Aesculap Spine

activ L®

Lumbar Intervertebral Disc Prosthesis

Operating technique

B BRAUN
SHARING EXPERTISE

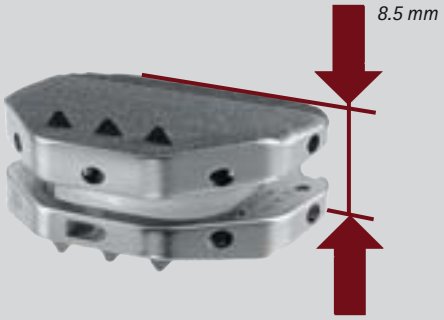
activ L®

Contents

A) Product Information

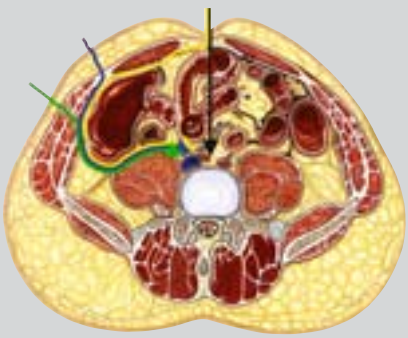
A.1 Product Features

Less risk of over-distraction.
Use also possible in low disc space cases:
Numerous surgeons started to use activ L® because of the low minimum height of the implant, which gives the option to treat patients without overdistraction even if the disc space is very small.



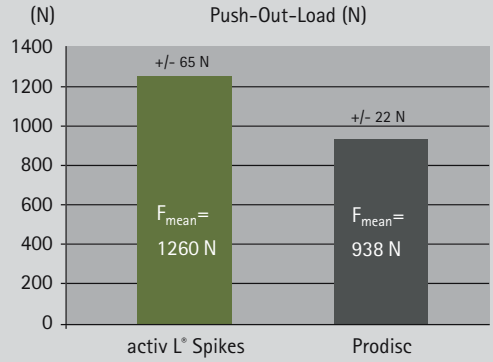
Clinical results show, that in approx 47.5 % the application of a small height (less then 9 mm) is indicated.

Spike version provides the option of intra-operative correction:
Insertion of the spike version is suitabel for both, the anterior and the anterolateral approach.
The spike version allows an intraoperative correction in the lateral, the anterior-posterior and rotational direction.



Primary stability of spike version is comparable (slightly better) to keel version:
Biomechanical tests show that the spike version has higher pull-out strength in anterior-posterior direction then the keel version.

Push-Out-Load in N of activ L® Spike Version and Prodisc (Keel Version)



In a Push-Out-Load test activ L® Spike Version showed a significantly higher push-out resistance versus Prodisc L with keels on both sides.

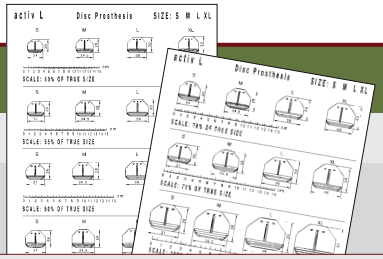
A.2 Safety Information

Under no circumstances may modular implant components from different suppliers be combined.
Previously implanted devices may not be reused.
Damage to the load-bearing structures of the implant may cause the loosening of components, their dislocation and migration, and other severe complications.
Postoperatively, the implant should be inspected on a regular basis to determine whether it is functioning properly.

A.3 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.

B) Pre-Operative Planning



B.1 Size Estimation

Assess the largest possible implant bed area using ct-scan diagnostics with x-ray templates and check the scale factor of the used template.

Control the anatomy of the major vessels, especially the left common iliac vein.
Is it possible to mobilize the vessels sufficiently and to move them away from your approach? Would a pararectus approach be easier?

Warning:
- There is a risk of selecting the wrong size of the prosthesis plate if an X-ray template with wrong scale is used.
- Be sure to use an X-ray template of the correct scale.
- Preoperative planning using X-ray templates is required.

Warning:
- There is an increased risk of migration if the prosthesis plate selected is too small. The plate must completely cover the end of the vertebral body. Select a prosthesis plate that provides maximum coverage of the vertebral body.

Warning:
- Select the correct inlay height to achieve height reconstruction whilst preserving adequate mobility in the joint.

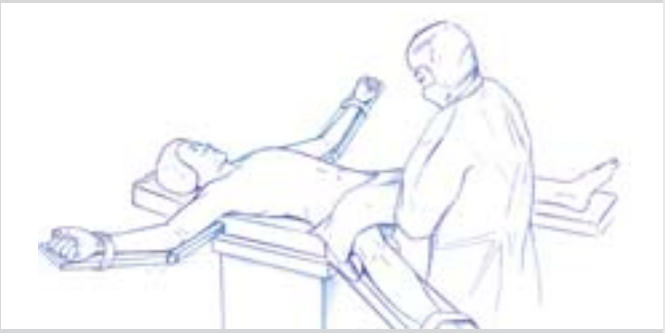
B.2 Patient Positioning

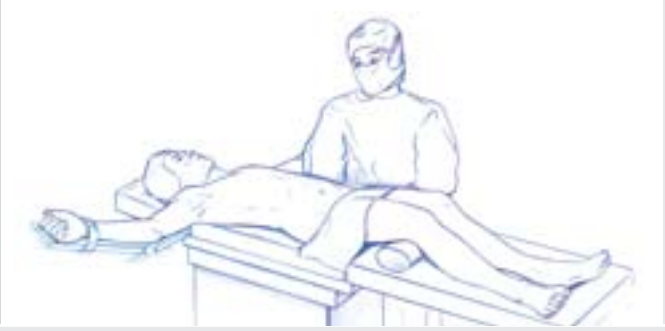
The operating table should permit image intensifier images in 2 planes in the operating zone.

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, 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.
A right side approach is recommended for the L5/S1 level and a left side approach for higher levels.





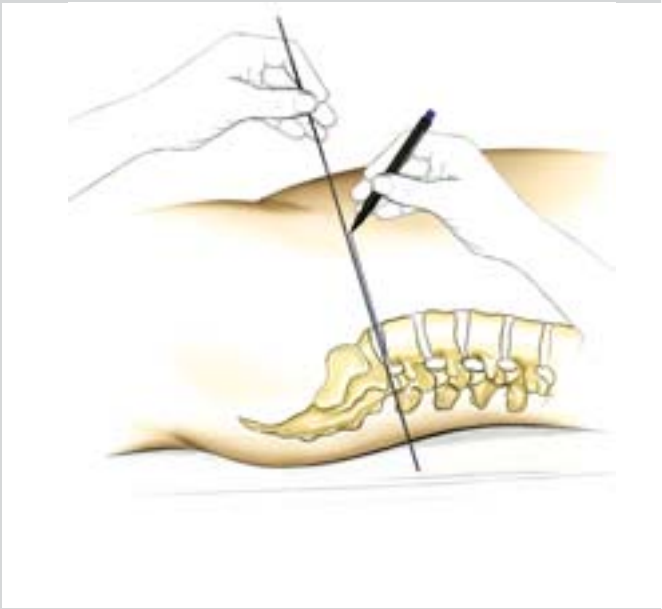
C) Approach

C.1 Marking the Approach

Anterior Approach L4/L5, L5/S1

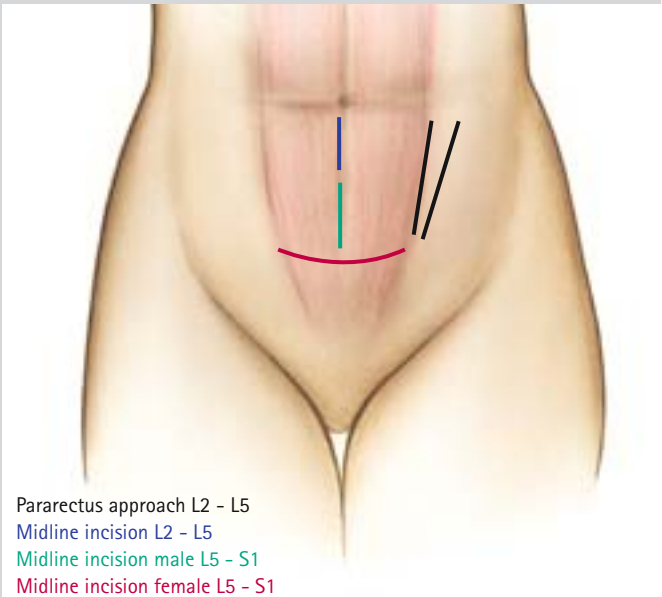
To mark the incision a lateral image is taken with a metal rod parallel to the defective disc compartment.
The extension of this marking corresponds to the midpoint of the skin incision.

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.



C.2 Skin Incision

The approach should be retroperitoneal. Transperitoneal approaches carry a considerably higher complication risk (ileus, lesion of the presacral plexus).



