CENTINEL SPINE®

PRODISC® C

Modular intervertebral disc prosthesis for restoring disc height and segmental motion in the cervical spine.

Surgical Technique

Image intensifier control

Warning
This description alone does not provide sufficient background for direct use of Centinel Spine products. Instruction by a surgeon experienced in handling these products is mandatory.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
www.centinelspine.com/prodisc_reprocessing.html
For general information about reprocessing, care and maintenance of Centinel Spine reusable devices, instrument trays and cases, please consult the Important Information leaflet (SE_023827) or refer to:
www.centinelspine.com/prodisc_reprocessing.html

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prodisc C. Modular intervertebral disc prosthesis for restoring disc height and segmental motion in the cervical spine.

Proven concept from the field of joint endoprosthetics

prodisc C is intended to replace a diseased and/or degenerated intervertebral disc of the cervical spine in patients with symptomatic cervical disc disease (SCDD). The prodisc C procedure is intended to significantly reduce pain by allowing for the removal of the diseased disc while restoring disc height and providing the potential for motion at the affected vertebral segment.

Tested materials
- Superior and inferior implant plate made of cobalt-chromium-molybdenum alloy
- Rough surface coating of pure titanium supports bony ongrowth within a few months
- Inlay made of ultra-high molecular weight polyethylene (UHMWPE)

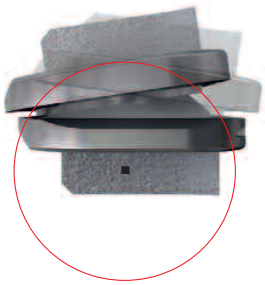
Modular anatomical design
- Optimal primary stability due to keel anchorage of the prosthesis in the vertebral body
- Anatomical footprint design for maximum end plate coverage

Ball and socket principle
- Permits a physiological range of motion in regard to flexion/extension, rotation, and lateral bending
- Restores anatomical balance
- Guided, controlled motion limits the load on facet joints

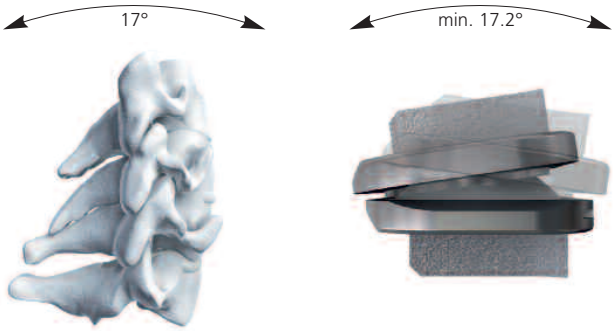
Kinematics

The kinematics correspond to the joint guidance in vertebral joints[1]:

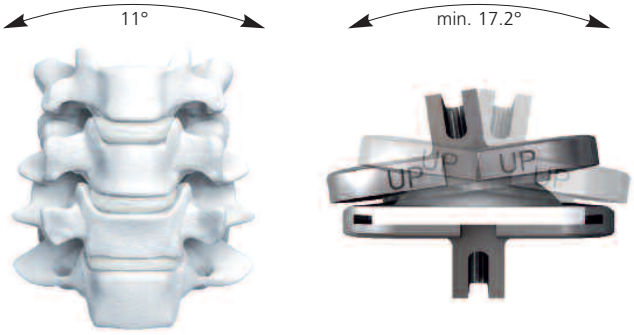
The center of rotation is located just below the superior end plate of the affected caudal vertebral body. The location of the center of rotation and the flexion radius correspond to the natural joint guidance in the vertebral joints. The physiological range of motion in regard to flexion/extension and lateral bending is restored. The axial rotation is limited only by the anatomical structures and not by the prosthesis. Pure translatory movements are not possible due to the ball and socket principle.



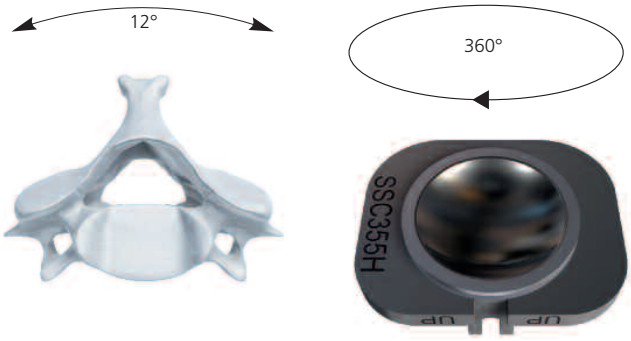
Flexion/extension



Lateral bending



Axial rotation



[1] White, Panjabi 1990

Intended use

prodisc C implants are used to replace a cervical intervertebral disc and to restore disc height and segmental motion.

Indications
Symptomatic cervical disc disease (SCDD), which is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI or X-rays):
– herniated nucleus pulposus,
– spondylosis (defined by the presence of osteophytes),
– loss of disc height.

Specific contraindications
– Fractures, infections, tumours
– Spinal stenosis by hypertrophic spondylarthrosis
– Facet joint degeneration
– Increased segmental instability
– Ossification of posterior longitudinal ligament (OPLL)

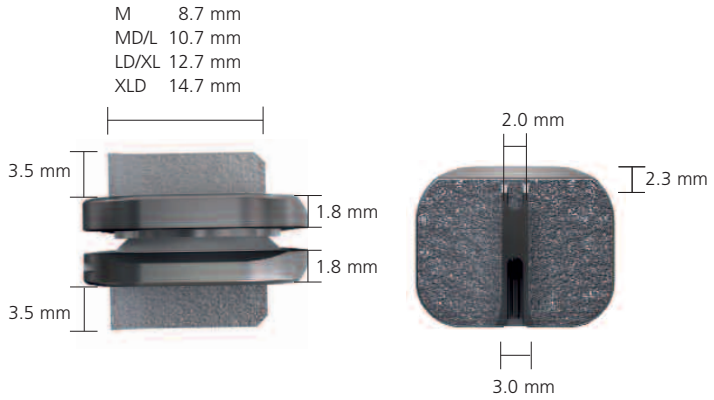
General contraindications
– Osteoporosis, Osteochondrosis, and severe Osteopenia
– Acute or chronic systemic, spinal, or localized infections
– Systemic and metabolic diseases
– Any medical and surgical conditions precluding the benefits of spinal surgery
– Foreign body sensitivity to the implant materials
– Dependency on pharmaceutical drugs, drug abuse or alcoholism
– Pregnancy
– Severe obesity (Body Mass Index above 40)
– Lack of patient cooperation

Patient exclusion recommendations
Patient selection is one of the most important factors contributing to the outcome of the total disc replacement procedure. The following may affect clinical outcomes:
– A condition of senility or mental illness, alcoholism or smoking
– Dependency on pharmaceutical drugs or drug abuse
– The patient's occupation or activity level
– Compromised vertebral bodies at affected level due to current or past trauma (fractures)
– Substantial loss of disc height, where applied segmental distraction may lead to damage of the great vessels
– Involved vertebral endplate dimensionally smaller than the minimum implant footprint size in both the medial-lateral and the anteriorposterior directions
– Severe abnormality of the endplate (e.g. large Schmorl nodes)

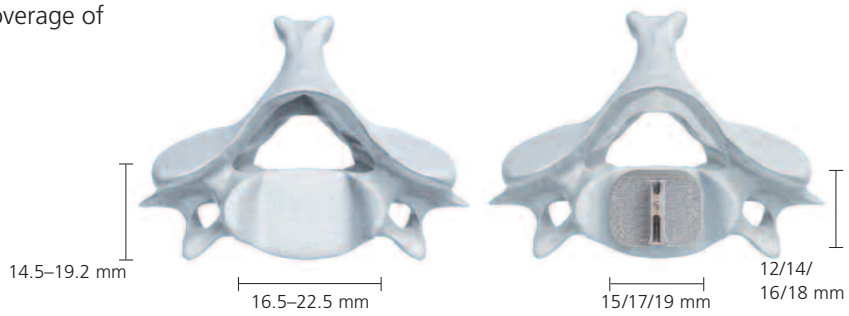
Successful clinical outcomes depend on a number of critical factors, including:
– Completion of a training program on the use of Prodisc-C
– Proper patient selection
– Adequate bone quality (investigation to determine bone quality is recommended)
– Complete and meticulous discectomy, decompression, and remobilization of the disc space
– Optimal implant sizing and placement
– Postoperative treatment

Implants

Dimensions

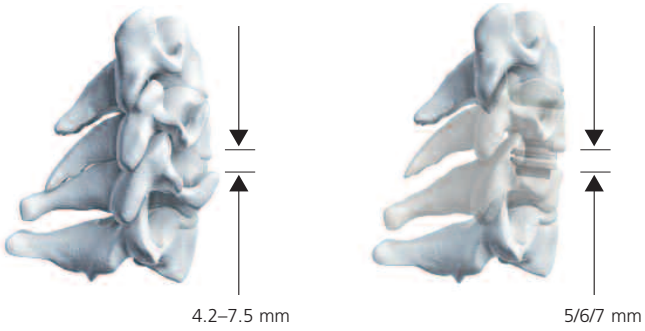


Six different footprints are available for optimal coverage of the vertebral end plate: M, MD, L, LD, XL, XLD



Panjabi 1991

Three different heights (5, 6, and 7 mm) allow adjustment to the individual dimensions of the patient's disc.

