Prodisc-C Nova. Cervical disc prosthesis to restore disc height and maintain segmental motion.

Technique Guide

SYNTHES®

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Image intensifier control

Warning
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is mandatory.

Reprocessing, Care and Maintenance of Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing

Prodisc-C Nova. Cervical disc prosthesis to restore disc height and maintain segmental motion.

Proven concept from the field of joint endoprosthetics

Prodisc-C Nova 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 Nova procedure is intended to significantly reduce pain by allowing for the removal of the diseased disc while restoring biomechanical stability, disc height and providing the potential for motion at the affected vertebral segment.

Proven materials
- Superior and inferior implant plates made of titanium alloy
- Rough surface coating of pure titanium supports bony ongrowth
- Inlay made of ultra-high molecular weight polyethylene (UHMWPE)
- Proven articulating surfaces: UHMWPE on CoCrMo alloy

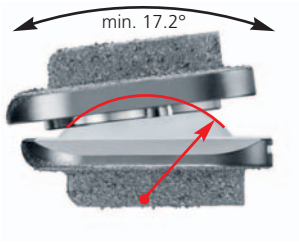
Anatomical design
- Optimal primary stability due to keel anchorage of the prosthesis in the vertebral body
- Trapezoidal footprint design for optimal anatomical fit and maximum end plate coverage
- Tripod keel configuration allows easy multilevel application

Ball and socket articulation
- Permits a physiological range of motion in flexion/extension, rotation, and lateral bending
- Restores anatomical balance
- Controlled translation limits the load on facet joints

Kinematics

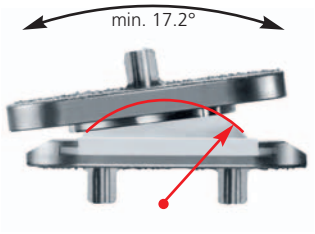
Prodisc-C Nova has a center of rotation which is located just below the inferior end plate of the prosthesis.
Pure translatory movements are controlled by the ball and socket interface.

Flexion/extension
The location of the center of rotation and the flexion radius correspond to the natural joint guidance in the vertebral joints.



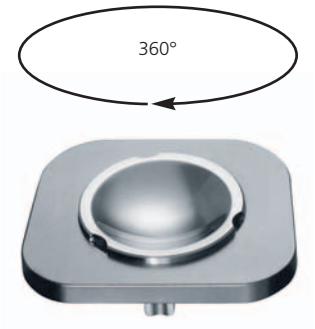
Center of rotation

Lateral bending
The physiological range of motion in lateral bending is restored.



Center of rotation

Axial rotation
The axial rotation is limited only by the anatomical structures and not by the prosthesis.



Indications and Contraindications

Intended use
Prodisc-C Nova 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

Successful clinical outcomes depend on a number of critical factors, including:
– Completion of a training program on the use of Prodisc-C or Prodisc-C Nova
– Proper patient selection
– Complete and meticulous discectomy, decompression, and remobilization of the disc space
– Optimal implant sizing and placement

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

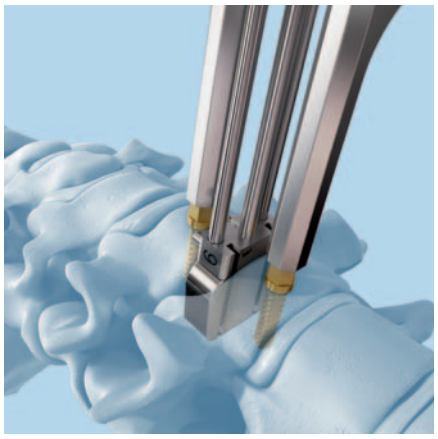
General contraindications
– Osteoporosis, osteochondrosis, and severe osteopenia
– Acute or chronic systemic, spinal, or localized infections
– Systemic and metabolic diseases
– Any medical and surgical conditions precluding the benefits of spinal surgery
– Foreign body sensitivity to the implant materials
– Pregnancy
– Severe obesity (Body Mass Index above 40)

Patient exclusion recommendations
In selecting patients for total disc replacement, the following factors are important for the outcome and success of the procedure:
– A condition of senility or mental illness, alcoholism or smoking
– Dependency on pharmaceutical drugs or drug abuse
– The patient's occupation or activity level

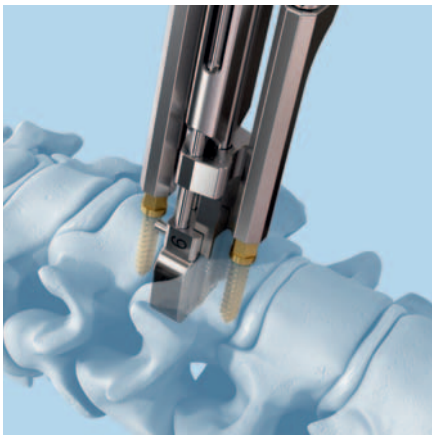
Minimally Invasive Access, Simple and Safe

The instruments are simple and safe to handle:
- 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 patient and short hospital stay, due to minimally invasive access