Pararectus approach L2 - L5
Midline incision L2 - L5
Midline incision male L5 - S1
Midline incision female L5 - S1

C) Approach

C.3 Approach

Midline Approach
L5/S1

A midline approach is always used for the L5/S1 level.

A Pfannenstiel´s incision or a linear midline incision are possible.

Both sides are possible for the approach. If no other level is to be operated on, the right side may be preferred.

Pararectus Approach
L3/4, L4/5

A midline approach or a pararectus approach (always left) are possible in the L3/4 and L4/5 segments.

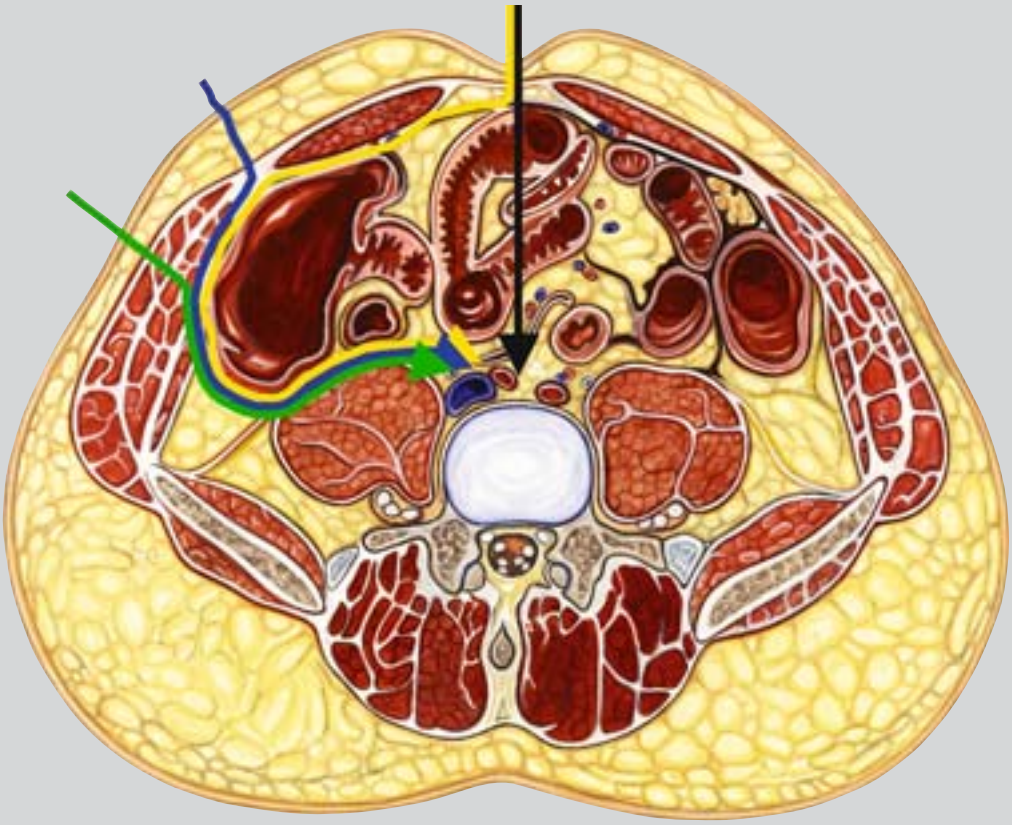
Note:
Advantages of the midline approach:
- Considerably easier implant positioning, less retraction of the abdominal muscles required.

Note:
Advantages of the pararectus approach:
- Simpler retroperitoneal preparation, less manipulation of the vessels in L4/5.

NB:
- All approaches demand the greatest care in the preparation of the major vessels.
- A vascular surgeon should be constantly available on call during this operation.

C.4 Anatomical structures

Midline + Pararectus Approach
L5/S1 + L3/4, L4/5



- Anterior transperitoneal
- Anterior retroperitoneal
- Antero-lateral retroperitoneal
- Antero-lateral transmucular

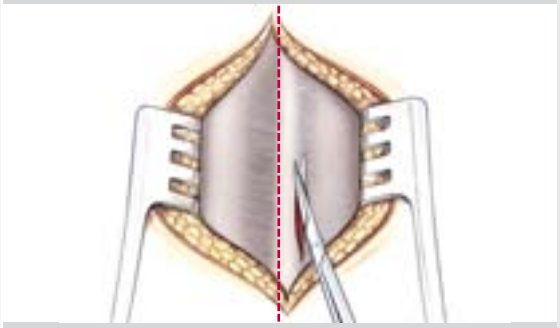
C) Approach

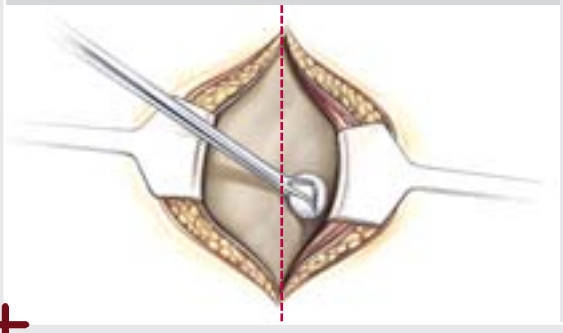
C.4 Anatomical Structures

Midline Approach
L5/S1

After the skin incision: linear incision of the anterior fascia of the rectus abdominis muscle 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 must be coagulated and dissected if necessary.



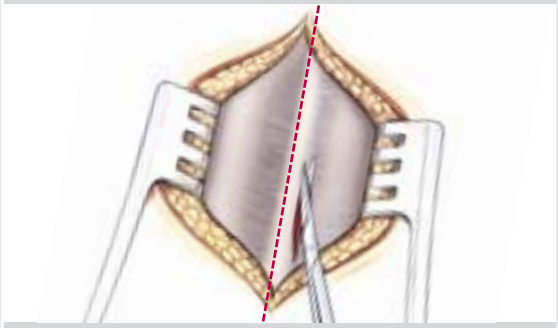


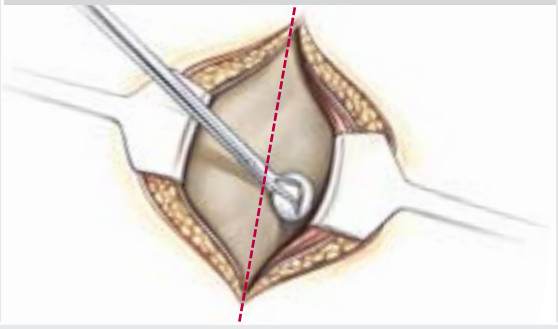
Pararectus Approach
L3/4, L4/5

Midline Approach:
As described for ventral L5/S1.
The essential difference from the L5/S1 level is that the rectus abdominis muscle in the central and upper abdomen also possesses a rear fascia which it does not have in the lower abdomen. Since this can only be removed from the peritoneum with great difficulty, it should be opened as far laterally as possible after retraction of the muscle.

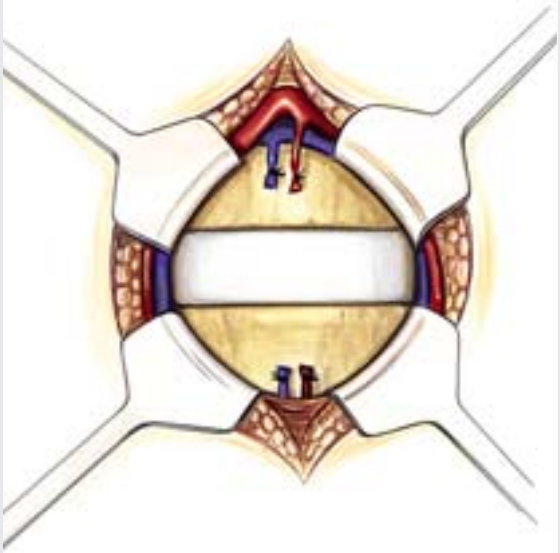
Pararectus Approach:
Considerably easier on the upper lumbar region of the spine, but only suitable for the spike version. Higher risk of segmental denervation of the abdominal muscles.

The muscle fascia is dissected longitudinally where it meets at the lateral margin of the rectus abdominis muscle.





Midline Approach
L5/S1



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 prosthesis size.

NB:

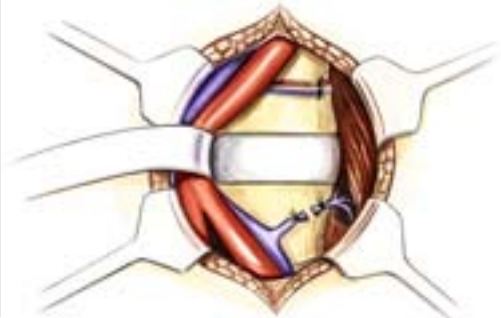
- The linea alba is not opened. The anterior fascia of the rectus is opened paramedially.