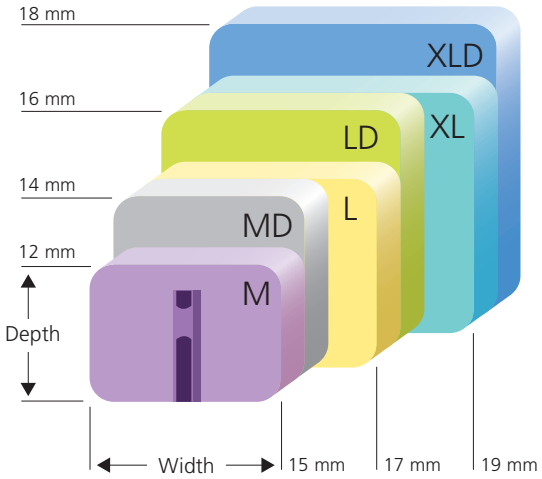


Yoganandan et al. 2001

H-keel design

H-keel is the latest design improvement of the prodisc C, manufactured since April 2006.

It has an additional cavity at the posterior end of both keels. This cavity can lodge potential residual bone debris and thereby facilitates the posterior positioning of the implant.



pro**disc C, uncemented**

Implant M
Width 15 mm
Depth 12 mm

Art. No.	Height
SSC255H	5 mm
SSC256H	6 mm
SSC257H	7 mm

Implant MD
Width 15 mm
Depth 14 mm

Art. No.	Height
SSC275H	5 mm
SSC276H	6 mm
SSC277H	7 mm

Implant L
Width 17 mm
Depth 14 mm

Art. No.	Height
SSC355H	5 mm
SSC356H	6 mm
SSC357H	7 mm

Implant LD
Width 17 mm
Depth 16 mm

Art. No.	Height
SSC375H	5 mm
SSC376H	6 mm
SSC377H	7 mm

Implant XL
Width 19 mm
Depth 16 mm

Art. No.	Height
SSC455H	5 mm
SSC456H	6 mm
SSC457H	7 mm

Implant XLD
Width 19 mm
Depth 18 mm

Art. No.	Height
SSC475H	5 mm
SSC476H	6 mm
SSC477H	7 mm

Instruments

The prodisc C instrument set was developed for a minimally invasive or microscopic procedure.

Retainer screw system

03.820.100 Center Punch

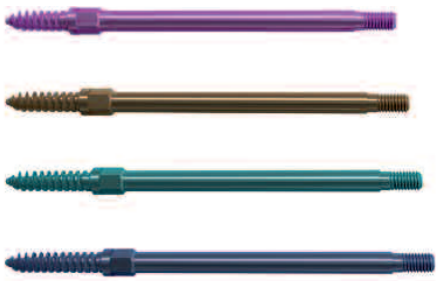
03.820.101 Screwdriver

03.820.111 Vertebral Body Retainer

The vertebral body retainer is used to maintain the distraction achieved with the vertebral distractor. This assures stabilization of the vertebral body for end plate preparation and implant insertion.

The retainer has a toggle switch mechanism to maintain distraction as well as compression.

Retainer Screw ∅ 3.5 mm		Retainer Screw ∅ 4.5 mm	
Art. No.	Length of thread	Art. No.	Length of thread
03.820.102	12 mm	03.820.106	13 mm
03.820.103	14 mm	03.820.107	15 mm
03.820.104	16 mm	03.820.108	17 mm
03.820.105	18 mm	03.820.109	19 mm



03.820.110 Locking Nut

03.820.112 Vertebral Distractor

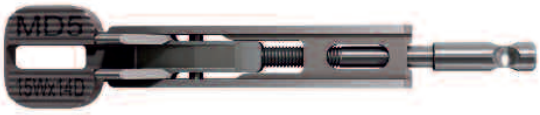
Trial implant system

Trial Implant M
Width 15 mm
Depth 12 mm

Art. No.	Height
03.820.025	5 mm
03.820.026	6 mm
03.820.027	7 mm

Trial Implant MD
Width 15 mm
Depth 14 mm

Art. No.	Height
03.820.035	5 mm
03.820.036	6 mm
03.820.037	7 mm



Trial Implant L
Width 17 mm
Depth 14 mm

Art. No.	Height
03.820.045	5 mm
03.820.046	6 mm
03.820.047	7 mm

Trial Implant LD
Width 17 mm
Depth 16 mm

Art. No.	Height
03.820.055	5 mm
03.820.056	6 mm
03.820.057	7 mm

Trial Implant XL
Width 19 mm
Depth 16 mm

Art. No.	Height
03.820.065	5 mm
03.820.066	6 mm
03.820.067	7 mm

Trial Implant XLD
Width 19 mm
Depth 18 mm

Art. No.	Height
03.820.075	5 mm
03.820.076	6 mm
03.820.077	7 mm

The integrated adjustable stop provides a positive stop against the anterior portion of the vertebral bodies and can be adjusted to ensure correct positioning of the trial implant.

03.820.000	Handle for Trial Implants

Milling system

The keel cuts are performed with the milling system or with the chisel instruments as a backup solution. The use of the milling instruments requires a power tool to drive the milling bits.

Milling Guides	
Art. No.	Height
03.820.114	5 mm
03.820.115	6 mm
03.820.116	7 mm

Milling Bits	
Art. No.	Type
03.820.117	Centinel Spine
03.820.153	Hex
03.820.155	Step
03.820.157	Cylindric
03.820.159	Flat

Orientation Pins	
03.820.136	Orientation Pin, sharp tip
03.820.137	Orientation Pin, blunt

03.820.126	Keel Cut Cleaner

Chisel instruments

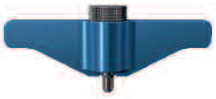
The chisels are meant to be a fallback solution, in the unlikely event that the milling system cannot be used.

Chisel, Keel Cutting	
Art. No.	Height
03.820.119	5 mm
03.820.120	6 mm
03.820.121	7 mm (optional)

Chisel, Box Cutting	
Art. No.	Height
03.820.122	5 mm
03.820.123	6 mm
03.820.124	7 mm (optional)

The keel cutting chisel, guided by the trial implant, is used to cut channels that lodge the implant keels. The box cutting chisel is used to prepare the posterior end of the keel cuts for the optimal insertion of the implant.

03.820.125 Wing for Chisel

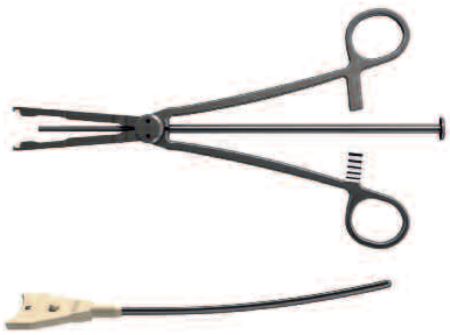


03.820.128 Chisel Cleaning Plate

03.820.113 Mallet

Insertion instruments

The pre-assembled and sterile packed prodisc C prosthesis can be easily secured on the implant inserter.



