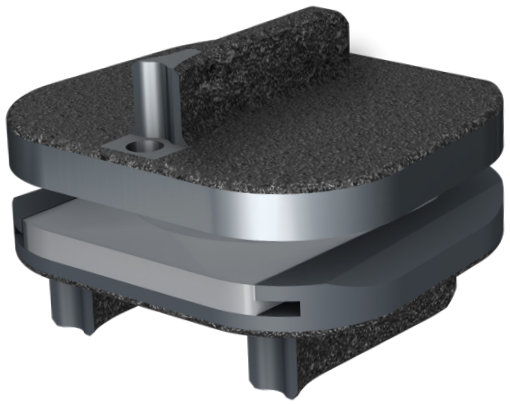
CENTINEL SPINE®

prodisc® C Nova

Cervical Total Disc Replacement System

SURGICAL TECHNIQUE GUIDE



prodisc® C Nova

Cervical Total Disc Replacement System

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

CENTINEL SPINE®

A dedicated spine company with a singular focus

30+ YEARS OF CLINICAL SUCCESS SINCE 1988

About Centinel Spine

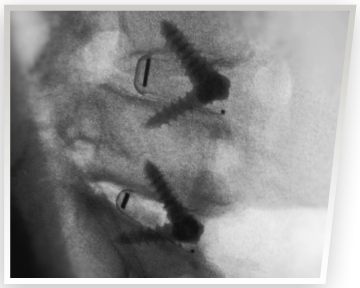
Centinel Spine was founded in 2008 through the merger-acquisition of two pioneering medical device companies (Raymedica, LLC and Surgicraft LTD.) and is the largest privately-held spine company focused on anterior column reconstruction. The company offers a continuum of motion-preserving and fusion solutions—providing the most robust Total Disc Replacement and Integrated Interbody™ portfolios in the world.

Pioneering Integrated Interbody Solutions

The Stand-Alone/No Profile® device category was founded in 1988 with the release of the Hartshill Horseshoe product, the foundation for the technology platform known today as **STALIF®**. Centinel Spine remains a leader in Stand-Alone solutions today, with over 30 years of clinical history and over 75,000[1] devices implanted. **STALIF** still remains the only Stand-Alone device demonstrating biomechanical equivalence to anterior plate & cage in independent peer-reviewed publications.[2,3]

STALIF technology incorporates a proven design rationale based on AO principles of fracture fixation and Wolff's Law of Bone Healing. The No Profile design utilizes unique integrated compressive lag fixation technology to enhance stability and compress endplates to the cage and graft material. The system utilizes simple, elegant instrumentation — perfected over years of clinical use and proven to reduce surgical time by 40%, compared to reported alternatives.[4,5] **STALIF** technology is currently available in PEEK, **Ti-ACTIVE**™ microporous texturized titanium surface, and **FLX**™ proprietary 3D-Printed titanium trabecular scaffold.