Pararectus Approach
L3/4, L4/5

A blunt instrument is used to push the peritoneum away from the abdominal wall whilst monitoring the epigastric vessels.
The ureter is prepared away from the operating site together with the peritoneum.
The ventrolateral spine is exposed at the anterior margin of the psoas muscle.
The neighbouring segment vessels are ligated and dissected, including the ascending lumbar vein for the approach to the L4/5 segment, so that the major vessels can be mobilized to the opposite side.
The sympathetic nerve is mobilized in a lateral direction. If possible the situs is "fixed" with self-retaining retractors.

Note:

- In the midline marking process, the lateral inclination of the operating table may have to be adjusted to compensate for any possible turning of the patient caused by retraction of the muscles and abdominal organs.
- Small errors in the axial orientation of the control x-ray can lead to serious malpositioning of the implant.



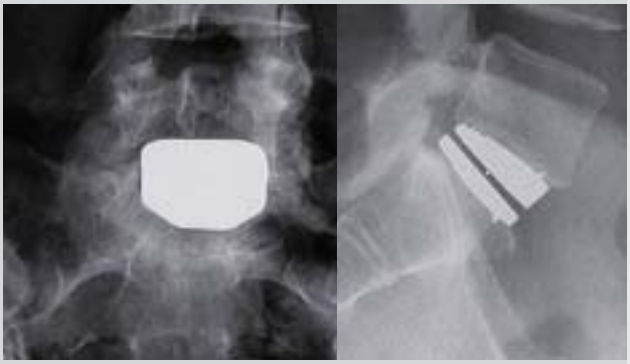
C) Approach

C.5 Spike Version vs. Keel Version

Generally the use of the spike version is indicated.

Biomechanical tests show that the spike version shows comparable pull-out strength in anterior-posterior direction then the keel version. This is due to the convex shape of the upper plate and the resistance of the three spikes compared to the resistance of only one keel.
The spike version allows an intraoperative correction in both the lateral and anterior-posterior direction.
There is less damage to the vertebral end-plates with the spike compared to the keel version. Therefore less risk for migration of the prothesis into the vertebral body and less risk of fusion due to the bleeding caused by chiseling.
The chiseling puts a lot of force into the whole structure and therefore could lead to a injury of the vertebral segment.

The keel version is indicated if the endplates show an extreme concave curve or extreme unevenness of the surface.
The keel version is not indicated if the vertebral endplates show a strong sclerotiziation.
In this case there is a high risk to injure the vertebral structure or to split the vertebral body due to the high forces necessary for chiseling and impacting the implant.



activ L®
spike version

activ L®
keel version

C.6 S1 Design

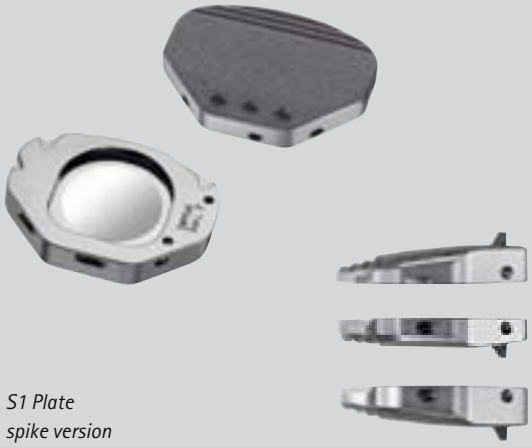
The S1 plate is an additional option for the surgeon to address patient`s anatomy.

There are patients who have a sacrum with a rather round or egg shaped cross-sectional footprint.
For those patients the S1 plate has rounded posterior edges and can therefore be placed close to the posterior rim 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, which reduces the risk of subsidence and nerve root irritation.

The S1 plate is just an option, there are of course 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 a proper fixation and alignment of the activ L® 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 activ L® surgery due to limitations in available sizes.
  An x-ray template is available which can be used for preoperative planning in order to determine the appropriate size.



S1 Plate
spike version

S1 Plate
keel version

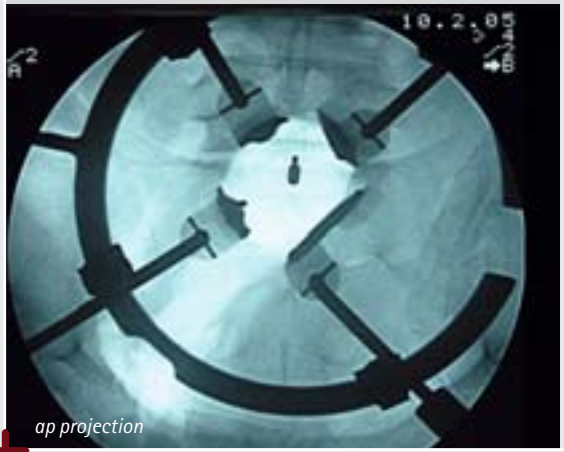
D1) Instrumentation – Spike Version

D.1.1 Midline Marking

activ L®
spike version

Midline Approach
L5/S1

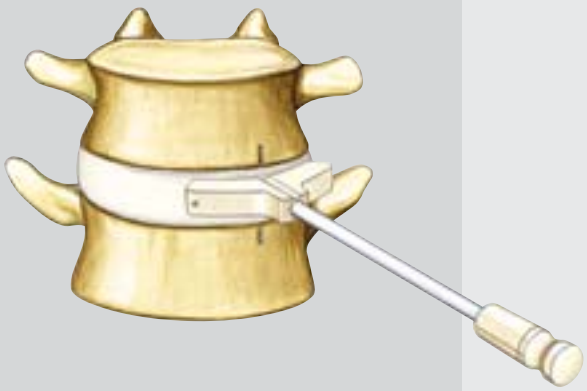
Define the midline of the vertebral body under ap x-ray control.



ap projection

Pararectus Approach*
L3/4, L4/5

The midline marker must be selected according to the preplanned implant size S, M, L or XL.



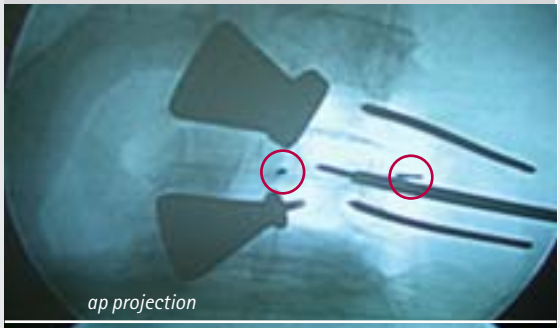
*** Pararectus Approach**
The pararectus approach is only explicitly described when the instruments or technique differ from those of the midline approach. Otherwise the midline approach is given as an example.

Midline Approach
L5/S1

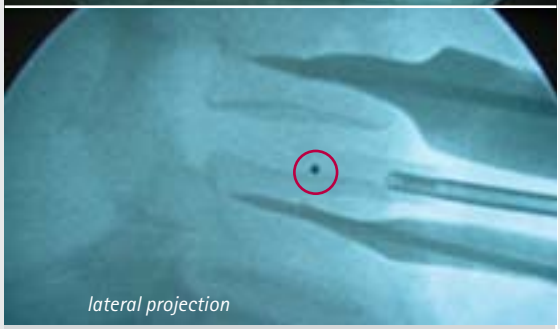
The midline is marked with the pin in the disc compartment under image intensifier control.
Alternatively, the marking can be set in the neighbouring vertebral body for the entire duration of the surgery.
Applicable only / mainly for the spike version.

Pararectus Approach
L3/4, L4/5

Define the 45° approach to the vertebral body with the help of the lateral midline marker under ap and lateral x-ray control.



ap projection



lateral projection

First an ap x-ray is done to check the midline position of the marker. If the ap-midline is correct a lateral x-ray is done.
Also in this view the Tantalum Marker of the device must be targeted to the lateral midline of the vertebral body. If the size selected does not fit, choose a different marker size.
Mark the 45° position with the pin in the disc compartment.

NB:

- Make sure that the vertebrae are portrayed in an orthograde position on the x-ray. The pedicles and the spinous process can be used for orientation and determination of the midline.
- The exact position of the implant is of vital importance for correct function.

