

MIS TLIF Surgical Technique

Featuring

Dimension® and Lucent XP®

An MIS Ultra® Procedural Solution



MIS Simplicity.

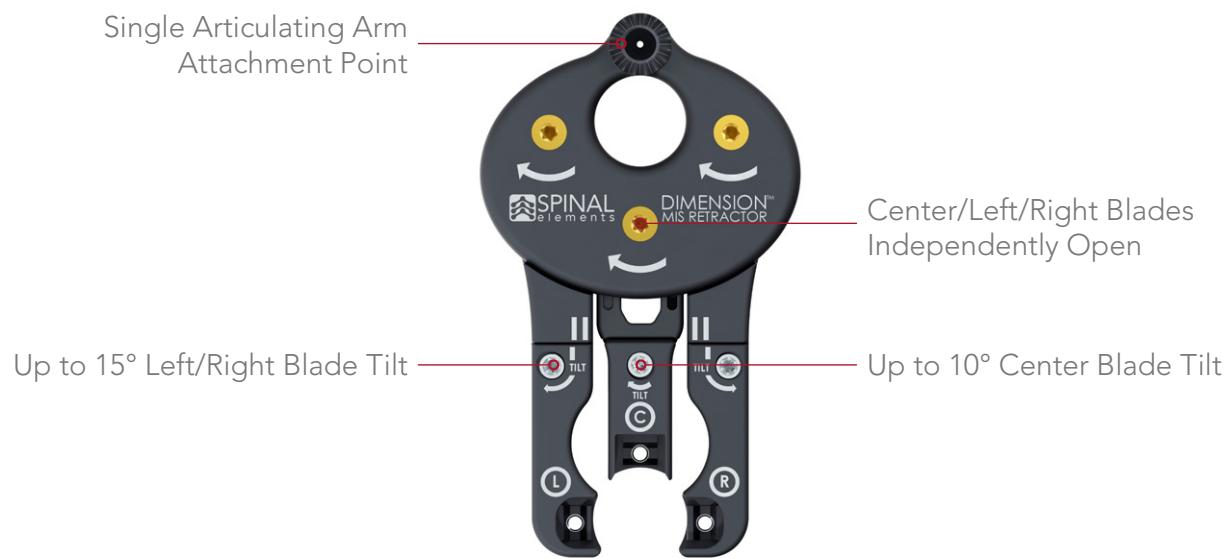


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Product Description

The Dimension MIS TLIF Retractor's 3-blade design facilitates soft tissue retraction to access the disc space utilizing a minimally invasive transforaminal approach.



Implant Overview

Lucent XP® Expandable Interbody System with Ti-Bond® Titanium Porous Coating



Lucent XP

Width	Depth	Height	Lordosis
10	24	8-12*	5-10°, 10-15°
10	27	8-12*	5-10°, 10-15°
10	32	8-12*	5-10°, 10-15°



Lucent XP Oblique

Width	Depth	Height	Oblique Lordosis
12	27	8-12*	5-10°, 10-15°
12	32	8-12*	5-10°, 10-15°



Dimensions expressed in millimeters.

*1mm increments, expansion adds 3mm

Preoperative and Intraoperative Recommendations

Preoperative Preparation

Review the surgical plan to ensure all the needed implants and instruments are available for surgery.

Note:

The Lucent® MIS TLIF Decompression and Discectomy Instruments Sets are available for use with the Dimension Retractor.

Intraoperative Preparation

Radiographs and MRIs should be available for planning and intraoperative assessment of the patient's anatomy.

The operative suite should be laid out such that it is conducive to prone positioning on a Radiolucent Table (Fig. 1).