1. Positioning of trial implant



2. Preparation of keel cut

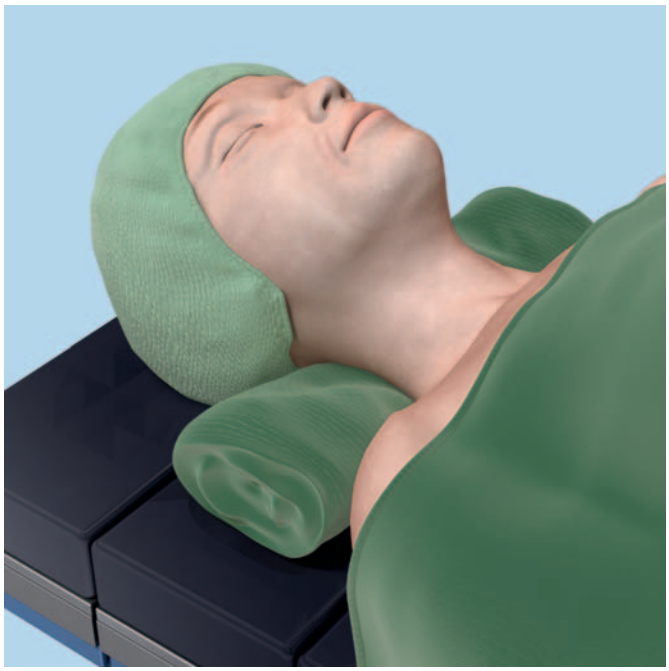


3. Insertion of implant

1
Prerequisites and patient positioning

Insertion of a Prodisc-C Nova 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 in a sagittally neutral position and supported by a cushion. When treating C6–C7 make sure that the shoulders do not limit the X-ray monitoring. In any case both vertebrae should be completely visible.



2
Access

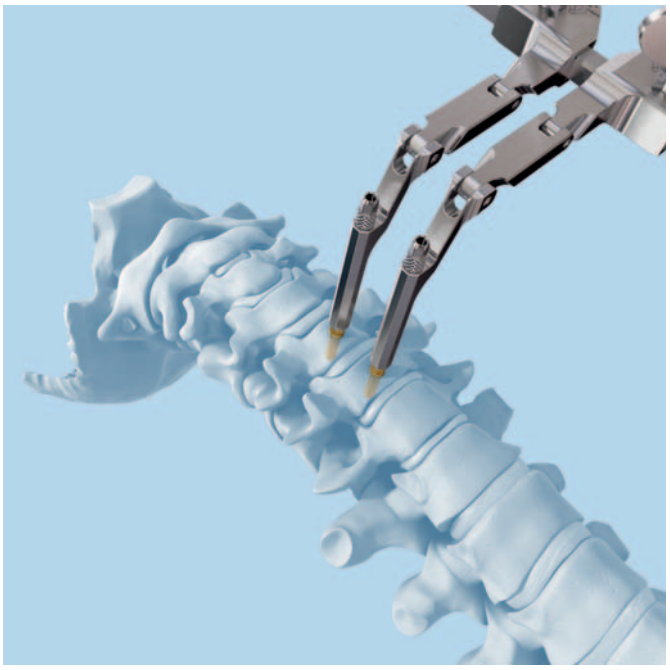
Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine. Mark the level of the surgery and expose the intervertebral disc segment.

Determine the midline using image intensifier control and make a permanent midline mark on the superior and inferior vertebral bodies, e.g. using an osteotome or electro cauterization.

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

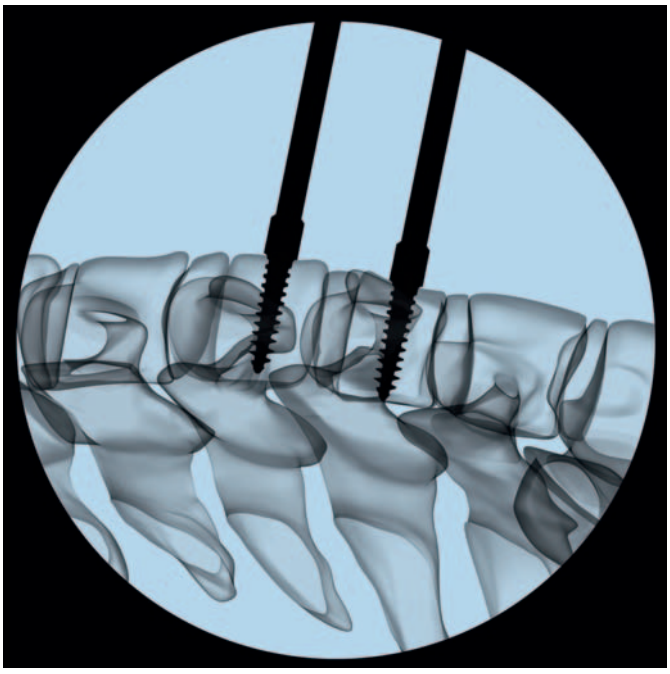
Perforate the anterior cortex of the superior and inferior vertebra in the lateral midline and vertical center with the center punch.



Insert retainer screws into the perforations and place them bicortically. Their trajectory should be parallel to the end plates of the treated disc. Begin with the smaller diameter screws (∅ 3.5 mm) of the longest possible length.
Use a larger diameter screw (∅ 4.5 mm) when extra bone purchase is needed or a smaller screw diameter has been used unsuccessfully ("rescue" screw).

Notes
- Insert screws under image intensifier control to allow optimal trajectory.
- 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 secures parallelism of the retainer screws and the vertebral end plates of the operated level.