D1) Instrumentation – Spike Version

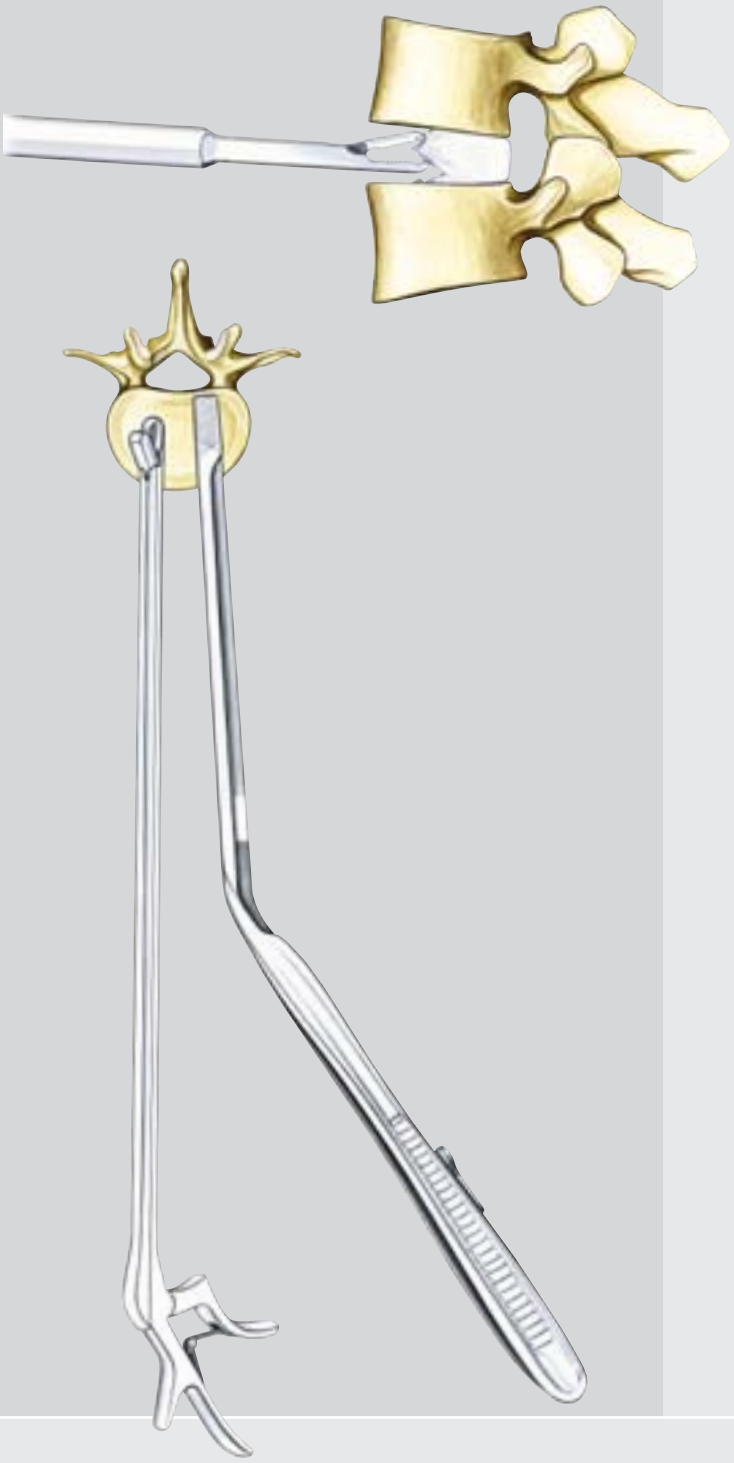
D.1.2 Discectomy and Mobilization of the Segment

Discectomy

A discectomy is performed and the endplates cleansed from disc residue with a curette. The cartilage is also removed to facilitate osteointegration of the Plasmapore® µ-CaP coating of the implant endplates.

If necessary, metal wedges available in different heights or the angled distractor can be used to maintain the correct distance.

The angled distractor provides a better view into the operating site and facilitates the discectomy and preparation of endplates.

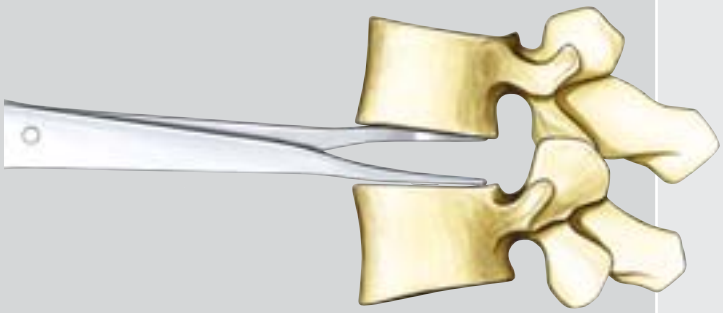


NB:

- The cartilage structures should be removed as completely as possible. Cartilage structures can impede osteointegration of the Plasmapore® µ-CaP coating of the implant endplates.
- Extensive preparation of the endplates could increase the risk of implant migration.
- The lateral preparation of the anulus should be adjusted to the extend of required mobilization and the needed space for the activ L® prosthesis, which can be assessed with the trial implants.

Mobilization

Mobilize the disc compartment with the distractor.
The mobilization of the segment is an important point and should be monitored under x-ray control.



Note:

- Use flouroscopic control to ensure that the instrument is fed forward as far as possible to the posterior part of the disc compartment to avoid loading peaks on the endplates, and to ensure a parallel distraction.
- Wedge shaped intervertebral disc space distraction:
  The posterior release of the segment is a critical point and should be monitored under x-ray control. The release and mobilization should be controlled for left and right compartment.
  The PLL should be released at least from the posterior rim of the vertebral bodies or even removed completely.
  An angled raspatory can be used for this release.

D1) Instrumentation – Spike Version

D.1.3 Parallel Distraction, Height Measurement and Size Verification

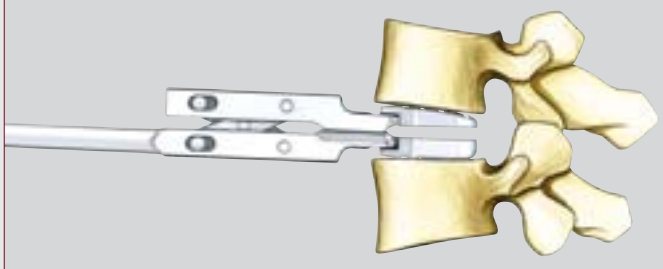
Mount the trial implant with the defined angle and size onto the parallel distractor.

Align the midline markings on the trial implant and the instrument.

Verify the size of the trial implant in the disc compartment by x-ray.
Expand the parallel distractor by turning the rear button until the resistance due to distraction increases (sufficient distraction is achieved when the button can not be turned easily by hand anymore).
Check carefully the position and placement of the implant by x-ray. If necessary try a different size of trial implant.

NB:

- If the loading is too high, the parallel distractor can be bended. In this case the scale will show the wrong height (too high). Please choose a smaller height for implantation. Please check during the whole size verification the parallel alignment of the two trial endplates with x-ray control.



Midline Approach
L5/S1

For the midline approach the trial implant is mounted in 0° position.

Pararectus Approach
L3/4, L4/5

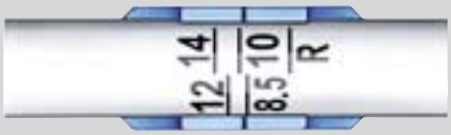
Align the side markings of the trial implant and the instrument.
Mount the trial implant in a 22.5° position.

The angle of the parallel distractor (22.5°) is half that of the inserter (45°) in order to make it easier for frequent insertions.

D1) Instrumentation – Spike Version

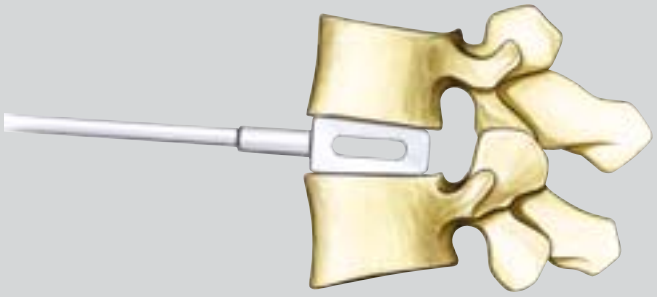
D.1.3 Parallel Distraction, Height Measurement and Size Verification

Read the height on the scale. If the indicator lies between two numbers, choose the smaller height.



Release and remove the parallel distractor. Position "R" for "Release" for disassembly.

If necessary use the spacer of the appropriate height to maintain the correct distance after removal of the parallel distractor.