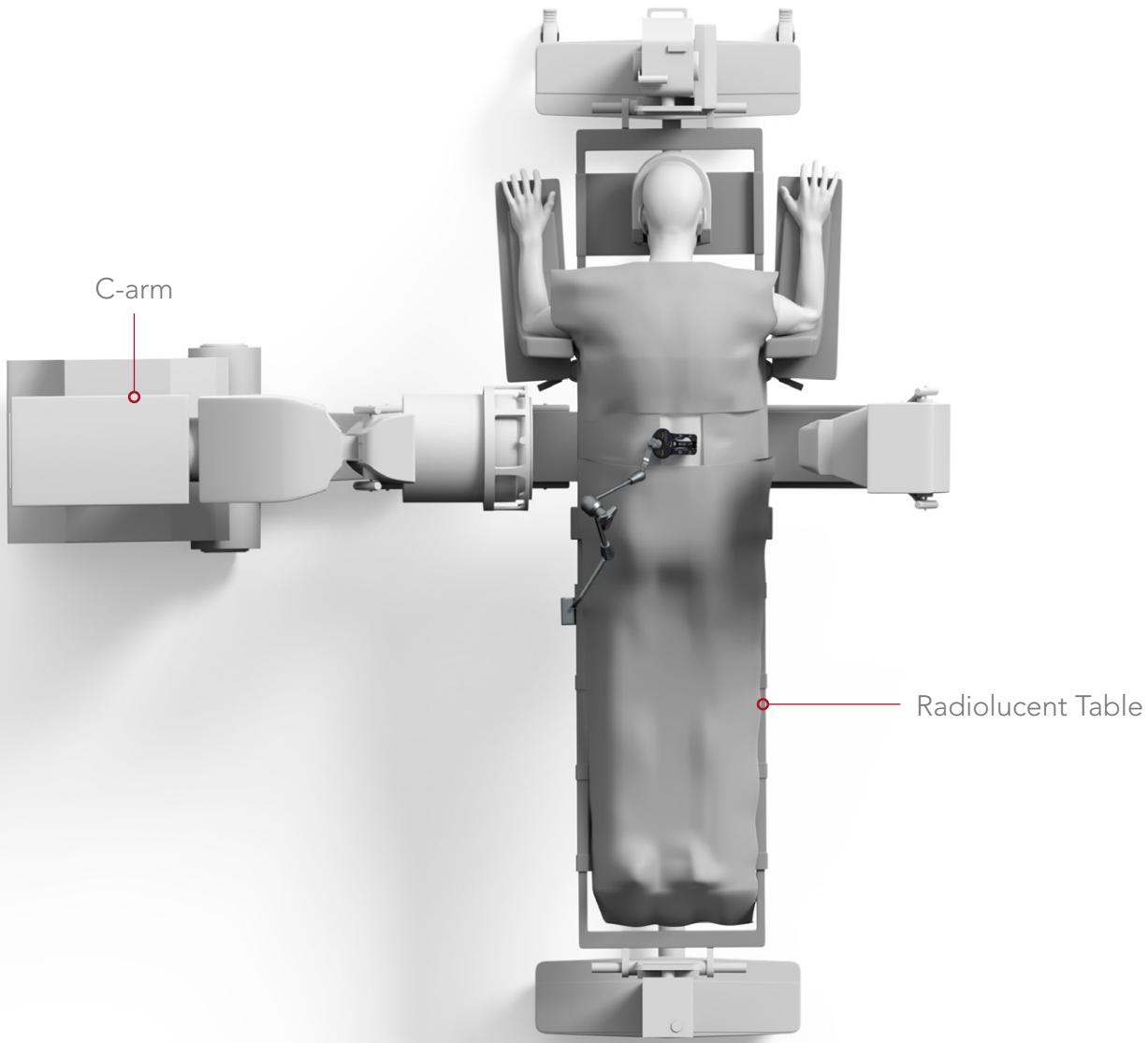


Fig. 1

Recommended Patient Preparation

Confirm that the OR table has side rails or a side rail adapter is available to attach the Radial Arm Clamp. The table should be positioned to facilitate C-arm access on the opposite side of the surgical approach (Fig. 2).