SFC602R	Implant Inserter, Scissors

Spacer for Implant Inserter SFC602R, radiolucent	
Art. No.	Height
SFC615R	5 mm
SFC616R	6 mm
SFC617R	7 mm (optional)

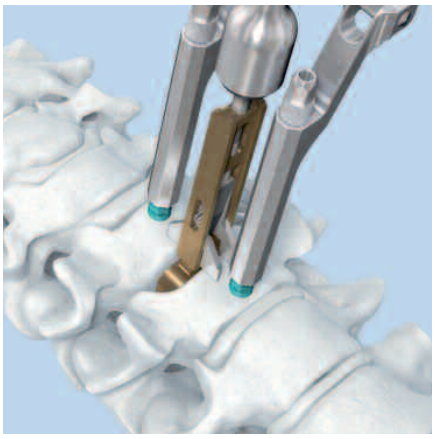
03.820.129	Implant Inserter (optional)

Spacers for Implant Inserter 03.820.129 (optional)		
Art. No.	Sizes	Height
03.820.130	M and MD	5 mm
03.820.131	M and MD	6 mm
03.820.132	M and MD	7 mm
03.820.133	L and LD	5 mm
03.820.134	L and LD	6 mm
03.820.135	L and LD	7 mm
03.820.140	XL and XLD	5 mm
03.820.141	XL and XLD	6 mm
03.820.142	XL and XLD	7 mm

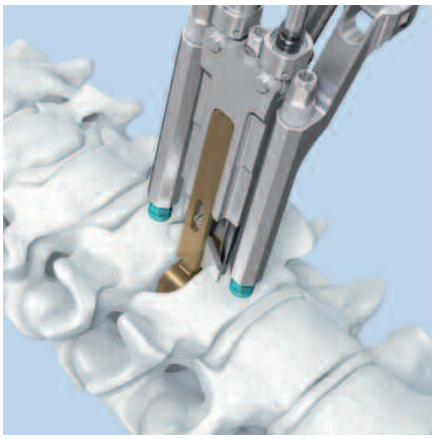
Minimally Invasive Access

The instruments:
– Vertebral body retainer for fixing the vertebral bodies
– Trial implant with an adjustable stop
– Orientation at the midline for precise implanting
– The pre-assembled design allows the prosthesis to be inserted en-bloc
– Early mobilization of the patients and short hospital stay due to minimally invasive access

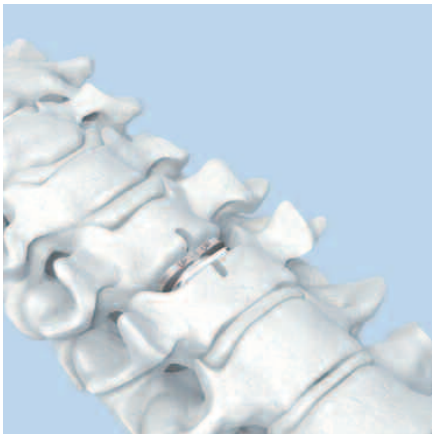
1. Positioning of trial implant



2. Preparation of keel cut



3. Insertion of implant

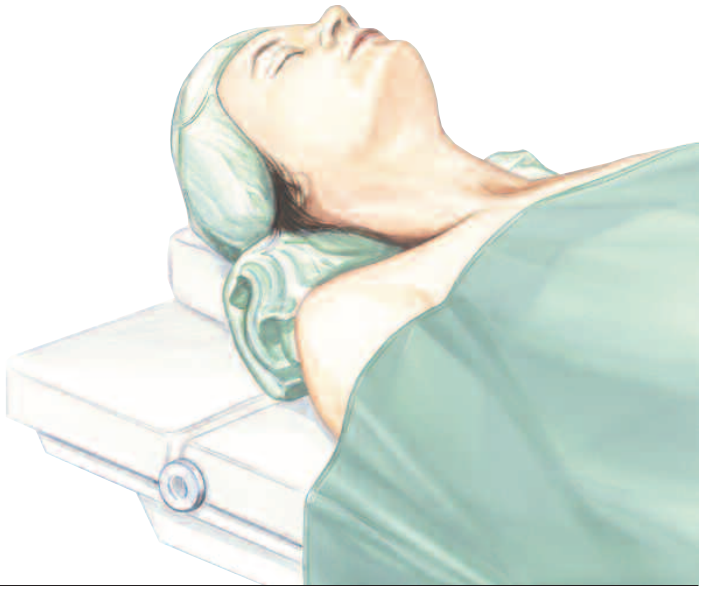


1

Prerequisites and patient positioning

Insertion of a prodisc C is dependent on the use of anterior-posterior (AP) and lateral fluoroscopy throughout the procedure. Patient positioning should allow for circumferential use of the C-arm at the operative level.

Position the patient in a supine, neutral position on a radiolucent operating table. Ensure that the neck of the patient is firmly positioned, using a cushioned but not too soft roll. When treating C6–C7 make sure that the shoulders do not limit X-ray monitoring. In any case both vertebrae have to be completely visible.



2

Access

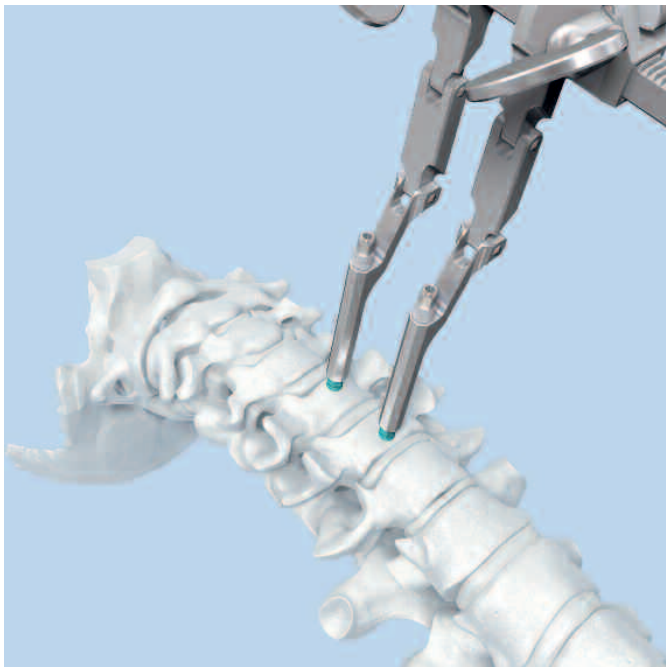
Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterolateral approach to the cervical spine. Mark the level of surgery and expose the intervertebral disc segment.

- Determine the midline using image intensifier control and make a permanent midline mark on the superior and inferior vertebral bodies.

3
Fix retainer screw system

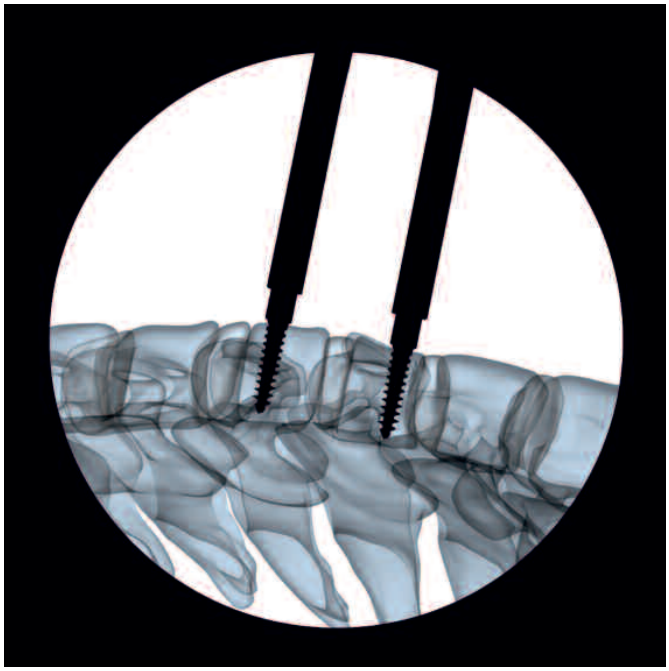
Instruments	
03.820.100	Center Punch
03.820.101	Screwdriver
03.820.111	Vertebral Body Retainer
03.820.102–109	Retainer Screws
03.820.110	Locking Nuts

Perforate the anterior cortex in the midline with the center punch in the upper third of the superior vertebra and in the lower third of the inferior vertebra. Ensure the spacing of the holes allows for the height of the implant keel.