Note:

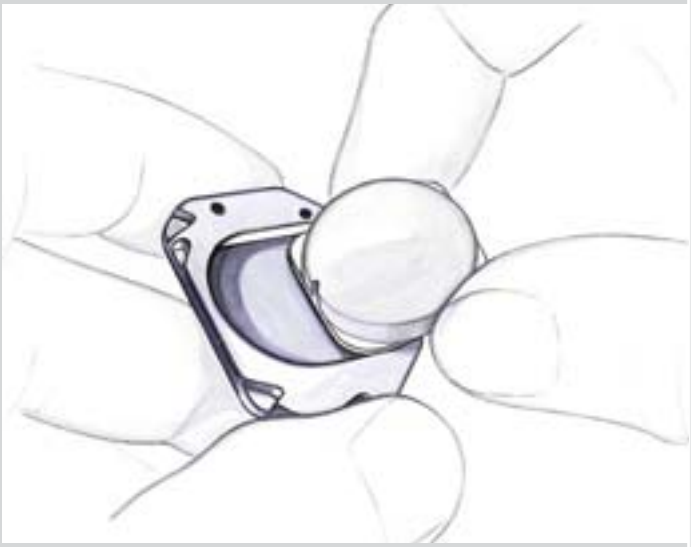
- The footprint of the implant should cover most of the vertebral endplates. Too small implants increase the risk of migration into the endplates.
- An oversized inlay may lead to over-distraction, which can irritate the facets, (dura) or nerves.
- An undersized inlay could mean that the implant sits too loosely in the degenerated disc compartment which could lead to instability.

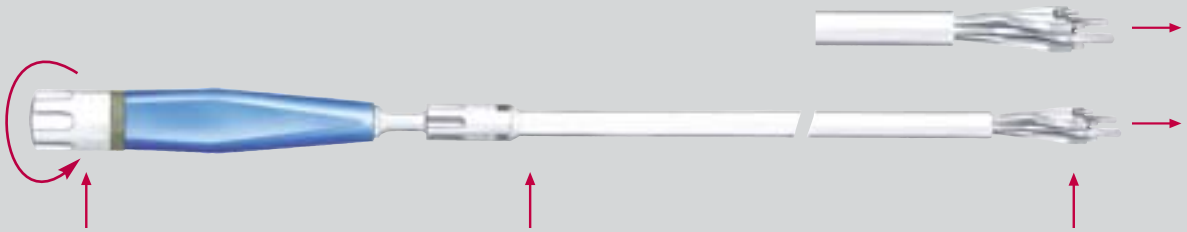
D.1.4 En Bloc Implantation

Slide the inlay into the inferior plate with the notch towards the posterior part of the prosthesis.

Select the inserter that corresponds to the height of the inlay. The inserter spacers are colour coded:
8.5 mm: blue
10 mm: green
12 mm: black
14 mm: yellow

Turn the rear button to move the spacer (fork) forward. The spacer ensures that the implant is introduced in a neutral position.





Turn the button to the right to move the spacer forward. Turn the button to the left to move the spacer backward.

Turn lock to the right to mount the implant.

Fork for neutral implant position.

D1) Instrumentation – Spike Version

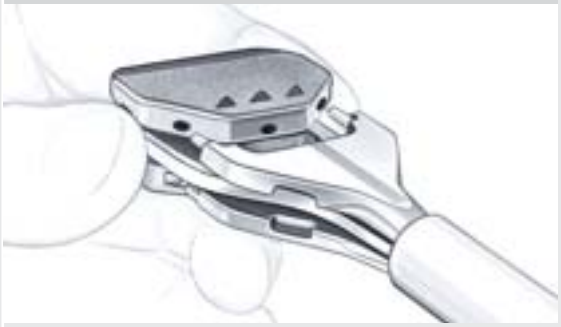
D.1.4 En Bloc Implantation

Mounting the Implant

Mount the completely assembled implant onto the inserter, connecting the superior plate with the "cranial" marking on the inserter.

Turn the lock on the inserter to the right side to tighten the implant securely.

For the midline approach the implant is mounted in 0° position.

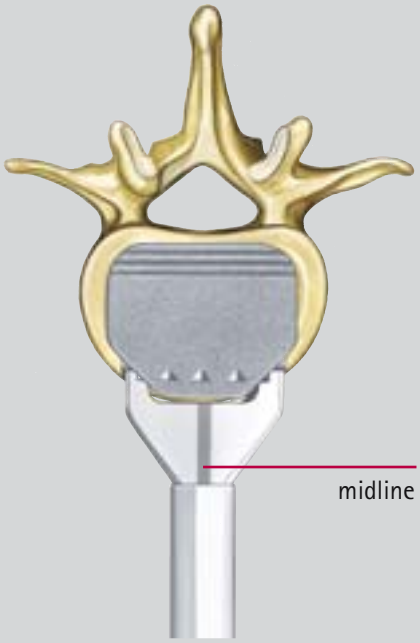


Pararectus Approach
L3/4, L4/5

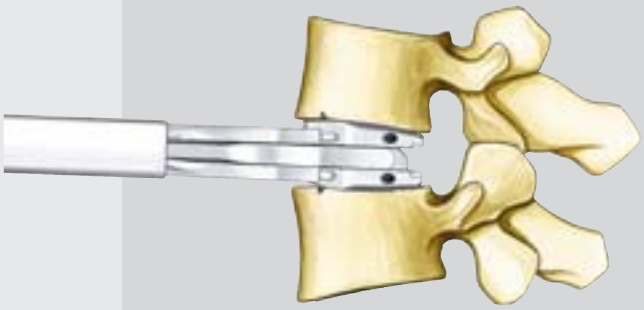
For the pararectus approach the implant is mounted at an angle of 45°.

Note:

- If possible do not touch the Plasmapore® coating while mounting the implant onto the inserter. Hold on to the sides of endplates.



Check the midline position during the whole implantation. The marking on the inserter must be aligned with the midline marking.



Punch in the implant as far as possible under x-ray control to a maximum depth just in front of the posterior rim of the vertebra.

Note:

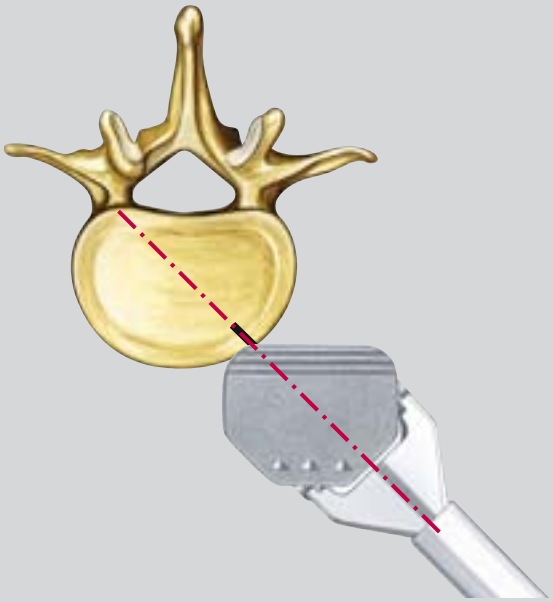
- Bring in the implant in an almost 90° angle to place both endplates to same ap-level.
- Use only the hammer with plastic end caps to implant the artificial disc.

D1) Instrumentation – Spike Version

Tips for Correct Lateral Implantation

Option 1:

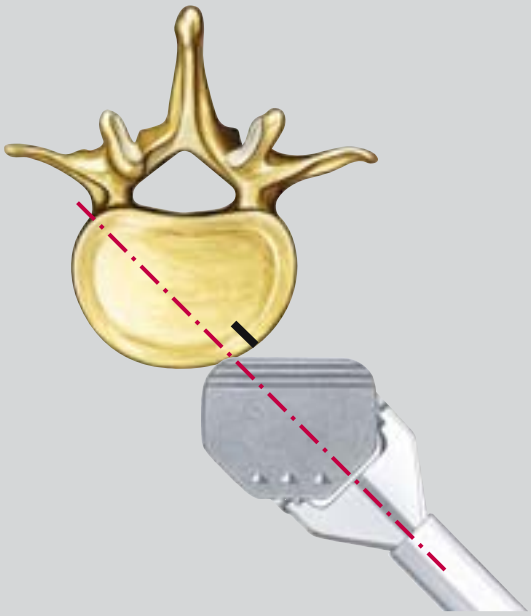
Entry point at 45° angle.
Insert the activ L® prosthesis in an approx 45°-angle to the final position.



activ L® is correctly positioned.

Option 2:

Entry point a little bit ahead of the 45° line:
Insert activ L® to the midline position.
Then push the implant in straight ap-direction to the final position now.



Manipulation and correct placement is possible with the activ L® impactor.

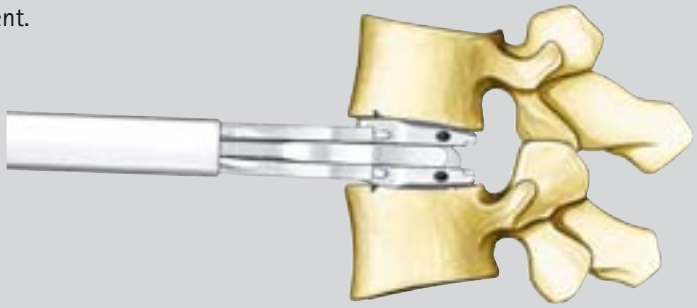
Note:
- When in doubt, select a more anterior entry point, since in this case correction is still possible.