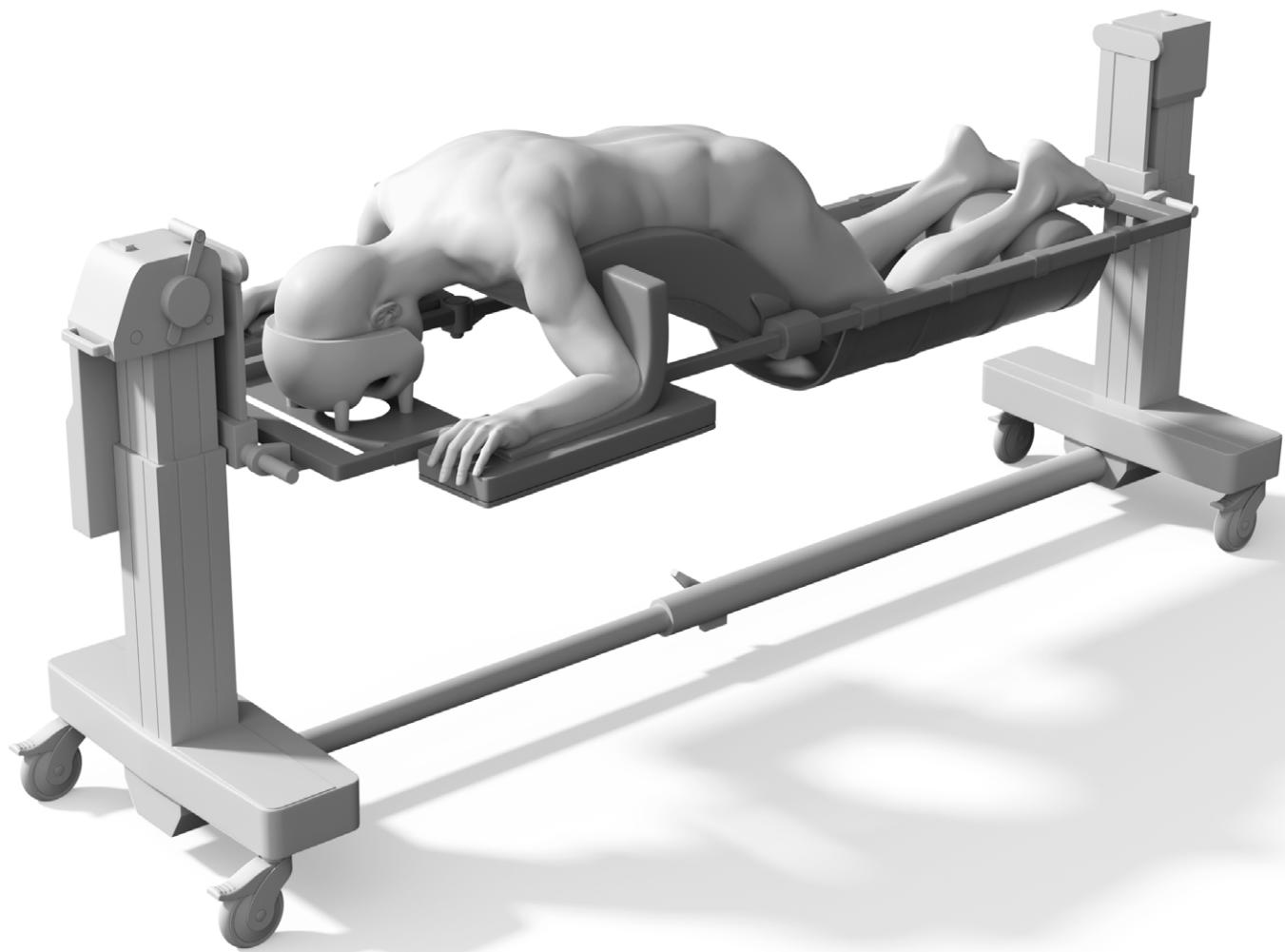


Fig. 2

Recommended Patient Positioning continued

The patient is placed in a prone position. Prep and drape the patient (Fig. 3).

Note:

Secure the Articulating Arm Table Clamp to the Universal Side Rail Adapter before draping. The Articulating Table Arm may be attached to the Table Clamp following patient draping.

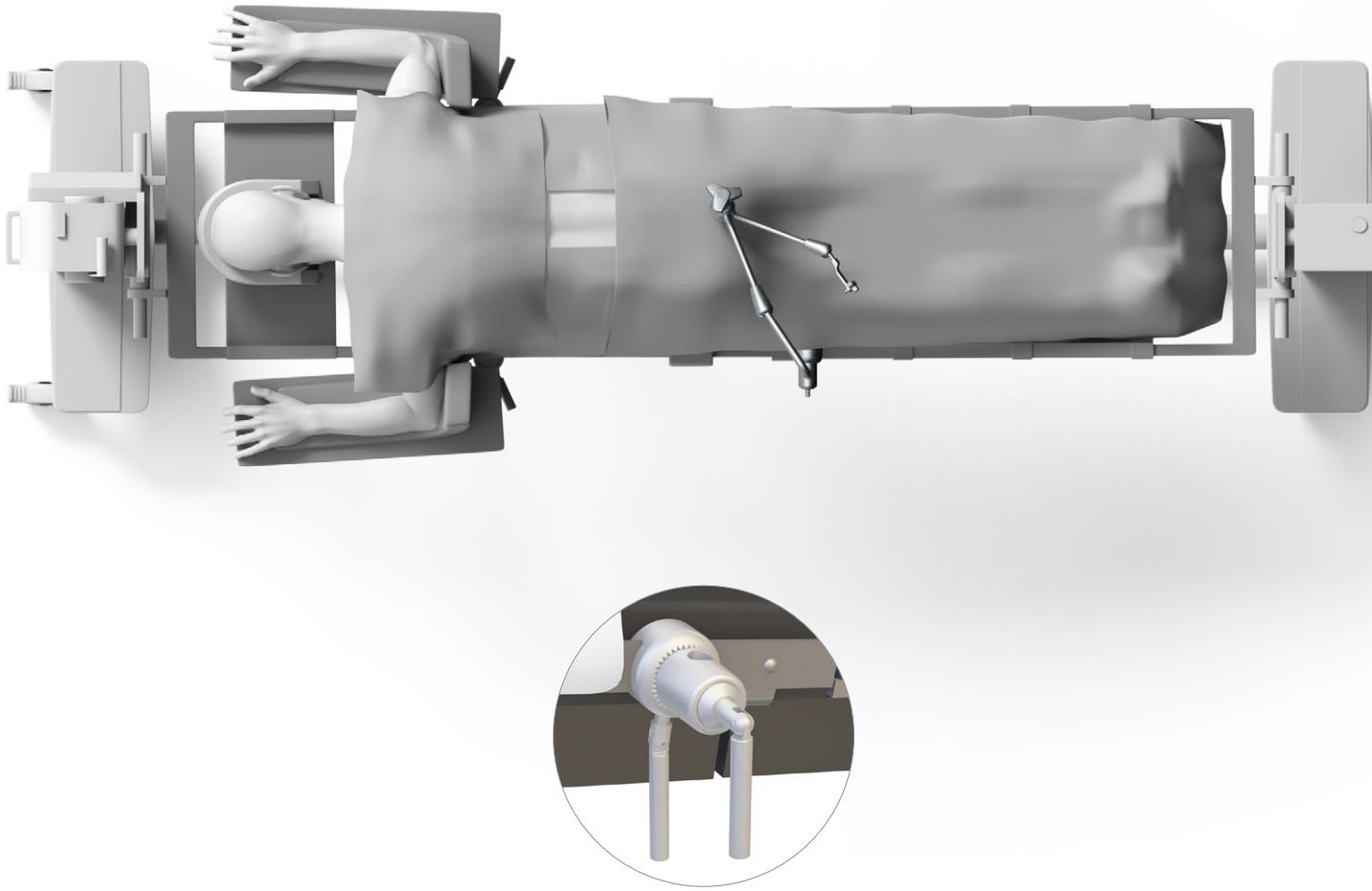


Fig. 3

Step 1: Incision and Dilation

Use fluoroscopy or anatomical landmarks to verify the location of the levels to be accessed.

