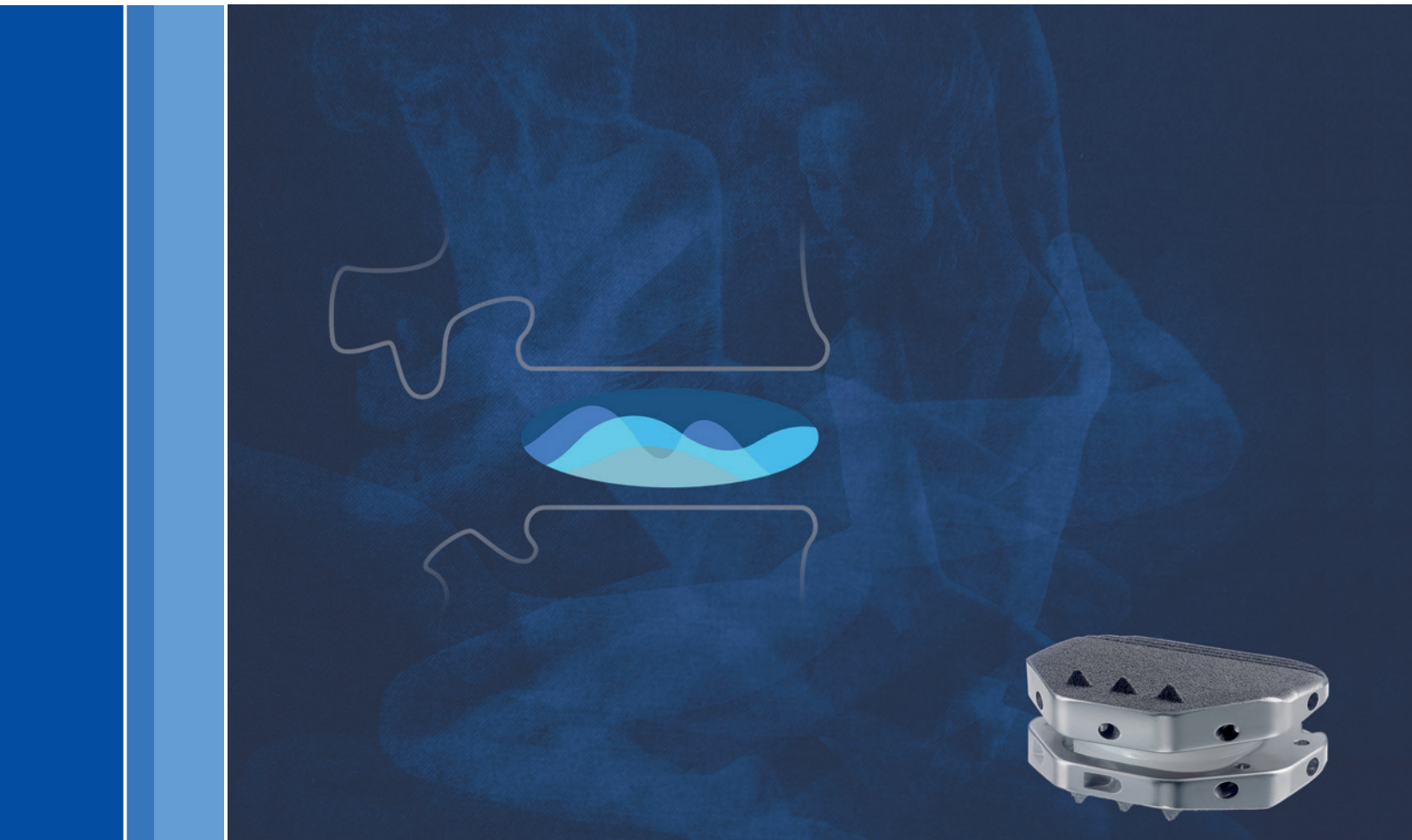


activL[®] Artificial Disc

Surgical Technique



Aesculap Spine

AESCULAP
Implant Systems

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

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I. System Overview

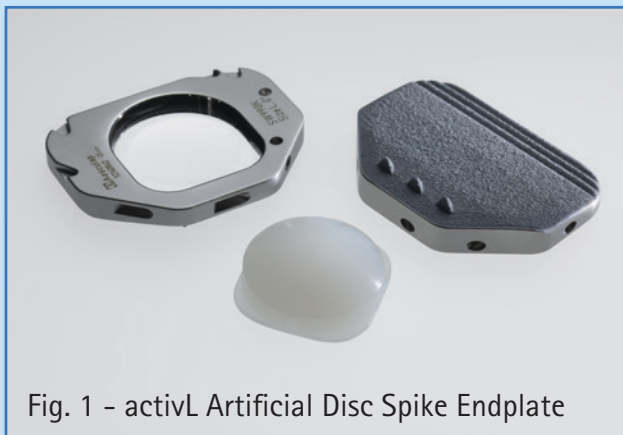


Fig. 1 – activL Artificial Disc Spike Endplate

The activL® Artificial Disc, designed as an alternative to fusion, is a weight-bearing modular implant consisting of two endplates and one polyethylene inlay.

The activL Artificial Disc features superior and inferior cobalt chromium alloy endplates, which are affixed to the vertebrae with spikes for initial stabilization.

The bone-contacting surfaces of the endplates are coated with Plasmapore® (Titanium) and a microscopic Calcium Phosphate over-coating which is intended to enhance the longer-term implant stability through bone in-growth.

The endplates are provided in four sizes. The superior endplates are provided in either 6° or 11° lordotic angle options, and the inferior endplates are provided in either 0° or 5° lordotic angle options. The activL Artificial Disc features a 5° inferior endplate option designed for cases where the sacrum has a rounded posterior edge to allow placement of the endplate closer to the posterior border of the S1 vertebra without the edges protruding.

The inlay is manufactured from ultra-high molecular weight polyethylene (UHMWPE) and also includes an integrated tantalum radiographic marker. It is available in four heights (8.5, 10, 12, and 14 mm), and fits any of the endplates by seating into the grooves in the side wall of the inferior endplate.

The activL Artificial Disc is designed to allow controlled motion at the surgery level. It can translate in the sagittal plane (anterior-posterior) up to 1.5 or 2.0 mm (based on device size) but does not translate laterally (semi-constrained). It is assembled in the sterile field in the operating room, prior to implantation. Two lateral wings on the inlay engage in grooves in the lateral walls of the inferior endplate. The superior endplate is then seated on the inferior endplate.

Once assembled, the activL Artificial Disc is mounted onto the inserter and implanted as a single unit via an anterior retroperitoneal approach.

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II. Indications and Contraindications

Indications for Use

The activL Artificial Disc is indicated for reconstruction of the disc at one level (L4–L5 or L5–S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL Artificial Disc should have failed at least six months of nonoperative treatment prior to implantation of the device.

Contraindications, Warnings and Precautions

The activL Artificial Disc should not be implanted in patients with the following conditions:

- Active systemic infection or localized infection near the surgical site.
- Osteoporosis or osteopenia defined as dual-energy X-Ray absorptiometry (DEXA) bone mineral density T-score less than or equal to -1.0
- Allergy or sensitivity to the implant materials (cobalt, chromium, polyethylene, titanium, tantalum, or calcium phosphate)
- Isolated radiculopathy, especially due to herniated disc
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year)
- Extruded disc material with sequestrum (i.e., free disc fragment)
- Myelopathy
- Spinal stenosis
- Spinal deformity such as scoliosis
- Spondylolysis/isthmic spondylolisthesis, degenerative spondylolisthesis > Grade I, or segmental instability
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., current or prior vertebral fracture) or disease (e.g., ankylosing spondylitis)
- Facet ankylosis or facet joint degeneration
- Preoperative remaining disc height < 3 mm
- Symptoms attributed to more than one vertebral level
- Abdominal pathology that would preclude an anterior retroperitoneal approach
- Involved vertebral endplates dimensionally smaller than 31 mm in the medial-lateral and/or 26 mm in the anterior-posterior directions

III. Warnings and Precautions

Warnings

Use of the activL Artificial Disc should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics, has had experience with anterior approach spinal surgeries, and has had hands-on – training in the use of this device. Only surgeons who are familiar with the activL implant components, instruments, procedure, clinical applications, biomechanics, and risks should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

Correct selection of the appropriate implant size and correct placement of the device are essential to ensure optimal performance and function of the device. Please refer to the activL surgical technique manual for step-by-step instructions on the required surgical technique.

Heterotopic Ossification (HO) is a potential complication associated with lumbar total disc replacement surgery, which could result in reduced motion in the lumbar spine. However, the clinical impact of the presence of HO is not clearly understood.

Precautions

The safety and effectiveness of this device has not been established in patients with the following conditions:

- More than one vertebral level with DDD
- Skeletally immature patients, children < 18 years old, or patients over the age of 60
- Prior surgery at any lumbar level other than intradiscal electro-thermal annuloplasty (IDET), percutaneous nucleoplasty, microdiscectomy, hemilaminectomy, or laminotomy
- Back or leg pain of unknown etiology
- Paget's disease, osteomalacia, or other metabolic bone disease
- Morbid obesity (BMI>35)
- Pregnancy
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g, steroids)
- Rheumatoid arthritis, lupus, or other autoimmune diseases
- Systematic disease including AIDS, HIV, Hepatitis
- Active malignancy
- Any degenerative muscular or neurological condition, including but not limited to Parkinson's disease, amyotrophic lateral sclerosis (ALS), or multiple sclerosis.
- Psychiatric or cognitive impairment.
- Current or recent history of illicit drug or alcohol abuse, or dependence as defined as the continued use of alcohol despite the development of social, legal, or health problems.
- Insulin-dependent diabetes.

IV. Potential Adverse Effects of the Device on Health

Potential Adverse Effects of the Device on Health

The following is a list of the potential adverse effects (i.e., complications, risks) associated with the use of the activL® Artificial Disc identified from the activL Artificial Disc clinical trial results, use of the activL Artificial Disc outside of the United States, approved device labeling for other lumbar total disc replacement devices, and published scientific literature including: (1) those associated with any surgical procedure; (2) those associated with lumbar spinal surgery using an anterior approach; and (3) those associated with a lumbar total disc replacement device (including the activL Artificial Disc). These risks may occur singly or in combination. In addition to the risks listed below, there is also the risk that the procedure may not be effective and may not relieve symptoms or may cause worsening of symptoms. Additional surgery may be required to correct some of the adverse effects.

1. Risks associated with any surgical procedure:

- Anesthesia complications including an allergic reaction or anaphylaxis;
- Infection (wound, local, and/or systemic) or abscess;
- Wound dehiscence or necrosis;
- Edema;
- Soft tissue damage or fluid collections, including hematoma or seroma;
- Pain/discomfort at the surgical incision and/or skin or muscle sensitivity over the incision which may result in skin breakdown, pain, and/or irritation;
- Heart or vascular complications including bleeding, hemorrhage or vascular damage resulting in catastrophic or potentially fatal bleeding, ischemia, myocardial infarction, abnormal blood pressure, venous thromboembolism including deep vein thrombosis and pulmonary embolism, thrombophlebitis, or stroke;
- Pulmonary complications including atelectasis or pneumonia;
- Impairment of the gastrointestinal system including ileus or bowel obstruction;
- Impairment of the genitourinary system including incontinence, bladder dysfunction, or reproductive system complications;

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- Neurological complications including nerve damage, paralysis, seizures, changes to mental status, or reflex sympathetic dystrophy;
- Complications of pregnancy including miscarriage or congenital defects;
- Inability to resume activities of daily living; and
- Death.

