Katana®

Lateral Access System
Surgical Technique

An **MIS Ultra®** solution

Reimagine Lateral Access.

SPINAL elements®

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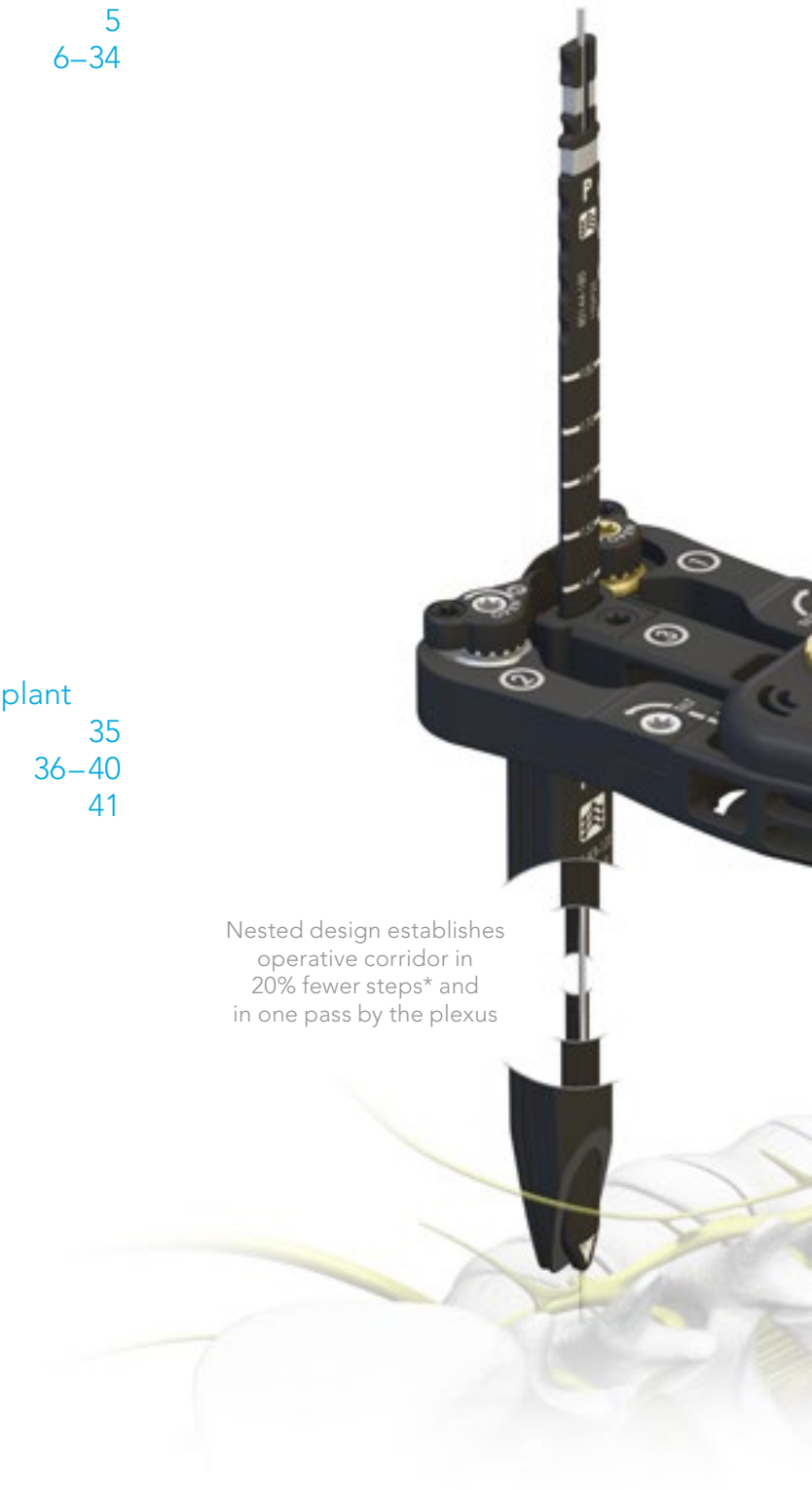


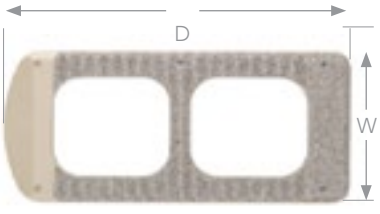
Nested design establishes operative corridor in 20% fewer steps* and in one pass by the plexus

*Compared to traditional sequential dilation systems

Product Description

Katana is a full-featured lateral access system with a novel nested Access Guide and Blade design that allows surgeons to gain lateral access in fewer steps* and with only a single pass by the plexus.

Implant Overview



Dimensions

Width	Depth	Height†	Lordosis
18	40–60‡	8–14§	6°, 12°
22	40–60‡	8–14§	6°, 12°, 18°

Dimensions expressed in millimeters.
† Measured at center of implant.
‡ 5mm increments.
§ 2mm increments.

* Compared to traditional sequential dilation systems.

Preoperative and Intraoperative Planning

Preoperative Preparation

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

Tip:

The Lucent Lateral Angled Instruments are available upon request. These instruments may better facilitate access to L4–L5 and other levels where angled instruments are desired.

Intraoperative Preparation

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

EMG neuromonitoring is required to safely navigate around the lumbar plexus during lateral spine trans-psoas procedures. The Katana Lateral Access System may be used with any commercially available neuromonitoring system with stimulated EMG capability.

The operative suite should be laid out such that it is conducive to the lateral approach procedure (Fig. 1).

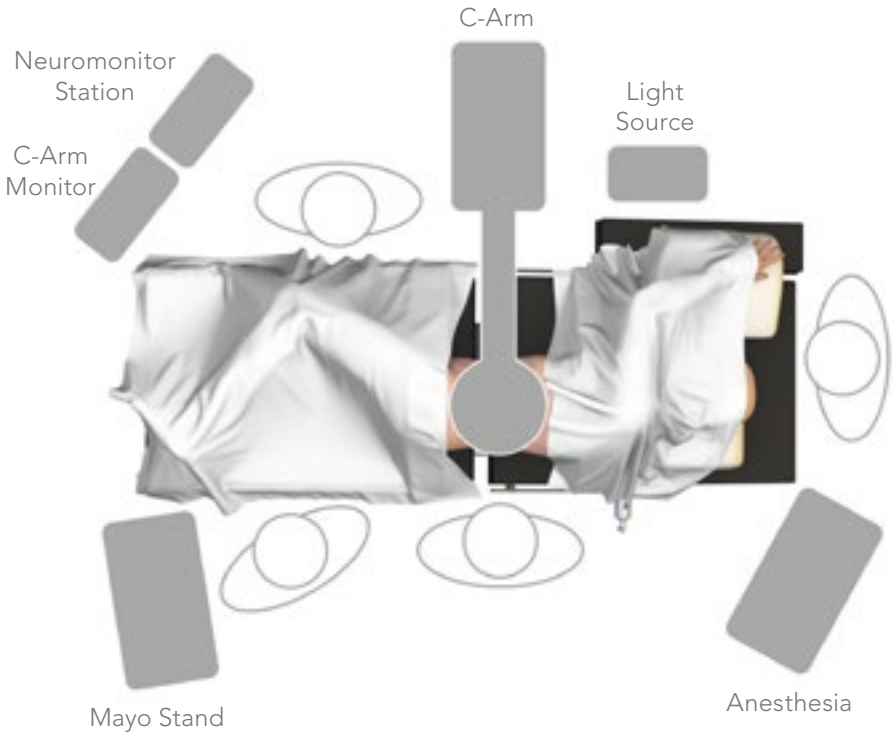


Fig. 1

Recommended Patient Preparation

When EMG neuromonitoring is used, the nurse or neurophysiologist should place the electrodes prior to patient positioning.

Confirm that a bendable, radiolucent surgical table is present and that the table has been reversed to permit C-Arm access.

The patient will be placed in a lateral decubitus position with the patient's greater trochanter sitting above the table break.

Following the patient's placement on the table, secure the patient with 3" surgical cloth tape. If the levels being accessed are in the lumbar spine, the patient should be taped at the following locations (Fig. 2):

1. Below the iliac crest.
2. Over the thoracic region.
3. From the iliac crest to the knee, taking care to pad the peroneal nerve.
4. From under the table on the ipsilateral side, to the knee, past the ankle and then to the contralateral side under the table.

Note:
Secure the Articulating Arm Table Clamp to the surgical table, based on surgeon preference, on the patient's back side near the armpit or pelvis prior to draping.

Tips:
Pressure points and bony prominences should be identified and properly padded. Use an Axillary roll under the armpit and hip bump underneath the patient's greater trochanter. Place pillows under the head, between the knees and under the upper arm. Cover sensitive areas as needed with a towel prior to taping.

