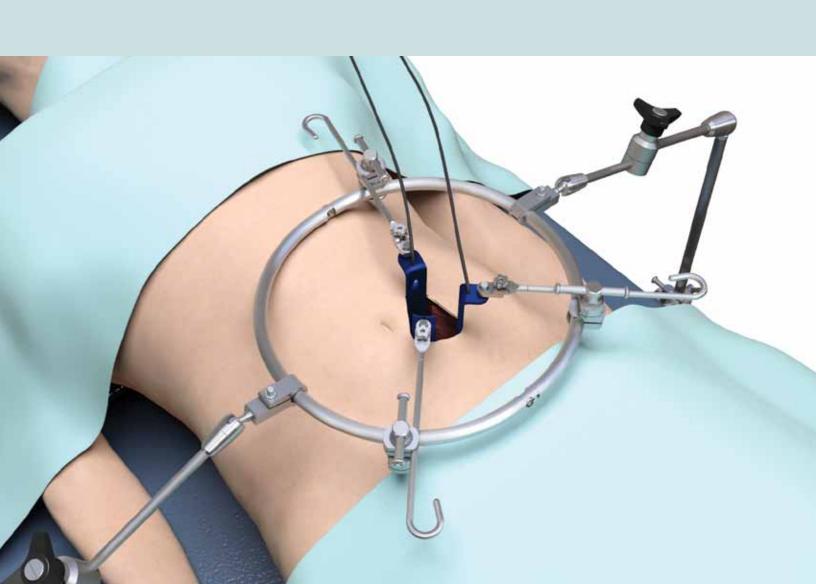
Spine

LITe® Anterior Retractor

Anterior Surgical Technique



Surgical Technique

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System Overview

Stryker Spine's LITe (Less Invasive Technologies) Anterior Retractor offers a slim, low-profile option for tissue retraction and visualization of the lumbar spine. Multifunctional blades attach to an expandable ring that can attach securely to the table, allowing surgeons the ability to make small intraoperative adjustments without disruption to the rest of the system. Radiolucent lighted blades allow for optimized visualization of the surgical site without the need for headlamps (Fig. 1).



Figure 1. Assembled Retractor with 3 Blades

The LITe Anterior Retractor functions on a low-profile, table-mounted ring. Articulating arms attach to various blades offering multi-plane mobility without compromising stability of the retraction. Blades range from 80-200mm in length and rigid or malleable designs with three widths available to accommodate a wide array of patients and pathologies (Fig 2).



Figure 2. Retractor Ring, Blade Options, Light Source with Cable

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Rotating Table Clamp **48870065**

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Step 1. Table Clamp Attachment

After the patient is positioned supine on the table, attach the Rotating Table Clamp to the table. Place the Rotating Table Clamp on the rail, making sure that the clamp securely captures the bar. Rotate the superior arm clockwise until tight to lock the clamp onto the table (Fig 3).



Figure 3. Locking the Clamp onto the Table

Step 2. Arm Bar Placement

Slide the long bar of the Articulating Arm through the corresponding hole in the Rotating Table Clamp. This portion of the clamp can rotate, allowing for angled position of the Arm. Once the desired angle is achieved, tighten the clamp by rotating the bar clockwise (Fig 4).



Figure 4. Tightening the Clamp



Articulating Arm **48870035**

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Step 3. Ring Assembly

Assemble the Retractor Ring. Using the Small Hex Driver, tighten the screws on either side of the ring to secure it into one piece (Fig 5).



Figure 5. Retractor Ring Assembly



Extension Bar **48870010**

Note: If necessary, the Extension Bars may be used to form a larger ring. If this is the case, assemble the ring with an extension bar on either side and tighten with the same technique.

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Step 4. Ring Placement



Attach the Retractor Ring to the Articulating Arms. Open the clamp at the distal end of the Articulating Arm. Place the Ring within, and tighten using the Large Hex Wrench. Repeat with the other Articulating Arm (Fig. 6).



Figure 6. Attaching the Retractor Ring to the Articulating Arm

The Ring can now be secured over the patient. Place the Ring just above the patient, and secure by tightening the knobs on the Articulating Arm (Fig. 7).