2. Risks specifically associated with lumbar spinal surgery using an anterior approach:

- Injury to surrounding organs and structures including the cauda equina, nerve roots, other neurologic structures adjacent to the spinal column, adjacent vertebrae, lymphatic vessels, blood vessels, soft tissue, dura, intestines, kidneys, or ureters;
- Neurological difficulties, including trouble with bowel and/or bladder function (including incontinence), sexual dysfunction (including retrograde ejaculation), muscle weakness or paralysis, changes in sensation (including numbness, dysesthesias, or paresthesias), chronic reflex sympathetic dystrophy, or pain;
- Back or leg pain;
- Epidural or retroperitoneal hematoma or fibrosis;
- Scarring, adhesions, or swelling including in the peritoneum;
- Hernia; and
- Meningitis.

3. Risks associated with a lumbar total disc replacement device (including the activL Artificial Disc):

- Risks directly related to the device including malposition, migration/displacement, subsidence/loss of disc height, device breakage, device disassembly, or early or late loosening of the device. Any of these issues may cause pain or injury to surrounding organs and structures including the cauda equina, nerve roots, or other neurologic structures adjacent to the spinal column (which could cause pain, paralysis, numbness, or retrograde

ejaculation in males) or blood vessel damage or erosion (which could cause catastrophic or fatal bleeding even in the late postoperative period);

- Deterioration in neurologic status;
- Development of new pain;
- Failure of the device to improve symptoms or function;
- Problems during placement of the device including trouble sizing the device, anatomical or technical difficulties implanting the device, or issues with the device instruments (e.g., bending or breakage) including the possibility that a fragment of a broken instrument may remain in the patient after implantation;
- Adverse reaction or allergy to the device materials (cobalt, chromium, polyethylene, titanium, tantalum, calcium phosphate) or device wear debris which may lead to an adverse reaction of the local tissues or chronic inflammation that may lead to implant loosening or failure of the device, osteolysis, tumor formation, autoimmune disease, metallosis, scarring, or other symptoms;
- Change in the alignment of the spine or loss of proper anatomic curvature, correction, height or reduction of the spine including spondylolisthesis, change in lordosis, or instability of the spine;
- Degeneration of other parts of the spine including the facet joints or adjacent discs;
- Spinal stenosis;
- Fracture of the surrounding vertebrae;
- Unintended bone formation (i.e., heterotopic ossification, annular ossification) that may result in bridging trabecular bone and may reduce spinal motion or result in unintended fusion at either the treated level or adjacent levels; and
- Device failure which may require a subsequent surgical intervention (including removal of the activL device, revision, re-operation or supplemental fixation).

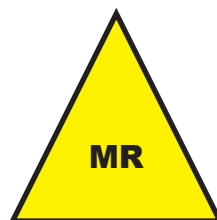
Some of the adverse effects listed above were observed in the activL Artificial Disc clinical trial. For more detailed information on the specific adverse effects that occurred during the clinical trial, please refer to the Clinical Study section of the activL Artificial Disc Instructions for Use.

V. Sterility

Sterility

- The implant components are provided in protective packaging that is labeled to indicate its contents.
- The implant components are provided sterile.
- Implant components may not be resterilized
- Components are to be kept in their original packaging until just prior to use.
- Prior to use, check the expiration date and assure the integrity of the packaging. Do not use components if they are past their expiration date or if the packaging has been damaged.

VI. MRI Safety Information



MR Conditional

Non-clinical testing has demonstrated the activL Artificial Disc is MR Conditional. It can be scanned safely under the following conditions;

- Static magnetic field of 1.5 and 3 T
- Maximum spatial gradient field of 2,000 gauss/cm (20T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the activL Artificial Disc is expected to produce a maximum temperature rise of 2.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 25 mm from the activL Artificial Disc when imaged using a gradient echo pulse sequence and a 3 tesla MRI system.

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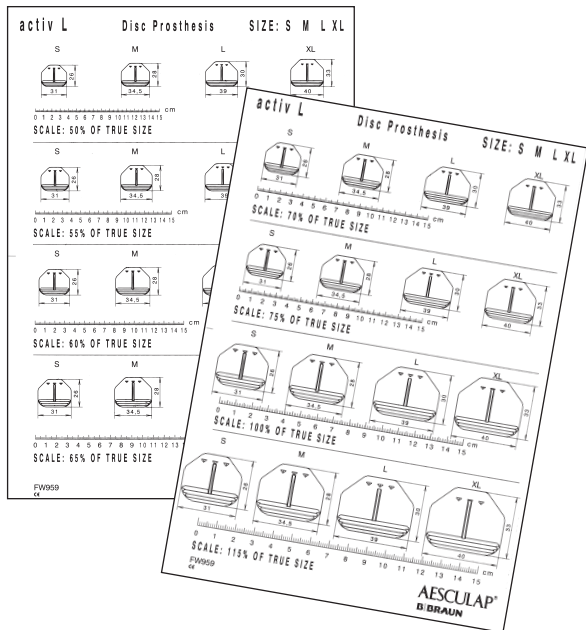


Fig. 2 – activL X-Ray Templates

1. Preoperative Planning

a. Size Estimation

- Measure the optimum or largest possible implant bed area using either X-Ray imaging or CT-scan diagnostics. If utilizing the X-Ray templates provided, make sure that the template scale factor is correct.
- Assess the anatomy of the major vessels, especially the left common iliac vein.
- Consider if the vessels can be mobilized sufficiently from the anterior aspect of the spine to allow for implantation.

Warning:

- Preoperative planning using X-Ray imaging or CT-scan diagnostics is required.
- There is a risk of selecting the wrong size endplate if an X-Ray template of the wrong scale is used.
- There is an increased risk of migration if the endplate selected is too small. The plate must completely cover the end of the vertebral body. Select an endplate that provides maximum coverage of the vertebral body.
- Select the correct inlay height to achieve height reconstruction while preserving adequate mobility in the joint.

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1

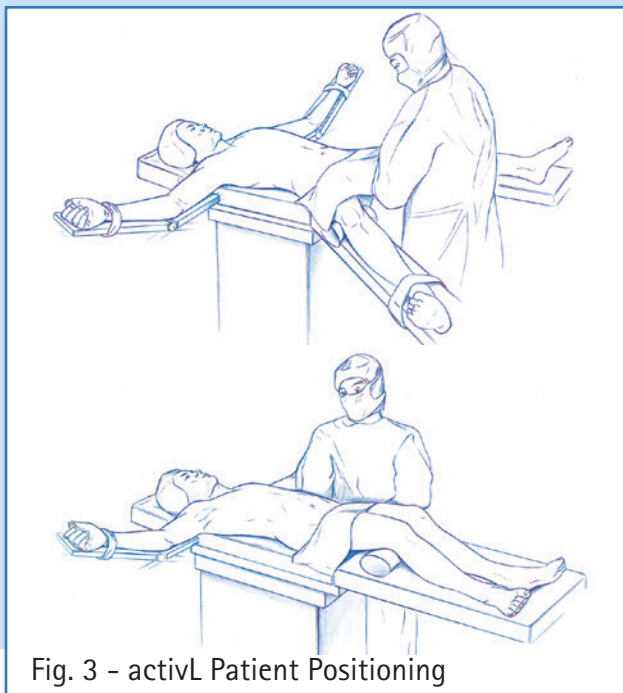


Fig. 3 - activL Patient Positioning

b. Patient Positioning

- The operating table should permit image intensifier images in two planes in the operating zone.
- Place the patient in a supine position with slightly flexed hips to relieve tension from the major blood vessels.
- If the operating table permits a spread leg position (DaVinci), this facilitates axially correct implantation of the prosthesis.
- Alternatively, the patient is positioned with both legs together. In this case the surgeon stands on the approach side of the patient.

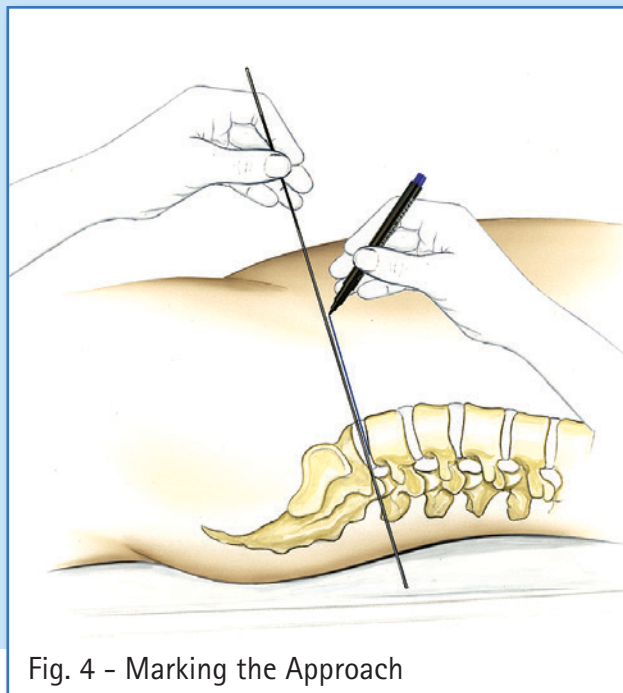


Fig. 4 - Marking the Approach

2. Anterior Access and Approach

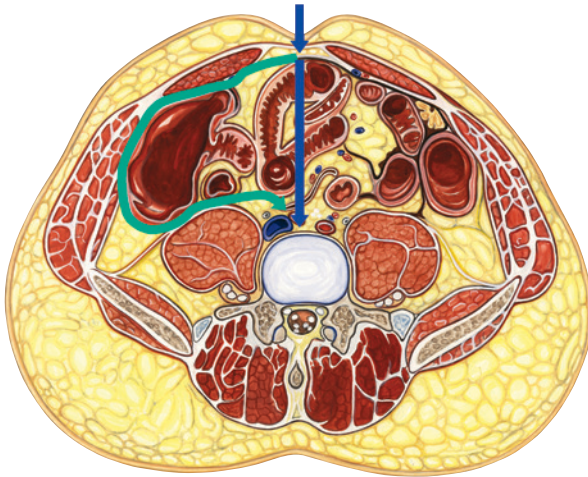
a. Marking the Approach

- A left-sided approach is generally recommended for the L4/L5 level. At the L5/S1 level, the side of approach should be determined by taking into consideration patient anatomy as well as surgeon experience and training.
- To mark the incision, a lateral image is taken with a metal rod parallel to the operative disc level. The extension of this marking corresponds to the midpoint of the skin incision.
- The skin incision is marked under X-Ray control so that the incision lies along the extended line of the intervertebral space. 5 – 8 cm is usually adequate for single level treatment.