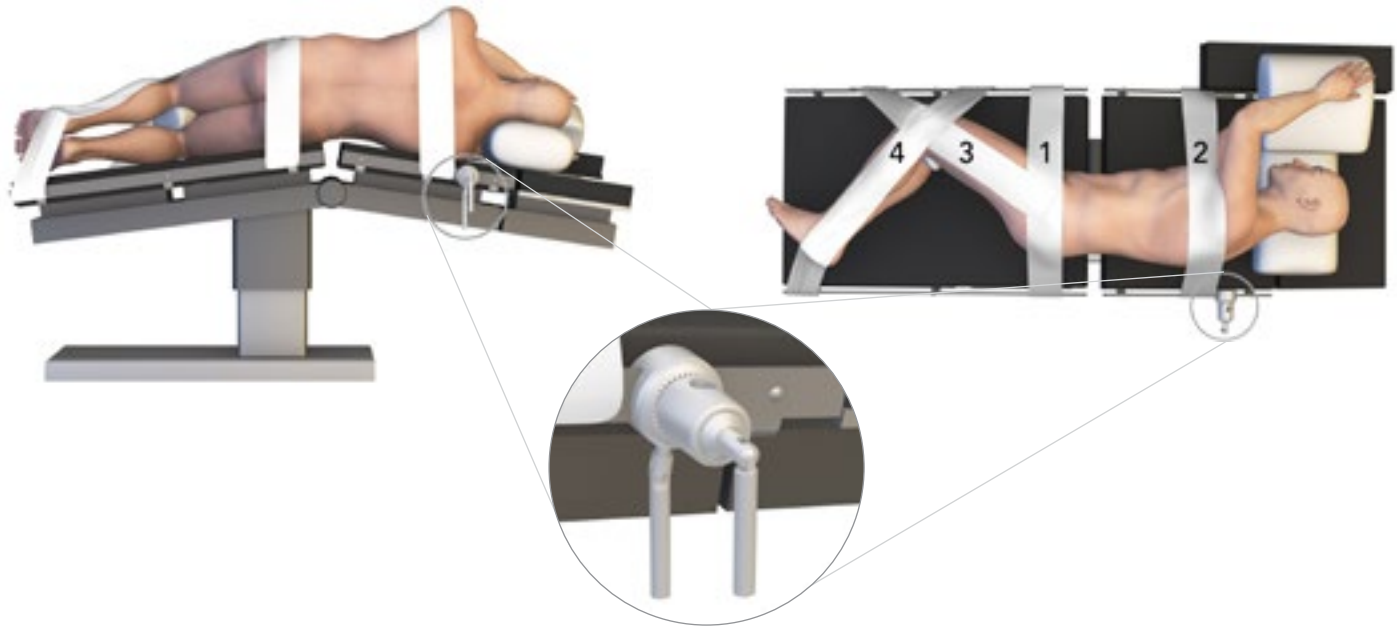


Fig. 2

Patient Positioning

Verifying Patient Position

Use fluoroscopy to verify the location of the levels to be accessed. Once the patient is properly secured, adjust the table so that the C-Arm can provide a true AP image, and a true lateral image (Fig. 3).

Note:
The C-Arm orientation should be set at 0 degrees for AP imaging and 90 degrees for lateral imaging. The C-Arm base may be rotated to obtain true AP with respect to lordosis.

Mark the level to be accessed using true lateral fluoroscopy. With a marking pen outline the disc level to be operated on the skin. The marks will serve as the location for the initial skin incision.

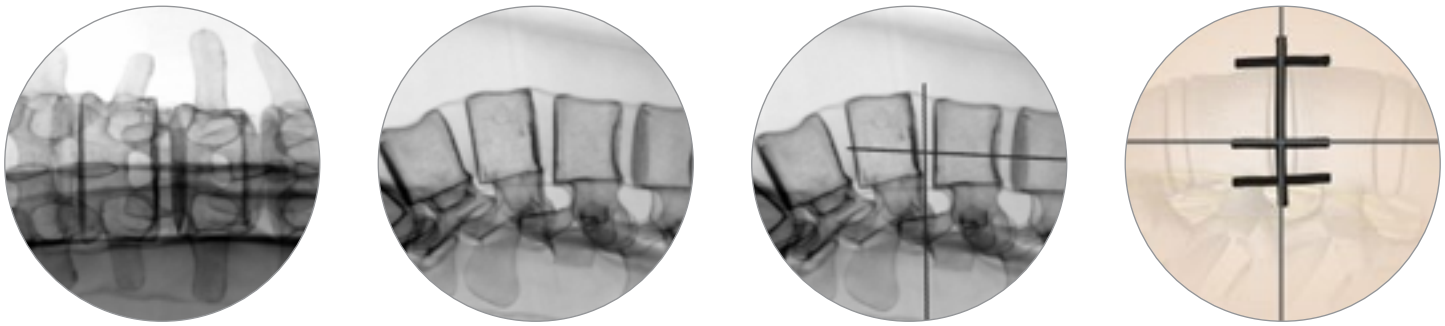


Fig. 3

Retroperitoneal Access

Surgical Approach

Using blunt dissection, separate the skin, subcutaneous fat, external oblique, internal oblique, transversus abdominis, and the transverse fascia to access the retroperitoneal space (Fig. 4).

Palpate the transverse process, iliac crest, 12th rib and psoas to confirm retroperitoneal space access. Move the peritoneum anterior (Fig. 5).

Swipe the peritoneum anterior, detaching the peritoneum from the abdominal wall (Fig. 6).

Using inserted finger to maintain peritoneum anterior, direct an Access Guide onto the psoas (Fig. 7).

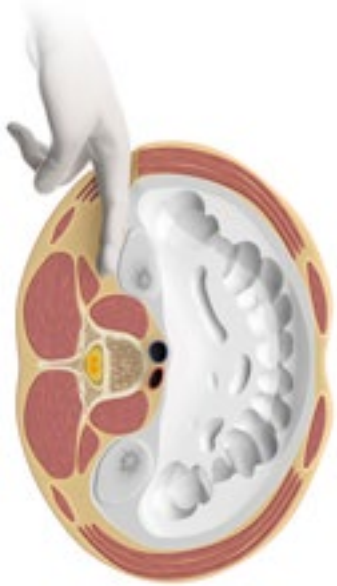


Fig. 4

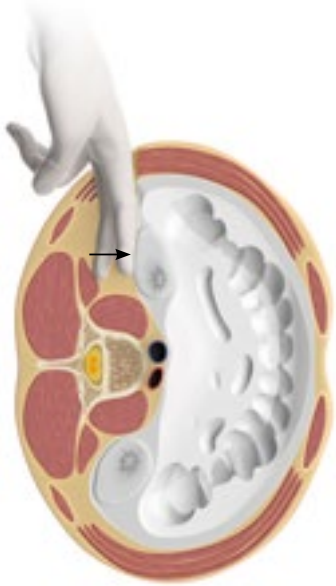


Fig. 5

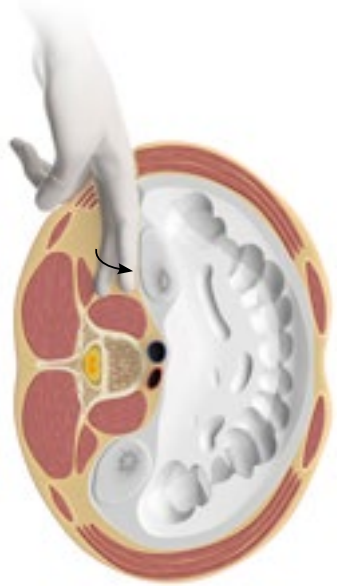


Fig.6.

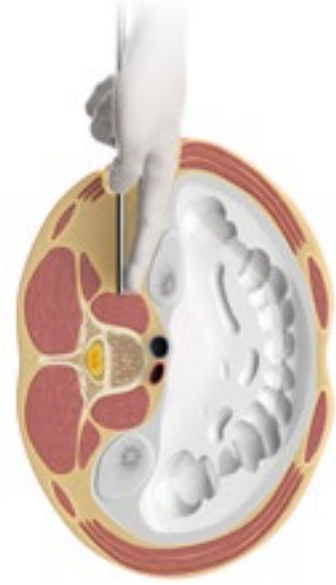


Fig. 7

Lateral Access

Carefully lead an Access Guide onto the surface of the psoas and confirm the posterior 1/3 of the disc space is targeted (Fig. 8).

Confirm Access Guide position with lateral fluoroscopy (Fig. 9).

Tip:
The Anterior/Posterior position should be in the posterior third of the disc space. The Cranial/Caudal Access Guide position should be the center of the disc space. The Katana Retractor opens anterior from this point.