STALIF® For Fusion

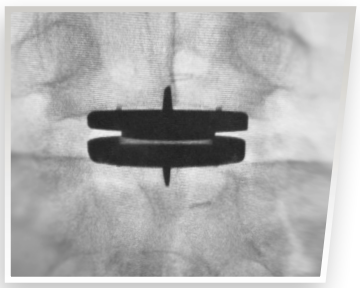


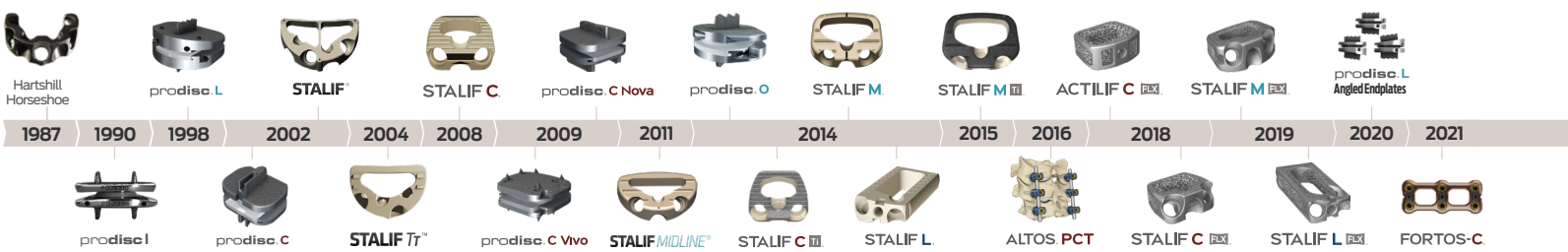
Clinically-Proven Motion Preservation

Centinel Spine couples its market-leading fusion portfolio with best-in-class **prodisc®** Total Disc Replacement (TDR) technology. Centinel Spine offers an unmatched number of six cervical / lumbar TDR products, globally, and is the only company with both lumbar and cervical approval in the U.S. No other disc replacement system has been studied to this extent, with over 13,000 patients reported on in more than 540 articles over a global clinical usage period of almost 30 years.[6]

prodisc®, the most clinically-proven Total Disc Replacement system in the world, utilizes a mechanism of action to deliver predictable and controlled motion. The **prodisc®** product line provides surgeons with a variety of options to suit a patient's activity levels and anatomy, as well as a variety of endplate configurations to suit different degenerative conditions. The **prodisc®** design has been validated with over 225,000 device implantations and a reported reoperation rate of less than 1%.[7]

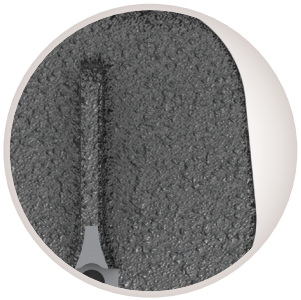
prodisc® For Motion





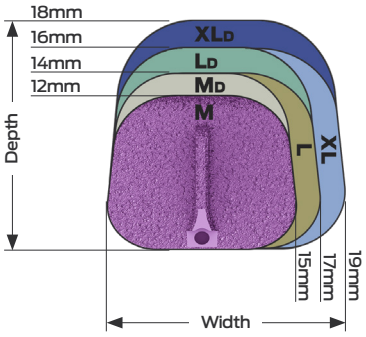
Introduction to prodisc® C Nova

prodisc C Nova devices are 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.



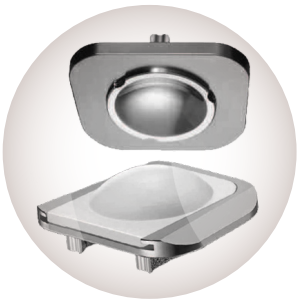
Proven Materials

- Titanium porous coating allows bony on-growth, aiding in long-term fixation
- Inlay made from ultra-high molecular weight polyethylene (UHMWPE)
- Proven articulating surfaces: UHMWPE on CoCrMo alloy



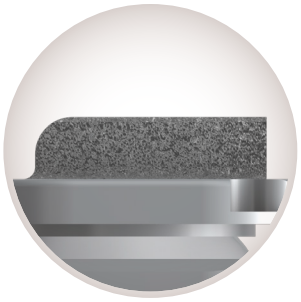
Anatomical Sizing

- Six (6) endplate footprints (medium, medium deep, large, large deep, extra large, extra large deep)
- 5 mm, 6 mm and 7 mm heights
- 18 implant configurations



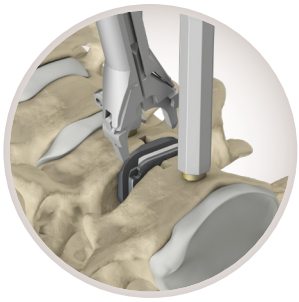
Kinematics

- Allows for the potential for motion in the treated segment
- Provides a fixed center of rotation
- Restores height and offloads the facets
- Resists shear forces



Anatomical Design

- Keel provides primary stability and facilitates midline placement
- Trapezoidal footprint design for optimal anatomical fit and maximum endplate coverage



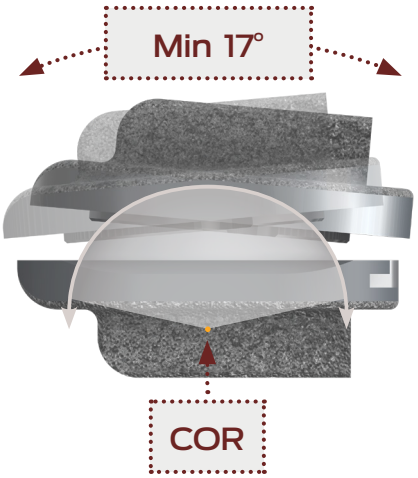
Simple Surgical Technique

- Simple technique: Decompression, remobilization, trialing, and insertion

prodisc **C Nova** has a center of rotation that is located just below the inferior endplate of the prosthesis. A/P translation occurs with flexion/extension rotation.