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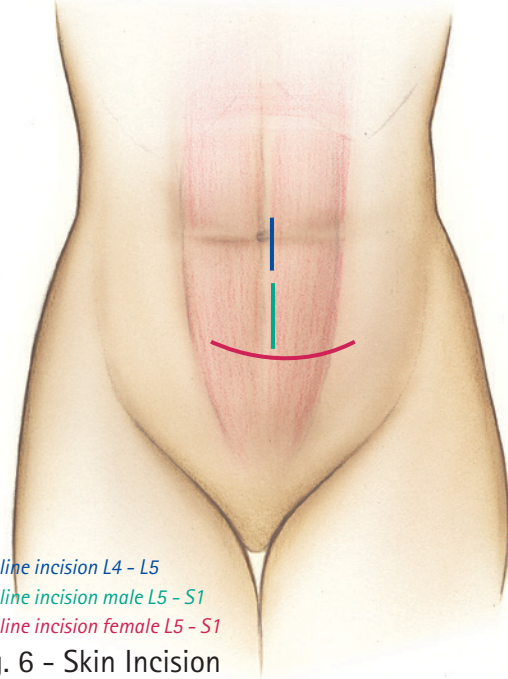
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VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)



Midline approach retroperitoneal

Fig. 5 - Retroperitoneal Approach



Midline incision L4 - L5

Midline incision male L5 - S1

Midline incision female L5 - S1

Fig. 6 - Skin Incision

b. Approach Type

- The Retroperitoneal Approach is the standard technique for the anterior approach.

c. Approach and Skin Incision

- Several surgical incisions are possible, including a Pfannensteil incision or a linear midline incision.
- Each surgeon should use his or her judgment in determining the appropriate approach side and incision type based on individual patient considerations.

Note:

- *All approaches require the greatest care in the preparation of the major vessels.*
- *Serious or fatal hemorrhage may occur as a consequence of injury to vascular structures during this procedure. A surgeon with expertise in the repair of such injuries should assist or be immediately available during the procedure.*
- *Sharp instruments may damage bowel, vessels, tissue and nerves.*

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

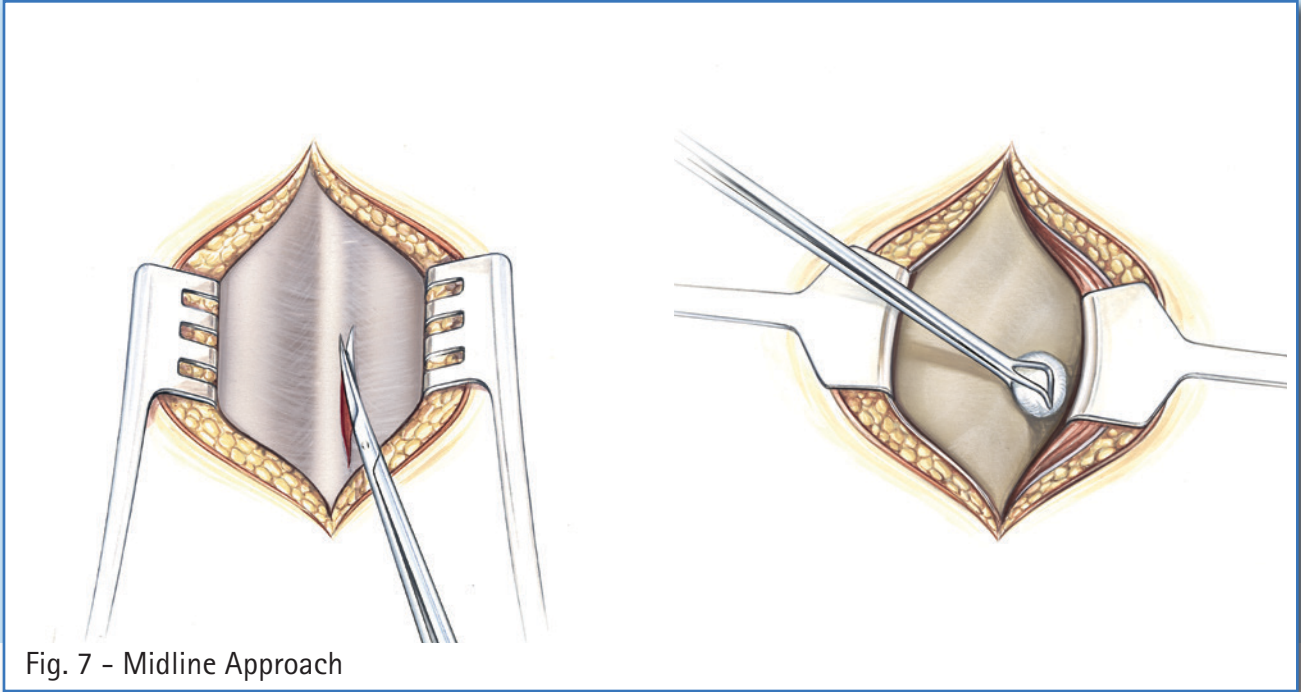


Fig. 7 - Midline Approach

d. Anatomical Structures

- After the skin incision, a linear incision of the anterior fascia of the rectus abdominus muscle is made a few millimeters paramedially.
- A blunt instrument is used to push the peritoneum away in a medial direction, first from the rear surface of the muscle and then from the lateral abdominal wall.
- Epigastric blood vessels should be coagulated and dissected if necessary.

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VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

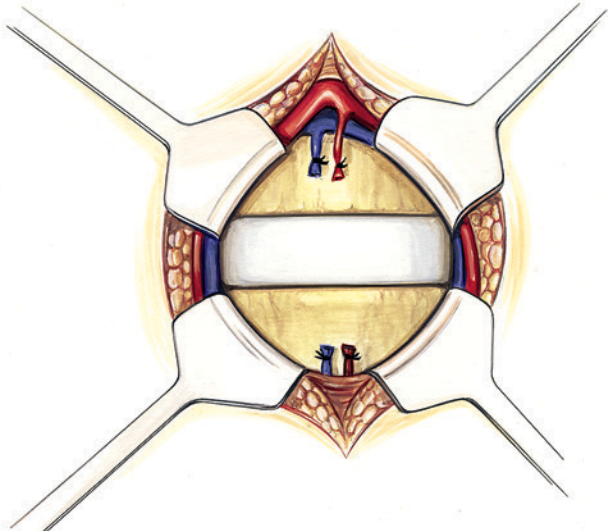


Fig. 8 - Vessel Retraction and Exposure of L5/S1

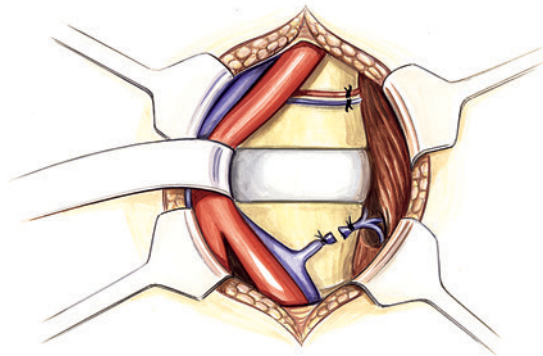


Fig. 9 - Vessel Retraction and Exposure of L4/L5

- The ureter and the presacral plexus are carefully mobilized and retracted together with the peritoneum (coagulation should be avoided).
- The medial sacral vessels are ligated and dissected in the bifurcation of the major vessels.
- The vessels are mobilized as far to the left as is necessary (or possible) to facilitate implantation of the planned implant size.

Note:

- *The linea alba is not opened.*
- *The anterior fascia of the rectus is opened paramedially.*

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)



Fig. 10 – activL® S1 Spike Endplate vs. Standard Spike Endplate

e. S1 Inferior Endplate

- The S1 plate provides an additional option for the surgeon to address varying patient anatomy.
- There are patients who have a sacrum with a very round posterior edge. For those patients the S1 plate has rounded posterior edges and can therefore be placed close to the posterior border of the S1 vertebra without these edges protruding into the spinal canal. This might enable the surgeon to use a larger size compared to the standard plate.

Note:

- The S1 plate is just an option, as there are cases, where the standard plate will fit better.
- X-Ray templates are available which can be used for preoperative planning in order to define the appropriate plate type.

Warning:

- In order to make sure that proper fixation and alignment of the activL Artificial Disc can be achieved, patients with endplate dimensions smaller than 31 mm in medial-lateral and/or 26 mm in anterior-posterior directions are not appropriate candidates for the activL Artificial Disc due to limitations in available sizes.

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VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

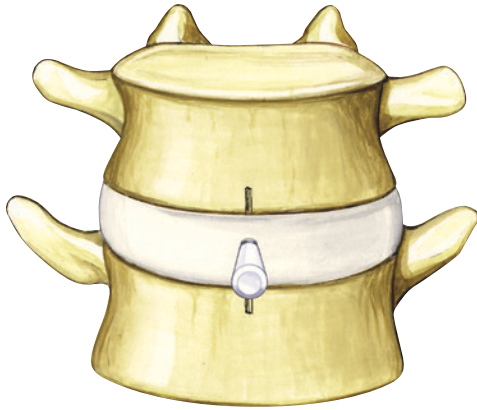


Fig. 11 - activL Midline Marker (FW938SU/FW955R)

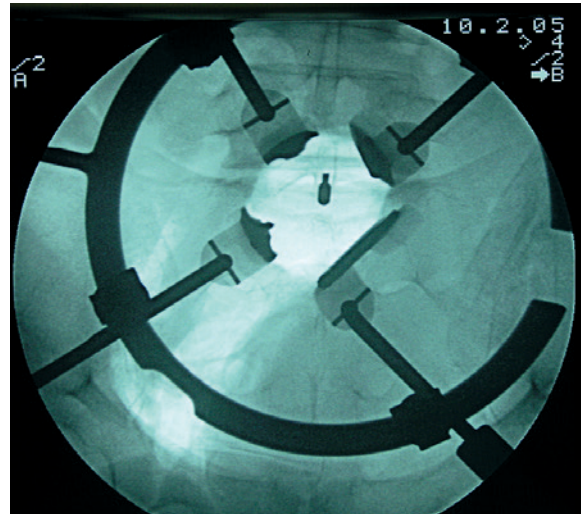


Fig. 12 - activL Midline Marker, AP Projection

3. Midline Marking

- Define the midline of the vertebral body under AP X-Ray control.
- Determine the center of the vertebral disc using the midline marker, under X-Ray visualization.
- Apply markings on the superior and inferior vertebral bodies
- The midline is marked with the single-use pin (FW938SU) using the provided Anterior Midline Marker tool (FW955R) in the disc compartment under image intensifier control. Alternatively, the marking can be set in the neighboring vertebral body for the entire duration of the surgery.

Warning:

- *Inaccurate marking of the midline may result in incorrect positioning of the implant.*
- *Always mark the midline under X-Ray visualization.*

Note:

- *Make sure that the vertebrae are portrayed in an orthograde position on the X-Ray. The pedicles and the spinous process serve as orientation aids for midline marking.*
- *The exact position of the implant is of vital importance for correct function.*

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

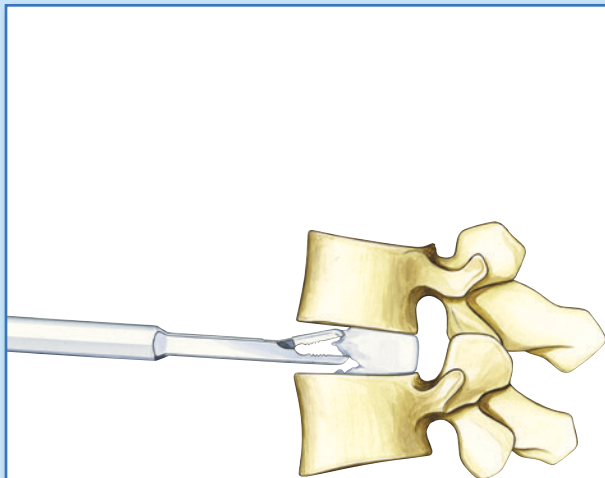


Fig. 13 - Discectomy

4. Discectomy, Endplate Preparation and Mobilization of the Segment

a. Discectomy

- A discectomy is performed and the endplates are freed from disc residue with a curette.