Insert the retainer screws (∅ 3.5 mm) into the perforations and place them bicortically. Their trajectory should be parallel to the adjacent end plate and not necessarily parallel to each other. Begin with the smaller diameter screw of the longest possible length. Use a larger diameter screw (∅ 4.5 mm) when extra bone purchase is needed or as a "rescue" screw.

Note: Insert screws under image intensifier control. Do not perforate the posterior cortex.



Slide the vertebral body retainer over the screws and lock it in place with the locking nuts. This assembly achieves parallelism of the retainer screws and the vertebral end plates of the operated level.

4
Mobilize segment

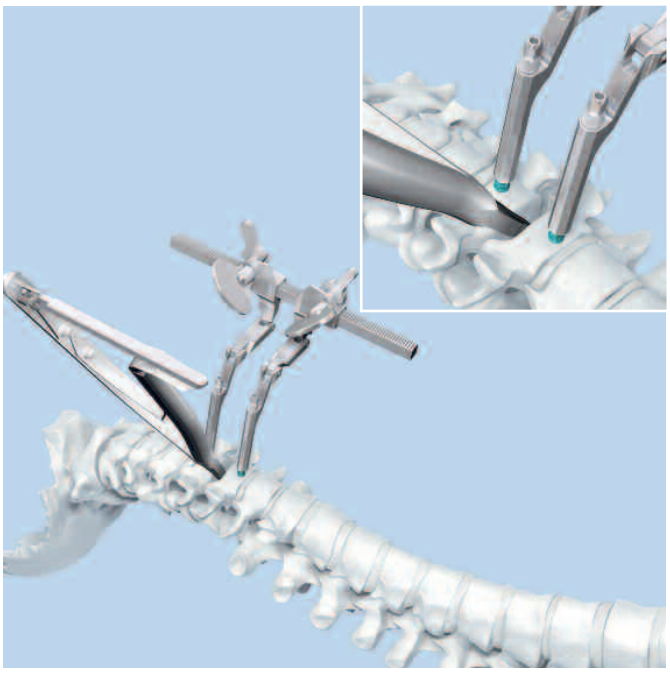
Instrument	
03.820.112	Vertebral Distractor

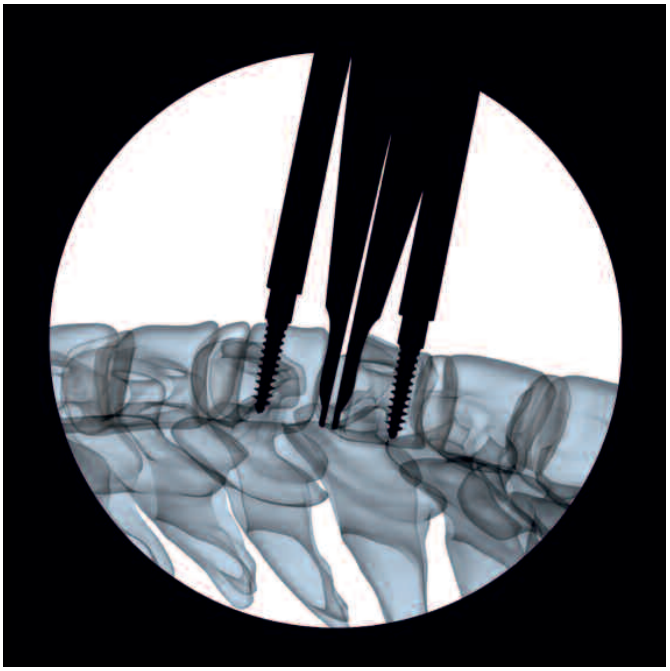
Start the discectomy using standard instruments.

Under image intensifier control, insert the vertebral distractor to the posterior margin of the vertebral bodies. Distract the intervertebral space with the vertebral distractor in a parallel manner to restore the height and to gain access to the posterior intervertebral space. Do not use the vertebral body retainer for distraction but readjust it to the distracted height of the intervertebral space. Then withdraw the vertebral distractor.

Remove all intervertebral disc tissue and cartilage fragments from the end plates. Care should be taken to minimize bone remodeling.

Continue the discectomy and decompression.





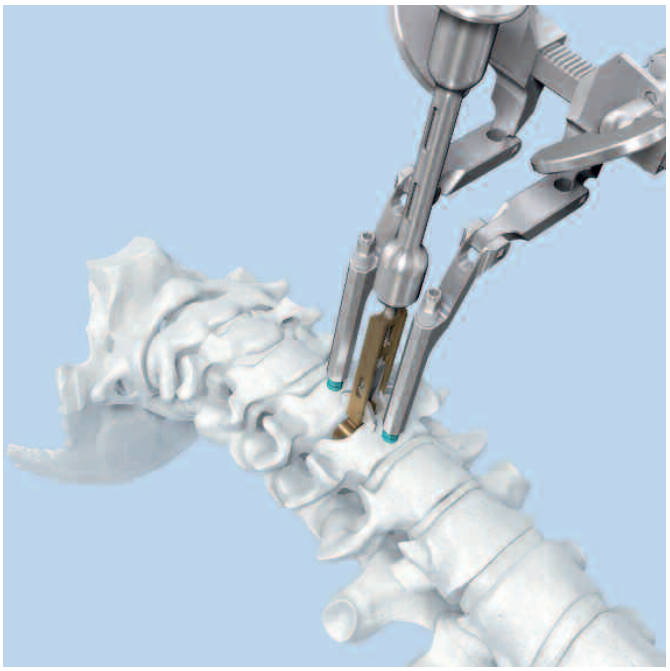
Notes:
- Avoid over-distraction with the vertebral distractor as this can lead to nerve root tension or improper implant selection.
- Avoid using the vertebral body retainer as a distractor. Excessive force on the vertebral body retainer can lead to bending and pull-out of the screws from the bone.
- Avoid excessive end plate removal. Excessive end plate removal increases the risk of implant subsidence.
- The uncinatus process should be preserved. If required for adequate bony decompression, the posterior third of the uncinatus process may be remodeled.
- Ensure the cartilageous tissue is removed from the end plates. Cartilageous tissue may prevent osseointegration of the implant and reduce the fixation strength.
- Expose the posterior longitudinal ligament to remobilize the segment. If required for decompression, the PLL may be resected.

5
Insert the trial implant

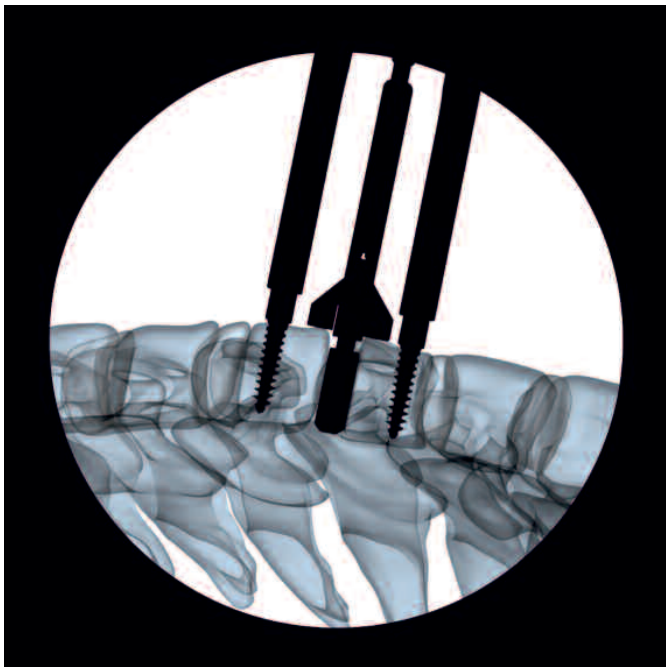
Instruments	
03.820.025-077	Trial Implants (see instruments page 9)
03.820.000	Handle for Trial Implants
03.820.113	Mallet

Trial implants are placed into the disc space intra-operatively to determine the appropriate implant height and size of footprint.