Note:
- Frequent x-ray checks in both planes are necessary. Best way might be to bring the implant in a slightly anterior position, in regards of the 45° approach and an entry point located somewhat (1 - 2 mm) medially of the marking (as described in case 2). When the midline position is achieved, exact posterior positioning can be achieved with the impactor.

D1) Instrumentation – Spike Version

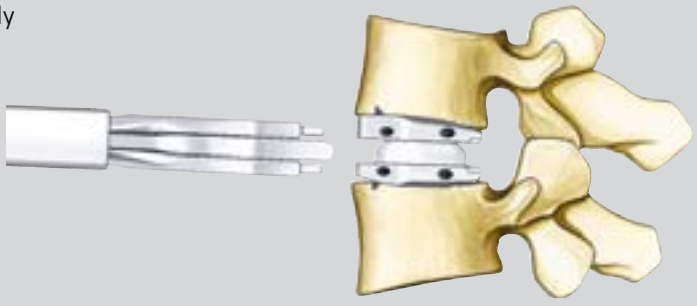
D.1.4. En-Bloc-Implantation

Release the lock of the insertion instrument.

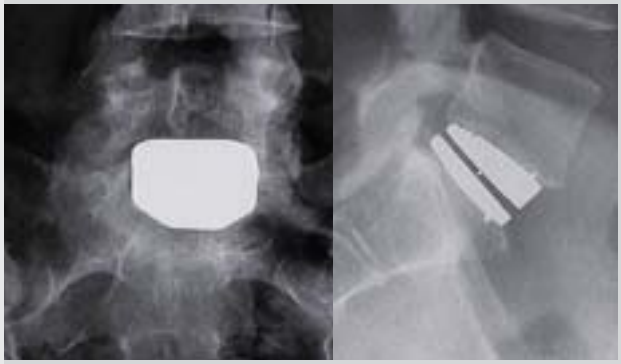


Turn the button on the instrument back to the left to remove the spacer.

Now the insertion instrument can be easily removed.



ap and lateral x-ray control of the
inserted implant.

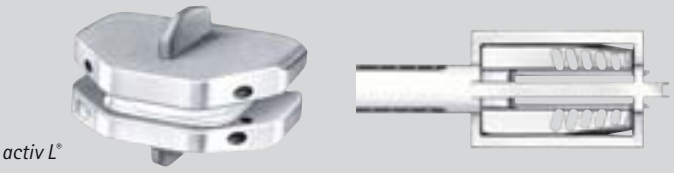


Source: Dr. Sola, University Hospital of Rostock

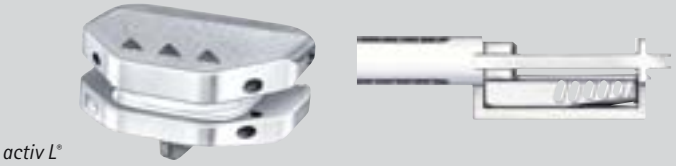
D2) Instrumentation – Keel Version

D.2.1. Chisels for Keel Fixation

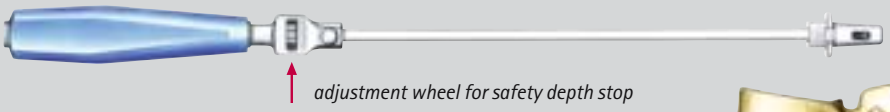
The surgical steps of discectomy to size verification are performed in the same way as for the spike version; please refer to pages 10 – 17.
The keel version allows only the midline approach.
For the keel version, the keel bed must be prepared using chisels. Depending on the combination of the implant version the double chisel or the single chisel has to be used.



activ L®
keel version



activ L®
combined version

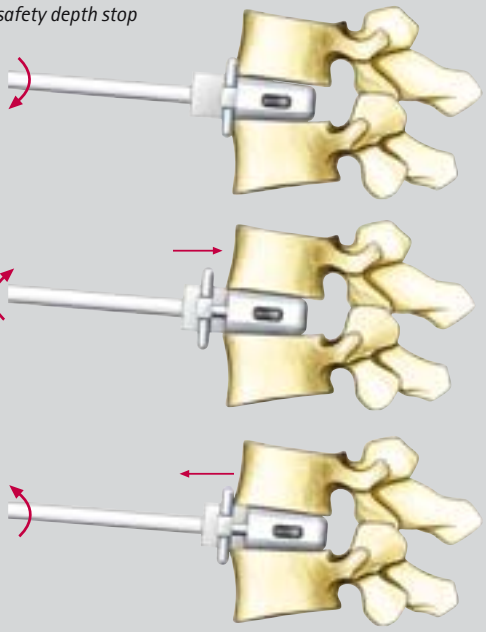


adjustment wheel for safety depth stop

Chisels
Mount the chisel guide for the desired implant height and angle onto the handle.

Bring the safety depth stop into anterior position by turning the wheel to the right.

Introduce the chisel guide centrally into the disc compartment and adjust the safety stop to the desired depth under x-ray control.



Note:
- The adjustable stop defines the depth to which the chisel can be hammered into the disc space.
- The chiseling procedure will determine the central position and the alignment of the intervertebral disc prosthesis in the intervertebral disc plane. The chisel penetration depth in ap-direction is controlled by the chisel depth stop which is adjusted on the chisel guide.

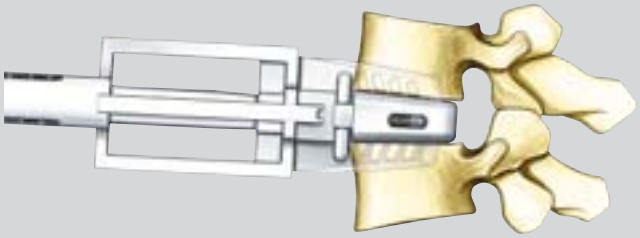
Remove the handle and introduce the single or double chisel over the chisel guide.

Hammer the chisel into the vertebral body under x-ray control. The protection sleeve will retract automatically.

The chisel guide must remain in the same position throughout the chiseling procedure.

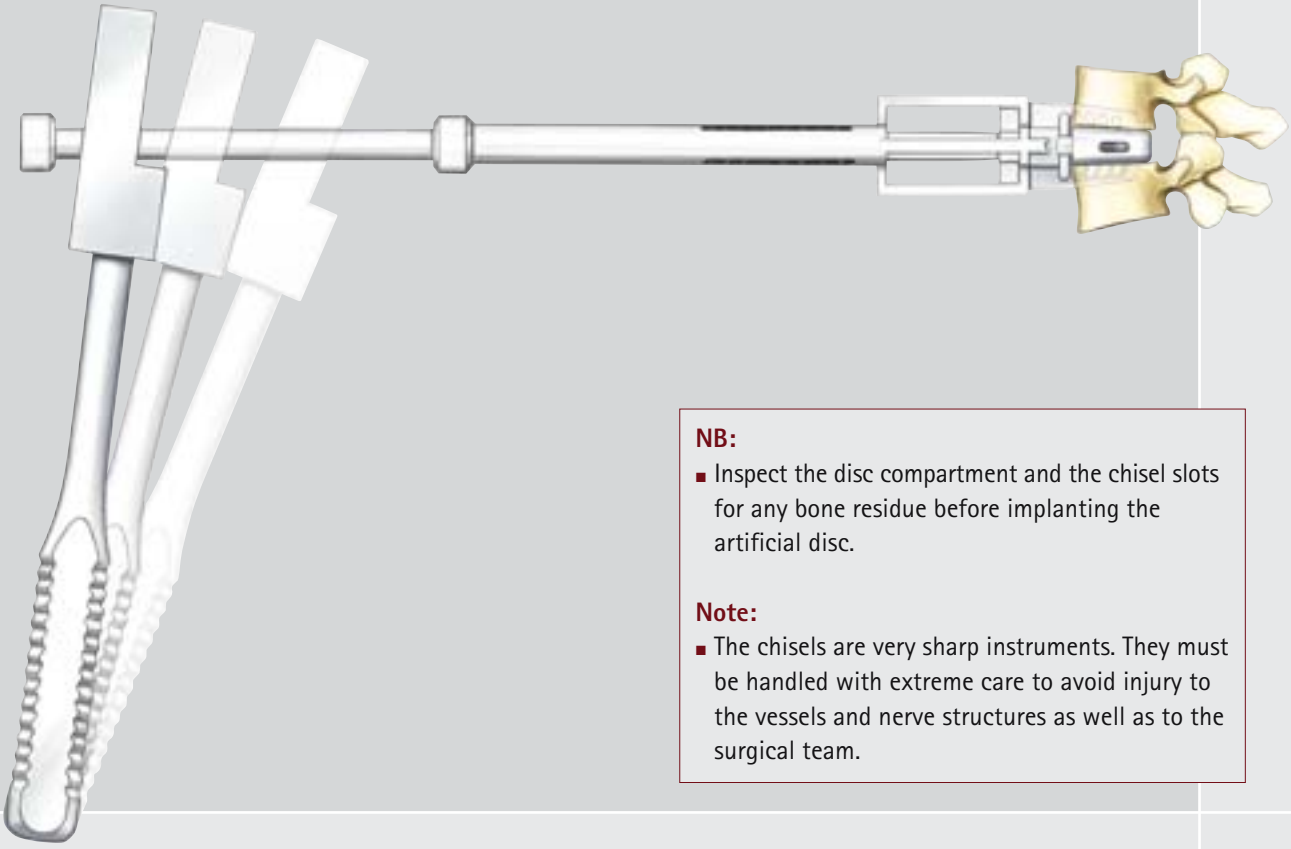
As soon as the safety stop is reached, do not hammer the chisel further in.