Make a 2cm longitudinal incision, approximately 4cm to 5cm from the midline at the level being fused (Fig. 4).

Using finger dissection, advance through the fascia and surrounding tissue until the facet joint is reached. Use the First Dilator or a blunt instrument to identify the facet. Confirm the location under lateral fluoroscopy (Fig. 5).

Place the First Dilator through the incision site, dock and palpate the facet joint. Sequentially place the Second Dilator (18mm or 22mm) over the First Dilator. Confirm the position of the dilators with lateral fluoroscopy (Fig. 6).

Note:

With the First Dilator fully advanced and docked on the facet, the blade length can be estimated by noting the depth marked at the skin.

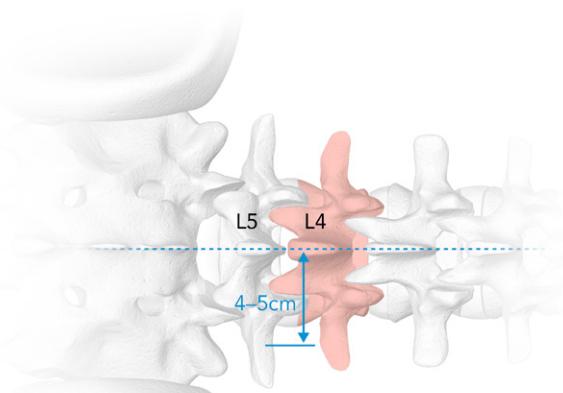


Fig. 4

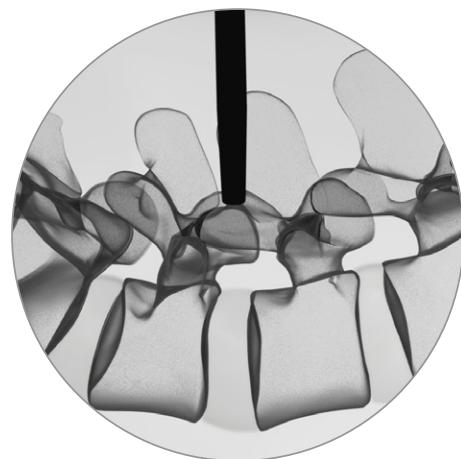


Fig. 5



Fig. 6

Step 2: Retractor Assembly

Select the appropriate blade length for the Retractor based on the skin depth marking on the First Dilator (Fig. 7). Place each blade into the blade slots at the top of the Retractor body.

Secure the blades to the Retractor body by tightening the black screws (Fig. 8) using the T25 Retractor Tool or Retractor Knobs (Fig. 9).

Note:

The blades are etched with C, L or R letters for Center, Left and Right orientation. These markings should match the C, L or R etchings on the Retractor arms.

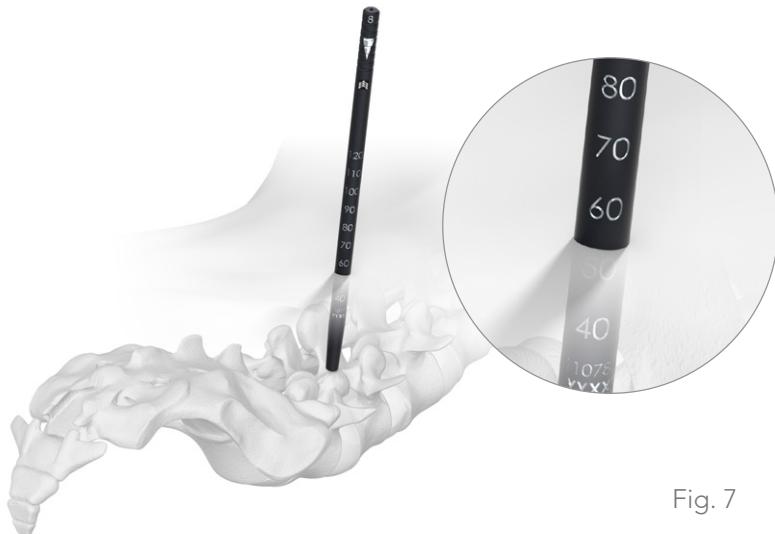


Fig. 7



Fig. 8



Fig. 9

Step 3: Retractor Insertion

Position the assembled Dimension Retractor over the Dilators and advance to the surface of the facet joint (Fig. 10). Using lateral fluoroscopy, confirm the Medial Blade tantalum markers are centered over the disc space and the Retractor Blades are in contact with the facet (Fig. 11).