Note:

- Create a window in the annulus, which is wide enough for the required size of the activL implant. Perform a thorough discectomy, using standard instruments.
- The annulus must only be resected laterally as far as is required by the implant size. If necessary, measure the size of the incision using the parallel distractor (FW970R) with the appropriate trial implant.

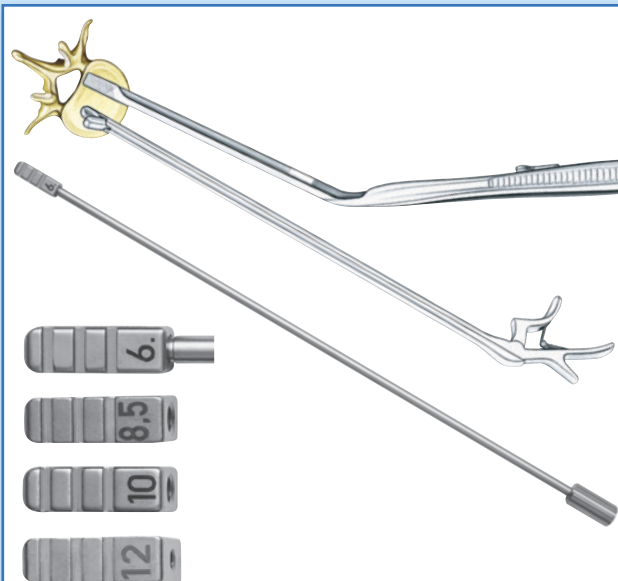


Fig. 14 - Endplate Preparation

- If necessary, wedges of the appropriate height (FW940R-FW944R) or the angled distractor (FW960R) can be used to maintain the correct amount of distraction.
- The angled distractor (FW960R) provides a better view of the operating site and makes simultaneous discectomy easier. Two are provided in each instrument set.

Warning:

- Incomplete removal of cartilage from the plateau of the endplates may result in insufficient anchoring stability.
- There is an increased risk of migration with over preparation of the vertebral body endplates.
 - The preparation of the endplates includes the complete removal of cartilage and soft tissue. It also includes the removal of osteophytes and the correction of unevenness caused by pathological changes of the vertebral endplate surface.

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VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

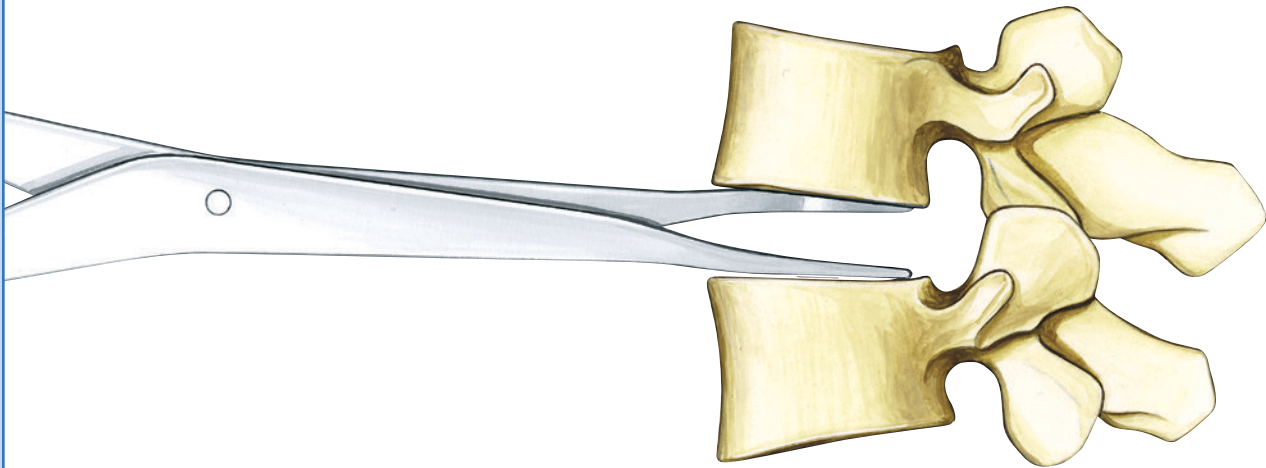


Fig. 15 – Endplate Mobilization

b. Mobilization

- Mobilize the disc compartment with the distractor. The mobilization of the segment is crucial.

Note:

- Use fluoroscopic control to ensure that the instrument is advanced as far as possible posteriorly into the disc compartment to avoid stress peaks on the endplates and so that distraction is as parallel as possible.
- Wedge shaped intervertebral disc space distraction: The posterior intervertebral disc space must be adequately released so that it can be distracted to an appropriate disc height.
- Release of the posterior longitudinal ligament (PLL) may be required for adequate mobilization. An angled curette may be utilized to release the PLL from the posterior margins of the vertebral body.

Warning:

- Introduce the distractor in the intervertebral space under X-Ray visualization.
- If the distractor is inserted too deeply, the spinal canal and other posterior elements may be compressed.

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

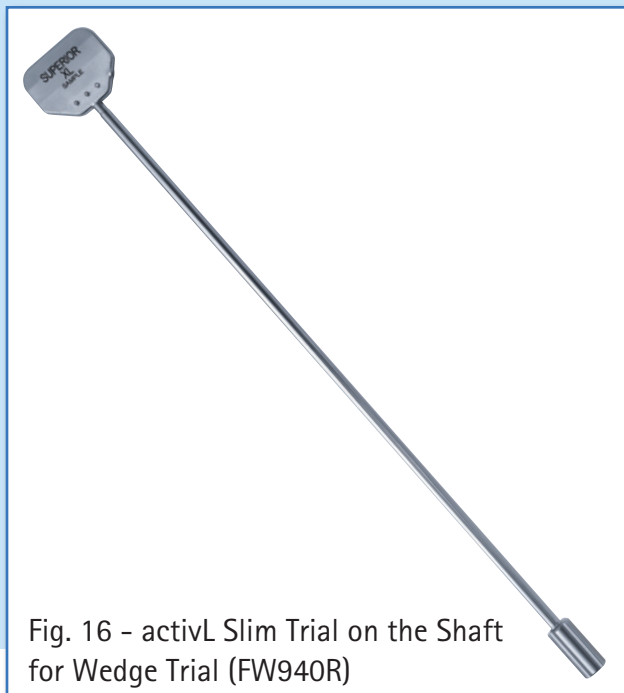


Fig. 16 - activL Slim Trial on the Shaft for Wedge Trial (FW940R)



Fig. 17 - activL Trial Endplates

5. Parallel Distraction, Height Measurement and Size Verification

a. Verification of Endplate Size and Appropriate Placement of Anterior Spikes

- There are eight slim trials available to verify endplate size and appropriate placement of the anterior spikes (ME568R-ME582R). All slim trials come in a lordosis of 9 degrees and in both standard and S1 endplate configurations.
- Attach a slim trial to the Wedge Trial Shaft (FW940R) by threading the slim trial endplate onto the distal end of the Shaft for Wedge Trial (FW940R).
- Carefully introduce the slim trial into the intervertebral space making sure that it is positioned centrally against the superior endplate. Check the size of the vertebral body endplate (Small, Medium, Large or Extra Large).

A margin of 1 -2 mm width is allowed between the lateral and posterior edges of the trial and the edge of the vertebral body.

- Use AP and lateral X-Ray views to ensure correct size, position, alignment and spike placement of the slim trial endplate.

b. Size Verification and Distraction

- The parallel distractor (FW970R) provides height, footprint and lordotic angle verification simultaneously.
- Mount the trial plates in orthogonal position on the parallel distractor (FW970R).
- The trial plates (FW922R-FW928R, FW971R-FW979R) snap on to the parallel distractor (FW970R).

Note:

- *Ensure the trial plates are loaded in the proper anatomical orientation, aligning the cranial marking on the trial plate with the cranial marking on the parallel distractor.*

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VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)



Fig. 18 – activL Parallel Distractor (FW970R)

- Carefully introduce the fully collapsed (so that no light is seen between the trial plates) parallel distractor into the intervertebral space, making sure that it is positioned centrally. Check the size of the vertebral body end plates.
- A margin of 1 – 2 mm width is allowed between the lateral and posterior edges of the trial plate and the edge of the vertebral body.
- Using AP and lateral X-Ray views, check to insure that the size, position, and alignment of the trial plates are correct.
- Turning the end cap on the distal end of the parallel distractor in a clockwise direction, open the distractor until it is firmly seated in the intervertebral space, as determined by tactile feel. Typically, two full rotations of the end cap will result in an increase in height, i.e., 8.5 mm to 10 mm.

Note:

- *In the activL Artificial Disc IDE study, 87% of the patients who were randomized to the activL cohort measured 8.5 mm.*

Warning:

- *Distract only enough to allow the instrument to fit firmly in the intervertebral space.*
 - *Irritation of the facet joints and strain on the dura and nerve roots can result from excessive or insufficient distraction.*

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

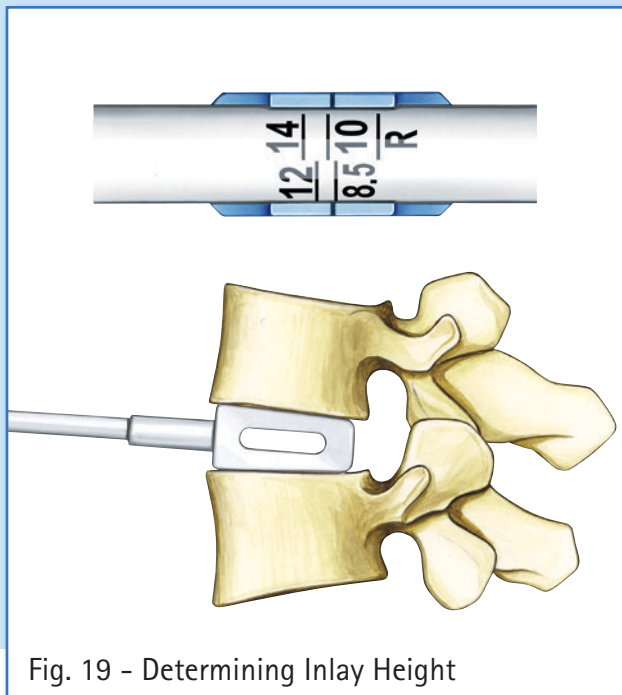


Fig. 19 - Determining Inlay Height

- Read the height on the scale. If the indicator lies between two numbers, choose the lower height.
- Release and remove the parallel distractor.
- Position 'R' for 'Release' for disassembly.
- If necessary use the spacer of the appropriate height (FW951R-FW954R) to maintain the correct distance after removal of the parallel distractor.