Figure 7. Securing the Ring Over the Patient

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Step 5. Ring Clamp Placement

Attach the spring-loaded Ring Clamps to the Retractor Ring by snapping them on. If the clamps do not attach easily, loosen slightly and reattach (Fig 8).



Step 6. Blade Selection and Assembly

Select the appropriate Retractor Blade. Rigid blades come in narrow (23mm), wide (32mm), and extra wide (50mm) options. The rigid blades are radiolucent and each features a portal into which a light cable can be inserted. Malleable blades are also available in a 32mm width (Fig.9).



Figure 9. Blade Options

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Once the appropriate blade is selected, attach to the Pivoting Blade Holder. The Pivoting Blade Holder has two positions. Provisional insertion will allow the blade to swivel freely within the holder. Full locking will lock the blade in place at 90° to the Blade Holder (Fig. 10).





Figure 10. Locking the Blade within the Blade Holder

Description	Reference #
Retractor Blade, Narrow, 80mm	48870080
Retractor Blade, Narrow, 100mm	48870100
Retractor Blade, Narrow, 120mm	48870120
Retractor Blade, Narrow, 140mm	48870140
Retractor Blade, Narrow, 160mm	48870160
Retractor Blade, Narrow, 180mm	48870180
Retractor Blade, Narrow, 200mm	48870200
Retractor Blade, Wide, 80mm	48871080
Retractor Blade, Wide, 100mm	48871100
Retractor Blade, Wide, 120mm	48871120
Retractor Blade, Wide, 140mm	48871140
Retractor Blade, Wide, 160mm	48871160
Retractor Blade, Wide, 180mm	48871180
Retractor Blade, Wide, 200mm	48871200
Retractor Blade, Extra Wide, 100mm	48873100
Retractor Blade, Extra Wide, 120mm	48873120
Retractor Blade, Extra Wide, 140mm	48873140
Retractor Blade, Extra Wide, 160mm	48873160
Retractor Blade, Extra Wide, 180mm	48873180
Retractor Blade, Extra Wide, 200mm	48873200
Retractor Blade, Malleable, 100mm	48874100
Retractor Blade, Malleable, 120mm	48874120
Retractor Blade, Malleable, 140mm	48874140
Retractor Blade, Malleable, 160mm	48874160
Retractor Blade, Malleable, 180mm	48874180
Retractor Blade, Malleable, 200mm	48874200

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Step 7. Blade Placement and Attachment

Attach the assembled blade and arm to the Ring Clamp. Once the arm is snapped into the Ring Clamp, tighten by rotating clockwise to secure.

Note: Be careful not to over-tighten the Ring clamp, as the rotating bar may have the ability to lock up and be difficult to loosen.

At this point, the towing feature of the blade may be desired. The knob at the attachment site of the Blade and Articulating Arm can be turned clockwise to tow the blade. If more leverage is needed, the Small Hex Driver may be used as well (Fig. 11).





Figure 11. Towing the Blade

At this point, if lighting is desired, plug the Light Cable into the Light Source located outside the sterile field. The distal tip of the light cable inserts into the top hole of the Lighted Retractor Blade, as shown (Fig. 12).



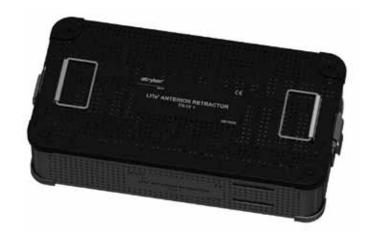


Figure 12. Light Cable and Light Source

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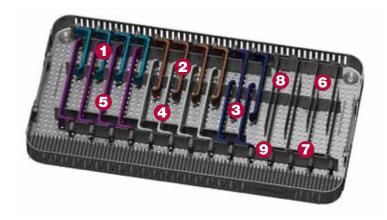
Tray Overview

Reference	Description
48870040	Sterilization Tray 1
48870040A	Sterilization Tray 1 (Lid Only)