The goal is to **select the largest footprint possible and the smallest height necessary.** The implant should cover the majority of the vertebral body end plate. Undersized implants lead to increased risk of implant subsidence.



Connect the trial handle to the trial implant. Ensure that the trial stop is fully screwed, closest to the footprint. Align the trial implant on midline and advance the trial implant under image intensifier control into the disk space.



The optimal position of the trial implant is at the posterior margin of the vertebral bodies, centered on the midline. If the stop does not allow the trial implant to enter deep enough it can be positioned deeper by turning the adjustable stop anticlockwise (1 rev = 0.5 mm).

Now release the distraction to determine optimal height of trial implant. Trial height should be the smallest appropriate height to match normal adjacent discs. Ensure that the trial stop is fully seated against the vertebral bodies, apply mild compression with the vertebral body retainer and remove the handle from the trial implant.

Check the position of the trial implant under lateral and AP image intensifier control.

Notes:
- Selecting an implant that is too tall can limit the segmental range of motion.
- Clinical experience has shown that in approximately 80% of all cases the correct trial implant has a height of 5 mm.

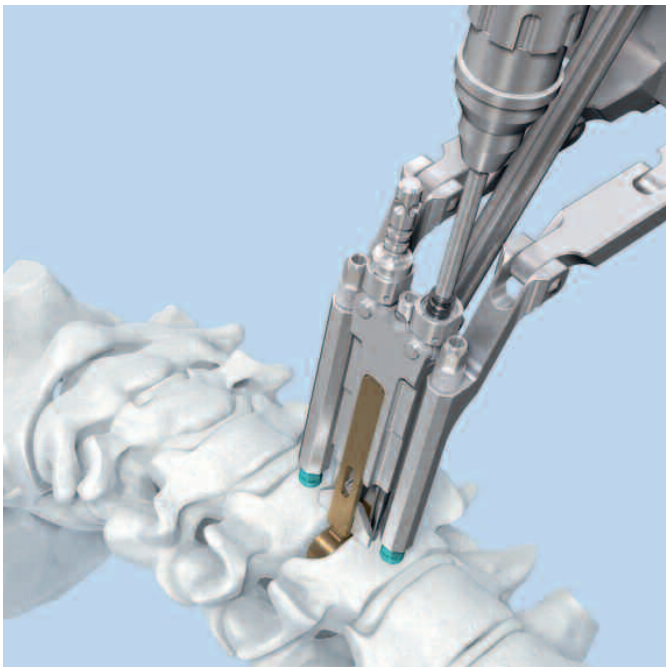
6
Milling for keel cut preparation

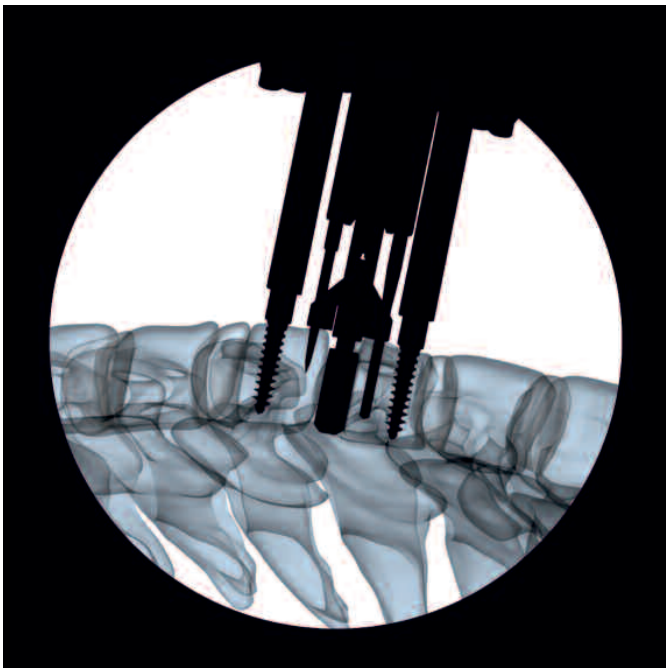
Instruments	
03.820.114–116	Milling Guides, Height 5, 6 or 7 mm
03.820.117	Milling Bit, Centinel Spine coupling
03.820.118	Milling Bit, long, Centinel Spine coupling
03.820.153–159	Milling Bits, other couplings
03.820.136–137	Orientation Pins

Choose the milling guide according to the height of the trial implant.

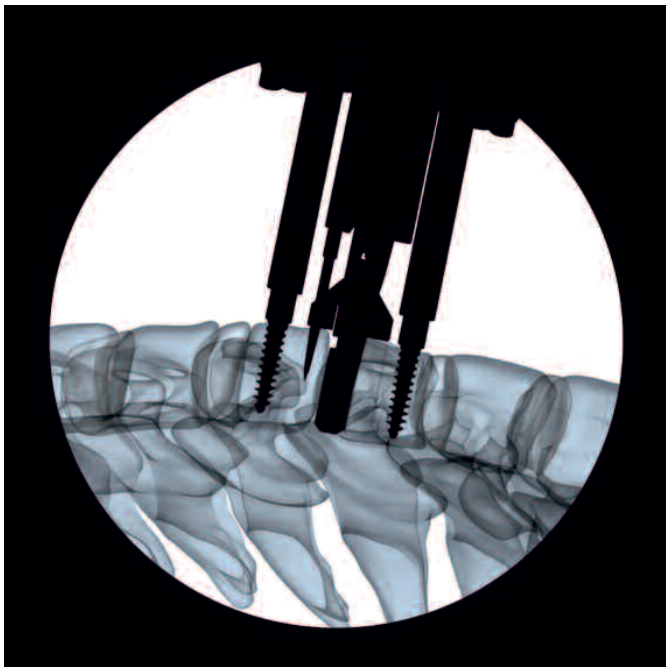
Slide the milling guide over the shaft of the trial implant and tighten the locking nut. Verify the milling guide is centered on midline. To ensure construct stability, place the sharp orientation pin through the superior hole in the milling guide and manually drive the pin into the bone.

Attach the milling bit with quick coupling to a high-speed power tool. Under image intensifier control insert the milling bit into the inferior hole of the milling guide and touch the anterior cortex. Under full power, plunge the milling bit into the vertebral body until it reaches the positive stop in the milling guide.





Keeping the drill at full power, sweep the milling bit towards the trial implant until it reaches the inner limit of the milling guide, then away from the trial implant to the full outer limit. Remove the milling bit and insert the blunt orientation pin into the inferior hole of the milling guide.



Remove the sharp pin and repeat the milling procedure in the superior vertebral body. Ensure that the superior keel cut has the same distance to the posterior border of the vertebra as the inferior keel cut. If the superior keel cut has to be deepened, a special, longer milling bit can be used.

Notes:
- The milling bits should never be used free hand or unguided.
- Centinel Spine recommends single use of the milling bits.
- Centinel Spine recommends using the Centinel Spine Electric Pen drive with 60,000 or 90,000 rpm.

Remove the milling guide. Re-open the vertebral body retainer slightly before removing the trial implant.