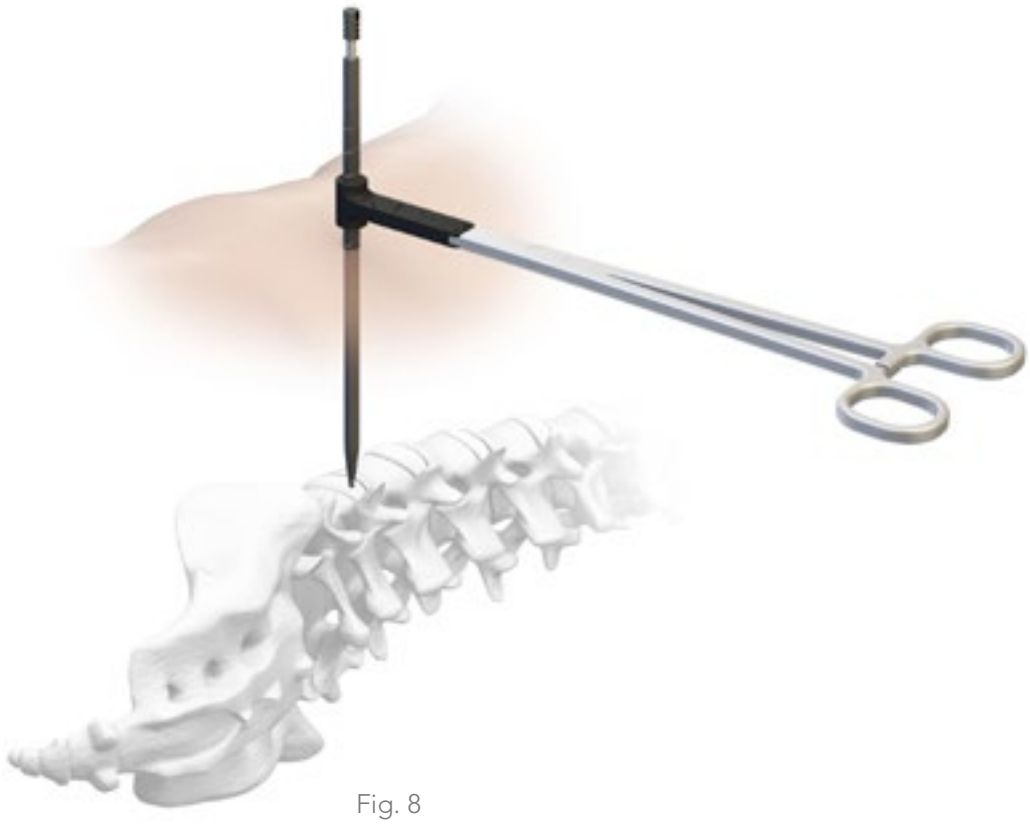


Fig. 8

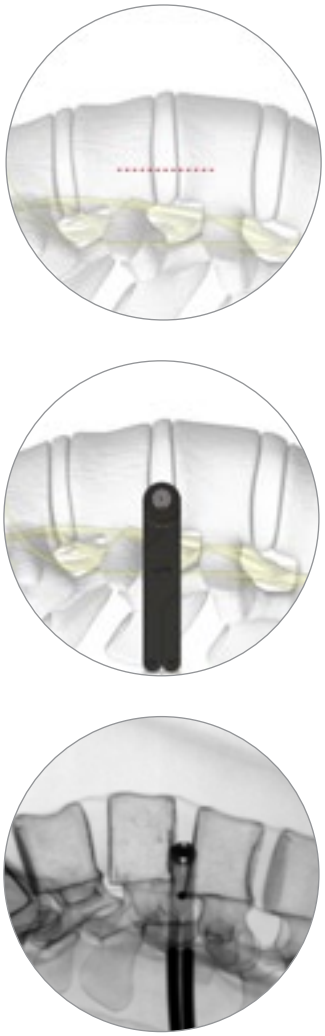


Fig. 9

Traversing the Psoas

Attach a Clip-On Lead Wire to an Access Guide and stimulate in the posterior direction while traversing the psoas.

Note:
Confirm with anesthesia and neurophysiology there is a 4-twitch response at the peripheral nerves.

Once the twitch test and stimulation direction has been confirmed, advance an Access Guide through the psoas. Use stimulated EMG to verify nerve proximity.

Stimulate in the anterior direction to verify nerve proximity with EMG.

Verify Access Guide position using AP fluoroscopy (Fig. 10).

Place a 12" K-wire through an Access Guide into the disc space. The K-wire will maintain Access Guide position as the retractor is prepared (Fig. 11).

With the Access Guide fully advanced the retractor blade length can be estimated by noting the depth marked on an acess guide at the skin.

Fig. 10

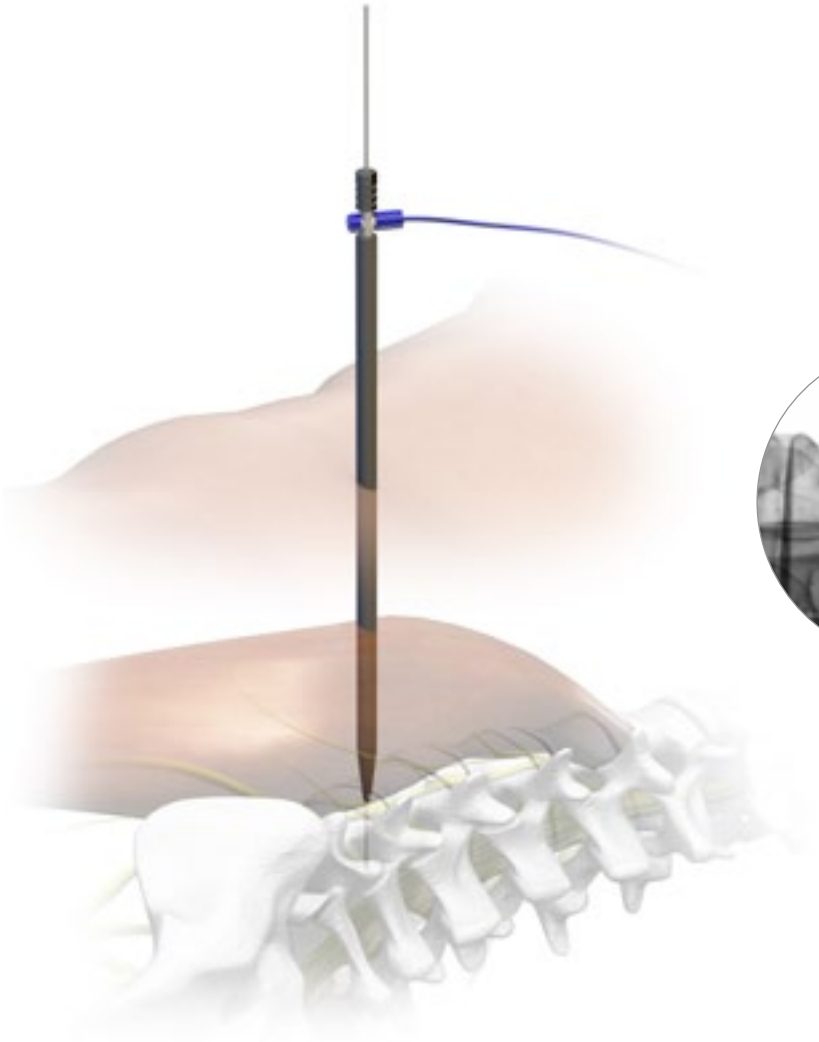


Fig. 11

Retractor Assembly

Select the appropriate blade length for the retractor based on the skin depth on the Access Guide (Fig. 12).

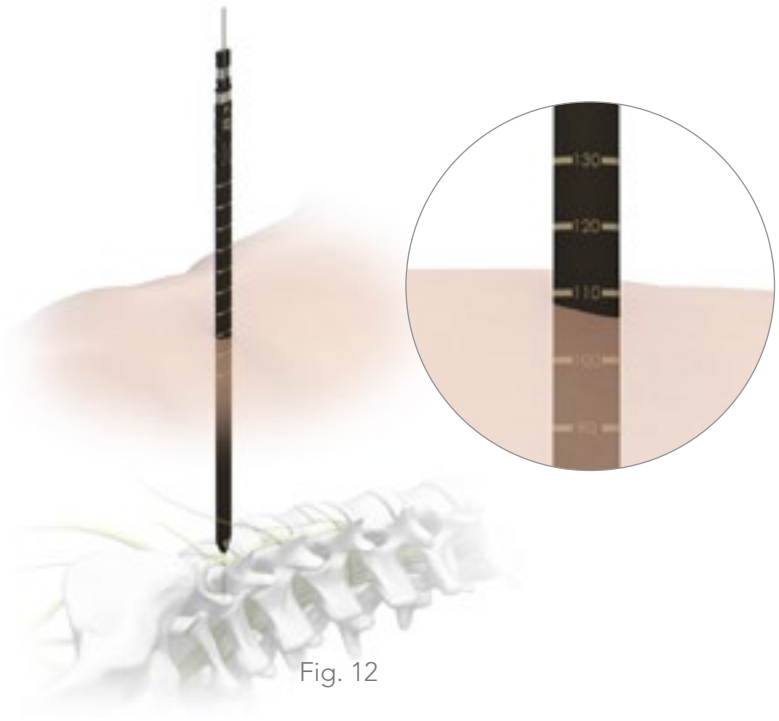


Fig. 12

Prepare the Retractor Body by rotating the Right Blade Screw past 50˚ followed by the Left Blade Screw (Fig. 13).