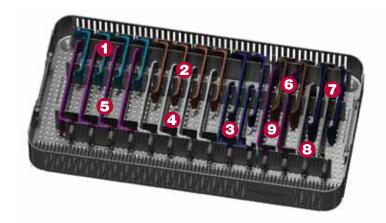


Sterilization Tray 1

Top Tray			
	Reference	Description	
0	48870080	Retractor Blade, Narrow, 80mm	
2	48870100	Retractor Blade, Narrow, 100mm	
3	48870120	Retractor Blade, Narrow, 120mm	
4	48870140	Retractor Blade, Narrow, 140mm	
6	48870160	Retractor Blade, Narrow, 160mm	
6	48874100	Retractor Blade, Malleable, 100mm	
0	48874120	Retractor Blade, Malleable, 120mm	
8	48874140	Retractor Blade, Malleable, 140mm	
9	48874160	Retractor Blade, Malleable, 160mm	



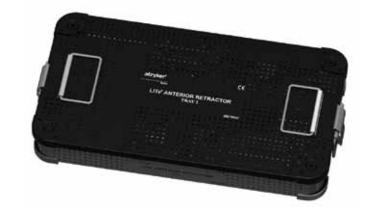
Bottom Tray		
	Reference	Description
0	48871080	Retractor Blade, Wide, 80mm
8	48871100	Retractor Blade, Wide, 100mm
3	48871120	Retractor Blade, Wide, 120mm
4	48871140	Retractor Blade, Wide, 140mm
6	48871160	Retractor Blade, Wide, 160mm
6	48873100	Retractor Blade, Extra Wide, 100mm
7	48873120	Retractor Blade, Extra Wide, 120mm
8	48873140	Retractor Blade, Extra Wide, 140mm
9	48873160	Retractor Blade, Extra Wide, 160mm



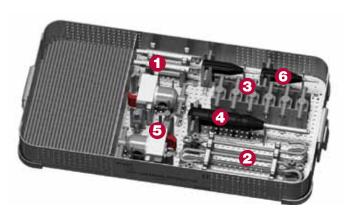
Surgical Technique

Sterilization Tray 2

Reference	Description
48870045	Sterilization Tray 2
48870045A	Sterilization Tray 2 (Lid Only)



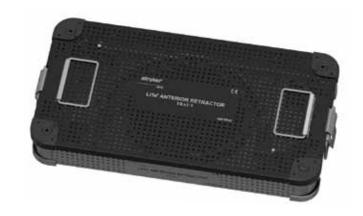
	Sterilization Tray 2				
	Reference	Description			
0	48870010	Extension Bar			
2	48870015	Pivoting Blade Holder			
3	48870020	Ring Clamp			
4	48870030	Large Hex Wrench			
6	48870065	Rotating Table Clamp			
6	48870070	Small Hex Driver			

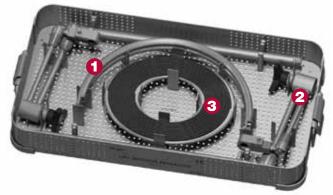


Sterilization Tray 3

Reference	Description
48870042	Sterilization Tray 3
48870042A	Sterilization Tray 3 (Lid Only)

		Sterilization Tray 3
	Reference	Description
0	48870005	Retractor Ring
9	48870035	Articulating Arm
3	48758451	Light Cable





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Instruments

	Reference	Description
	48870080	Retractor Blade, Narrow, 80mm
4	48870100	Retractor Blade, Narrow, 100mm
V	48870120	Retractor Blade, Narrow, 120mm
	48870140	Retractor Blade, Narrow, 140mm
	48870160	Retractor Blade, Narrow, 160mm
	48870180	Retractor Blade, Narrow, 180mm
,	48870200	Retractor Blade, Narrow, 200mm
	48871080	Retractor Blade, Wide, 80mm
-	48871100	Retractor Blade, Wide, 100mm
1 8/1	48871120	Retractor Blade, Wide, 120mm
	48871140	Retractor Blade, Wide, 140mm
	48871160	Retractor Blade, Wide, 160mm
	48871180	Retractor Blade, Wide, 180mm
	48871200	Retractor Blade, Wide, 200mm
	48873100	Retractor Blade, Extra Wide, 100mm
	48873120	Retractor Blade, Extra Wide, 120mm
	48873140	Retractor Blade, Extra Wide, 140mm
	48873160	Retractor Blade, Extra Wide, 160mm
	48873180	Retractor Blade, Extra Wide, 180mm
	48873200	Retractor Blade, Extra Wide, 200mm
	48874100	Retractor Blade, Malleable, 100mm
	48874120	Retractor Blade, Malleable, 120mm
	48874140	Retractor Blade, Malleable, 140mm
	48874160	Retractor Blade, Malleable, 160mm
	48874180	Retractor Blade, Malleable, 180mm
	48874200	Retractor Blade, Malleable, 200mm