Fig. 10

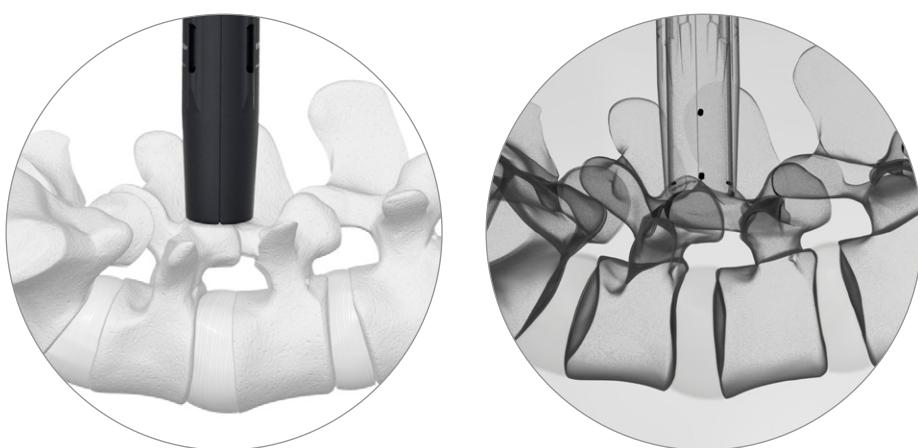


Fig. 11

Step 4: Retractor Arm Attachment

Attach the Retractor to the Surgical Arm Mount by inserting the male portion of the mount into the mounting point of the Retractor. With slight downward pressure, turn the Arm Mount Knob clockwise to tighten (Fig. 12).

Note:

Tantalum markers in the Center Blade provide fluoroscopic visualization of Retractor placement (Fig 13).



Fig. 12

Fig. 13

Tip:

Preliminary tightening of Arm Mount Knob facilitates Retractor adjustments that may be needed after positioning is confirmed with fluoroscopy.

Step 5: Retraction and Exposure

Open the Retractor arms by turning the gold screws clockwise in the direction of the arrows (Fig. 14).

Note:

The Medial Retractor Blade translates 10mm. The Right and Left Blades translate 12mm each. If it is not possible to expand the Retractor, make sure the skin and fascia cut is large enough to facilitate expansion. If not, enlargement may be necessary.



Fig. 14

Step 5: Retractor Arm Attachment continued

To increase exposure, toe the blades to the preferred degree of angulation by turning the silver screws in the direction indicated (Fig. 15). The Left and Right Blades tilt up to 15° (Fig. 16) and the Center Blade tilts up to 10° (Fig. 17).

Note:

Over angulation of the retractor blades may cause soft tissue encroachment.



Fig. 15



Fig. 16



Fig. 17

Step 6: Light Cable

Align the Light Cable tips with the inner channel of the Center, Left or Right Retractor Blades.

Advance the Light Cable tips until they reach the bottom of the blade channel (Fig. 18). Position the Light Cable away from the Retractor so it does not interfere with visualization. Connect the Light Cable to an Adapter and light source.

Note:

Light source cable and adapters are included in the Dimension Retractor Tray.



Fig. 18

Step 7: Decompression and Discectomy

Identify key anatomy including the facet joint, pars interarticularis and the lamina. A facetectomy is completed using an osteotome or high-speed burr and additional instruments such as pituitary rongeurs, kerrisons, and curettes (Fig. 19).

Note:

The Right and Left Retractor Blades feature a scallop geometry to facilitate the use of surgical instruments through a minimally invasive corridor (Fig. 20).

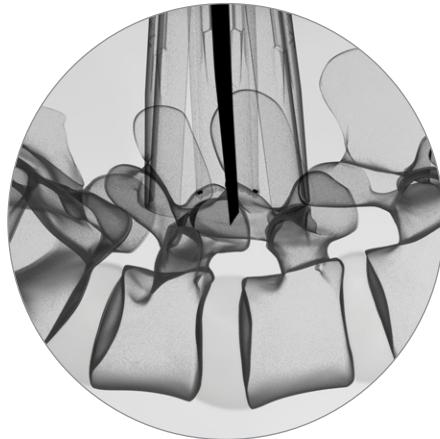


Fig. 19



Fig. 20

Step 8: Discectomy and Implant Sizing

Perform an annulotomy and use a series of pituitaries/kerrisons and curettes for a discectomy. Remove cartilaginous endplates with a series of paddle shavers and rasps. Roughen the endplates to achieve bleeding bone to aid in fusion.

Paddle Shavers, Straight Trials or Curved Trials are used to determine the size of the interbody spacer (Fig. 21 and 22).