Note:

- *Appropriate implant sizing is critical. An undersized implant increases the risk of subsidence into the endplates.*
- *An oversized inlay may lead to over-distraction, which can irritate the facet joints, dura, or nerves. In addition, an undersized inlay could mean that the implant sits too loosely in the disc compartment and that insufficient stability is achieved.*

Note:

- *The height of the adjacent disc levels is the main criterion for determining the maximum height of distraction.*
- *Maximize the size of the implant with this constraint in mind.*

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

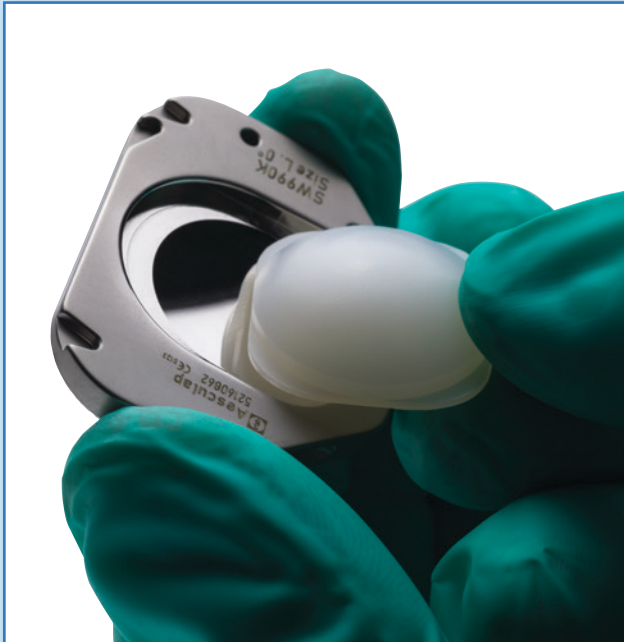


Fig. 20 – activL Implant Assembly

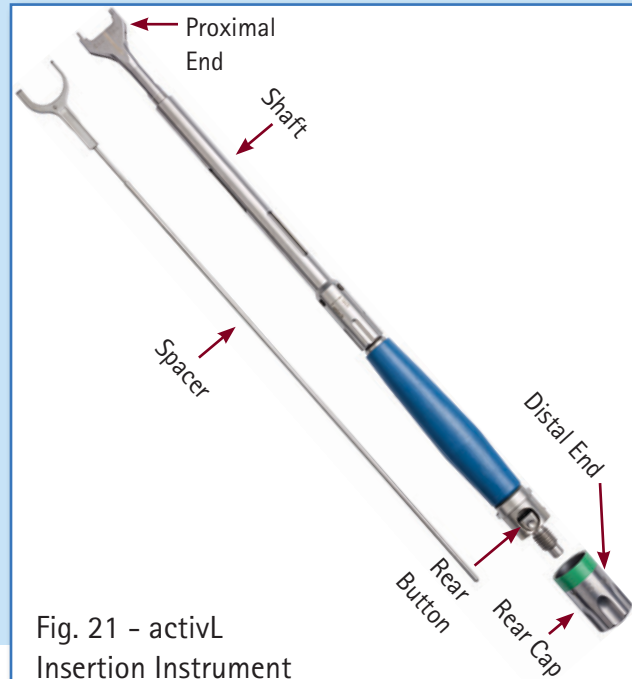


Fig. 21 – activL Insertion Instrument

6. Implant Preparation and Insertion

a. Implant Preparation

- Slide the inlay into the inferior plate with the alignment dimple towards the posterior end (away from the spikes).
- Engage the lateral tabs of the inlay into the groove of the inferior endplate. Advance the inlay to the posterior edge of the inferior plate. The inlay is now maximally secured.
- The inlay is correctly placed, if the inlay still translates easily and does not fall out of this position when the plate is turned upside down.

Note:

- Each Inlay is notched with a small, pen-tip-sized alignment dimple centered on the posterior facing side, below the dome. If any resistance is met upon insertion of the inlay into the endplates, the alignment dimple is likely misaligned. Do not force the inlay into the endplate.

b. Inserter Preparation

- The inserter will come through the sterile processing department (SPD) fully disassembled as pictured in Figure 20)
- To assemble the inserter (FW961R-FW964R), insert the inserter spacer through the proximal opening of the inserter shaft by using the alignment tabs. On the distal end of the inserter shaft, press the button while simultaneously pushing in the spacer from the proximal end using the opposite hand. Pull on the most distal component of the shaft to confirm that the spacer is locked into the shaft.

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

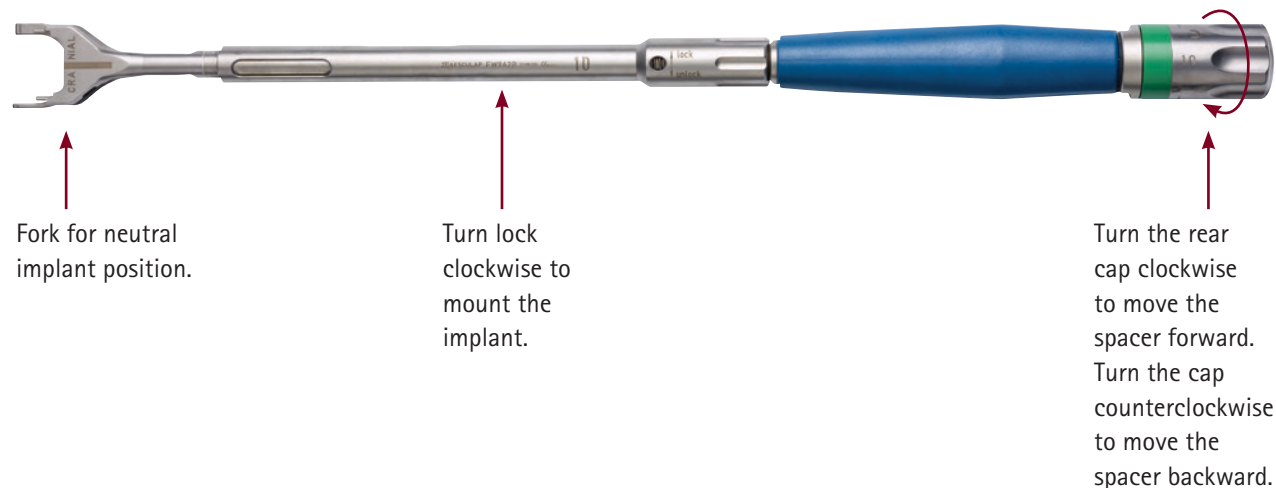


Fig. 22 - activL® Insertion Instrument

- Select the inserter that corresponds to the height of the inlay as determined during trialing.
- Turn the rear cap on the back of the inserter clockwise two full turns to move the spacer forward. The spacer insures that the implant is introduced in a neutral position.



activL Insertion Instruments (FW961R-FW964R)

Note:

- If rear cap comes loose during impaction with the mallet, turn the cap one full turn counter clockwise to re-secure. This results in a full transfer of force from mallet to implant insertion into the disc space.
- If this does not solve the issue, the inserter rear caps may have been damaged in SPD. Should this happen, the rear caps are interchangeable between inserter sizes and an alternate cap can be utilized as back-up.

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)



Fig. 23 - activL En Bloc Insertion Assembly

- Mount the completely assembled implant onto the inserter using the pins as guides.
- The inferior prosthesis plate must be at the part of the insertion instrument clamp that is marked 'CAUDAL' and the superior prosthesis plate must be at the part marked 'CRANIAL'.
- Turn the lock on the inserter to mount the implant securely.

Note:

- *Avoid touching the Plasmapore® coating while mounting the implant onto the inserter. Hold on to the sides of endplates.*

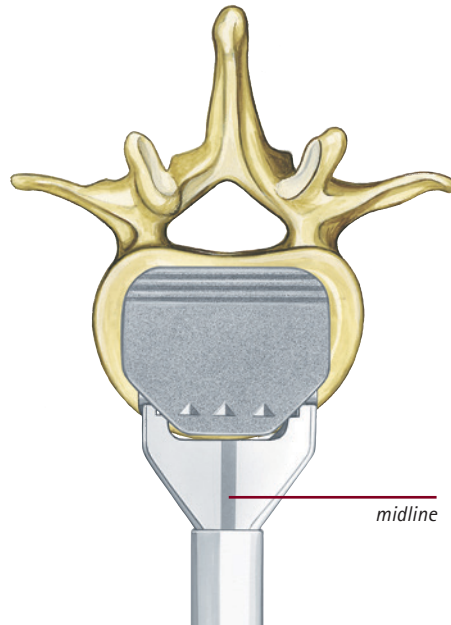


Fig. 24 - activL En Bloc Midline Insertion

c. Implant Insertion

- Continue to refer to the midline position during implantation. The marking on the inserter must be aligned with the midline marking. You may refer to the central spike of the endplates as an indicator of midline during AP X-Ray visualization.
- Impact the device into the disc space under fluoroscopy control.
- Under X-Ray visualization, drive the disc prosthesis into the intervertebral space until the posterior edge of the prosthesis is at the posterior edge of the vertebral body or 1 – 2 mm in front of it. While doing this, check the insertion depth on lateral X-Ray image because the depth is not limited by the instrument.

Continued on page 23.

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

Note:

- *Avoid tilting the implant sector caudally or cranially in order to advance both endplates evenly.*
- *Use only a hammer with plastic end caps to implant the artificial disc.*
- *The individual endplates can be impacted further posterior using the impactor (FW969R). It is recommended that the superior endplate be tapped back slightly further posterior than the inferior endplate utilizing this tool. Do this under X-Ray visualization.*

Warning:

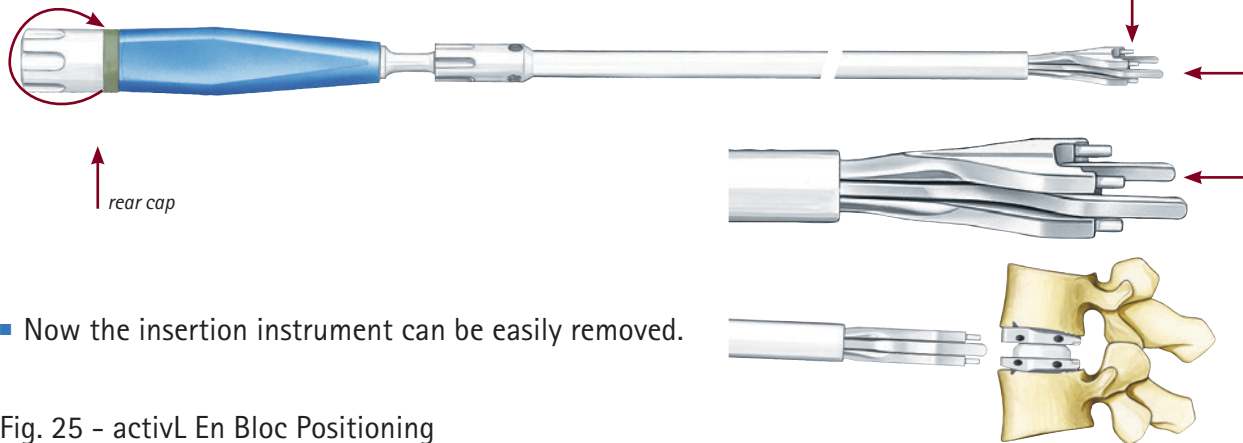
- *If the prosthesis is inserted too deeply, the spinal canal and other posterior elements may be compressed.*
- *Introduce the inserter into the intervertebral space under X-Ray visualization. Using AP and lateral X-Ray views, check to insure that the position and alignment of the prosthesis are correct. Carefully introduce the prosthesis into the intervertebral space. The superior prosthesis plate must be oriented toward cranial and the inferior toward caudal.*
- *Do not disconnect the inserter from the construct until you are satisfied with the position of the device. It cannot be re-attached.*
- *If the device cannot be driven posterior enough assess if release of the PLL and mobilization was properly achieved.*
- *Do not windshield wiper the implant while mounted on the inserter. This can potentially cause implant disengagement. It is important to maintain the implant trajectory.*

Surgical Technique

Specific to activL[®] Artificial Disc Spike Endplate

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 (continued)

- Release the lock of the insertion instrument.
- Turn the rear cap on the instrument counterclockwise to remove the spacer.