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Instruments

	Reference	Description
	48870005	Retractor Ring
	48870010	Extension Bar
C	48870015	Pivoting Blade Holder
=	48870020	Ring Clamp
	48870030	Large Hex Wrench
	48870070	Small Hex Driver
	48870035	Articulating Arm
	48870065	Rotating Table Clamp
	48758451	Light Cable
	48252106	Light Source

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Instruments

Reference	Description
48870050	Light Cable Flex Arm* Special Order Only
48870040	Sterilization Tray 1
48870040A	Sterilization Tray 1 (Lid Only)
48870045	Sterilization Tray 2
48870045A	Sterilization Tray 2 (Lid Only)
48870042	Sterilization Tray 3
48870042A	Sterilization Tray 3 (Lid Only)

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IMPORTANT PRODUCT INFORMATION

Quality Statement:

TeDan Surgical Innovations, LLC, (TSI) is dedicated to providing innovative high quality specialty surgical instrumentation. TSI guarantees that all of our products have been manufactured by skilled instrument craftsmen, using only quality materials. Every effort is made to manufacture the finest quality surgical instruments at exacting specifications.

Warranty:

TeDan Surgical Innovations, LLC products are warranted to be free from defects in material and workmanship when used under normal condition for its intended purpose for 10 years from invoice date. Any instrument that proves to be defective during this period, TSI will, at its sole discretion, either repair or replace the defective product at no charge.

This limited warranty is null and void if a TSI product is repaired or modified in any way by any party that is not explicitly TSI authorized. TeDan Surgical Innovations, LLC shall not be held responsible for consequential or indirect damage arising from the sale or use of any product.

Please 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.

Refer to the package insert for proper cleaning and sterilization instructions, maintenance, inspection and lubrication information, and additional instructions for use.

The Light Source Operator's Manual will help you to install the device and optimally integrate it with other components of your system. It will also instruct you how to operate the LED Light Source and how to keep it clean. It will give you maintenance and service guidelines as well as recommendations for best performance results.

INDICATIONS FOR USE:

The LED Light Source is used to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery) and in Endoscopy (general, gastroenterological and ENT surgery) The light is transmitted from the light source through a fiber optic cable.

NOTE: Light source is designed to work with TeDan Surgical Innovations light cable (TSI) only and is used during spine, hip, neuro, cardiac, vascular and thoracic surgeries.

The LED Light Source is used with the proprietary TSI lights cables. The ferrule (end of the cable) is specifically designed to work with this TSI Light Source. The light port is also proprietary and designed to only accept TSI light cables.

Contact TeDan Surgical Innovations for additional information or needs.

WARNINGS/CAUTIONS

Caution Federal law restricts this device to sale by or on the order of a licensed practitioner.

Caution To prevent fire or electric shock, do not open or expose the LED light source unit to rain or moisture. Refer all servicing to qualified personnel only.

Caution Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Caution To prevent any potential electromagnetic interference, do not use any kind of cellular phone near the light source.

Caution This product should be used only with type BF endoscopic instruments which have been certified according to IEC 60601-1 for medical equipment and IEC 60601-2-18 for endoscopic equipment.

This symbol indicates type BF equipment.

Caution User must not alter this device in any fashion. Doing so voids all warranties and statements of suitability for any purpose.

Caution All devices connecting to the LED Light Source must be classified as medical equipment. Additional information processing equipment connected to the LED Light Source, a Medical System and the operator must determine that all equipment complies with the appropriate end-product standards (such as IEC 60950 or IEC 60065 and the Standard for Medical System, IEC 60601-1-1).