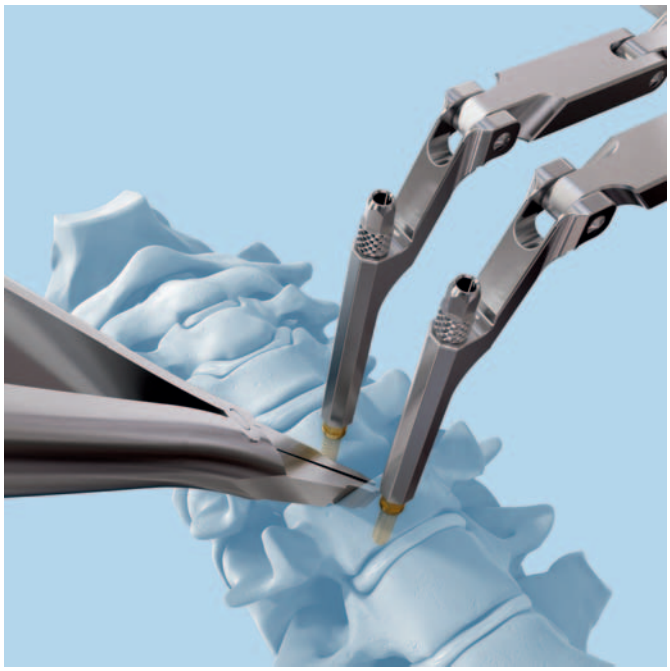
4
Mobilize and distract the segment

Instrument	
03.820.112	Vertebral Distractor

Start the discectomy using standard instruments

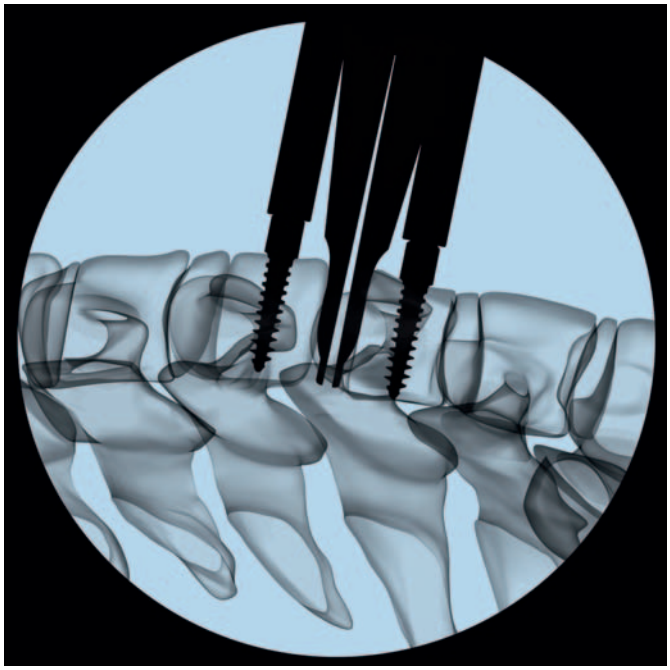
Remove as much disc material as possible to allow the vertebral distractor to be applied completely to the posterior intervertebral space. Mild pre-distraction with the retainer can be used to support disc removal.

Under fluoroscopic control, insert the tip of 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. Readjust the retainer to the distracted height of the intervertebral space. This step should be repeated until maximum distraction has been achieved. Then withdraw the vertebral distractor.



Continue the discectomy and remove the cartilageous endplate carefully. All soft tissue must be removed from the end plates. Care should be taken to minimize bone remodeling.

Continue canal and foraminal decompression.



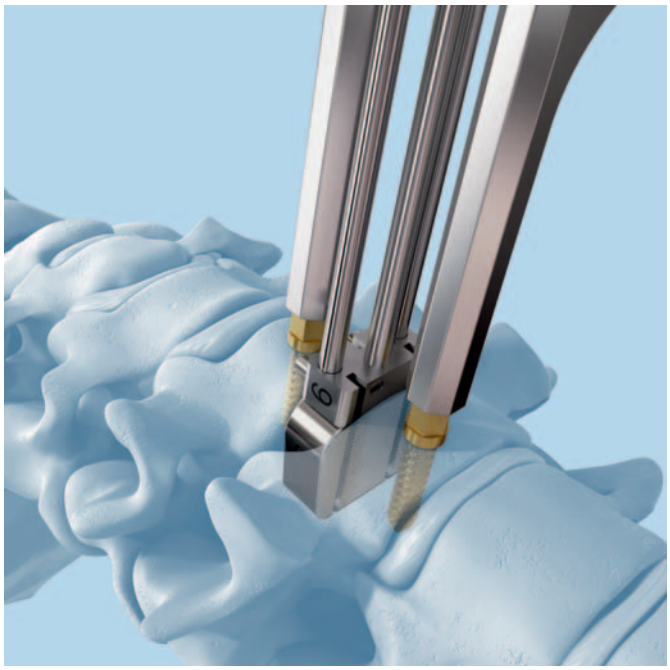
Notes

- 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. Excess force on the vertebral body retainer can lead to bending and/or pull-out of the screws from the bone.
- Avoid excessive end plate damage or removal. It increases the risk of implant subsidence.
- The uncinate process should be preserved. If required for adequate bony decompression, the posterior third of the uncinate 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

Define the implant size

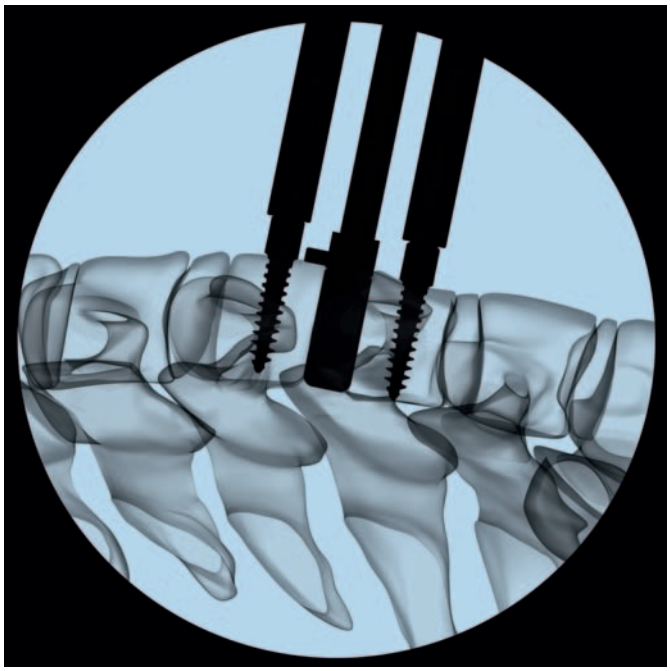
Instruments	
03.820.222–274	Trial Implants, M, MD, L, LD, XL, XLD
03.820.279–281	Shafts for Trial Implants
03.820.204	Handle for Trial Implants
03.820.113	Mallet



Trial implants are placed into the disc space intra-operatively to determine the appropriate disc 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 and heterotopic ossification.