Carefully withdraw the chisel using the slotted hammer.



En bloc implantation

Please refer to the spike version for this operating step, pages 17 – 23.



NB:

- Inspect the disc compartment and the chisel slots for any bone residue before implanting the artificial disc.

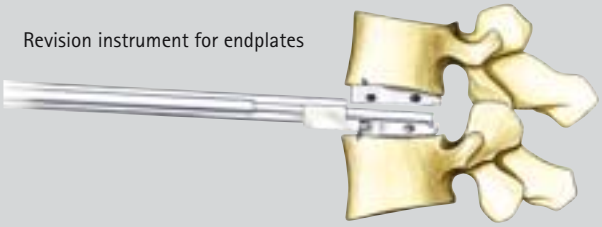
Note:

- The chisels are very sharp instruments. They must be handled with extreme care to avoid injury to the vessels and nerve structures as well as to the surgical team.

E) Correction of Implant Position and Inlay Revision

E.1 Correction of Implant Position

Instrument for:
- revision
- correction of implant position
- intraoperative implant exchange


Revision instrument for endplates

To mount the revision instrument onto either the inferior or superior endplate you have to bring the hooks of the revision instrument into the anterior position.
To insert the revision instrument you have to slide the hooks inbetween the two implant endplates beyond the posterior rim of the implant.

The pins always show the same orientation as the hooks.

Now, rotate the arms of the hooks to the downside position (to manipulate the inferior plate) and draw back the hooks till they lock into the grooves in the posterior side of the implant endplates.

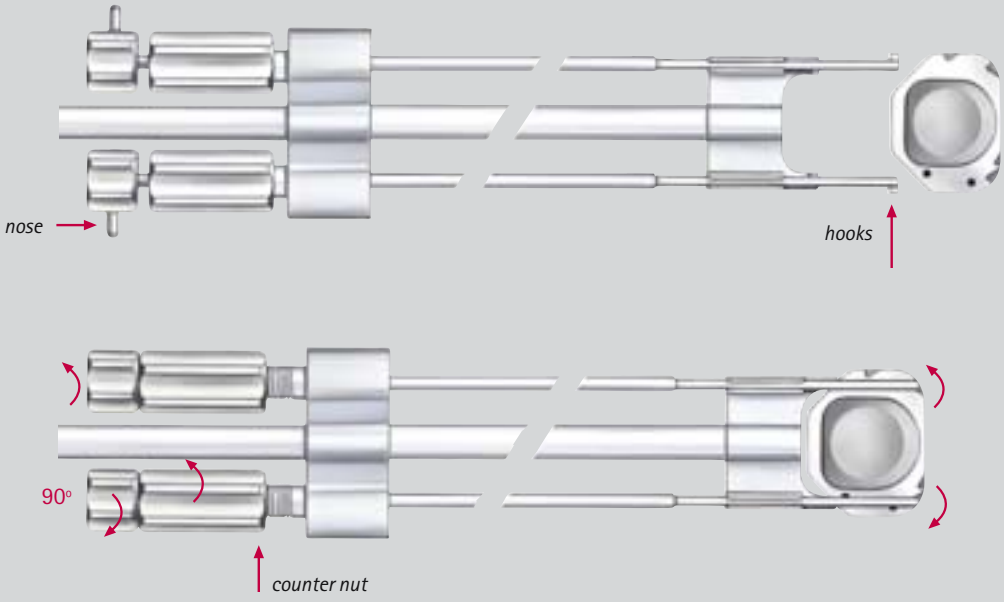
If the hooks are in position turn the counterscrew forward to lock the hook in this position.
Now it is possible to rotate or to draw back the implant carefully.

To remove the endplate completely use the slot hammer.

After removing the first endplate the revision instrument can be mounted onto the second endplate, which can be removed or corrected as the first one.

For complete implant revision the endplates are removed separately.

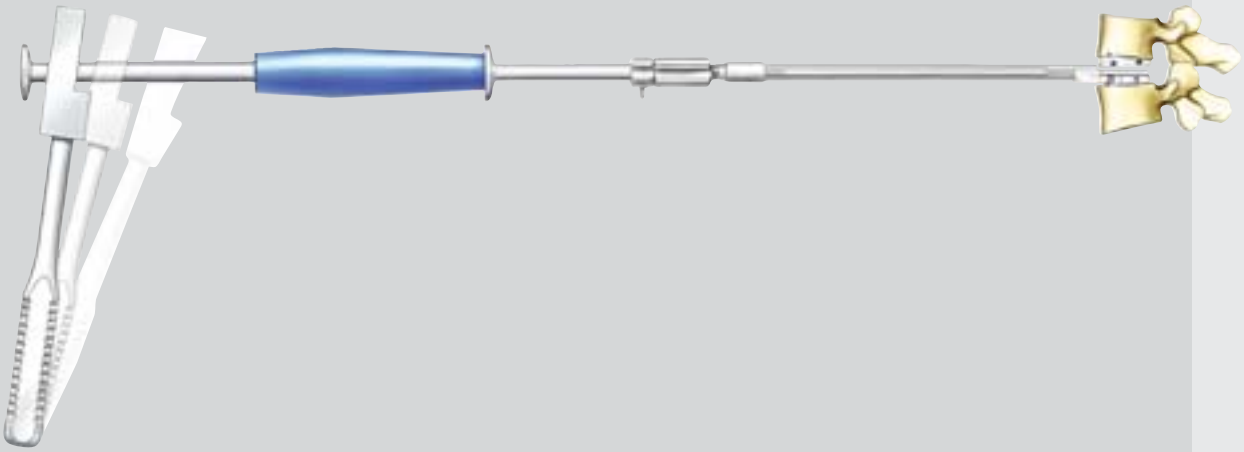
Note:
- Make sure the anchoring rods do not turn while fixing the counter nut. Otherwise the hooks are disconnected.


nose
hooks
90°
counter nut

E) Correction of Implant Position and Inlay Revision

E.1 Correction of Implant Position

Remove the endplate using the slotted hammer, alternately if necessary.



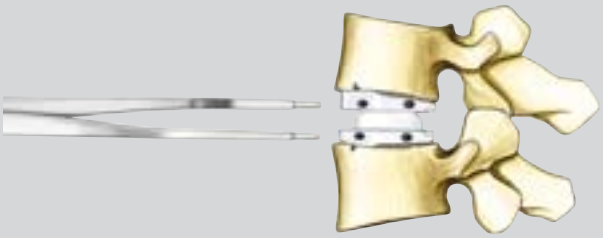
The revision instrument can also be used to correct the implant position.

Note:

- Substantial integration of the endplates into the vertebral body may have occurred. This can make the revision procedure considerably more difficult.
- If such integration has developed over a long period, it may be necessary to quarry out the endplate from the vertebral body using a chisel or elevator before the revision instrument is used.

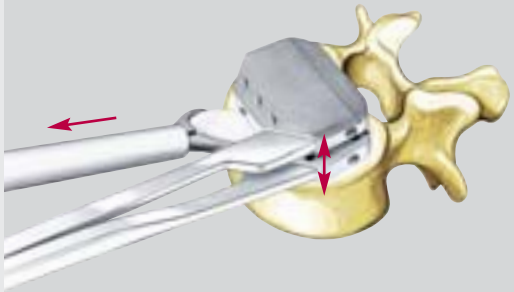
E.2 Inlay Revision

Special revision instruments for the endplates and the inlay are available for revision cases.

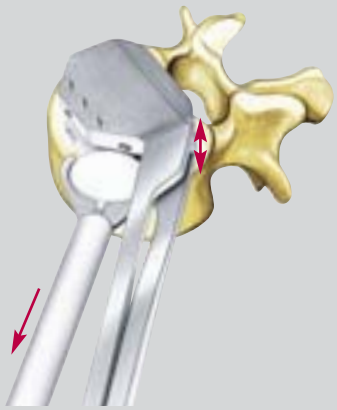


Distract the endplates carefully with the revision distractor.