Fig. 13

Retractor Assembly continued

Engage Retractor Tool to Retractor Body (Fig. 14). Attach the Center Blade and tighten the Black Screw (Fig. 15).

Fig. 14

Fig. 15

Attach the Right ① and Left ② Blades and tighten the Black Screws (Fig. 16).

Fig. 16

Retractor Assembly continued

Rotate all three dials on the Retractor Tool counterclockwise (Fig. 17).

Fig. 17

Rotate the Left Blade ② to the closed position (Fig. 18).

Fig. 18

Retractor Assembly continued

Rotate the Right Blade ① to the closed position (Fig. 19).

Fig. 19

Zero blade tilt by turning both Right and Left Tilt Screws medially, adjust as necessary to line up distal tip of blades (Fig. 20).

Note:

There should be no gap between any of the blade tips. Additionally, the sides of the blades should be aligned (Fig. 21).

Fig. 20

Fig. 21

Retractor Insertion

Align the Access Guide and the Center Blade cannula of the assembled retractor. Advance the Center Blade cannula over the Access Guide (Fig. 22). Confirm the retractor is in contact with the annulus using lateral fluoroscopy. Using AP fluoroscopy confirm the retractor blades are in contact with the annulus (Fig. 23).

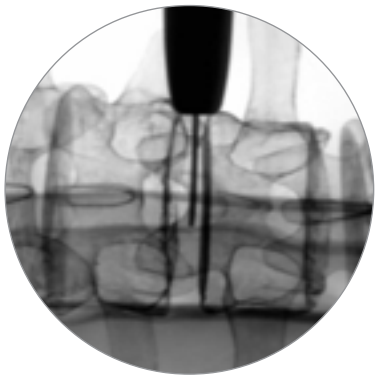


Fig. 23

Fig. 22

Retractor Arm Attachment

Attach the retractor to the Surgical Arm Mount by inserting the male portion of the mount into the gold female mounting point of the retractor. With slight downward pressure turn the Arm Mount Knob clockwise to tighten (Fig. 24).

Tighten the Articulating Arm Knob to secure retractor position.

Tip:
If additional grip on the arm mount is required final tighten with the Surgical Arm Knob.

Fig. 24

Intradiscal Shim Insertion

Align the arrows on the anterior side of the Intradiscal Shim and Shim Inserter and slide together and push lever down into the lock position (Fig. 25).

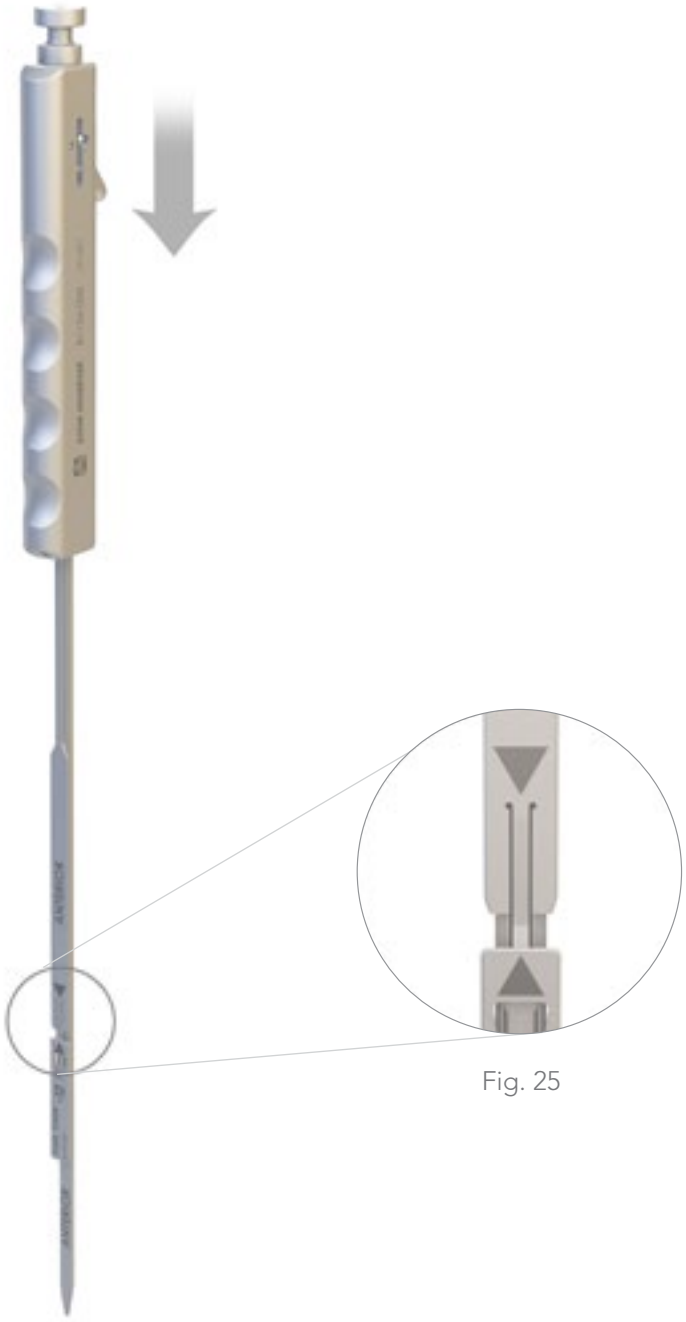


Fig. 25

Intradiscal Shim Insertion continued

Remove the Anterior half of the two-piece Access Guide (Fig. 26).

Guide the Shim between the Center Blade and the Posterior Access Guide. Insert Shim into the disc space (Fig. 27).

Note:
When fully seated, the Intradiscal Shim will be protruding 25mm past the Center Blade tip.

Fig. 26

Fig. 27

Intradiscal Shim Insertion continued

Confirm the Shim position is within the disc space with AP fluoroscopy (Fig. 28).

Detach Shim Inserter by lifting lever to the unlock position and remove from Center Blade (Fig. 29).

Keep the Access Guide and K-wire in place.

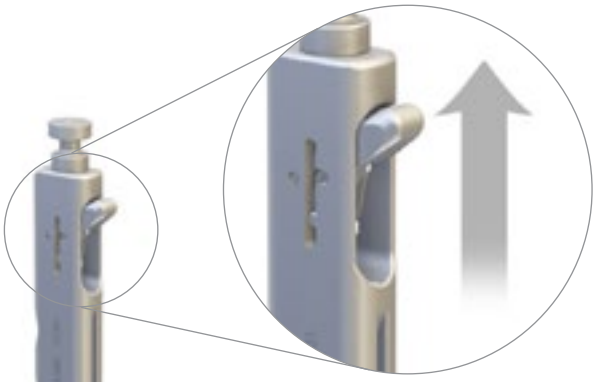


Fig. 29

Fig. 28

Retraction

With the Long Blade Tool rotate the Right Blade ① past 50° followed by the Left Blade ② (Fig. 30).

Verify retractor position over the disc space with lateral fluoroscopy (Fig. 31).

Fig. 30

Fig. 31

Retraction continued

If additional anterior retraction is desired, turn the large dial on the Retractor Tool clockwise to translate the retractor arms in the anterior direction (Fig. 32).

Fig. 32

Retraction continued

If additional superior/inferior retraction is desired, turn the middle dial on the Retractor Tool clockwise to expand the retractor blades in the superior/inferior direction (Fig. 33).

Note:
If additional posterior retraction is desired, remove the Shim and turn the small dial on the Retractor Tool clockwise to translate the Center Blade in the posterior direction.

Fig. 33

Retraction continued

The Katana Retractor offers up to 15° of blade tilt (Fig. 34).

To expand the distal opening of the Retractor Blades, turn the gold or silver Tilt Screws located on the retractor arms in the direction indicated (Fig. 35).

Fig. 34

Fig. 35

Light Cable

Remove the Posterior Access Guide, followed by the K-wire.

Align the Light Cable tips with the inner channel of the Left and Right Retractor Blades.

Note:
The Light Cable is designed to fit into the retractor blades with the "UP" laser mark facing inward (Fig. 36).

Advance the Light Cable tips until they reach the bottom of the blade channel. Bend the Light Cable away from the retractor so it does not interfere with visualization.

Tip:
The one-piece Katana Light Cables efficiently utilize light input. Set initial light source brightness to 25%, adjust to surgeon preference. To remove the Retractor Tool, press the Retractor Tool release button and remove from Retractor Body.

Fig. 36

Available Options

Verify surgical corridor is free of nerves.

Visualize and probe any tissue within and surrounding the retractor blades using a ball-tip neuromonitoring probe to verify that the working area is free of nerves (Fig. 37).