Assemble the corresponding shaft to the trial implant of your choice. Ensure that the shaft is fully screwed and there is no gap between trial implant and stop. Attach the handle for trial implants to the hexagonal end of the (central) shaft. Align the trial implant on midline with the stops pointing cranially and advance it under image intensifier control into the disk space.



In the **lateral view** of the image intensifier the optimal position of the trial implant is at the posterior margin of the vertebral bodies. At the same time the trial implant should be 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 shaft anticlockwise (1 rev = 0.5 mm, max. 4.5 mm). Remove the handle.

Now release the distraction to determine the optimal height of the trial implant. Its height should be the smallest appropriate height to match normal adjacent discs. The vertebral bodies should stay in parallel position to each other.

Notes
- Selecting an implant that is too tall can limit the segmental range of motion.
- Avoid kyphotic position of the corresponding vertebrae.
- Clinical experience has shown that in approx. 80% of all cases the correct implant has a height of 5 mm.
- Do not unscrew stop more than 4 mm or contact to trial implant might to lost. Take next size of trial implant instead.

6
Keel preparation

Instruments	
05.001.080	Air Pen Drive 60.000 rpm*
05.001.082	Hand Switch, for Air Pen Drive*
05.001.083	Double Air Hose, length 3 m*
03.820.295–297	Cutting Blades, height 5, 6 or 7 mm
03.820.216	Prodisc-C Saw Attachment

* or Electric Pen Drive equipment

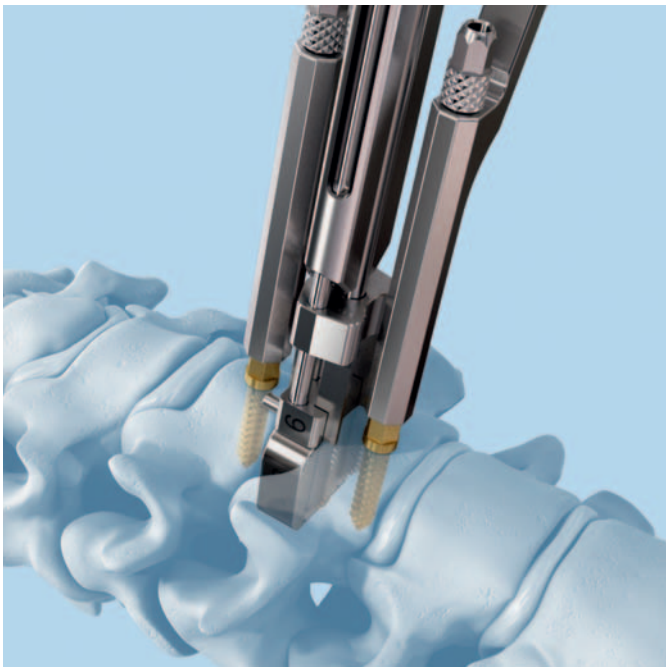
Prepare the power tool with the Prodisc-C saw attachment and connect the cutting blade to it:
- Lock the Air-/E-Pen Drive.
- Turn the release sleeve clockwise until it engages.
- Insert the shaft of the cutting blade in the central hole of the saw attachment. Make sure the single blade is "UP" and push the shaft into the release sleeve until it automatically engages.

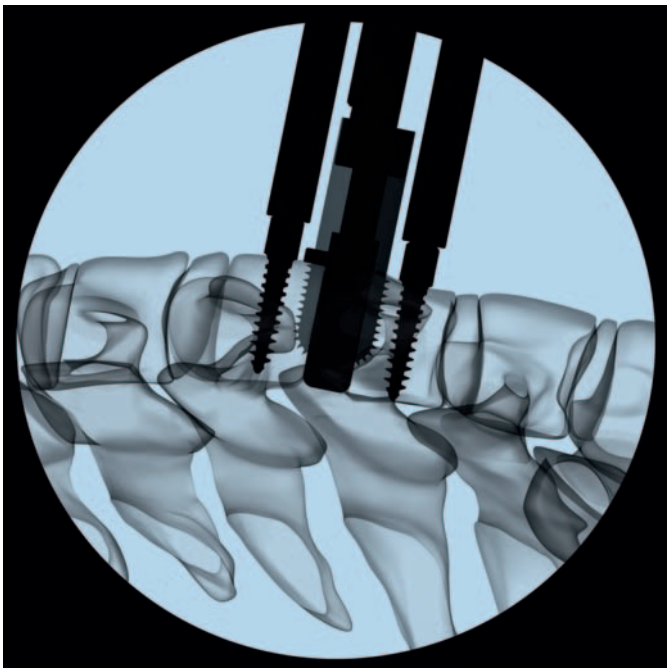
Slide the cutting blade of the appropriate height over the shafts of the trial implant and touch the anterior cortex. Verify the trial implant is still centered on midline.

Under lateral fluoroscopy, advance the cutting blade into the vertebral body until it reaches the positive stop in the trial implant. Remove the cutting blade and stop the machine when tips of the sawing blades are outside of the vertebrae.

Caution: Never run the cutting blades for more than 30 seconds.

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





Notes

– The cutting blades should never be used free hand or unguided.
– The cutting blades will become blunt during multiple uses. Blunt cutting blades will produce more heat during the keel cutting procedure. To avoid the danger of necrosis, blunt cutting blades should immediately be exchanged against new ones.
– The depth of the keel cut can be checked in image intensifier control using the chisel but not the cutting blades.