Midline approach
L5/S1



Pararectus approach
L3/4, L4/5



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.

F1) Implant Overview

Implants

The implants are delivered sterile packed.

PE Inlay

*Height**	8.5	10	12	14
PE Inlay	SW965	SW966	SW967	SW968

**) The height given corresponds to the height of the implant measured at the posterior end.*

Endplates with Spikes

Components			*Size*			
			S (26 x 31)	M (28 x 34.5)	L (30 x 39)	XL (33 x 40)
Superior Plate	*Angle*	*6°*	SW971K	SW981K	SW991K	SW891K
		11°	SW972K	SW982K	SW992K	SW892K
S1 Superior Plate		*6°*	SW912K	SW914K	SW916K	SW918K
Inferior Plate		*0°*	SW970K	SW980K	SW990K	SW890K
S1 Inferior Plate		*5°*	SW976K	SW986K	SW996K	SW888K
		0°	SW978K	SW988K	SW998K	SW886K

superior plate

inferior plate

Endplates with Keel

Components			*Size*			
			S (26 x 31)	M (28 x 34.5)	L (30 x 39)	XL (33 x 40)
Superior Plate	*Angle*	*6°*	SW974K	SW984K	SW994K	SW894K
		11°	SW975K	SW985K	SW995K	SW895K
S1 Superior Plate		*6°*	SW913K	SW915K	SW917K	SW919K
Inferior Plate		*0°*	SW973K	SW983K	SW993K	SW893K
S1 Inferior Plate		*5°*	SW977K	SW987K	SW997K	SW889K
		0°	SW979K	SW989K	SW999K	SW887K

superior plate

inferior plate

F2) Instrument Overview

System Overview

Article no.	*Description*
FW931	**Standard Implantation**
Layer 1	Midline marking
Layer 2	Distraction
Layer 3	Insertion instruments

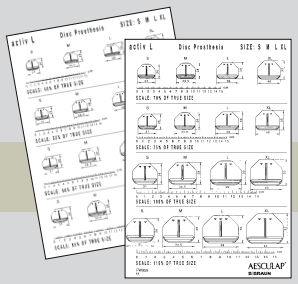
FW933	**Lumbar Discectomy**
Layer 1	Rongeurs, punch
Layer 2	Rongeurs, nerve hooks, scoops

FW935	**Keel Preparation**
Layer 1	Chisel guides
Layer 2	Double chisels
Layer 3	Single chisels

FW937	**Revision and Repositioning**
Layer 1	Revision and repositioning instruments for endplates and inlay

FW919P/920P	**S1 Trays**
FW919P	S1 tray for trail implants S / XL
FW920P	S1 tray for trail implants M / L

FW959/921	**X-Ray Templates**
FW959	X-ray templates
FW921	X-ray template S1 plate

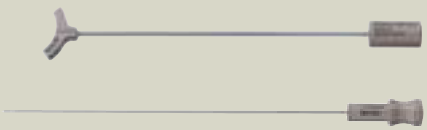


F2) Instrument Overview

System Overview

Standard Implantation

Midline Marking – Layer 1

FW955R	Anterior midline marker		
FW956R	Lateral midline marker	Size S	
FW957R	Lateral midline marker	Size M	
FW958R	Lateral midline marker	Size L	
FW929R	Lateral midline marker	Size XL	
FW938SU	Tip for anterior midline marker, Single use		
FW939SU	Tip for lateral midline marker, Single use		
FW940R	Shaft for wedge		
FW941R	Wedge	Height 6 mm	
FW942R	Wedge	Height 8 mm	
FW943R	Wedge	Height 10 mm	
FW944R	Wedge	Height 12 mm	
FW969R	Impactor		
FW999R	Impactor		

Distraction – Layer 2

FW960R	Angled distractor		
FW951R	Spacer, height 8.5 mm		
FW952R	Spacer, height 10 mm		
FW953R	Spacer, height 12 mm		
FW954R	Spacer, height 14 mm		
FW970R	Parallel distractor		
FW971R	Trial implant inferior plate	Size S 0°	
FW972R	Trial implant inferior plate	Size M 0°	
FW973R	Trial implant inferior plate	Size L 0°	
FW926R	Trial implant inferior plate	Size XL 0°	
FW922R	Trial implant inferior plate	Size S 5°	
FW923R	Trial implant inferior plate	Size M 5°	
FW924R	Trial implant inferior plate	Size L 5°	
FW825R	Trial implant inferior plate	Size XL 5°	
FW974R	Trial implant superior plate	Size S 6°	
FW975R	Trial implant superior plate	Size S 11°	
FW976R	Trial implant superior plate	Size M 6°	
FW977R	Trial implant superior plate	Size M 11°	
FW978R	Trial implant superior plate	Size L 6°	
FW979R	Trial implant superior plate	Size L 11°	
FW927R	Trial implant superior plate	Size XL 6°	
FW928R	Trial implant superior plate	Size XL 11°	
FW922R	Trial implant S1 inferior plate	Size S 5°	
FW923R	Trial implant S1 inferior plate	Size M 5°	
FW924R	Trial implant S1 inferior plate	Size L 5°	
FW925R	Trial implant S1 inferior plate	Size XL 5°	

F2) Instrument Overview

System Overview

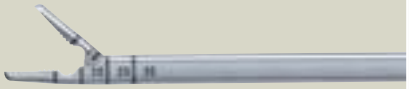
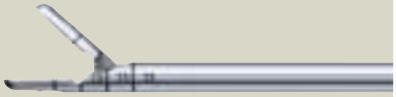
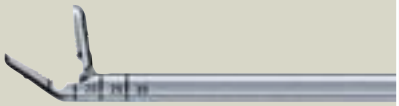
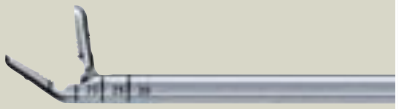
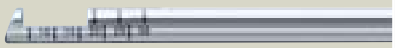
Standard Implantation

Implantation Instruments – Layer 3

FW961R	Inserter	8.5 mm	
FW962R	Inserter	10 mm	
FW963R	Inserter	12 mm	
FW964R	Inserter	14 mm	
FW945R	Key for inserter		
L045R	Hammer		

Lumbar Discectomy

Rongeurs, Punch – Layer 1

FF839R	Rongeur, straight	4 x 14 mm	
FF840R	Rongeur, straight	6 x 16 mm	
FF850R	Rongeur, angled	6 x 14 mm	
FF851R	Rongeur, angled	4 x 14 mm	
FG894R	Punch, 90° upward	2.5 mm	

F2) Instrument Overview

System Overview

Lumbar Discectomy

Curettes, Nerve Hooks, Scoops – Layer 2

FK826R	Curette, round	6.4 mm	
FK822R	Curette	7 x 5 mm	
FK780R	Scoop, straight	4.4 x 6.2 mm	
FK781R	Scoop, straight	5.2 x 7.3 mm	
FK791R	Scoop, angled	5.2 x 7.3 mm	
FK392R	Raspatory	8 mm	
BT070R	Probe hook		

Keel Preparation

Chisel Guides – Layer 1

FW980R	Handle for chisel guide		
FW981R	Chisel guide	Height 8.5 mm 6°	
FW982R	Chisel guide	Height 10 mm 6°	
FW983R	Chisel guide	Height 12 mm 6°	
FW984R	Chisel guide	Height 14 mm 6°	
FW993R	Chisel guide	Height 8.5 mm 11°	
FW994R	Chisel guide	Height 10 mm 11°	
FW995R	Chisel guide	Height 12 mm 11°	
FW996R	Chisel guide	Height 14 mm 11°	
FW997R	Osteotome		
FW579R	Slotted hammer		

F2) Instrument Overview

System Overview

Keel Preparation

Double Chisels – Layer 2

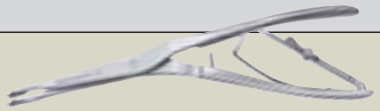
FW985R	Double chisel	Height	8.5 mm
FW986R	Double chisel	Height	10 mm
FW987R	Double chisel	Height	12 mm
FW988R	Double chisel	Height	14 mm

Single Chisel – Layer 3

FW989R	Single chisel	Height	8.5 mm
FW990R	Single chisel	Height	10 mm
FW991R	Single chisel	Height	12 mm
FW992R	Single chisel	Height	14 mm

Revision

Revision Instruments – Layer 1

FW965R	Distractor for revision		
FW966R	Revision instrument	S, M	
FW967R	Revision instrument	L, XL	
FW968R	Revision instrument for PE inlay		
FW998R	Handle for Revision instrument		

For further information please refer to the instructions for use for the implants and instruments supplied with the original delivery:

TA011430 Implants
TA011450 Distraction instruments
TA011458 Insertion instruments

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