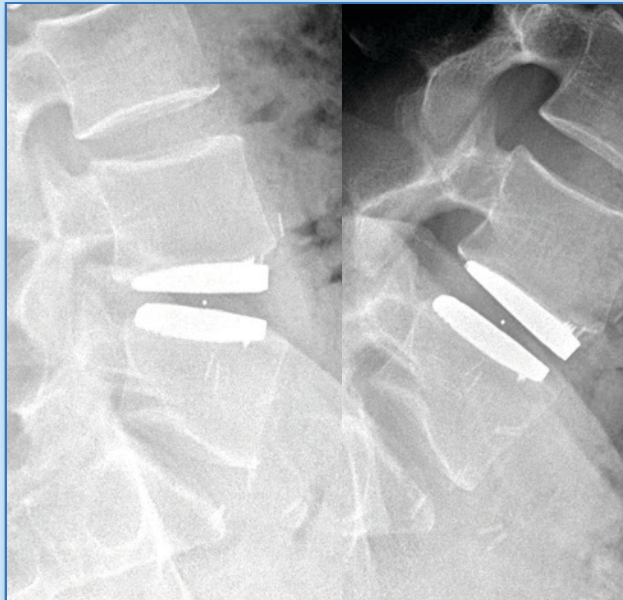


- Now the insertion instrument can be easily removed.

Fig. 25 - activL En Bloc Positioning

- Release the clamping sleeve on the insertion instrument and remove the insertion instrument. If necessary, utilize the activL key for inserter instrument (FW945R).
- Confirm the position of the prosthesis on the operative X-Ray, in the AP and lateral views.

VII. Surgical Technique: Anterior Approach L4/L5, L5/S1 *(continued)*



Source: Dr. Sola, University Hospital of Rostock

Fig. 26 - activL X-Ray Implant Verification

7. Final Implant Verification

AP and Lateral X-Ray images of the inserted implant.

Warning:

- *Vascular damage may be caused by protruding implants.*
- *Check to make certain that the prosthesis is positioned centrally as indicated by the radiographic marker inside the PE inlay of the prosthesis.*

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

VIII. Implant Revision/Reposition Technique

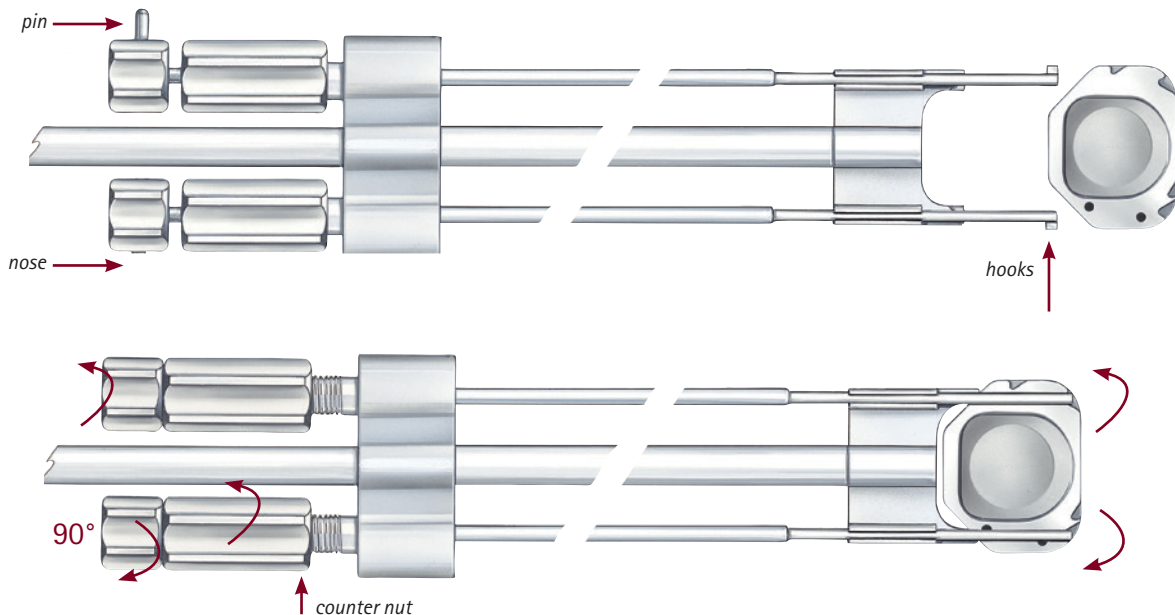


Fig. 27 - Overview of activL Revision Instrumentation

a. Implant Revision/Repositioning (if necessary)

- Instrument for:
 - Revision
 - Correction of implant position
 - Intraoperative implant exchange
- To mount the revision instrument onto either the inferior or superior endplate, rotate the hooks of the revision instrument into the anterior position.
- To insert the revision instrument, slide the hooks in between the two implant endplates beyond the posterior rim of the implant. The pins (located on the working end of the instrument for verification) should always show the same orientation as the hooks.
- Rotate the arms of the hooks to the downward position (to manipulate the inferior plate) and pull back the hooks until they lock into the grooves located on the posterior side of the implant endplates.

VIII. Implant Revision/Reposition Technique *(continued)*

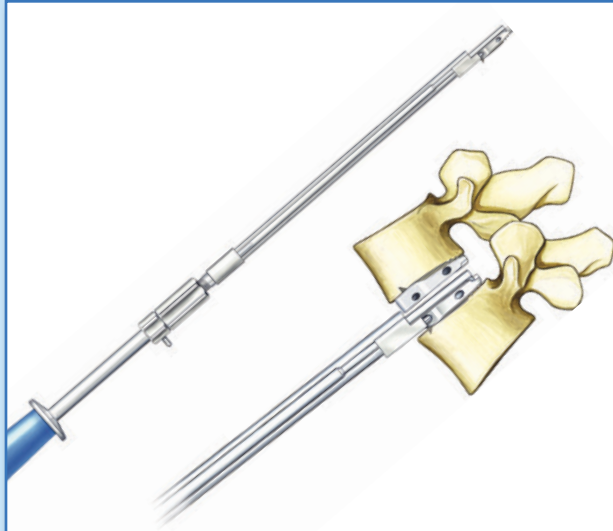


Fig. 28 - activL Revision Instrument for Endplates

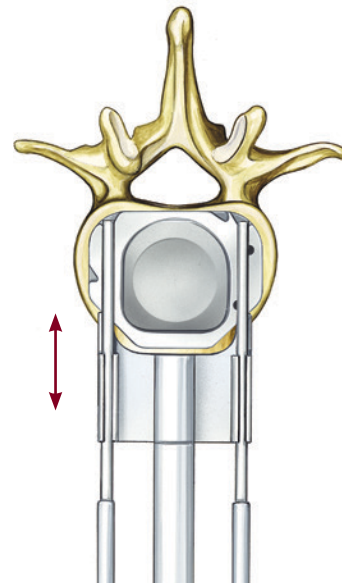


Fig. 29 - activL Revision Instrument Placement

- Once the hooks are in position, turn the counter-screw forward to lock the hook into position.
- Remove the implant carefully.
- After the first endplate is removed, the revision instrument can be mounted onto the second endplate and the same method can be used to remove the second endplate.
- In the case of complete implant revisions, remove implant endplates separately.

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

VIII. Implant Revision/Reposition Technique *(continued)*

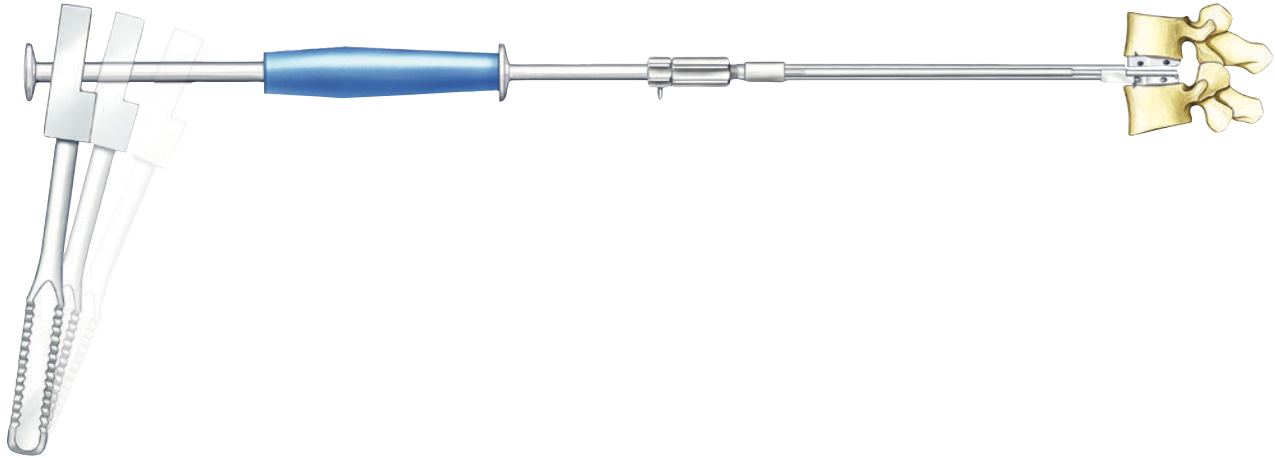


Fig. 30 – activL Endplate Removal Technique

- The revision instrument can also be used to correct the endplate position.