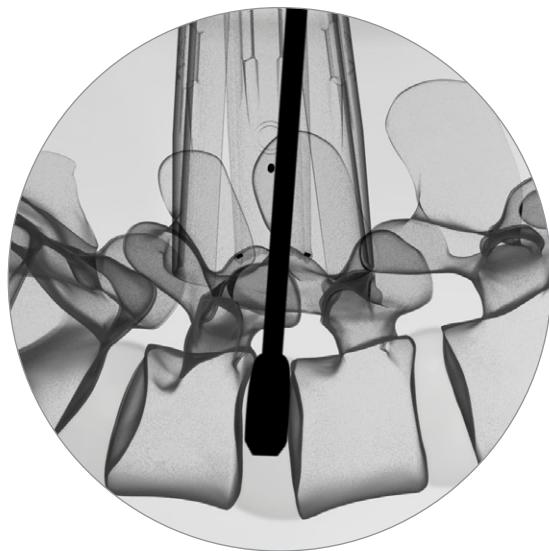


Fig. 21

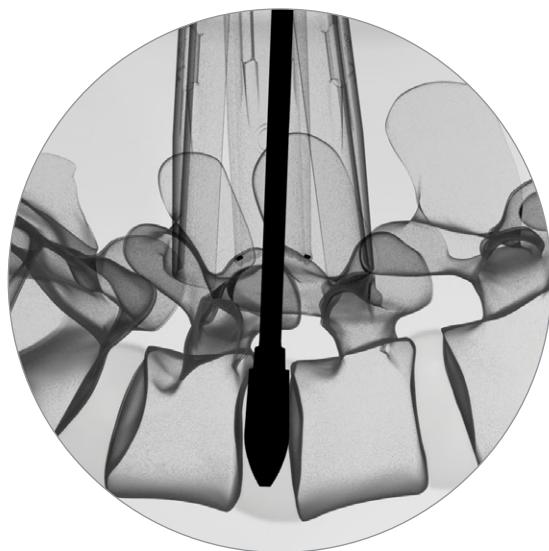


Fig. 22

Step 9: Lucent XP® Implant Preparation and Insertion

Before loading the implant onto the Inserter, open the Inserter tangs by turning the knob on the shaft counterclockwise (Fig. 23).

Align the Inserter tangs with the implant as illustrated. The black tang should align with the side of the implant identified with a black line (Fig. 24 and 25).

Note:

If Lucent XP Oblique is being used (as illustrated below), medial markings are positioned on the Inserter and implant to correspond with directional positioning (angulation) of the implant.



Fig. 23



Fig. 24



Fig. 25

Lucent XP® Implant Preparation and Insertion continued

Pack the implant with autograft or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. Telegraft® may be used to pre-pack and post-pack the disc space.

Snap the implant into place and secure it by turning the Inserter knob clockwise (Fig. 26).

Insert the implant into the disc space by gently impacting the backside of the inserter with a mallet. Confirm implant position, depth and endplate contact with direct visualization and fluoroscopy (Fig. 27).

Note:

Tantalum markers are located 1mm from the distal end and 2.5mm from the proximal end of the implant.



Fig. 26



Fig. 27

Step 10: Lucent XP® Implant Expansion

Insert the Expansion Driver Shaft through the Inserter Shaft.

To confirm the Expansion Driver is properly seated and has full engagement with the implant, the black circumferential line on the Expansion Driver Shaft should be flush with the back end of the Inserter Shaft (Fig. 28).



Fig. 28

Step 10: Lucent XP® Implant Expansion continued

Expansion is achieved by turning the Expansion Driver clockwise.

The black line on the barrel of the Expansion Driver can be referenced as a guide to count the number of rotations during expansion. Each full rotation of the Expansion Driver expands the implant by approximately 1mm.

The Expansion Driver will torque out at 15 in-lbs when the implant is fully expanded, or when maximum distraction force has been achieved (Fig. 29).

Confirm final placement and expansion of the implant with A/P and lateral fluoroscopy before removing the Expansion Driver and Inserter.



Fig. 29

Step 11: Lucent XP® Inserter Removal

Remove the Expansion Driver from the Inserter. Loosen the knob of the Inserter in a counterclockwise direction, carefully disengaging it from the implant (Fig. 30).



Fig. 30

Step 12: Retractor Removal

Place the Retractor Tool in the silver screws and rotate to collapse angulation of the blades. Place the Retractor Tool in the gold screws to close the arms of the Retractor (Fig. 31).

Loosen the Articulating Arm Knob and disconnect the arm from the Retractor by loosening the thumbscrew. Carefully remove the Retractor.

Follow standard wound closure technique.



Fig. 31

Dimension System Components

Dimension MIS TLIF Retractor

Part Number	Part Description
11074-000	TLIF Retractor Body
11077-840	Center Blade, 18mm x 40mm
11077-850	Center Blade, 18mm x 50mm
11077-860	Center Blade, 18mm x 60mm
11077-870	Center Blade, 18mm x 70mm
11077-880	Center Blade, 18mm x 80mm
11077-890	Center Blade, 18mm x 90mm
11077-800	Center Blade, 18mm x 100mm
11077-810	Center Blade, 18mm x 110mm
11077-820	Center Blade, 18mm x 120mm
11076-840	Left Blade, 18mm x 40mm
11076-850	Left Blade, 18mm x 50mm
11076-860	Left Blade, 18mm x 60mm
11076-870	Left Blade, 18mm x 70mm
11076-880	Left Blade, 18mm x 80mm
11076-890	Left Blade, 18mm x 90mm
11076-800	Left Blade, 18mm x 100mm
11076-810	Left Blade, 18mm x 110mm
11076-820	Left Blade, 18mm x 120mm
11075-840	Right Blade, 18mm x 40mm
11075-850	Right Blade 18mm x 50mm
11075-860	Right Blade, 18mm x 60mm
11075-870	Right Blade, 18mm x 70mm
11075-880	Right Blade, 18mm x 80mm
11075-890	Right Blade, 18mm x 90mm
11075-800	Right Blade, 18mm x 100mm
11075-810	Right Blade, 18mm x 110mm
11075-820	Right Blade, 18mm x 120mm