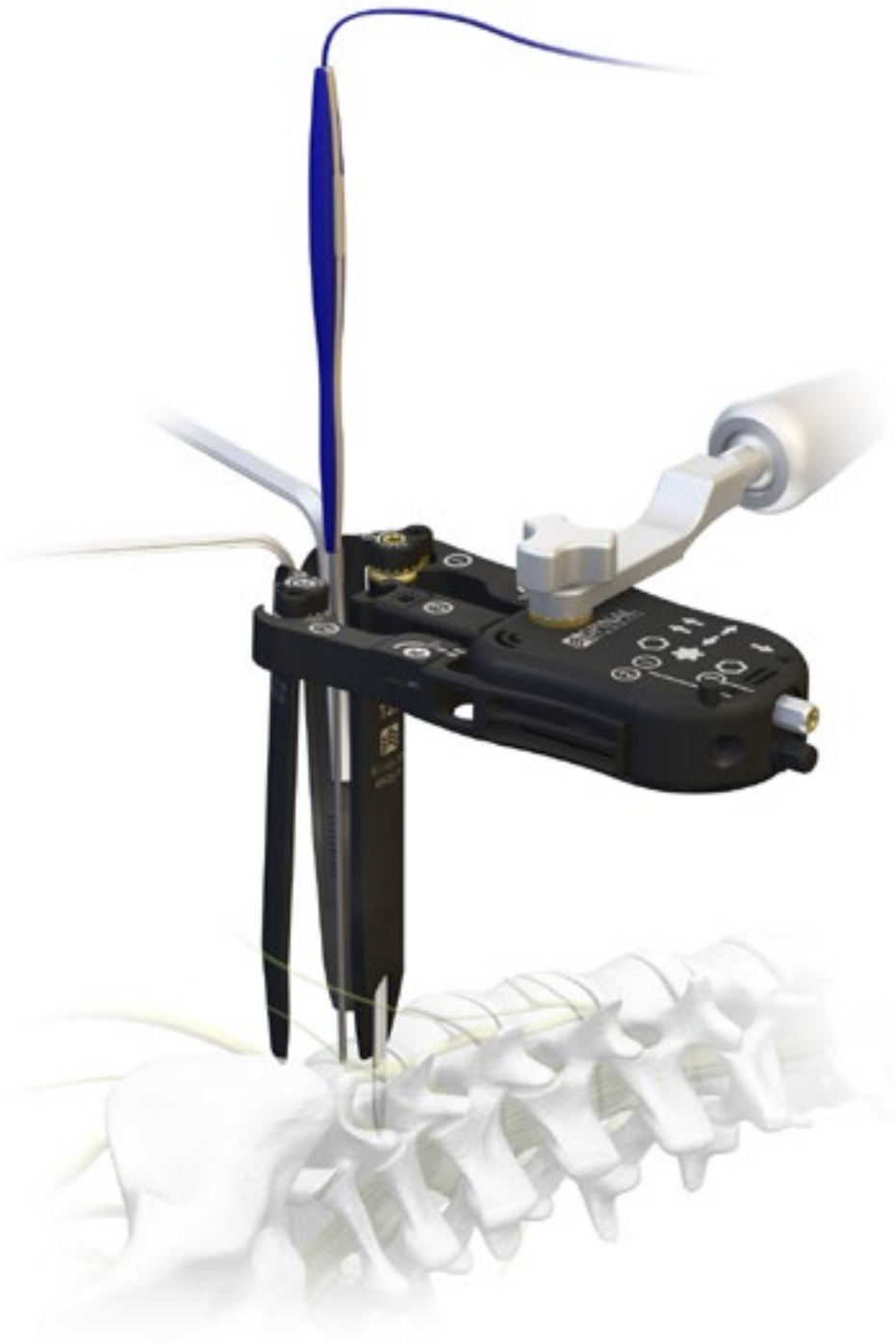


Fig. 37

Available Options continued

Optional Fourth Blade

Select the appropriate length and width of the Fourth Blade. Localize the anterior longitudinal ligament and insert a Fourth Blade as needed.

The Fourth Blade should be placed to the desired depth and securely positioned with the cross bar located to the anterior side of the retractor blades (Fig. 38).

Fig. 38

Available Options continued

Blade Extensions

A variety of Blade Extensions are available to provide additional blade length, expand the surgical corridor and provide fixation to the vertebral body.

Select the appropriate Blade Extension and attach to the Extension Inserter. Guide the Blade Extension down the appropriate blade (Fig. 39). Release the Blade Extension Inserter handle and remove. The Blade Extensions are removed with the Blade Extension Inserter.

Note:

The Blade Extensions are color coded and numbered indicating the Left (silver) and Right (gold) position. The Katana Retractor Blades are designed to allow the Blade Extensions to be inserted with the Light Cable in place.

Fig. 39

Annulotomy and Discectomy

To avoid incising the anterior longitudinal ligament (ALL), identify the anterior border of the intervertebral disc. Use this landmark to avoid incising the ALL. Use the Bayonetted Annulotomy Knife to incise the annulus. The length of the annulotomy should be approximately the same length as the implant width.

Pass a Cobb Elevator along the superior and inferior endplates and release the contralateral annulus (Fig. 40).

Additional Lucent Lateral disc prep instruments such as Pituitary Rongeurs, Kerrisons, Curettes, Stirrup Scrapers, Box Cutters, Paddle Shavers and Rasps can be used to resect the disc material and prepare the endplates for fusion.

Note:
Avoid unintentional resection of the ALL or violation of the bony endplate.

Note:
A Slap Hammer and Slap Hammer Adapters are available which may be used in conjunction with disc prep instruments.

Tip:
The Lucent Lateral Angled Instruments are available upon request. These instruments may facilitate access to L4–L5 and other levels where angled instruments are desired.

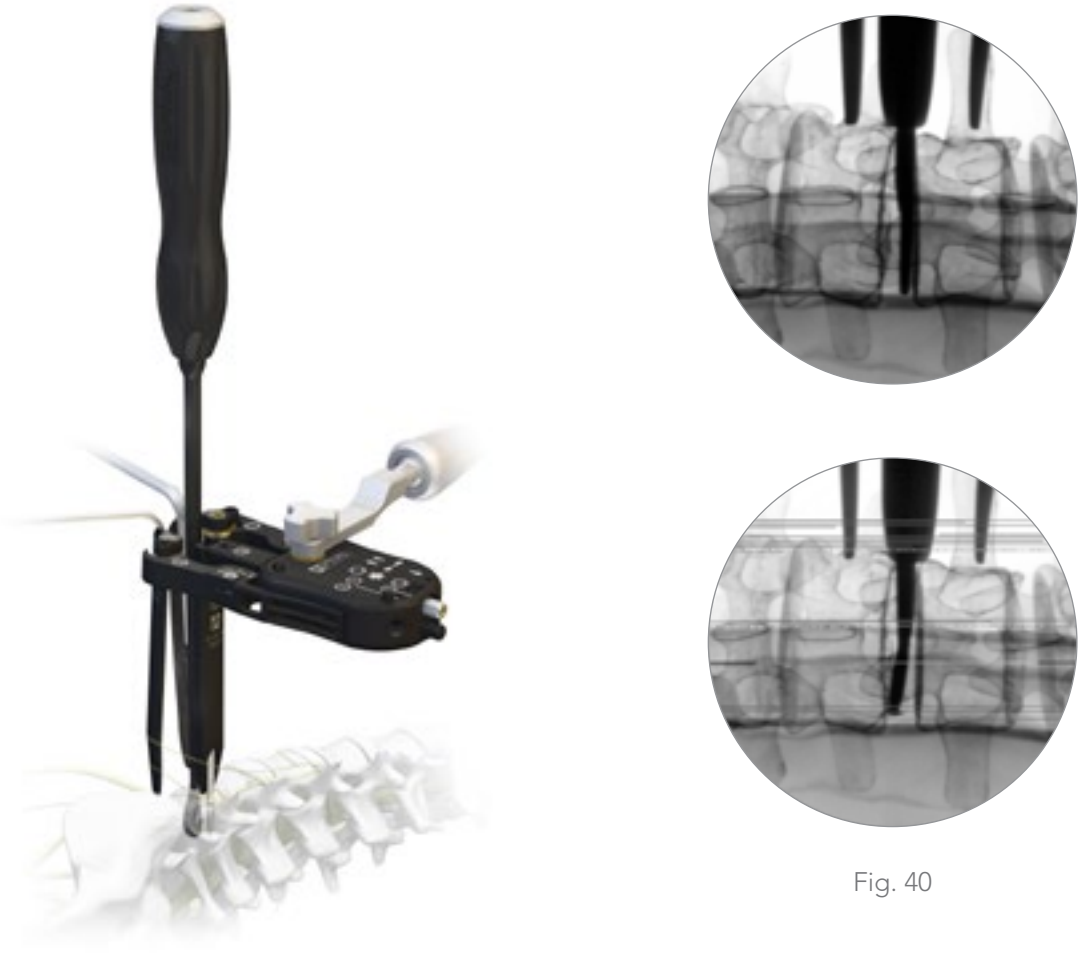


Fig. 40

Trialing and Implant Selection

Utilize straight or angled Lucent Lateral Trials to determine appropriate implant height and length. Implant length is estimated using the holes located in the Trial at 40mm, 45mm, 50mm, 55mm and 60mm increments (Fig. 41).