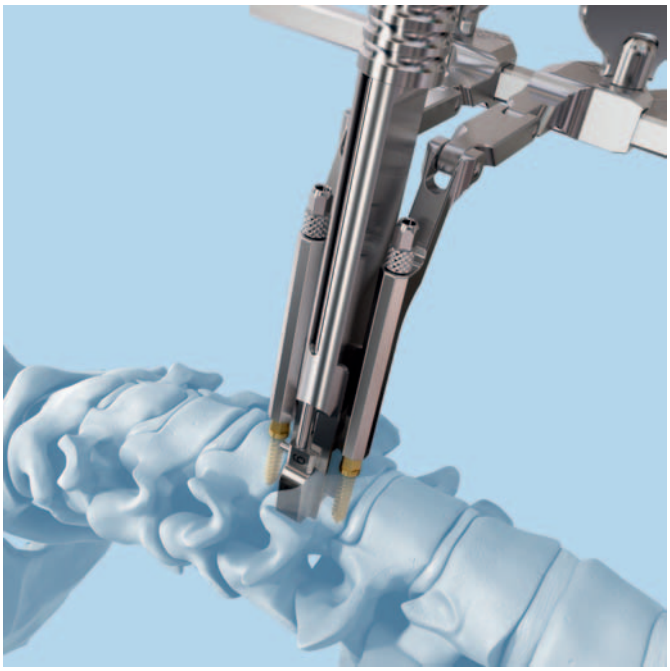
Option: Chiseling for keel preparation

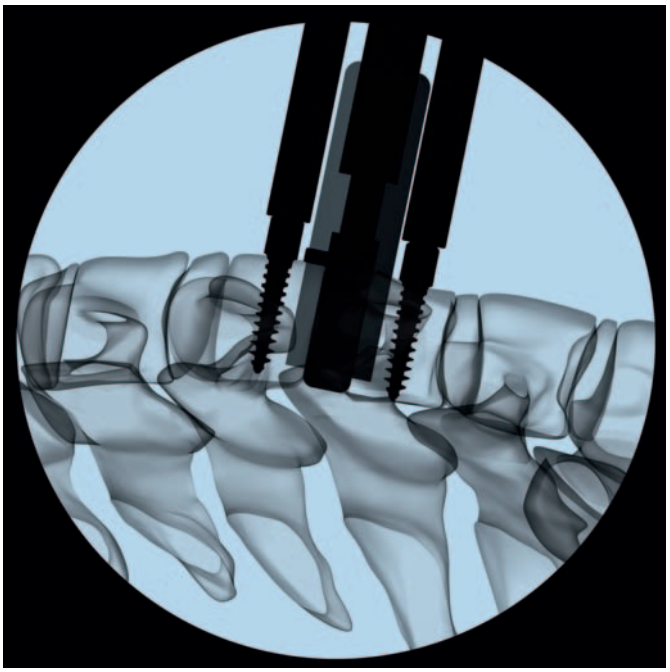
Instruments	
03.820.285–287	Chisels, height 5, 6 or 7 mm
03.820.113	Mallet

Slide the chisel of the appropriate height over the shafts of the trial implant and touch the anterior cortex. Verify the trial implant is still centered on midline.

Under lateral fluoroscopy, 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.

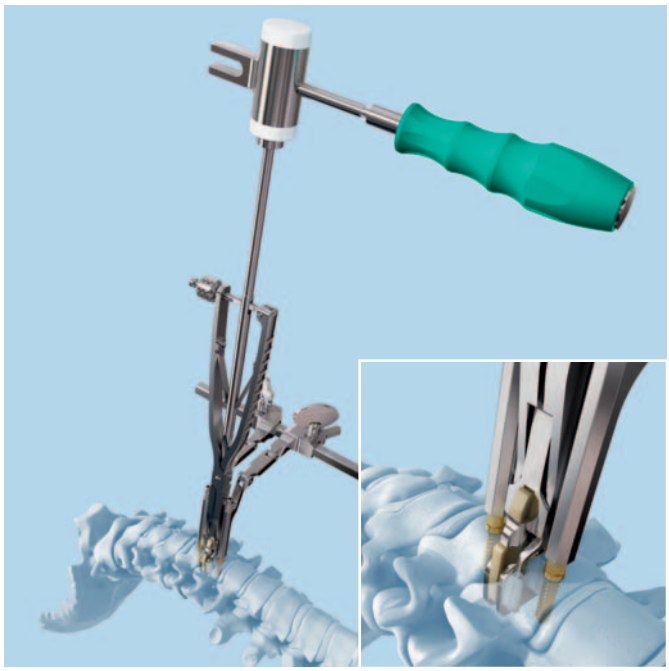
Remove the chisel. Re-open the vertebral body retainer slightly to allow removing the trial implant.





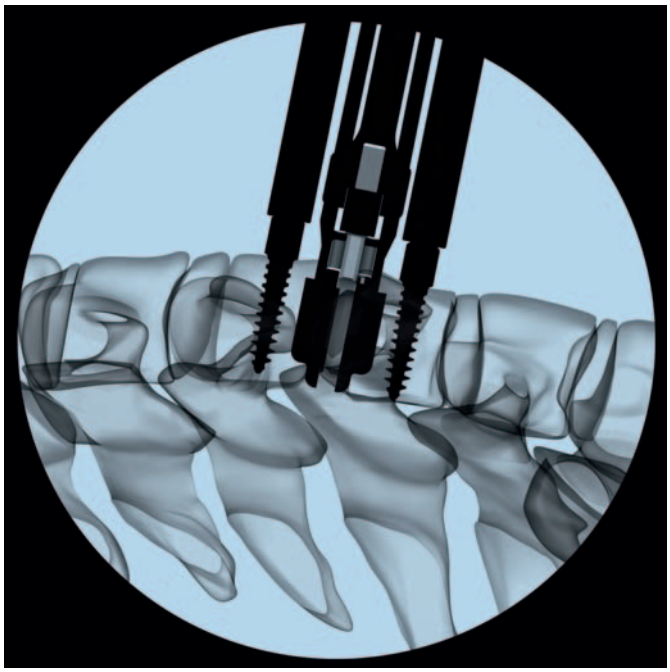
7
Insert implant

Instruments	
03.820.210	Implant Inserter
03.820.130–142	Tips for Implant Inserter
03.820.113	Mallet
03.820.101	Screwdriver
03.670.205	Handle for Positioner
03.670.206	Positioner Head (exchangeable)



Preparation
Spread the distal tips of the implant inserter and install the appropriate sized tip as determined by the selected implant. 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 inserter and pull the implant en-bloc out of the packaging.