Note:

- *Make sure the anchoring rods do not turn while fixing the counter nut. This will cause the hooks to disconnect.*
- *Substantial integration of the endplates into the vertebral body may have occurred. This can make the revision procedure considerably more difficult.*
- *Where such integration has developed over a long period, it may be necessary to free the endplate from the vertebral body using a chisel or elevator before the revision instrument is used.*

VIII. Implant Revision/Reposition Technique *(continued)*

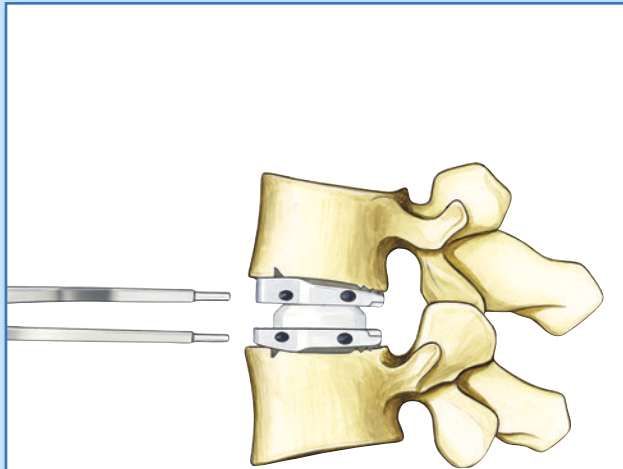


Fig. 31 - activL Inlay Revision

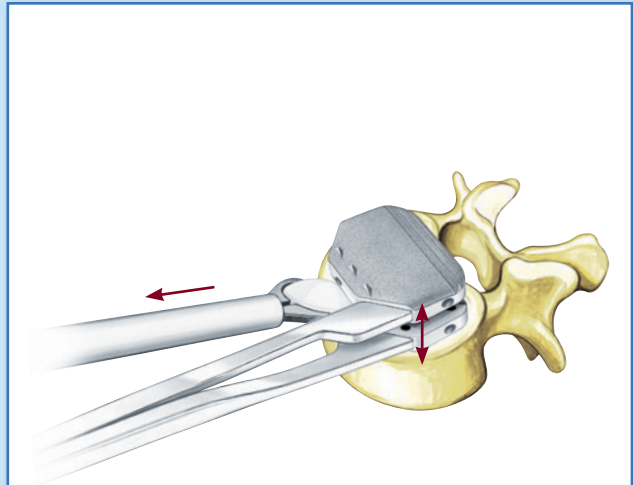


Fig. 32 - activL Inlay Removal

b. Inlay Revision

- Distract the endplates carefully with the revision distractor.
- Clamp the inlay with the inlay revision instrument and remove it.
- If necessary, implant a new inlay using the same method.

Note:

- *The inlay must be lifted over the edge of the inferior endplate.*

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

VIII. Implant Revision/Reposition Technique (*continued*)

c. Handling of Explanted Devices

Should it be necessary to explant an activL Artificial Disc, prior to explant, please contact Aesculap Implant Systems, LLC (see page 33), to receive instructions regarding the data collection, including histopathological, mechanical, patient, and adverse event information. Please refer to the activL Artificial Disc Surgical Technique for step-by-step instruction on the required surgical technique for device retrieval (see pages 26-29). All explanted devices must be returned to Aesculap Implant Systems, LLC for analysis, in a leakproof container, with the date of explantation, explanting surgeon, and any known information regarding initial implantation, reasons for removal, and adverse event information.

The following must be considered during activL revision and explantation procedures:

- If any components are misaligned in any way due to migration, expulsion, or original surgical malpositioning, every effort should be made to mark the components prior to removal in order to preserve their in situ orientation. Ideally, the

operating surgeon should be asked to make a small mark(s) with a fine osteotome at the mid-line position of the device components before removal. If the surgeon does not want to mark the components, then a photographic record as well as a written note of the position should be made. If the implants are not marked or photographed before extraction or immediately after, then the true location of the device or wear/damage features can only be guessed. If possible, photographs of the marks made should be taken immediately after the marks are made.

- Shortly after removal, a detailed record of any damage caused to the components during extraction should be performed, especially in the presence of the operating surgeon. Adequate 'macro' photography can also be helpful. This information should be adequately labeled and should accompany the explanted components. This will make it easy to differentiate between damaged regions caused in vivo and those caused during extraction.

VIII. Implant Revision/Reposition Technique *(continued)*

- A photographic record of both the retrieved components and any tissues/bone dissections should be performed immediately after revision surgery. This can be done after the scrub nurse has wiped the components free of excess blood and passed them from the sterile field, ideally onto a tray covered with a clean surgical towel. A surgery label as used with tissue specimens (i.e. showing the patient ID/number, date etc) should be photographed at the beginning of the series and included in the photos where possible. One photo should be taken at a magnification that allows all of the removed components to be viewed together, and subsequent photos should be taken of individual components at a magnification that allows their features to be clearly seen, including the laser markings and any obvious wear or damage to the parts. The retrieved components should be photographed on both sides. It is imperative to adequately label the retrieved parts for future identification.
- When decontaminating/sterilizing the device components, it should be done in a manner that does not alter features or surfaces which may be essential in determining failure modes. Cold sterilization techniques are recommended. The explanted components should be wiped with surgical swabs to remove excess blood and fluids then placed into separate plastic containers filled with 10% neutral buffered formalin at least twice the volume of the implant. Formalin is an acceptable method of decontaminating surgical explants and has the added benefit of preserving adherent tissues for future histological analysis. The containers must each have a standard surgical specimen label showing the medical record number, date of procedure, surgeon and the patient number. The member of the surgical staff who provides this container and receives the specimen should write the description of the individual specimens on the individual containers (for example, removed superior implant).

Surgical Technique

Specific to activL[®] Artificial Disc Spike Endplate

VIII. Implant Revision/Reposition Technique *(continued)*

- Formalin acts as a tissue preservative and as a decontamination method. A period of 24 hours is sufficient for explants with no or minimal tissue adherence, but specimens with substantial amounts of adherent bone (for example HA-coated end-plate components) will require more time in formalin, and permanent storage in formalin is typically used for these specimens. Formalin does not adversely affect the subsequent analysis of the surfaces. Other methods of decontamination such as autoclaving are not recommended as they might result in irreversible damage in the form of permanent adherence of residual blood or fluids, and will render adherent tissues unsuitable for subsequent histological analysis.
- Care should be taken during any subsequent handling of the specimens to avoid damage to the parts such as rubbing the surfaces together, dropping or knocking the parts or allowing tissue attached to the implants to dry out.
- When handling, packaging and shipping the retrieved components, avoid putting all the components in the same container without separating packaging. Each retrieved component should be individually wrapped and stored in its own container, then placed in a larger container with all the other retrieved components. This will prevent further damage to the explants, which can be difficult to distinguish from in situ damage.

VIII. Implant Revision/Reposition Technique *(continued)*

Should an activL® implant require explantation, it is imperative that the following information is collected:

- i. Date of implantation and device removal;
- ii. Identification of hospitals, or physicians' offices, where device implantation and removal was performed;
- iii. Confidential, unique, patient ID code to link to hospitals implantation and removal records;
- iv. Patient age and gender;
- v. Patient identification;
- vi. Identification of device/components (device lot number);
- vii. Reasons for device removal (primary clinical diagnosis);
- viii. Surgical site, spinal level, etc.;
- ix. Tissue samples, descriptions of tissues;
- x. Number of previous surgeries prior to implantation of current device;
- xi. Patient height and weight at time of implantation and removal;
- xii. Qualitative assessment of bone quality;
- xiii. Description of the surgical site at time of removal (e.g., debris, metallosis, osteolysis, etc.);
- xiv. Description of how the device was removed;
- xv. Any complications occurring during the removal procedure;
- xvi. Radiographs and other imaging;
- xvii. Main observations at revision;
- xviii. Patient activity;
- xix. Patient experience with implant;
- xx. Clinical performance;
- xxi. Original diagnosis;
- xxii. Length of follow-up; and,
- xxiii. Other mitigating factors.

Note:

■ *All implant removals must be reported immediately to Aesculap Implant Systems, LLC via the customer service line at 1-800-282-9000.*

CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician.

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

IX. Implant Overview

Implants

The implants are delivered sterile packed.

ST0565 – activL Implant Bank

PE Inlay

Height (mm)	8.5	10	12	14
PE inlay	SW965	SW966	SW967	SW968

The height shown corresponds to the height of the implant measured at the posterior end of the fully assembled construct.



activL Spike Endplates

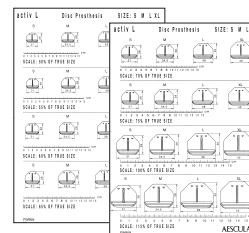
Components		Size (mm)			
		S (26x31)	M (28x34.5)	L (30x39)	XL (33x40)
Superior Plate	6°	SW971K	SW981K	SW991K	SW891K
	11°	SW972K	SW982K	SW992K	SW892K
Inferior Plate	0°	SW970K	SW980K	SW990K	SW890K
S1 Inferior Plate	5°	SW976K	SW986K	SW996K	SW888K



ST0565 – activL Implant Bank

activL® Artificial Disc Accessories

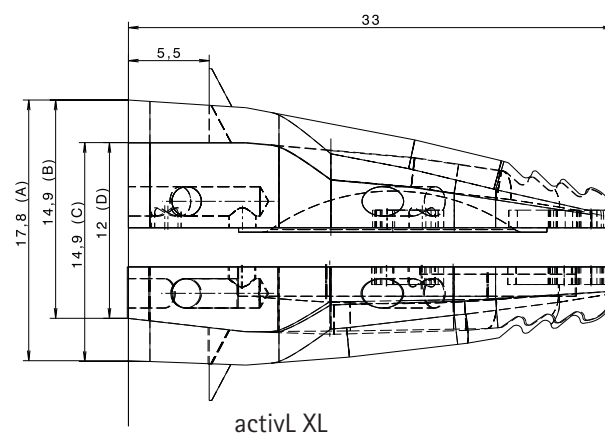
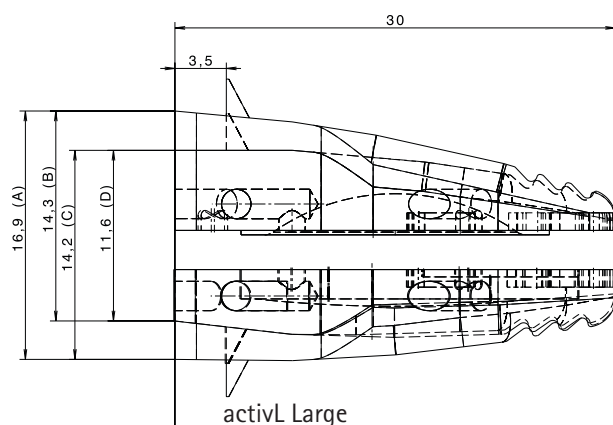
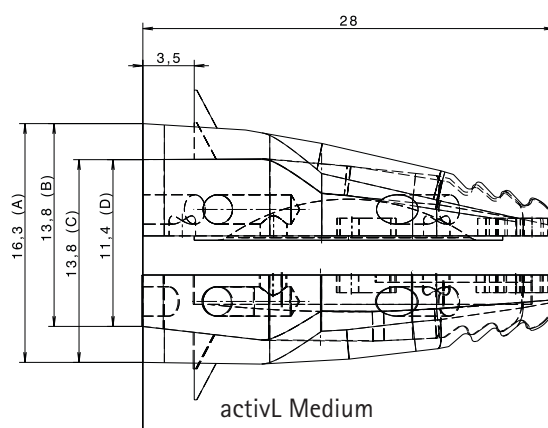
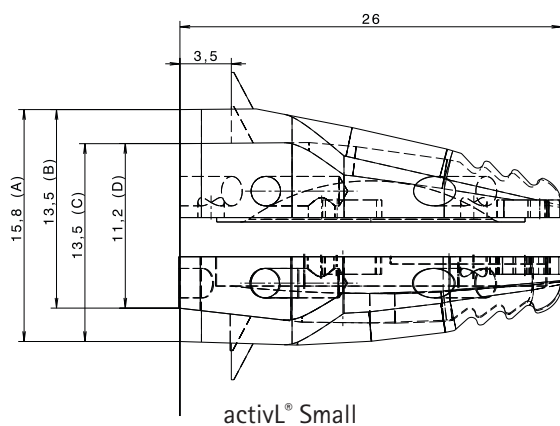
Qty.	Item No.	Description
1	FW921	activL X-Ray Template for S1 Implants
1	FW959	activL X-Ray Template



2	FW938SU	activL Tip for Anterior Midline Marker
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X. Sizing Charts

Anterior Height Measurements when Device is in Neutral Position



(A) Anterior Height with 5° Inferior Endplate and 11° Superior Endplate

(B) Anterior Height with 0° Inferior Endplate and 11° Superior Endplate

(C) Anterior Height with 5° Inferior Endplate and 6° Superior Endplate

(D) Anterior Height with 0° Inferior Endplate and 6° Superior Endplate

Note: All heights specific to 8.5 mm inlay.