Confirm correct placement of the Trial using AP and lateral fluoroscopy (Fig. 42).

Note:
The Slap Hammer can be used to assist with removal of the Trial from the disc space.

Fig. 41

Fig. 42

Trialing and Implant Selection continued

Select the Lucent Lateral Implant which corresponds with the height, width, length and lordosis of the Trial (Fig. 43).

Pack the implant with autograft or allograft bone.

Tip:
The height of Lucent Lateral Trials are 1:1 with coated implants. Implant height is measured at the center of the implant. Distractors are available in 4mm and 6mm parallel heights to help open tight disc spaces.

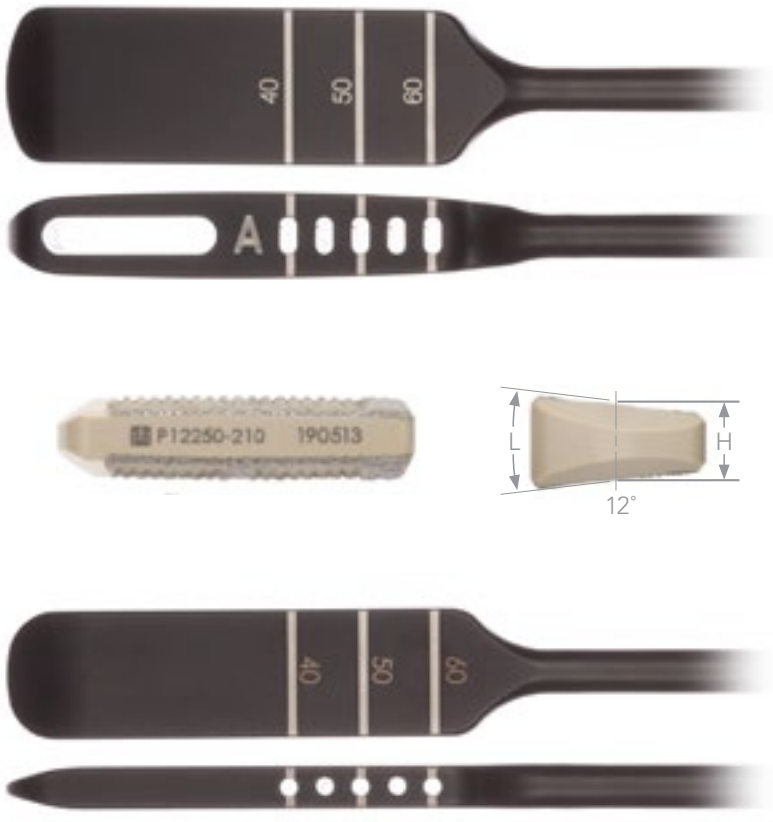


Fig. 43

Implant Insertion Options

Surgeons can choose either Straight, Offset or Angled Implant Inserters (Fig. 44).

Lateral Implant Sleds are designed to ease lateral implant insertion and graft containment during impaction (Fig. 45).

Slap Hammer Adapters are available to facilitate removal of Lateral Implant Sleds.

Tip:
Angled Inserters are available for procedures at L4–L5 and other levels where angled instruments are desired.

Fig. 44

Fig. 45

Implant Insertion Options continued

Offset Inserter

Attach the implant to the Offset Inserter by aligning the implant's lateral notches with the tangs of the Lucent Lateral Inserter.

Rotate the inserter handle clockwise to thread the implant on to the inserter (Fig. 46).

Tip:
Offset Inserter Handle can be rotated in 4 different positions and may be removed for improved fluoroscopic visualization.

Turn the inserter knob counterclockwise to remove the inserter from the implant.

Fig. 46

Straight Inserter

Attach the implant to the Straight Inserter by aligning the implant's lateral notches with the tangs of the Lucent Lateral Inserter.

Rotate the inserter handle clockwise to thread the implant on to the inserter (Fig. 47).

Tip:
Straight Inserter Handle can be removed for improved fluoroscopic visualization and use with the slap hammer.

Press button and turn the inserter handle counterclockwise to remove the inserter from the implant.

Fig. 47

Implant Insertion

Implant the interbody cage using the inserter and Lateral Sleds, if desired (Fig. 48).

Utilize AP fluoroscopy during insertion to confirm the location of the implant (Fig. 49).

Confirm final orientation through AP and lateral fluoroscopic images. Tantalum markers will help to identify the orientation of the implant (Fig. 50).

Note:
A Slap Hammer and Slap Hammer Adapters are available which may be used in conjunction with disc prep instruments.

Tip:
The Lucent Lateral Angled Instruments are available upon request. These instruments may better facilitate access to L4–L5 and other levels where angled instruments are desired.

Fig. 48

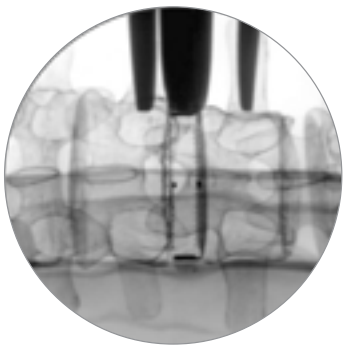


Fig. 49

Fig. 50

Retractor Removal

Attach the Retractor Tool to the Retractor Body if previously detached.

Guide the Shim Inserter down the Center Blade channel and engage the Intradiscal Shim. Depress the thumb lever to the lock position and lift the Shim Inserter to remove the Shim from the Center Blade.

Note:
The Slap Hammer may be used to assist with removal of the Intradiscal Shim.

Remove the Fourth Blade if used.

If the blades were tilted, return them to the neutral position.

Rotate all dials on the Retractor Tool counterclockwise to return the retractor arms to their closed position.

Remove the retractor Light Cable tips from the Right and Left Blades.

With the Long Blade Tool, rotate the Left Blade clockwise. Then rotate the Right Blade counterclockwise to close the retractor (Fig. 51).

Loosen the Articulating Arm Knob and disconnect the arm from the retractor by loosening the thumb screw.

Carefully remove the Retractor.

Follow standard wound closure techniques.

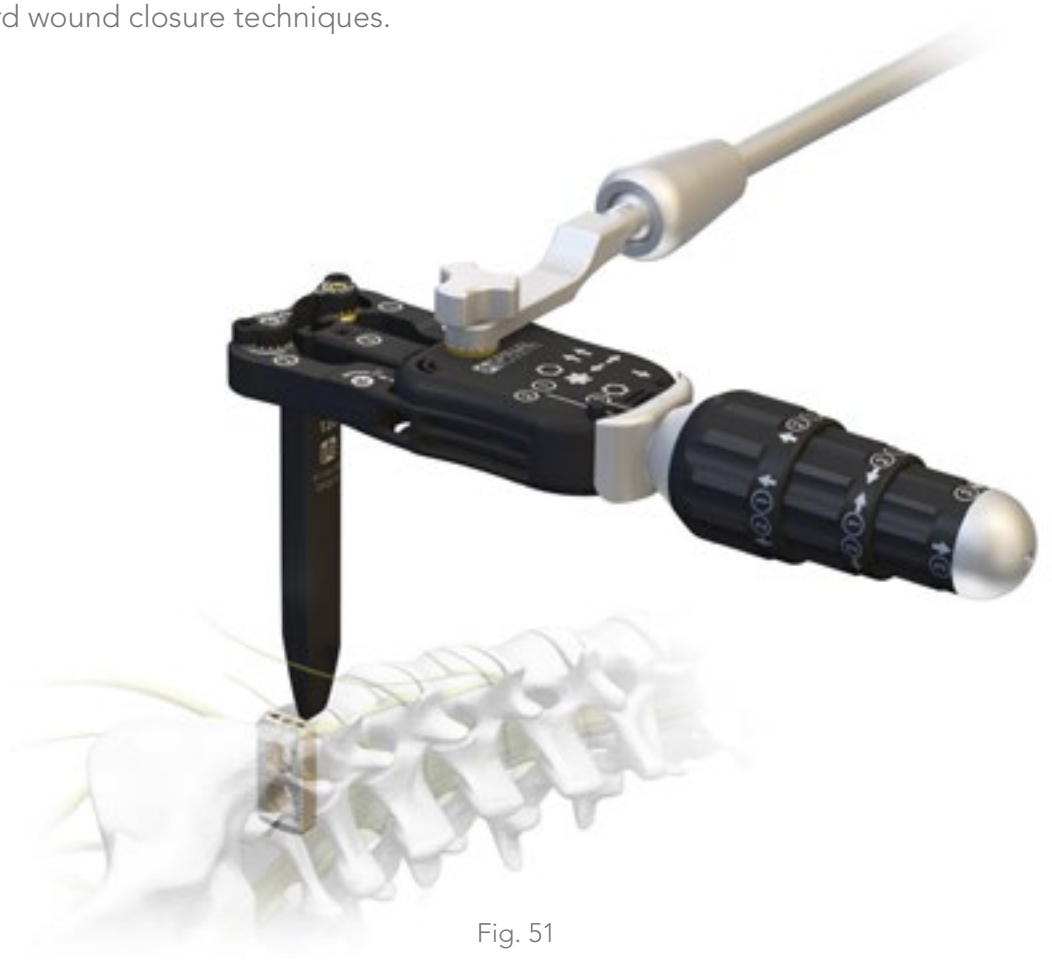


Fig. 51

Removal or Revision of the Lucent Lateral Implant

Attach the Implant Inserter or Implant Removal Tool to remove the implant (Fig. 52).