Option: Chiseling for keel cut preparation

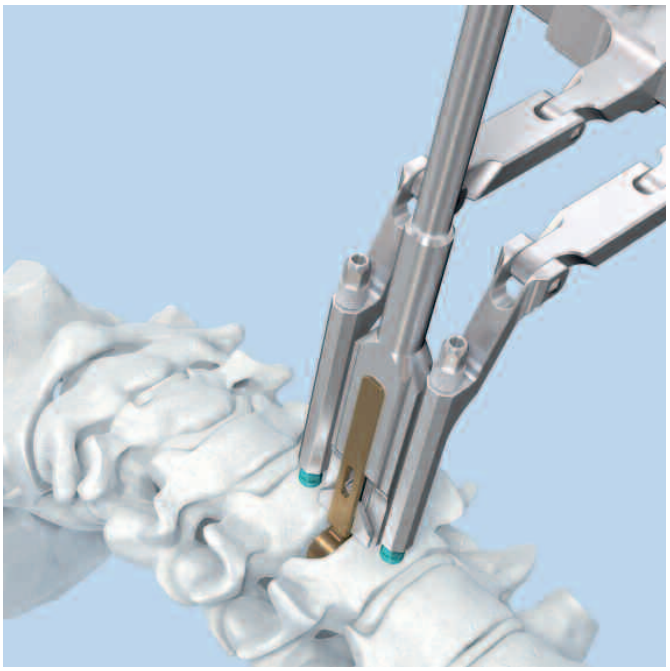
Instruments	
03.820.119-121	Chisels, Keel Cutting, Height 5, 6, or 7 mm
03.820.122-124	Chisels, Box Cutting, Height 5, 6, or 7 mm
03.820.125	Wing for Chisel
03.820.113	Mallet

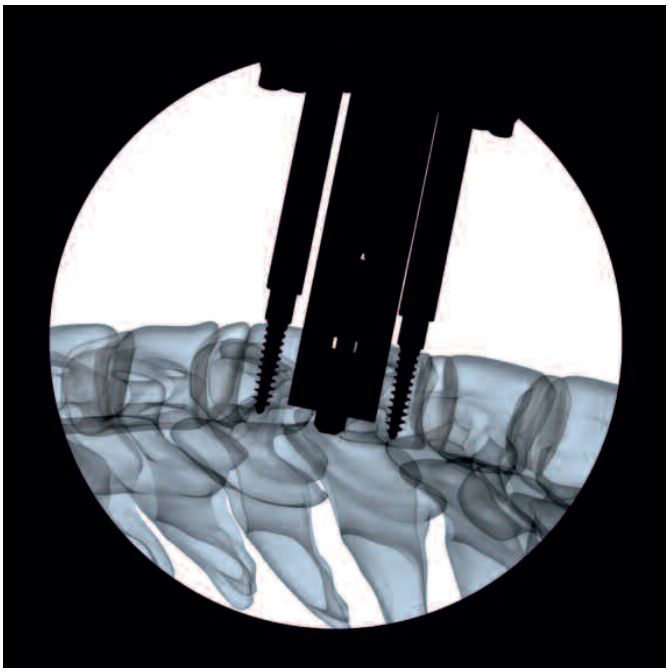
The selected trial implant serves as a guide for the two chisels and sets the chisel depth. Ensure that the trial stop is fully seated against the vertebral bodies. The trial stop helps to avoid posterior advancement of the trial implant and chisel.

Slide the keel cutting chisel over the shaft of the trial implant. Confirm the chisel is centered on midline and oriented in the sagittal plane. Under lateral image intensifier control, advance the chisel into the vertebral bodies with the mallet. The trajectory of the chisel should remain on midline while advancing. Continue advancing the chisel until it is fully seated on the trial implant.

Ensure that the depth of the keel cuts is equal in the superior and inferior vertebral bodies. Repeat the chisel procedure with the box cutting chisel. Again check with the image intensifier.

Remove the box cutting chisel. Re-open the vertebral body retainer slightly before removing the trial implant.



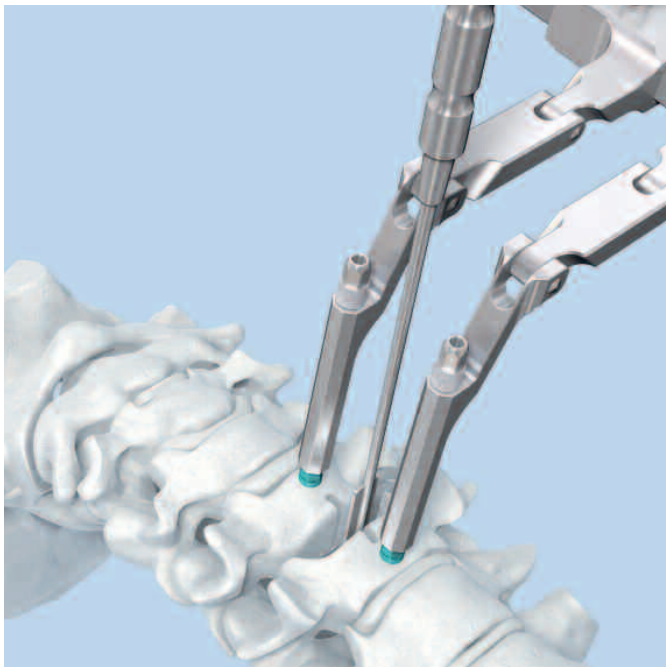


7
Clean and check the keel cut

Instrument	
03.820.126	Keel Cut Cleaner

Removal of bone material

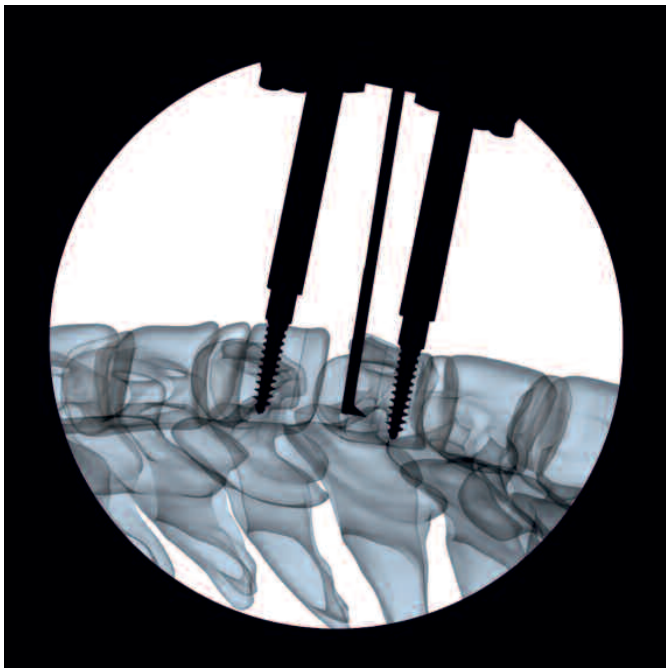
Use the sharp tip of the keel cut cleaner to remove any bone material in the superior and inferior keel cuts. Irrigate and suction the wound to ensure the disc space is clear of any debris.



Check the depth of the keel cuts

Insert the sharp tip of the keel cut cleaner at the posterior end of the keel cuts and check its position under lateral image intensifier control.

If the desired position is not reached, insert the trial implant again and repeat the procedure described in step 6.



8

Insert implant

Instruments	
SFC602R	Implant Inserter
SFC61xR*	Spacer for Implant Inserter, Height 5, 6 or 7 mm
03.820.113	Mallet
03.820.101	Screwdriver

* x = corresponds to the height of 5, 6 or 7 mm

Preparation

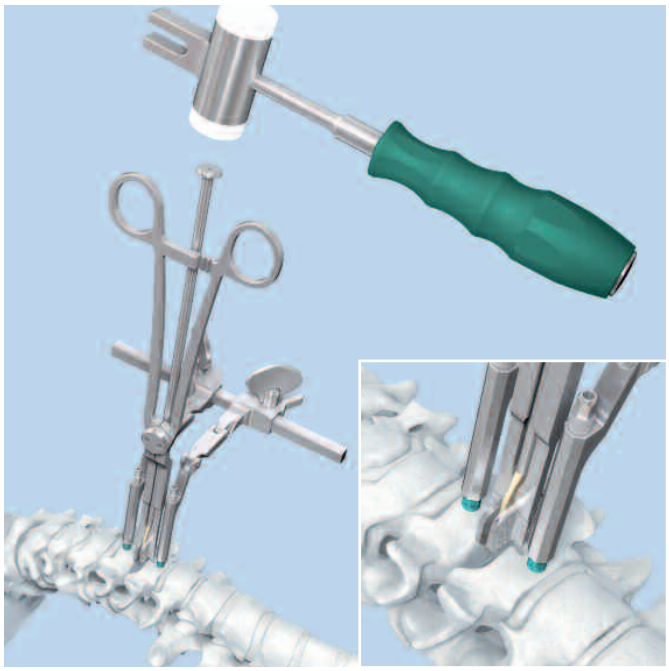
Spread the distal tips of the implant inserter and install the appropriate sized spacer as determined by the selected implant height. Open the implant packaging and place the inserter in the anterior openings of the implant keels. Make sure that the arm marked "down" corresponds to the inferior plate with the PE-inlay. Securely lock the inserter and pull the implant en-bloc out of the packaging.