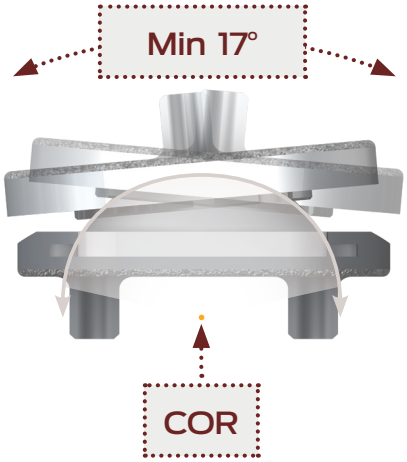
Flexion/Extension

- The location of the center of rotation (COR) and the flexion/extension radius are in accordance with the kinematics of the intact spine



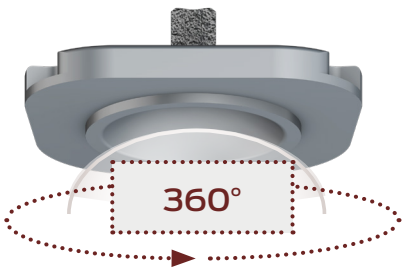
Lateral Bending

- The physiological range of motion in lateral bending is maintained



Axial Rotation

- Axial rotation is limited by the anatomical structures and not by the prosthesis



Device Description

The prodisc **C Nova** Total Disc Replacement device consists of the following three components. The first is the inferior CoCrMo (cobalt chromium molybdenum) alloy plate with a midline keel that anchors to the inferior vertebral body. The second component is an Ultra High Molecular Weight Polyethylene (UHMWPE) insert that is pre-assembled snap-locked into a tray detail in the inferior CoCrMo alloy plate and provides the inferior convex bearing surface. The third component is a CoCrMo alloy plate with keels that anchor to the superior vertebral body endplate and has a highly polished concave bearing surface that articulates with the convex UHMWPE spherical dome.

The endplate footprints range from 15-19 mm wide (medial-lateral) x 12-18 mm deep (anterior-posterior). Each endplate size is available in three disc heights: 5, 6, and 7 mm. This allows for a wide range of sizing to accommodate individual patient anatomy.

The bone contacting surfaces of the inferior and superior plates, as well as both keels, are titanium plasma spray coated, which may provide additional fixation through bony ongrowth.

The maximum range of motion allowed by the prodisc **C Nova** Total Disc Replacement device design is 20° in flexion/extension (17° for the 5mm Large, Large Deep, Extra Large, and Extra Large Deep implants), 20° in lateral bending (17° for the 5mm Large, Large Deep, Extra Large, and Extra Large Deep implants), and the device is unconstrained in axial rotation as measured through in vitro testing.

Indications for Use

The prodisc **C Nova** Total Disc Replacement is indicated in skeletally mature patients for reconstruction of a single disc from C3-C7 following discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease 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), and/or loss of disc height.

The prodisc **C Nova** Total Disc Replacement is implanted via an open anterior approach. Patients receiving the prodisc **C Nova** Total Disc Replacement should have failed at least six weeks of nonoperative treatment prior to implantation of the prodisc **C Nova** Total Disc Replacement.

The prodisc **C Nova** instruments are intended for the placement, positioning, and removal of the prodisc **C Nova** devices.

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:

- The patient's occupation or activity level
- A condition of senility, mental illness, alcoholism, or drug abuse
- Degenerative diseases that may be so advanced at the time of implantation that they limit the expected life of the implant

Contraindications

The prodisc **C Nova** Total Disc Replacement device should not be implanted in patients with the following conditions:

1. Active systemic infection or infection localized to the site of implantation
2. Osteoporosis defined as DEXA bone density measured T-score ≤ -2.5
3. Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3 mm and/or > 11° of rotational difference to either adjacent level
4. Allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
5. Spondylosis within levels C1-C7
6. Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion)

Warnings

Correct placement of the device is essential to optimal performance. Use of the prodisc **C Nova** Total Disc Replacement should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics, has experience with anterior cervical spinal surgeries, and has received hands-on training in the use of this specific device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device.