Dimension MIS TLIF Retractor

Part Number	Part Description
11077-240	Center Blade, 22mm x 40mm
11077-250	Center Blade, 22mm x 50mm
11077-260	Center Blade, 22mm x 60mm
11077-270	Center Blade, 22mm x 70mm
11077-280	Center Blade, 22mm x 80mm
11077-290	Center Blade, 22mm x 90mm
11077-200	Center Blade, 22mm x 100mm
11077-210	Center Blade, 22mm x 110mm
11077-220	Center Blade, 22mm x 120mm
11076-240	Left Blade, 22mm x 40mm
11076-250	Left Blade, 22mm x 50mm
11076-260	Left Blade, 22mm x 60mm
11076-270	Left Blade, 22mm x 70mm
11076-280	Left Blade, 22mm x 80mm
11076-290	Left Blade, 22mm x 90mm
11076-200	Left Blade, 22mm x 100mm
11076-210	Left Blade, 22mm x 110mm
11076-220	Left Blade, 22mm x 120mm
11075-240	Right Blade, 22mm x 40mm
11075-250	Right Blade, 22mm x 50mm
11075-260	Right Blade, 22mm x 60mm
11075-270	Right Blade, 22mm x 70mm
11075-280	Right Blade, 22mm x 80mm
11075-290	Right Blade, 22mm x 90mm
11075-200	Right Blade, 22mm x 100mm
11075-210	Right Blade, 22mm x 110mm
11075-220	Right Blade, 22mm x 120mm

Dimension System Components continued

Dimension MIS TLIF Retractor

Part Number	Part Description
11078-008	First Dilator
11078-018	Second Dilator, 18mm
11078-022	Second Dilator, 22mm
11079-000	T-Handle Driver
11179-000	Retractor Tool
11174-000	Knobs
11173-000	Light Cable, Reusable Cable
80301-000	Adapters - ACMI
80302-000	Adapters - Olympus
80303-000	Adapters - Storz
80304-000	Adapters - Wolf

Single-Use Items

Part Number	Part Description
11172-000	Light Cable, Illuminator

Articulating Arm Tray

Part Number	Part Description
11064-000	Lucent Surgical Arm Knob
80501-000	Surgical Arm Radial Clamp
80503-001	Surgical Arm Assembly

Lucent® MIS TLIF Instruments

Lucent MIS Decompression

Part Number	Part Description
11045-200	MIS Pituitary, 2mm Straight
11045-201	MIS Pituitary, 2mm Up
11045-400	MIS Pituitary, 4mm Straight
11045-401	MIS Pituitary, 4mm Up
11047-240	MIS Kerrison, 2mm
11047-440	MIS Kerrison, 4mm
11047-640	MIS Kerrison, 6mm
11047-840	MIS Kerrison, 8mm
11031-000	MIS Woodson Elevator
11033-000	MIS Ball Probe
11035-000	MIS Penfield Push
11037-000	MIS Penfield Pull
11039-000	MIS Nerve Hook
11044-000	MIS Scalpel Handle
11042-000	MIS Nerve Retractor
11052-000	MIS Curved Chisel
11053-000	MIS Straight Chisel
11041-000	MIS Straight Curette, 3mm
11046-000	MIS Up Angled Curette, 3mm

Lucent MIS Discectomy

Part Number	Part Description
11043-000	MIS Straight Curette, 5mm
11048-000	MIS Up Angled Curette, 5mm
11034-000	MIS Back Angled Curette, 5mm
11038-000	MIS Right Angled Curette, 5mm
11036-000	MIS Left Angled Curette, 5mm
11040-000	MIS Ring Curette
11115-000	MIS Curved Rasp
11116-000	MIS Straight Rasp
11045-800	MIS Pituitary, 8mm Straight
11045-801	MIS Pituitary, 8mm Up
11059-005	5mm Paddle Scraper
11059-006	6mm Paddle Scraper
11059-007	7mm Paddle Scraper
11059-008	8mm Paddle Scraper
11059-009	9mm Paddle Scraper
11059-010	10mm Paddle Scraper
11059-011	11mm Paddle Scraper
11059-012	12mm Paddle Scraper
11059-013	13mm Paddle Scraper
11059-014	14mm Paddle Scraper

Lucent® MIS TLIF Instruments continued

Implants and Inserters

Part Number	Part Description
10091-000	Hudson Handle
11004-507	Straight Trial, 7mm
11004-508	Straight Trial, 8mm
11004-509	Straight Trial, 9mm
11004-510	Straight Trial, 10mm
11004-511	Straight Trial, 11mm
11004-512	Straight Trial, 12mm
11004-513	Straight Trial, 13mm
11004-514	Straight Trial, 14mm
11023-507	Curved Trial, 12 x 27 x 7mm
11023-508	Curved Trial, 12 x 27 x 8mm
11023-509	Curved Trial, 12 x 27 x 9mm
11023-510	Curved Trial, 12 x 27 x 10mm
11023-511	Curved Trial, 12 x 27 x 11mm
11023-512	Curved Trial, 12 x 27 x 12mm
11023-513	Curved Trial, 12 x 27 x 13mm
11023-514	Curved Trial, 12 x 27 x 14mm
11017-000	8mm Offset Inserter
11018-000	Offset Inserter Wrench
11019-000	10mm Offset Inserter
11125-000	MIS Curved Tamp
11120-000	MIS Straight Tamp