Add 1.5 mm to all dimensions for the 10 mm inlay

Add 3.5 mm to all dimensions for the 12 mm inlay

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

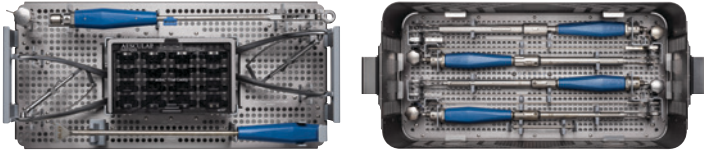
XI. Instrument Overview

System Overview

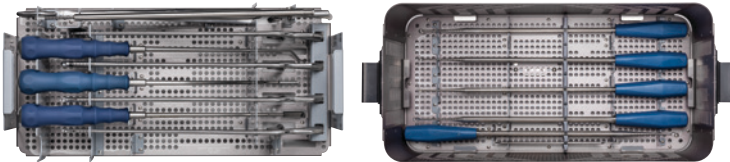
ST0566 – activL Instrument Set

Description

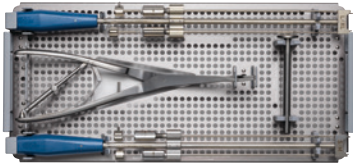
Distraction, Trialing and Insertion Tray



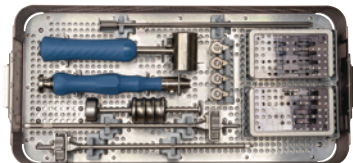
Discectomy Tray



Auxiliary and Repositioning Tray










Auxiliary Trialing and Confirmation Tray



XI. Instrument Overview *(continued)*

activL® Artificial Disc Distraction, Trialing and Insertion Tray
















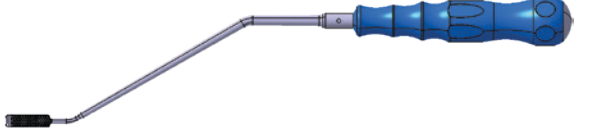
Qty.	Item No.	Description	
Base			
1	FW961R	activL Insertion Instrument for 8.5 mm	
1	FW962R	activL Insertion Instrument for 10 mm	
1	FW963R	activL Insertion Instrument for 12 mm	
1	FW964R	activL Insertion Instrument for 14 mm	
1	FW945R	activL Key for Insertion Instrument	
Top Level			
1	FW999R	activL Impactor with Pins	
1	FW970R	activL Parallel Distractor	
2	FW960R	activL Distraction Forceps Angled	
1	FW922R	activL Trial Implant Inferior, S1 Size S 5°	
1	FW923R	activL Trial Implant Inferior, S1 Size M 5°	
1	FW924R	activL Trial Implant Inferior, S1 Size L 5°	
1	FW925R	activL Trial Implant Inferior, S1 Size XL 5°	
1	FW971R	activL Trial Implant Inferior, Size S 0°	
1	FW972R	activL Trial Implant Inferior, Size M 0°	
1	FW973R	activL Trial Implant Inferior, Size L 0°	
1	FW926R	activL Trial Implant Inferior, Size XL 0°	
1	FW974R	activL Trial Implant Superior, Size S 6°	
1	FW976R	activL Trial Implant Superior, Size M 6°	
1	FW978R	activL Trial Implant Superior, Size L 6°	
1	FW927R	activL Trial Implant Superior, Size XL 6°	
1	FW975R	activL Trial Implant Superior, Size S 11°	
1	FW977R	activL Trial Implant Superior, Size M 11°	
1	FW979R	activL Trial Implant Superior, Size L 11°	
1	FW928R	activL Trial Implant Superior, Size XL 11°	

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

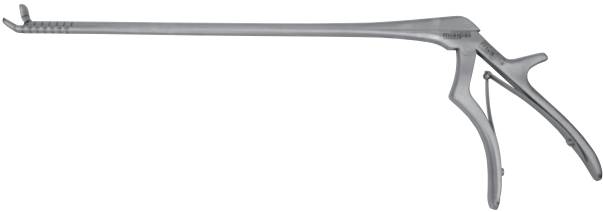



XI. Instrument Overview *(continued)*

activL Artificial Disc Discectomy Tray








Qty.	Item No.	Description	
Base			
1	ME182R	Cobb Elevator Anterior Approach (1/2")	
1	ME183R	Cobb Elevator Anterior Approach (3/4")	
1	ME184R	Osteotome Anterior Approach, 12.6 mm	
1	BT070R	miaspas TL Exploration Hook, 5 mm	
1	BB085R	Scalpel, #4L	
1	FK826R	miaspas® TL Ring Curette, D 6.4 mm	
1	FK822R	miaspas TL Curette Rectangular, 7 x 5 mm	
1	FK780R	Curette Endo straight, 4.4 x 6.2 mm 80 mm Working Length	
1	FK781R	Curette Endo, 5.2 x 7.3 mm 80 mm Working Length, Straight	
1	FK791R	Curette Endo, 5.2 x 7.3 mm 80 mm Working Length, Curved	
Top Level			
1	FW914R	Curette, Bilateral, Round, Angled 10 mm	
1	ME185R	Reverse Angle Cup Curette, 60°, 5.2 mm x 7.3 mm	
1	FF529R	Soft Tissue Rongeur Endo Straight, 4 x 14 mm	
1	FW912R	Rasp, Straight	
1	FF530R	Soft Tissue Rongeur Endo, Straight, 6 x 16 mm	
1	FW913R	Rasp, Angled	

XI. Instrument Overview *(continued)*

activL Artificial Disc Discectomy Tray *(continued)*

Qty.	Item No.	Description	
		Base	
1	FF541R	miaspas® TL Rongeur, 30° Up, 6 x 16 mm	
1	FF539R	miaspas TL Rongeur, 30° Up, 4 x 14 mm	
1	FG052R	Sypert Bone Rongeur, 8/360 mm	
1	FG894R	Kerrison Rongendo 4.0 mm 90° Up 310 mm	

activL® Artificial Disc Auxiliary and Repositioning Tray



Qty.	Item No.	Description	
		Lower Level	
1	FW965R	activL Revision Instrument Distraction fork	
1	FW966R	activL Revision Instrument for Plate, Size S/M	
1	FW967R	activL Revision Instrument for Plate, Size L/XL	
1	FW998R	activL Handle for Revision Instrument	
		Top Level	
1	FW955R	activL Anterior Midline Marker	
1	FL045R	Mallet Removable-Discs, 30 mm 200gr. 248 mm	
1	FW940R	activL Stem for Wedge	
1	FW951R	activL Spacer for 8.5 mm	
1	FW952R	activL Spacer for 10 mm	
1	FW953R	activL Spacer for 12 mm	
1	FW954R	activL Spacer for 14 mm	

Surgical Technique

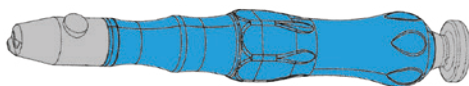
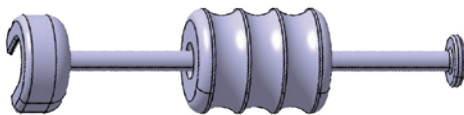

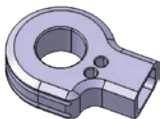
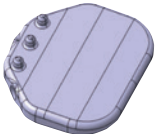

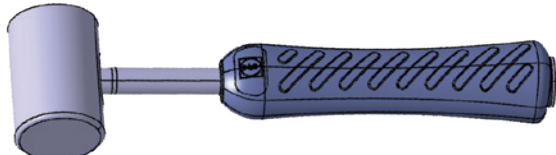
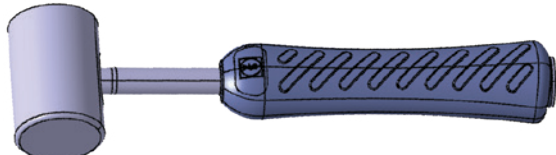
Specific to activL® Artificial Disc Spike Endplate

XI. Instrument Overview *(continued)*

activL® Artificial Disc Auxiliary and Repositioning Tray *(continued)*

Qty.	Item No.	Description	
Lower Level			
1	FW968R	activL Revision Instrument for PE-Inlay	 
1	FW941R	activL Wedge for 6 mm	
1	FW942R	activL Wedge for 8.5 mm	
1	FW943R	activL Wedge for 10 mm	
1	FW944R	activL Wedge for 12 mm	

activL Artificial Disc Ancillary Trialing and Confirmation Tray

Qty.	Item No.	Description	
1	ME245R	Silicon Handle	
1	SJ709R	Slap Hammer	
2	ME246R	Trial Insertion Instrument	
1	ME586R	8.5 mm Anterior Trial Adapter	
1	ME587R	10 mm Anterior Trial Adapter	
1	ME588R	12 mm Anterior Trial Adapter	
1	ME589R	14 mm Anterior Trial Adapter	
1	ME568R	Small Slim Trial	
1	ME570R	Medium Slim Trial	
1	ME572R	Large Slim Trial	
1	ME574R	Extra Large Slim Trial	
1	ME576R	Small S1 Slim Trial	
1	ME578R	Medium S1 Slim Trial	
1	ME580R	Large S1 Slim Trial	
1	ME582R	Extra Large S1 Slim Trial	
2	FW940R	activL Stem for Wedge	
1	FL066R	Hammer Ombredanne Head, D: 40 mm, 520 gr, 240 mm	

For further information please refer to the instructions for use (IFU) for the implants and instruments by visiting the Aesculap website at www.aesculapimplantsystems.com or calling customer service at 1-800-282-9000.

SOP-AIS-5000179	Implants
TA011450	Parallel Distraction Instrument
TA011458	Insertion Instrument
TA011904	Distraction Forceps Revision Instrument

Surgical Technique

Specific to activL® Artificial Disc Spike Endplate

XII. Product Complaints

Product Complaints

Any health care professional (e.g., customer or user of this system), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness or performance, should notify Aesculap Implant Systems, LLC. Further, if any of the implanted system component(s) ever "malfunction," (does not meet any of its performance specification or otherwise does not perform as intended), or may have caused or contributed to the death or serious injury of a patient, Aesculap Implant Systems, LLC, 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, and the nature of the complaint. Complaints may also be reported directly to Medwatch at <http://www.fda.gov/medwatch>. You will be contacted by Aesculap Implant Systems, LLC to provide specific information regarding your clinical experience regarding the complaint and overall experience with the device. In the event that the activL implant requires removal for any reason, follow the instruction provided on page 30 in the Handling of Explanted Devices section.

Notes

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