Insertion
Align the keels of the Prodisc-C Nova with the keel cuts. Under lateral fluoroscopic control, advance the implant to the posterior margin of the vertebral bodies.



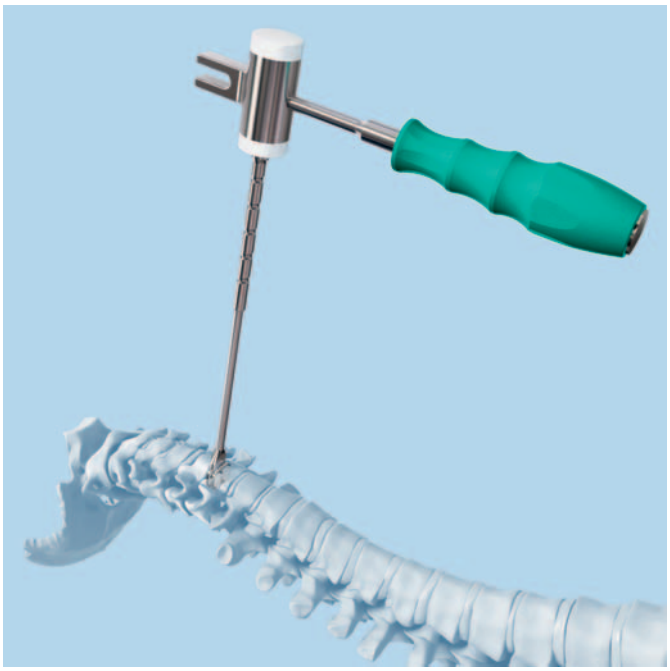
View in the image intensifier
The PE inlay of the implant and the inserter tip (PEEK) are not visible in the image intensifier.

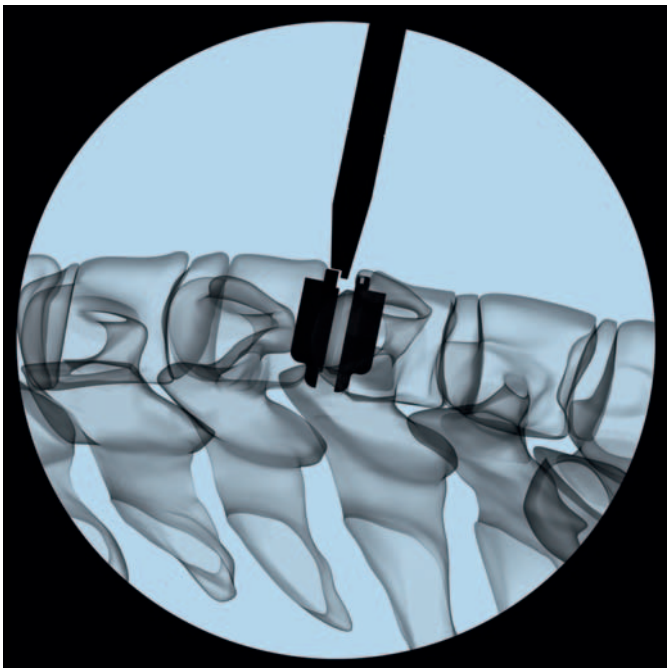
After the implant is seated, push the release button of the inserter. The springs of the inserter will open the scissors and the instrument can be removed by pulling it straight back out of the operative field.

Adjustment of the implant (optional)
After the implant inserter has been disengaged from the implant, the positioner can be used on the endplates of the prosthesis to push them individually more posterior if necessary.

Screw the head of positioner to its handle. Have the head of the positioner seated to the anterior rim of the superior or inferior plate of the implant.

- Under image intensifier control, use the mallet on the rear end of the handle to gently push the plate in posterior direction. If both plates have to be adjusted it should be done in alternating manner starting with the lower end plate.



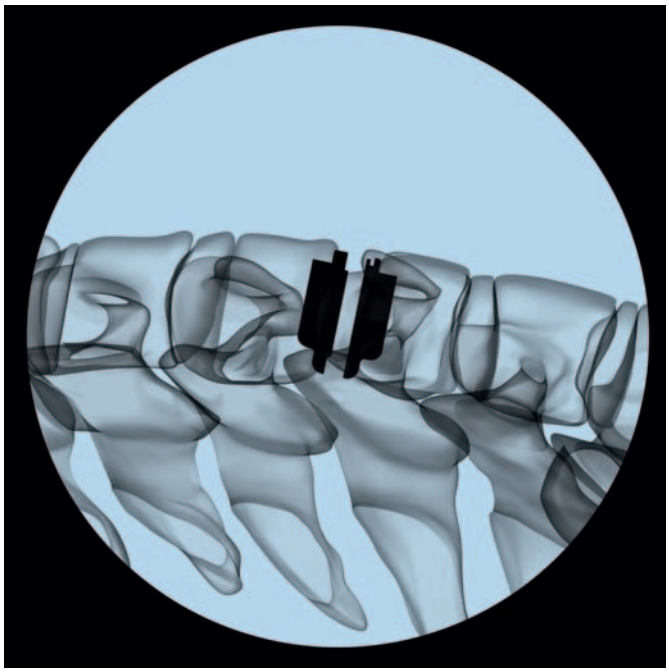


After the implant is seated correctly, apply compression to the retainer pins to allow full settling of the keels.