Attach a Slap Hammer to the instrument and tap up until the implant is removed from the disc space.

Note:
Implants are single use only and should be discarded after removal and, if necessary, replaced with a new implant.

Fig. 52

System Components

Katana Lateral Access System (KATA RET)

Part Number	Part Description
81156-000	Katana Retractor
81143-090	Katana Center Blade, 90mm
81143-100	Katana Center Blade, 100mm
81143-110	Katana Center Blade, 110mm
81143-120	Katana Center Blade, 120mm
81143-130	Katana Center Blade, 130mm
81143-140	Katana Center Blade, 140mm
81143-150	Katana Center Blade, 150mm
81143-160	Katana Center Blade, 160mm
81143-170	Katana Center Blade, 170mm
81143-180	Katana Center Blade, 180mm
81178-090	Katana Left Blade, 90mm
81178-100	Katana Left Blade, 100mm
81178-110	Katana Left Blade, 110mm
81178-120	Katana Left Blade, 120mm
81178-130	Katana Left Blade, 130mm
81178-140	Katana Left Blade, 140mm
81178-150	Katana Left Blade, 150mm
81178-160	Katana Left Blade, 160mm
81178-170	Katana Left Blade, 170mm
81178-180	Katana Left Blade, 180mm
81179-090	Katana Right Blade, 90mm
81179-100	Katana Right Blade, 100mm
81179-110	Katana Right Blade, 110mm
81179-120	Katana Right Blade, 120mm
81179-130	Katana Right Blade, 130mm
81179-140	Katana Right Blade, 140mm
81179-150	Katana Right Blade, 150mm
81179-160	Katana Right Blade, 160mm
81179-170	Katana Right Blade, 170mm
81179-180	Katana Right Blade, 180mm
81055-180	Posterior Probe, 180mm
81044-180	Anterior Probe, 180mm

Katana Lateral Access System (KATA RET)

Part Number	Part Description
81144-000	Blade Install Tool
81159-151	Beveled 12" 1.5mm K-Wire
81159-153	Beveled 18" 1.5mm K-Wire
81057-000	Retractor Body Tool
81180-000	Retractor Tool
81028-002	Blade Tool, Long
81235-525	Shim, 25mm
81234-000	Shim Inserter
81050-000	Lateral Access Guide Holder
82002-245	4th Blade, 12x145mm
82002-290	4th Blade, 12x190mm
82002-845	4th Blade, 18x145mm
82002-890	4th Blade, 18x190mm
50083-000	AO Quick-Release Handle
81202-001	Blade Extension, Left, Small
81203-001	Blade Extension, Right, Small
81202-002	Blade Extension, Left, Large
81202-002	Blade Extension, Right, Large
81204-000	Blade Extension, Left, Concave
81205-000	Blade Extension, Right, Concave
81153-000	Blade Extension Inserter
81201-001	Fixation Shim Left
81201-002	Fixation Shim Right
81199-020	Fixation Screw
81200-000	Fixation Driver
80008-000	Katana Lateral Access System Tray

Single Use Items

Part Number	Part Description
302430-000-200	Ball Tip Stim Probe, 200MM
302773-200	Clip-On Lead Wire

System Components

Katana® Articulating Arm (KATA ARM)

Part Number	Part Description
80012-000	Katana Articulating Arm Tray
81141-000	Fluoro Contrast Puck
81140-000	Localizer
81038-180	Retractor Light
80301-000	ACMI Adapter
80302-000	Olympus Adapter
80303-000	Storz Adapter
80304-000	Wolf Adapter
80501-000	Surgical Arm Radial Clamp
80503-001	Surgical Arm
11064-000	Surgical Arm Knob

Lucent Lateral Instruments (LCLL TRY1)

Part Number	Part Description
80002-000	Lucent Lateral Instruments Tray
10080-000	Medium Mallet
81167-030	Straight Pituitary, 3mm
81167-060	Straight Pituitary, 6mm
81067-000	Chisel
81095-340	Bayoneted Kerrison, 3mm
81095-540	Bayoneted Kerrison, 5mm
81190-000	Quick Attach Large Slap Hammer
81119-000	Slap Hammer Hook Adapter
81098-000	Straight Rasp, Small Angle
81066-061	Back Angled Curette, 6.1mm
81065-061	Up Angled Curette, 6.1mm
81064-061	Straight Curette, 6.1mm
81063-000	Scraper, Angled Stirrup
81062-000	Scraper, Flat Stirrup
81060-018	Straight Cobb, 18mm
81060-012	Straight Cobb, 12mm
81091-000	Bipolar Forceps
81068-015	Long Suction, 15F
81070-000	Annulotomy Knife Handle
81072-004	Penfield Push, #4
81073-210	Nerve Root Retractor, 210mm
81071-004	Penfield Pull, #4

Lucent Lateral Inserters & Trials (LCLL TRY2)

Part Number	Part Description
80009-000	Lucent Lateral Inserters & Trials Tray
81183-000	Offset Inserter
81076-000	Axial Inserter
81089-000	Tamp
81191-001	Hudson Handles
81120-000	Implant Sleds
11836-001	Implant Removal Tool
81094-001	Slap Hammer Adapter
11842-608	Trial, 18mm x 8mm 6°
11842-610	Trial, 18mm x 10mm 6°
11842-612	Trial, 18mm x 12mm 6°
11842-614	Trial, 18mm x 14mm 6°
11842-208	Trial, 18mm x 8mm 12°
11842-210	Trial, 18mm x 10mm 12°
11842-212	Trial, 18mm x 12mm 12°
11842-214	Trial, 18mm x 14mm 12°
11841-164	Distractor, 16mm x 4mm
11841-184	Distractor, 18mm x 4mm
11841-186	Distractor, 18mm x 6mm
11824-004	Box Cutter, 4mm
11824-006	Box Cutter, 6mm
11824-008	Box Cutter, 8mm
11837-008	Paddle Shaver, 8mm
11837-010	Paddle Shaver, 10mm
12242-208	Trial, 22mm x 8mm 12°
12242-210	Trial, 22mm x 10mm 12°
12242-212	Trial, 22mm x 12mm 12°
12242-214	Trial, 22mm x 14mm 12°
12242-608	Trial, 22mm x 8mm 6°
12242-610	Trial, 22mm x 10mm 6°
12242-612	Trial, 22mm x 12mm 6°
12242-614	Trial, 22mm x 14mm 6°

System Components

Lucent Lateral Implants Tray

Part Number	Part Description
80005-000	Lucent Lateral Implants Tray
80005-000-50	Lucent Lateral Caddy (22mm x 12°)
80005-000-60	Lucent Lateral Caddy (22mm x 6°)
80005-000-80	Lucent Lateral Caddy (18mm x 12°)
80005-000-70	Lucent Lateral Caddy (18mm x 6°)

Lucent Lateral Caddy (18mm x 6°)

Part Number	Part Description
80005-000-70	Lucent Lateral Caddy (18mm x 6°)
P11840-608	18mm x 40mm x 8mm 6° Cage
P11840-610	18mm x 40mm x 10mm 6° Cage
P11840-612	18mm x 40mm x 12mm 6° Cage
P11840-614	18mm x 40mm x 14mm 6° Cage
P11845-608	18mm x 45mm x 8mm 6° Cage
P11845-610	18mm x 45mm x 10mm 6° Cage
P11845-612	18mm x 45mm x 12mm 6° Cage
P11845-614	18mm x 45mm x 14mm 6° Cage
P11850-608	18mm x 50mm x 8mm 6° Cage
P11850-610	18mm x 50mm x 10mm 6° Cage
P11850-612	18mm x 50mm x 12mm 6° Cage
P11850-614	18mm x 50mm x 14mm 6° Cage
P11855-608	18mm x 55mm x 8mm 6° Cage
P11855-610	18mm x 55mm x 10mm 6° Cage
P11855-612	18mm x 55mm x 12mm 6° Cage
P11855-614	18mm x 55mm x 14mm 6° Cage
P11860-608	18mm x 60mm x 8mm 6° Cage
P11860-610	18mm x 60mm x 10mm 6° Cage
P11860-612	18mm x 60mm x 12mm 6° Cage
P11860-614	18mm x 60mm x 14mm 6° Cage

Lucent Lateral Caddy (22mm x 6°)