Note:
– The spacer must be fully inserted into the cylindrical part of the inserter.
– The pro**disc C** implants are not designed to be used with bone cement.

Insertion

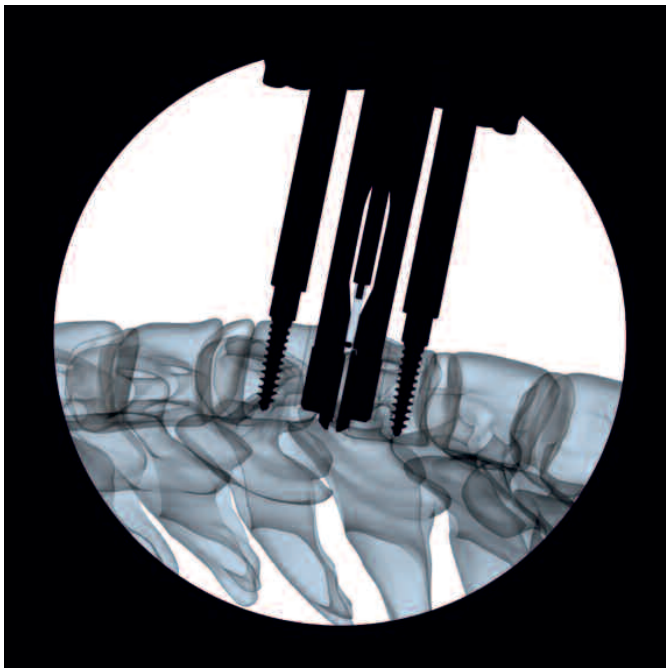
Align the keels of the prodisc C with the keel cuts. Ensure that the inferior plate with the PE-inlay is caudal.

- Under lateral image intensifier control, advance the prodisc C implant to the posterior margin of the vertebral bodies.



View with the image intensifier

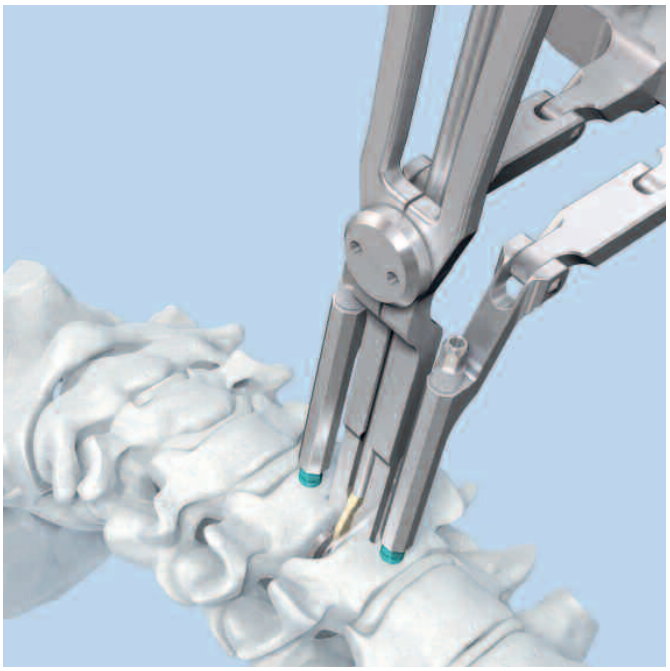
- The polymeric part of the spacer is not visible in the lateral view of the image intensifier. A small tantalum marker represents the anterior rim of the prodisc C implant.

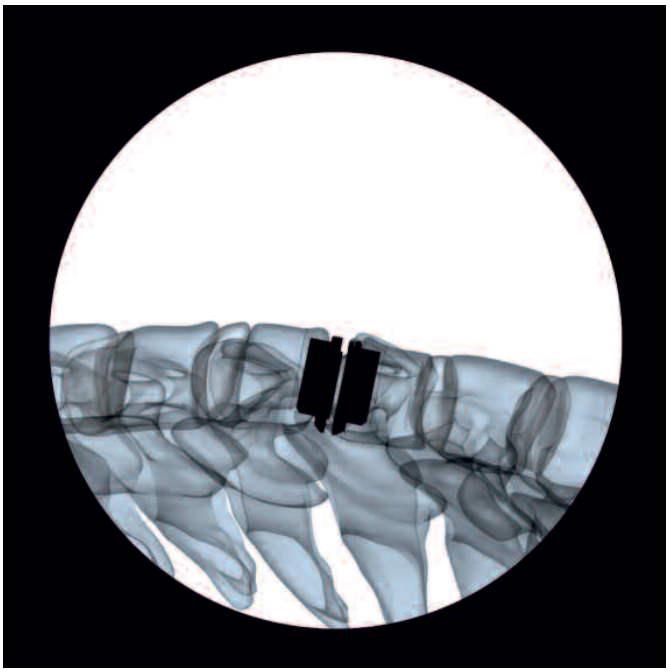


Release the implant inserter from the implant by opening the scissors and remove it by pulling it straight back out of the operative field.

Step by step remove the securing nuts, the vertebral body retainer and the retainer screws.

Precaution: Heterotopic ossification (HO) is a possible cause for fusion of the treated segment. Copious saline lavage is recommended to remove osteogenic stimuli (blood/bone marrow). HO might be reduced when bone wax is used to close cavities in the bone (screw holes) and open bone surfaces after removal of anterior osteophytes[1].





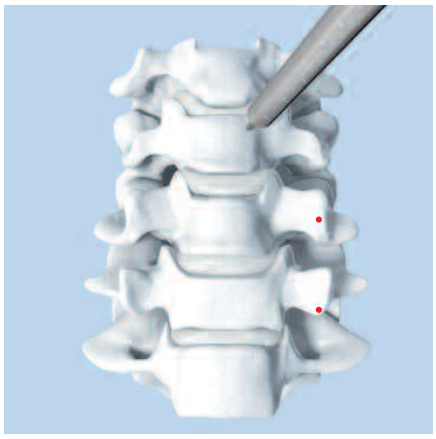
[1] See Barbagallo 2014

Multi-Level Cases

Multi-level prodisc C surgeries should be performed level by level. The more symptomatic level should be operated first.

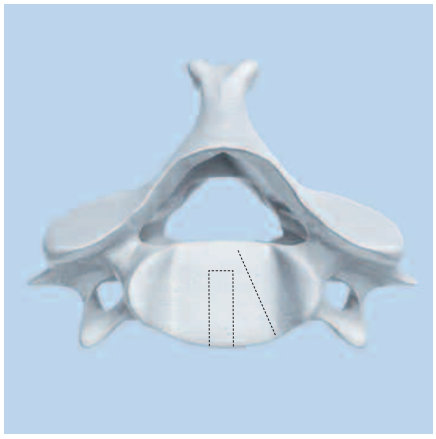
In multi-level cases, there must be sufficient bone between the keels of the adjacent prosthesis.

The screws in the upper and lower vertebrae should be placed in the upper and lower third of the respective vertebra. The screw in the vertebra in the middle should be placed in line with the others screws, but in the middle of the vertebra.

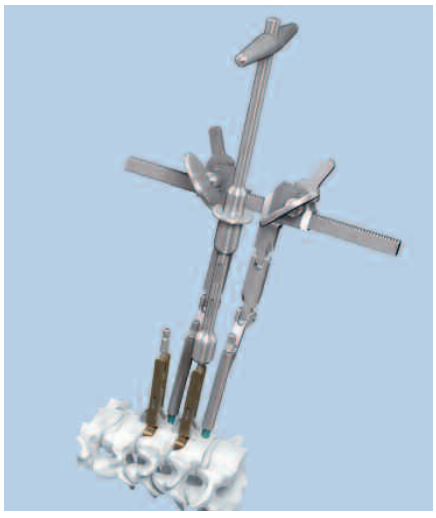


If necessary, e.g. with small vertebral bodies, the retainer screws of the vertebral body retainer can also be inserted obliquely.

- Insert the screws under image intensifier control.



If both levels show severe symptomatic degeneration, the discectomy should be performed on both levels at the same time. To stabilize the treated segments a trial implant should be placed into one level while mobilizing and preparing the second level. The second trial is only used as a spacer; it is not important to choose the correct size. The three screws to mount the vertebral body retainer are in place during preparation of the disc space and insertion of the implant. Always position the vertebral body retainer over the segment you are currently working on.