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

Remove osteophytic bone formations that are overlapping the disc prosthesis anterior.

Note: Heterotopic ossification (HO) is a possible cause for the latter fusion of the treated segment. HO might be reduced when bone wax is used to close cavities in the bone (screw holes; anterior end of keel channels; open bone surfaces).



Multi-Level Cases

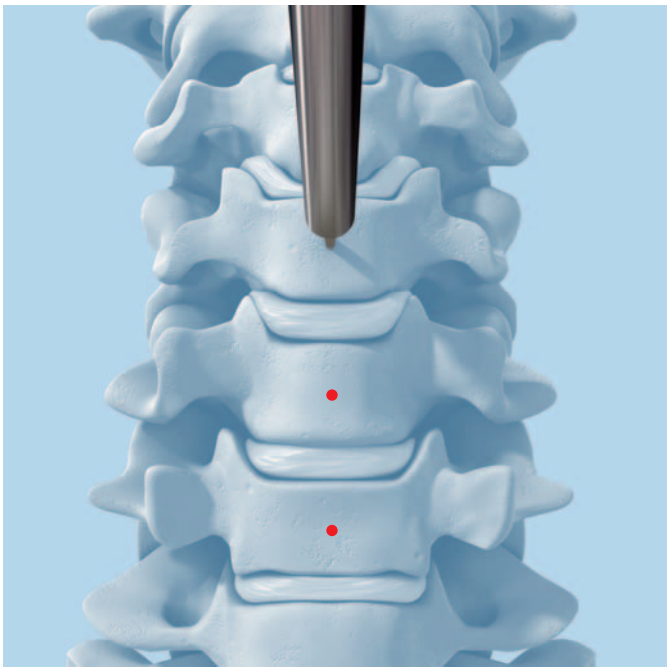
The asymmetric keel design (tripod) allows optimal multilevel application.

Multi-level Prodisc-C Nova surgeries should be performed sequentially level by level.

To create an optimal balance and alignment of the disc prostheses start with the lower level first.

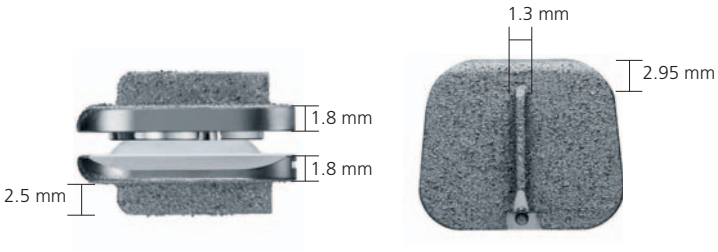
The retainer screws should be placed centrally in the vertebrae, like in the surgical technique for single levels. Insert the screws under image intensifier control.

Repeated image intensifier control in A-P direction will be necessary to ensure proper alignment of the disc prostheses.

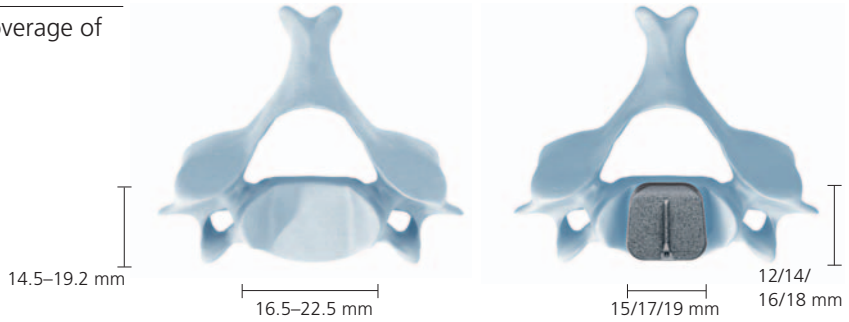


Implants

Dimensions

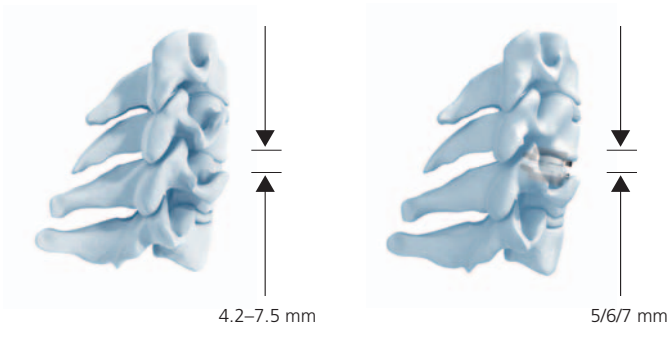


Six different footprints are available for optimal coverage of the vertebral end plate: M, MD, L, LD, XL, XLD.



Panjabi 1991

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

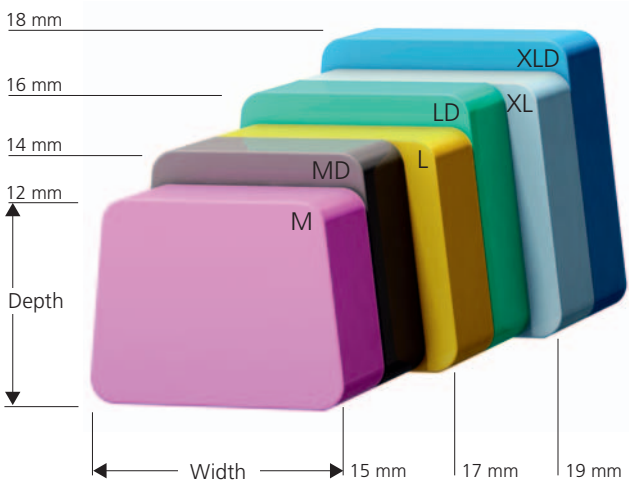


Yoganandan et al. 2001

Implant

Prodisc-C Nova is based on the clinical and biomechanical experience with Prodisc-C. The implant consists of two titanium end plates; the cranial end plate has one central keel while the caudal end plate has two lateral keels.