Part Number	Part Description
80005-000-60	Lucent Lateral Caddy (22mm x 6°)
P12240-608	22mm x 40mm x 8mm 6° Cage
P12240-610	22mm x 40mm x 10mm 6° Cage
P12240-612	22mm x 40mm x 12mm 6° Cage
P12240-614	22mm x 40mm x 14mm 6° Cage
P12245-608	22mm x 45mm x 8mm 6° Cage
P12245-610	22mm x 45mm x 10mm 6° Cage
P12245-612	22mm x 45mm x 12mm 6° Cage
P12245-614	22mm x 45mm x 14mm 6° Cage
P12250-608	22mm x 50mm x 8mm 6° Cage
P12250-610	22mm x 50mm x 10mm 6° Cage
P12250-612	22mm x 50mm x 12mm 6° Cage
P12250-614	22mm x 50mm x 14mm 6° Cage
P12255-608	22mm x 55mm x 8mm 6° Cage
P12255-610	22mm x 55mm x 10mm 6° Cage
P12255-612	22mm x 55mm x 12mm 6° Cage
P12255-614	22mm x 55mm x 14mm 6° Cage
P12260-608	22mm x 60mm x 8mm 6° Cage
P12260-610	22mm x 60mm x 10mm 6° Cage
P12260-612	22mm x 60mm x 12mm 6° Cage
P12260-614	22mm x 60mm x 14mm 6° Cage

System Components

Lucent Lateral Caddy (18mm x 12°)

Part Number	Part Description
80005-000-80	Lucent Lateral Caddy (18mm x 12°)
P11840-208	18mm x 40mm x 8mm 12° Cage
P11840-210	18mm x 40mm x 10mm 12° Cage
P11840-212	18mm x 40mm x 12mm 12° Cage
P11840-214	18mm x 40mm x 14mm 12° Cage
P11845-208	18mm x 45mm x 8mm 12° Cage
P11845-210	18mm x 45mm x 10mm 12° Cage
P11845-212	18mm x 45mm x 12mm 12° Cage
P11845-214	18mm x 45mm x 14mm 12° Cage
P11850-208	18mm x 50mm x 8mm 12° Cage
P11850-210	18mm x 50mm x 10mm 12° Cage
P11850-212	18mm x 50mm x 12mm 12° Cage
P11850-214	18mm x 50mm x 14mm 12° Cage
P11855-208	18mm x 55mm x 8mm 12° Cage
P11855-210	18mm x 55mm x 10mm 12° Cage
P11855-212	18mm x 55mm x 12mm 12° Cage
P11855-214	18mm x 55mm x 14mm 12° Cage
P11860-208	18mm x 60mm x 8mm 12° Cage
P11860-210	18mm x 60mm x 10mm 12° Cage
P11860-212	18mm x 60mm x 12mm 12° Cage
P11860-214	18mm x 60mm x 14mm 12° Cage

Lucent Lateral Caddy (22mm x 12°)

Part Number	Part Description
80005-000-50	Lucent Lateral Caddy (22mm x 12°)
P12240-208	22mm x 40mm x 8mm 12° Cage
P12240-210	22mm x 40mm x 10mm 12° Cage
P12240-212	22mm x 40mm x 12mm 12° Cage
P12240-214	22mm x 40mm x 14mm 12° Cage
P12245-208	22mm x 45mm x 8mm 12° Cage
P12245-210	22mm x 45mm x 10mm 12° Cage
P12245-212	22mm x 45mm x 12mm 12° Cage
P12245-214	22mm x 45mm x 14mm 12° Cage
P12250-208	22mm x 50mm x 8mm 12° Cage
P12250-210	22mm x 50mm x 10mm 12° Cage
P12250-212	22mm x 50mm x 12mm 12° Cage
P12250-214	22mm x 50mm x 14mm 12° Cage
P12255-208	22mm x 55mm x 8mm 12° Cage
P12255-210	22mm x 55mm x 10mm 12° Cage
P12255-212	22mm x 55mm x 12mm 12° Cage
P12255-214	22mm x 55mm x 14mm 12° Cage
P12260-208	22mm x 60mm x 8mm 12° Cage
P12260-210	22mm x 60mm x 10mm 12° Cage
P12260-212	22mm x 60mm x 12mm 12° Cage
P12260-214	22mm x 60mm x 14mm 12° Cage

Optional System Components

Lucent Lateral Angled Instruments (LCLL ANG1)

Part Number	Part Description
80010-000	Lucent Lateral Angled Instruments Tray
81161-003	Left Angled Pituitary, 3mm
81161-103	Right Angled Pituitary, 3mm
81195-003	Left Angled Kerrison, 3mm
81195-103	Right Angled Kerrison, 3mm
81160-018	Up Angled Cobb, 18mm
81160-118	Down Angled Cobb, 18mm
81162-001	Angled Endplate Scraper
81162-101	Double Angled Endplate Scraper
81164-261	Double Up Angled Curette, 6.1mm
81164-161	Down Angled Curette, 6.1mm
81196-002	Angled Rasp, Double

Lucent Lateral Angled Trials (LCLL ANG2)

Part Number	Part Description
80011-000	Lucent Lateral Angled Instruments Tray
11843-608	Modular Trial, 18mm x 8mm 6°
11843-610	Modular Trial, 18mm x 10mm 6°
11843-612	Modular Trial, 18mm x 12mm 6°
11843-614	Modular Trial, 18mm x 14mm 6°
11843-208	Modular Trial, 18mm x 8mm 12°
11843-210	Modular Trial, 18mm x 10mm 12°
11843-212	Modular Trial, 18mm x 12mm 12°
11843-214	Modular Trial, 18mm x 14mm 12°
12220-608	Modular Trial, 22mm x 8mm 6°
12220-610	Modular Trial, 22mm x 10mm 6°
12220-612	Modular Trial, 22mm x 12mm 6°
12220-614	Modular Trial, 22mm x 14mm 6°
12220-208	Modular Trial, 22mm x 8mm 12°
12220-210	Modular Trial, 22mm x 10mm 12°
12220-212	Modular Trial, 22mm x 12mm 12°
12220-214	Modular Trial, 22mm x 14mm 12°
81183-015	Angled Offset Inserter
81192-000	Offset Inserter Slap Hammer Attachment
81076-015	Angled Axial Inserter
81189-000	Angled Tamp
11841-364	Angled Distractor, 16mm x 4mm
11841-384	Angled Distractor, 18mm x 4mm
11841-386	Angled Distractor, 18mm x 6mm
11824-104	Angled Box Cutter, 18mm x 4mm
11824-106	Angled Box Cutter, 18mm x 6mm
11824-108	Angled Box Cutter, 18mm x 8mm

Optional System Components

Lucent Lateral 18° Implants & Trials Tray

Part Number	Part Description
80006-000	Lucent Lateral 18° Implants & Trials Tray
80006-000-50	Lucent Lateral Caddy (22mm x 18°)
12242-808	Lateral Trial, 22mm x 8mm 18°
12242-810	Lateral Trial, 22mm x 10mm 18°
12242-812	Lateral Trial, 22mm x 12mm 18°
12220-808	Modular Trial, 22mm x 8mm 18°
12220-810	Modular Trial, 22mm x 10mm 18°
12220-812	Modular Trial, 22mm x 12mm 18°

* The Lucent Lateral Angled Instruments and 18° Implant tray are available upon request.

Lucent Lateral Optional Instruments

Part Number	Part Description
81060-022	Straight Cobb, 22mm
81074-000	Suction Nerve Retractor
81096-000	Straight Rasp
81259-152	Trocar 12", Lateral 1.5mm SS K-Wire
11837-012	Paddle Shaver, 12mm
11837-014	Paddle Shaver, 14mm

Lucent Lateral Caddy (22mm x 18°)

Part Number	Part Description
80006-000-50	Lucent Lateral Caddy (22mm x 18°)
P12240-808	22mm x 40mm x 8mm 18° Cage
P12240-810	22mm x 40mm x 10mm 18° Cage
P12240-812	22mm x 40mm x 12mm 18° Cage
P12245-808	22mm x 45mm x 8mm 18° Cage
P12245-810	22mm x 45mm x 10mm 18° Cage
P12245-812	22mm x 45mm x 12mm 18° Cage
P12250-808	22mm x 50mm x 8mm 18° Cage
P12250-810	22mm x 50mm x 10mm 18° Cage
P12250-812	22mm x 50mm x 12mm 18° Cage
P12255-808	22mm x 55mm x 8mm 18° Cage
P12255-810	22mm x 55mm x 10mm 18° Cage
P12255-812	22mm x 55mm x 12mm 18° Cage
P12260-808	22mm x 60mm x 8mm 18° Cage
P12260-810	22mm x 60mm x 10mm 18° Cage
P12260-812	22mm x 60mm x 12mm 18° Cage

Indications / Contraindications

INDICATIONS

Lucent and Lucent Ti-Bond® are intervertebral body fusion devices 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). These devices are intended to be used with autogenous or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with these devices.

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.

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