Preoperative Considerations

Perform a thorough review of patient history, physical exam, and imaging studies to identify possible contraindications to total disc replacement and to identify the appropriate symptomatic level. Upon reviewing all pertinent information, determine whether a bone density scan is appropriate.

Precautions

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

- Not skeletally mature
- Patients under the age of 18 or over the age of 69
- More than one vertebral level with SCDD
- Prior fusion surgery at an adjacent vertebral level
- Prior surgery at the level to be treated
- Advanced facet joint disease or degeneration at the level to be treated
- Neck or arm pain of unknown etiology
- Paget's disease, osteomalacia, or other metabolic bone disease
- Pregnancy
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids)
- Rheumatoid arthritis or other autoimmune disease
- Severe diabetes mellitus requiring daily insulin treatment
- Systemic disease including AIDS, HIV, and hepatitis
- Active malignancy
- Patients with progressive symptoms and signs of spinal cord/nerve root compression with less than six weeks of conservative treatment
- When implanted at more than one cervical spinal level and/or adjacent to an anterior cervical discectomy and fusion (ACDF)
- prodisc **C Nova** device has not been studied in the clinical situation of prior cervical fusion.

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all comorbidities, past and present medications, previous treatments, etc. A screening questionnaire for osteoporosis, i.e. SCORE (Simple Calculated Osteoporosis Risk Estimation), may be used to screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, the patient should be excluded from receiving the device (per the contraindications listed above) if the DEXA bone density measured T-score is ≤ -2.5, as the patient may be osteoporotic.

Use care when handling the prodisc **C Nova** Total Disc Replacement implant to ensure that it does not come in contact with objects that could damage the implant. Exercise care to ensure that implantation instruments do not contact the highly polished articulating surfaces of the endplates. Damaged implants are no longer functionally reliable.

To prevent unnecessary damage to the bearing surfaces, ensure that blood or other debris is not trapped within the device.

prodisc **C Nova** Total Disc Replacement implants should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique guide for step-by-step instructions.

Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. This includes the avoidance of heavy lifting, repetitive bending, and prolonged or strenuous activity initially and for a period of weeks to months depending on the individual patient's progress and the stability and functioning of the implant.

MRI information

Centinel Spine prodisc C Nova implants are labeled MR Conditional where they have been demonstrated to pose no known hazards in a specified MR enviroment with specified conditions of use, according to the terminology specified in ASTM F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Enviroment.

Nonclinical testing of the prodisc® C as a proxy for prodisc C Nova demonstrated that the implant is MR Conditional. A patient with a prodisc C Nova implant may be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla at Normal Operating Mode or First Level Controlled Mode
- Highest spatial gradient magnetic field of 900 Gauss/cm or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning.

Note: In nonclinical testing, a prodisc® C implant of largest geometrical volume and mass was tested for heating and results showed a maximum observed heating of 1.1ºC for 1.5 T and a maximum observable heating of 1.9ºC for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg as assessed by calorimetry.

Patients may be safely scanned in the MRI chamber at the above conditions. Under such conditions, the maximal expected temperature rise is less than 2ºC. To minimize heating, the scan time should be as short as possible and the SAR as low as possible. Temperature rise values obtained were based upon a scan time of 15 minutes.

The above field conditions tested in a 1.5 T and a 3.0 T Philips Achieva (Philips Healthcare, Software release 2.6.3 SP4) MR scanner should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. Centinel Spine MR Conditional prodisc C Nova implants may have the potential to cause artifacts in the diagnostic imaging.

Artifact Information:

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the prodisc C Nova implant and it may be necessary to optimize MR imaging parameters in order to compensate for the presence of the implant.

A representative implant has been evaluated in the MRI chamber and worst case artifact information is provided below. Overall, artifacts created by prodisc C Nova implants may present issues if the MR imaging area of interest is in or near the area where the implant is located.