Prodisc-C Nova is based on the ball and socket principle with a "poly-on-metal" pairing. The polyethylene inlay (ball) is securely locked in the lower end plate while the upper end plate embraces the calotte (socket), made of CoCrMo alloy.

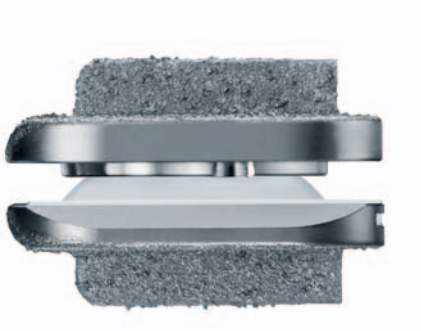


Implant M
Width 15 mm
Depth 12 mm

Art. No.	Height
04.820.225S	5 mm
04.820.226S	6 mm
04.820.227S	7 mm

Implant MD
Width 15 mm
Depth 14 mm

Art. No.	Height
04.820.235S	5 mm
04.820.236S	6 mm
04.820.237S	7 mm



Implant L
Width 17 mm
Depth 14 mm

Art. No.	Height
04.820.245S	5 mm
04.820.246S	6 mm
04.820.247S	7 mm

Implant LD
Width 17 mm
Depth 16 mm

Art. No.	Height
04.820.255S	5 mm
04.820.256S	6 mm
04.820.257S	7 mm

Implant XL
Width 19 mm
Depth 16 mm

Art. No.	Height
04.820.265S	5 mm
04.820.266S	6 mm
04.820.267S	7 mm

Implant XLD
Width 19 mm
Depth 18 mm

Art. No.	Height
04.820.275S	5 mm
04.820.276S	6 mm
04.820.277S	7 mm

Instruments

The Prodisc-C Nova 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	

Precision-Cutting System

The keel cuts are performed with highly specialized cutting blades in combination with guiding instruments. They guarantee the precise generation of the keel cuts.
The precision-cutting system requires a power tool to drive the cutting blades. It is specifically adapted to Synthes Air Pen Drive or Electric Pen Drive.

Trial Implant M

Art. No.	Height
03.820.222	5 mm
03.820.223	6 mm
03.820.224	7 mm

Trial Implant MD

Art. No.	Height
03.820.232	5 mm
03.820.233	6 mm
03.820.234	7 mm

Trial Implant L

Art. No.	Height
03.820.242	5 mm
03.820.243	6 mm
03.820.244	7 mm

Trial Implant LD

Art. No.	Height
03.820.252	5 mm
03.820.253	6 mm
03.820.254	7 mm

Trial Implant XL

Art. No.	Height
03.820.262	5 mm
03.820.263	6 mm
03.820.264	7 mm

Trial Implant XLD

Art. No.	Height
03.820.272	5 mm
03.820.273	6 mm
03.820.274	7 mm

Shaft for Trial Implants

Art. No.	Height
03.820.279	5 mm
03.820.280	6 mm
03.820.281	7 mm

03.820.204	Handle for Trial Implants

Cutting Blades

Art. No.	Height
03.820.295	5 mm
03.820.296	6 mm
03.820.297	7 mm

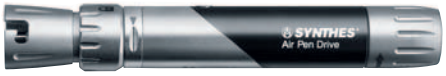
Synthes recommends using new sterile cutting tools for each operation.

Detailed cleaning and sterilization instructions for instruments and cases can be found in the general leaflet "Important Information" and the "Reprocessing, Care & Maintenance" folder (available at www.synthes.com).

Air Pen Drive

The Prodisc-C Nova instrument set includes standard items of the Synthes Air Pen Drive System, which are mandatory for the performance of the Prodisc-C Nova surgical procedure.

05.001.080	Air Pen Drive 60.000 rpm



05.001.082	Hand Switch, for Air Pen Drive

05.001.083	Double Air Hose, length 3 m, for Air Pen Drive
05.001.086	Protective Cap, for Air Pen Drive
05.001.091	Seal Nipple for Double Air Hose

03.820.216	Prodisc-C Saw Attachment This saw attachment is specifically adapted to the Prodisc-C Nova implant design. It must only be used with the Synthes Air Pen Drive or the Synthes Electric Pen Drive System.

Maintenance

Compliance with the maintenance specifications can considerably extend the service life span of the Air Pen Drive.

To ensure proper operation of the machine follow the instructions for use Air Pen System (036.000.503). Special attention must be paid to the chapter about "Care and Maintenance".

Chisel instruments

The chisels are meant to be a fallback solution, for the unlikely case that the precision-cutting system cannot be used. They must not be used without the trial implants.

Art. No.	Height
03.820.285	5 mm
03.820.286	6 mm
03.820.287	7 mm

03.820.113	Mallet

Insertion instruments

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

03.820.210	Implant Inserter

Tips for Implant Inserter

Art. No.	Sizes	Height
03.820.130	M/MD	5 mm
03.820.131	M/MD	6 mm
03.820.132	M/MD	7 mm
03.820.133	L/LD	5 mm
03.820.134	L/LD	6 mm
03.820.135	L/LD	7 mm
03.820.140	XL/XLD	5 mm
03.820.141	XL/XLD	6 mm
03.820.142	XL/XLD	7 mm

03.670.205	Handle for Positioner

03.670.206	Positioner Head (exchangeable)

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Synthes GmbH
Eimattstrasse 3
CH-4436 Oberdorf
www.synthesprodisc.com

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