Caution Always set the intensity control to the minimum level and insert the fiberoptic cable into the unit before turning on the power. When light is not required at the surgical site, the intensity control should be should be set to the fully dimmed position. If it becomes necessary to remove the fiber optic cable without turning the unit off, turn the intensity control to the fully dimmed position.

Caution EQUIPMENT
CONNECTION - The fiber optic cable
must be a NON-CONDUCTIVE CABLE.
It should not have conductive shielding or
any other conductive connection between the
patient and equipment. Such connection will
impair safety of the equipment. It must be
rinsed free of soaking/disinfectant solution
and dried before plugging into the LED light

source receptacle. Ensure the optical surface

is clean before engaging into the light source.

Caution User is responsible for determining if interruption of light output will create an unacceptable risk. If this determination is made arrangements should be taken to reduce the risk.

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SPECIFICATIONS:

Item	Specification
Light Source type	LED (Light Emitting Diode)
Color Temperature	6500° K
LED Life	50,000 hours (typical)
Light Guide Adapter	TSI
Brightness Control	PWM (Pulse-width Modulation) – 0-100% Dimming
Input Voltage	100-240V AC, 50/60 Hz
Consumption Power	52 watt (nominal)
Regulatory Approvals	UL60601-1,CAN/CSA C22.2 No.601.1 (SUP1+AM2), EN 60601-1-2 and CE marked
Equipment Class	BF-type
Mode of Operation	Continuous operation
Water Resistant	Not Protected Equipment, IPX0
Operating Environment Temperature Relative Humidity Air Pressure	+0° to +40° C (32° to 104° F) 0 to 85%rh, non condensing 700 to 1060 hPa
Storage Environment Temperature Relative Humidity Air Pressure	-20° to +60° C (-4° to 140° F) 30 to 95%rh, non condensing 700 to 1060 hPa
Dimensions	4.65" W x 3.32" H x 7.25" D
Weight	2.5 lbs./1.14 kg

Instructions for use for Light Cable:

- 1. Once the Light Source (48252106) is plugged in, turn it on and open the shutter to confirm that the light is functional. Once confirmed, close light source shutter.
- 2. Remove the Reusable Light Cable (48758451 or 48252005) from the sterilization container.
- 3. Hold single fiber optic end 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%) are broken, the light cable may need to be replaced as light output will be slightly diminished.
- 4. After confirming that the Reusable Light Cable has no visible breaks or damage, plug the end of the into the Light Source.
- 5. Once the Reusable Light Cable is plugged in to the light source, open the light source shutter to confirm that the Reusable Light Cable is transmitting light. Once confirmed, close the light source shutter. The light source shutter must remain closed until the Reusable Light Cable is inserted into the light channel of the retractor blades.

- Choose the desired blades and gently insert the bifurcated end into the light channels of the retractor blades.
- 7. Open the light source shutter and confirm that the Reusable Light Cable is transmitting light. The light source can remain on once the Reusable Light Cable is inserted into the retractor blades.
- 8. The attenuator on the Light Source (may be adjusted to provide the amount of light preferred.
- 9. Close the light source shutter prior to removing the Reusable Light Cable from the retractor blades. The light source shutter must remain closed until the Light Source power is turned off.

Please examine instrument prior to use for functionality and damage. Dispose of at end of life In accordance with national regulations and approved hospital practices for surgical instrumentation disposal.

Warning:

- 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. The Reusable Light cable (48758451 or 48252005) is designed to only be used with TSI Light Source (48252106).
- 4. The light source shutter must remain closed until the Reusable Light Cable is inserted into the retractor blades.
- 5. Place the light source away from items that are flammable.
- 6. Do not place the Reusable Light Cable that is connected to the light source on drapes, sponges, or anything else that is flammable.
- 7. Do not allow the Reusable Light Cable that is connected to the light source to hang over the side of the sterile field if the light source is on.
- 8. TSI Reusable Light Cable and Light Source are for use only with the ARIA, Phantom, LITe Anterior Lumbar, LITe Pedicle Based Retractor and LITe Midline Retractor systems and may not be used with other manufacturer's products.
- Normal repeated use has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.
- 10. 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 can be located by means of an X-Ray.

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Neurotechnology & Spine

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Interventional Spine

Neurosurgical, Spine & ENT

Neurovascular

Spinal Implants



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