- For FFE sequence: Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15º, worst case artifact will extend approximately 3.5 cm from the implant
- For SE sequence: Scan duration: 4 min, TR 500 ms, TE 20 ms, flip angle 70º, worst case artifact will extend approximately 2.5 cm from the implant

Processing, Reprocessing, Care, & 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:

http://prodiscguides.centinelspine.com

For general information about reprocessing, care, and maintenance of Centinel Spine reusable devices, instrument trays, and cases, please refer to:

http://prodiscguides.centinelspine.com

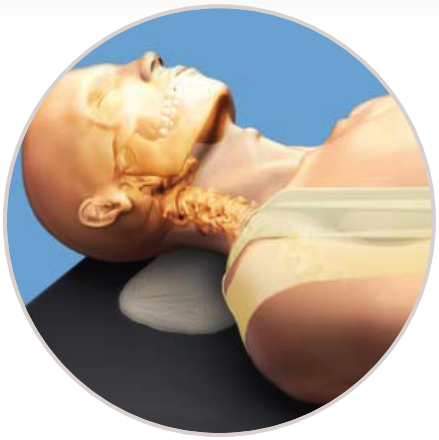
Patient Positioning

AP and lateral imaging is used frequently throughout the prodisc C Nova surgical procedure. Set up the OR table, patient and C-arm to allow for circumferential use of fluoroscopy at the operative level; and for unobstructed cranial and caudal movement of the C-arm, avoiding frequent passage in and out of the sterile field **(Figure 1)**.

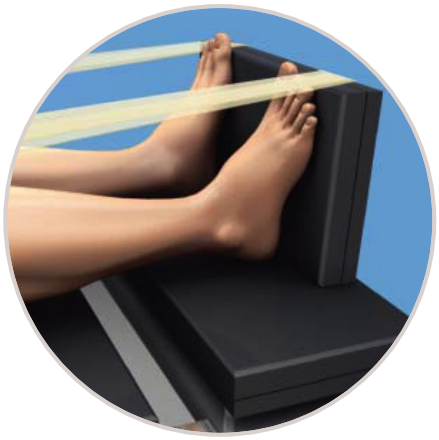
Position the patient supine on the operating table. Support the neck with a radiolucent cushioned neck roll to keep the neck in a normal lordotic ("neutral") position **(Figure 2)**. Correct any malrotation of the neck and head. Confirm true A/P orientation with spot fluoroscopy. Tape or strap the head in place to maintain this position.

1. Taping Shoulder to the Foot Board

2. Supporting the Neck with a Radiolucent Cushioned Neck Roll



3. Demonstrating Use of Foot Board



please NOTE *The inability to reproduce neutral alignment in the sagittal plane may result in improper implant position.*

A fusion procedure may be necessary if visualization of the target disc space does not allow for an optimal lateral view.

Exposure

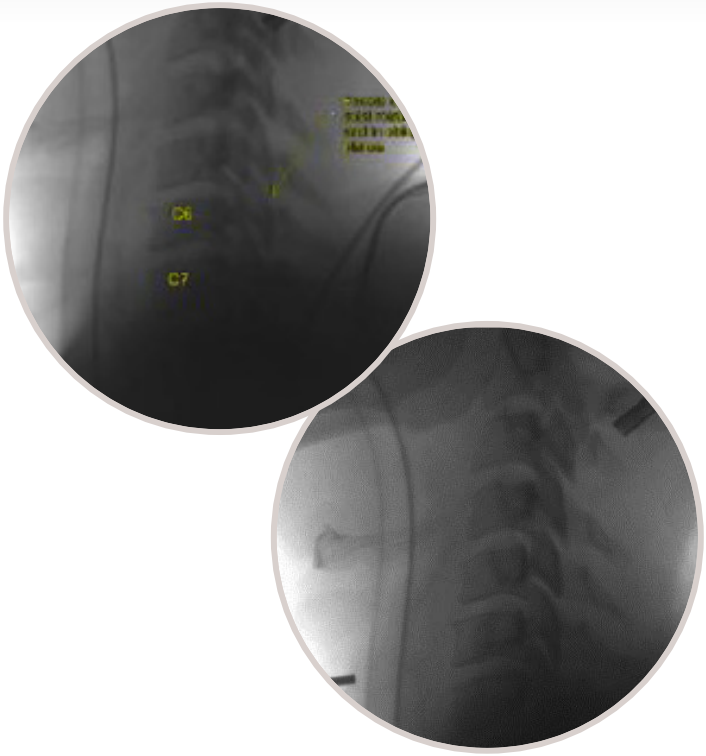
Both vertebral bodies of the affected level must be clearly visible on fluoroscopy before proceeding with surgery. If the shoulders obstruct the view of the operative level, depress the shoulder girdle using caudal traction **(Figures 1, 2, 3)**.