Case Examples

Case 1: Symptomatic cervical disc disease C5–C7

Patient: Male, 50 years

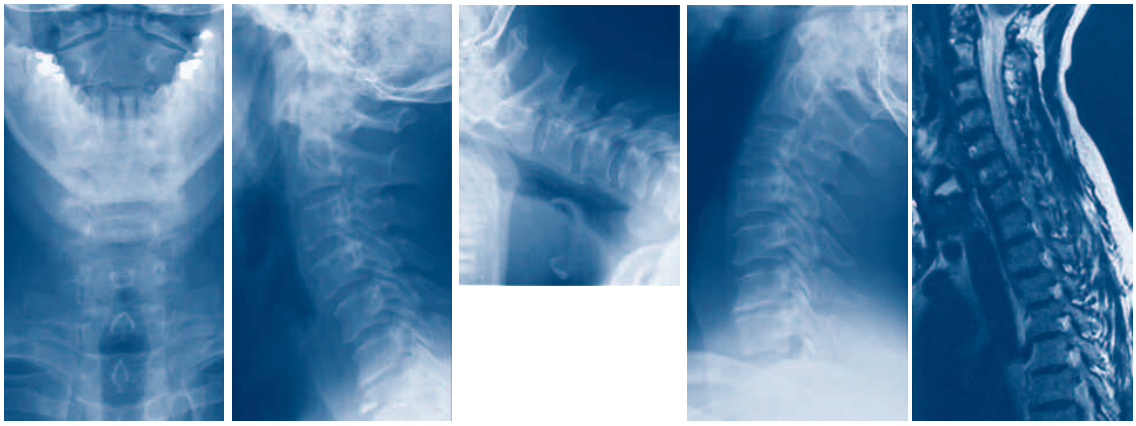
Symptoms:
- Arm pain
- Abnormal motor function C7 right (active movement against resistance)

Diagnosis:
- Symptomatic cervical disc disease C5–C7
- Osteophytes formation C5–C6 and C6–C7
- Disc herniation C5–C6 and C6–C7
- Radiculopathy C6–C7
- Loss of disc height C6–C7

History:
- Arm and neck pain for more than 6 weeks
- Physiotherapy, chiropractic and injection without success

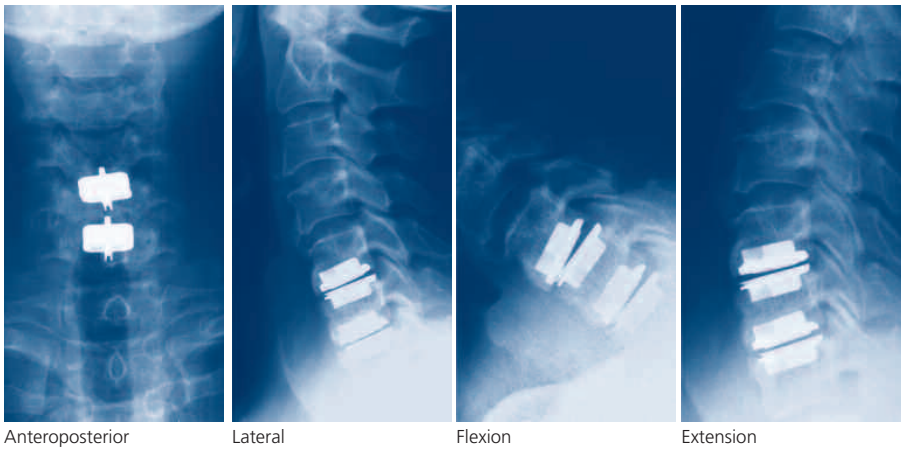
Visual analog scale	pre-op	6 months post-op	12 months post-op
VAS for neck pain intensity	1.5	0.3	1.0
VAS for neck pain frequency	1.5	0.3	0.6
VAS for arm pain intensity	3.2	0.0	0.8
VAS for arm pain frequency	2.9	0.0	0.5
VAS for satisfaction		10.0	10.0

Preoperative



Anteroposterior | Lateral | Flexion | Extension | MRI lateral

12 months follow up



Anteroposterior | Lateral | Flexion | Extension

Case 2: Degenerated disc disease C6–C7

Patient: Female, 42 years

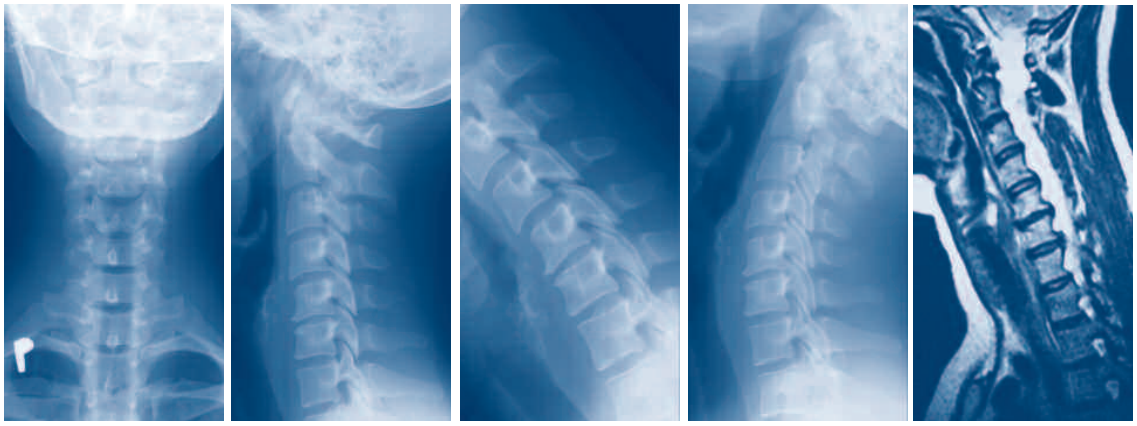
Symptoms:
- Frequently arm and neck pain
- Sensory dysfunctions left

Diagnosis:
- Symptomatic cervical disc disease C6–C7
- Degenerated disc C5–C6
- Disc herniation C5–C6 and C6–C7
- Sensory dysfunction C6–C7

History:
- Arm and neck pain for more than 6 weeks

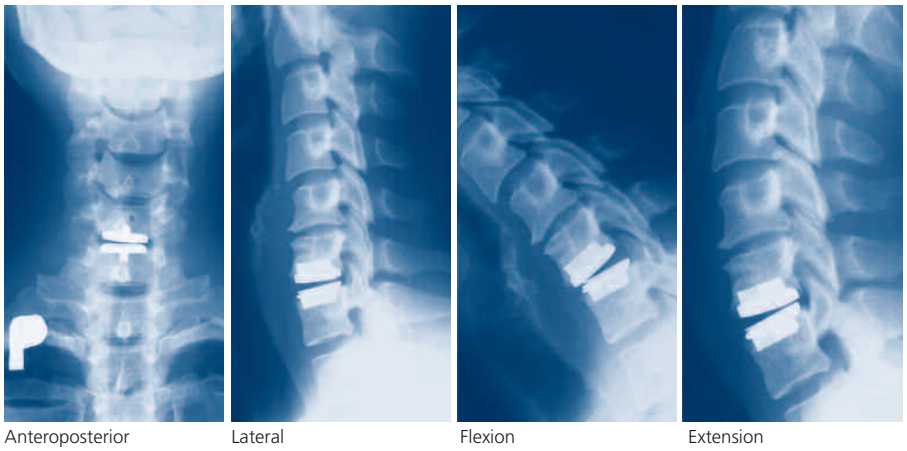
Visual analog scale	pre-op	6 months post-op	12 months post-op
VAS for neck pain intensity	1.7	0.7	0.4
VAS for neck pain frequency	10.0	1.5	0.2
VAS for arm pain intensity	6.1	0.0	0.0
VAS for arm pain frequency	10.0	0.0	0.0
VAS for satisfaction		10.0	10.0

Preoperative



Anteroposterior | Lateral | Flexion | Extension | MRI lateral

12 months follow up



Anteroposterior | Lateral | Flexion | Extension

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LBL427 Rev 1 (10/2017)

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CE 0123