Lucent XP® Oblique Expandable Interbody System

Lucent XP Oblique Instrument Tray

Part Number	Part Description
11341-003	Lucent XP 12mm Offset Inserter
11341-103	Lucent XP 12mm Inserter Shaft
11343-000	Lucent XP Expansion Driver
11347-507	XP Wide Trial, 12mm x 7mm
11347-508	XP Wide Trial, 12mm x 8mm
11347-509	XP Wide Trial, 12mm x 9mm
11347-510	XP Wide Trial, 12mm x 10mm
11347-511	XP Wide Trial, 12mm x 11mm
11347-512	XP Wide Trial, 12mm x 12mm

Lucent XP Oblique Caddy 12mm x 27mm, 5-10°

Part Number	Part Description
P11311-508	12mm x 27mm x 8mm, 5-10° Cage
P11311-509	12mm x 27mm x 9mm, 5-10° Cage
P11311-510	12mm x 27mm x 10mm, 5-10° Cage
P11311-511	12mm x 27mm x 11mm, 5-10° Cage
P11311-512	12mm x 27mm x 12mm, 5-10° Cage

Lucent XP Oblique Caddy 12mm x 27mm, 10-15°

Part Number	Part Description
P11311-008	12mm x 27mm x 8mm, 10-15° Cage
P11311-009	12mm x 27mm x 9mm, 10-15° Cage
P11311-010	12mm x 27mm x 10mm, 10-15° Cage
P11311-011	12mm x 27mm x 11mm, 10-15° Cage
P11311-012	12mm x 27mm x 12mm, 10-15° Cage

Lucent XP Oblique Caddy 12mm x 32mm, 5-10°

Part Number	Part Description
P11312-508	12mm x 32mm x 8mm, 5-10° Cage
P11312-509	12mm x 32mm x 9mm, 5-10° Cage
P11312-510	12mm x 32mm x 10mm, 5-10° Cage
P11312-511	12mm x 32mm x 11mm, 5-10° Cage
P11312-512	12mm x 32mm x 12mm, 5-10° Cage

Lucent XP Oblique Caddy 10mm x 32mm, 10-15°

Part Number	Part Description
P11312-008	12mm x 32mm x 8mm, 10-15° Cage
P11312-009	12mm x 32mm x 9mm, 10-15° Cage
P11312-010	12mm x 32mm x 10mm, 10-15° Cage
P11312-011	12mm x 32mm x 11mm, 10-15° Cage
P11312-012	12mm x 32mm x 12mm, 10-15° Cage

Lucent XP® Expandable Interbody System

Lucent XP Instrument Tray

Part Number	Part Description
11341-002	Lucent XP 10mm Offset Inserter
11341-102	Lucent XP 10mm Inserter Shaft
11343-000	Expansion Driver

Lucent XP Caddy 10mm x 27mm, 5-10°

Part Number	Part Description
P11351-508	10mm x 27mm x 8mm, 5-10° Cage
P11351-509	10mm x 27mm x 9mm, 5-10° Cage
P11351-510	10mm x 27mm x 10mm, 5-10° Cage
P11351-511	10mm x 27mm x 11mm, 5-10° Cage
P11351-512	10mm x 27mm x 12mm, 5-10° Cage

Lucent XP Caddy 10mm x 27mm, 10-15°

Part Number	Part Description
P11351-008	10mm x 27mm x 8mm, 10-15° Cage
P11351-009	10mm x 27mm x 9mm, 10-15° Cage
P11351-010	10mm x 27mm x 10mm, 10-15° Cage
P11351-011	10mm x 27mm x 11mm, 10-15° Cage
P11351-012	10mm x 27mm x 12mm, 10-15° Cage

Lucent XP Caddy 10mm x 32mm, 5-10°

Part Number	Part Description
P11352-508	10mm x 32mm x 8mm, 5-10° Cage
P11352-509	10mm x 32mm x 9mm, 5-10° Cage
P11352-510	10mm x 32mm x 10mm, 5-10° Cage
P11352-511	10mm x 32mm x 11mm, 5-10° Cage
P11352-512	10mm x 32mm x 12mm, 5-10° Cage

Lucent XP Caddy 10mm x 32mm, 10-15°

Part Number	Part Description
P11352-008	10mm x 32mm x 8mm, 10-15° Cage
P11352-009	10mm x 32mm x 9mm, 10-15° Cage
P11352-010	10mm x 32mm x 10mm, 10-15° Cage
P11352-011	10mm x 32mm x 11mm, 10-15° Cage
P11352-012	10mm x 32mm x 12mm, 10-15° Cage

Indications / Contraindications

INDICATIONS

Lucent XP® intervertebral body fusion devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

These devices are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

This device is intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this device.

CONTRAINdications

1. Patients with known or probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any patient that has had prior fusion surgery at the levels to be treated.
7. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
8. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
9. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
10. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
11. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
12. Any case not described in the indications for use.
13. Reuse or multiple use.

SEE PACKAGE INSERT/INSTRUCTIONS FOR USE FOR FULL CLEANING AND STERILIZATION INSTRUCTIONS.

FOR FULL INSTRUCTIONS, PLEASE VISIT IFU.SPINALELEMENTS.COM

MIS TLIF Surgical Technique

Featuring

Dimension® and Lucent XP®

An MIS Ultra® Procedural Solution



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