Use A/P spot fluoroscopy to look at rotation and lateral fluoroscopy to line up and perfectly superimpose the facets **(Figure 4)**.

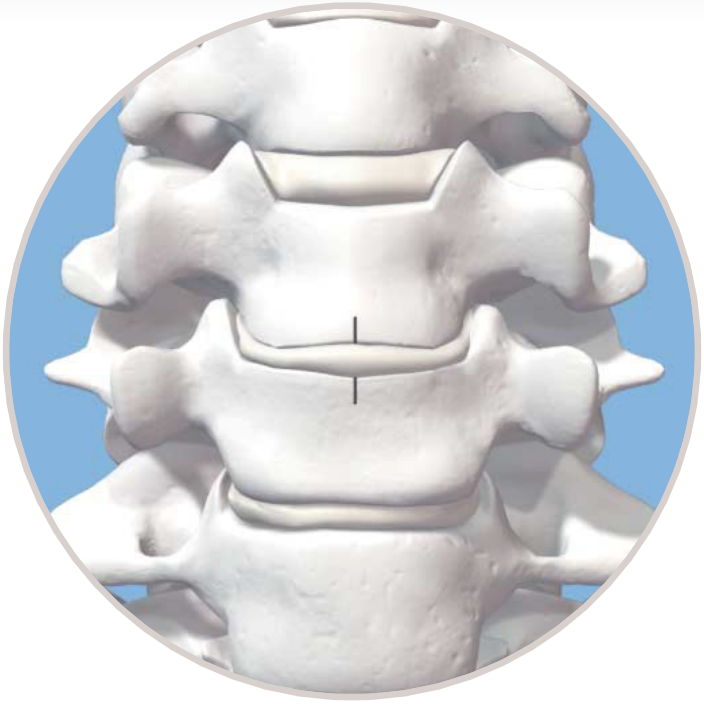
Expose the operative level via a standard transverse approach to the anterior cervical spine. Verify the operative level with fluoroscopy.

Use A/P fluoroscopy to identify the midline of the operative level. Mark both the superior and inferior bodies at the disc so the mark is visible throughout the implantation procedure **(Figure 5)**.

4. Fluoroscopy Demonstrating Final Patient Positioning



5. Marking the Midline of the Superior & Inferior Vertebral Bodies



Discectomy, Decompression, & Remobilization

Thorough disc space preparation is best performed with controlled, parallel distraction of the operative level. Distraction should be obtained using the vertebral distractor and then maintained with the vertebral body retainer system.

To avoid the risk of migration or subsidence, it is critical that greater than 90% of the weight-bearing surface of the bone endplate is not violated with a burr or curettes.

Retainer screws maintain parallel distraction of the disc space. Screws should be inserted parallel to the operative disc space of the vertebral body to allow adequate working window for keel preparation and implant insertion **(Figure 6)**.

Awl, 12mm
03.820.100

Short Screwdriver
IN1444

Vertebral Body Retainer
03.820.111/1

Retainer Screw (3.5mm or 4.5mm)
03.820.102-03.820.109

Retainer Nut
03.820.110

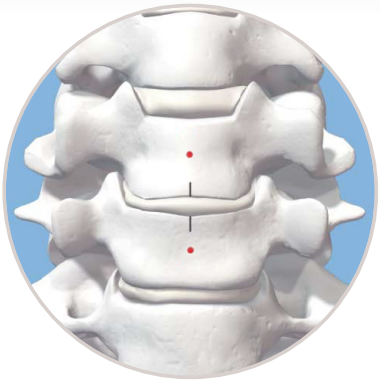
Vertebral Distractor
03.820.112

please NOTE *Performing a complete and meticulous discectomy, decompression, and remobilization of the disc space is critical to the success of the surgery. The surgeon must remobilize the diseased segment and restore the disc height prior to implantation of the prodisc C Nova Total Disc Replacement.*

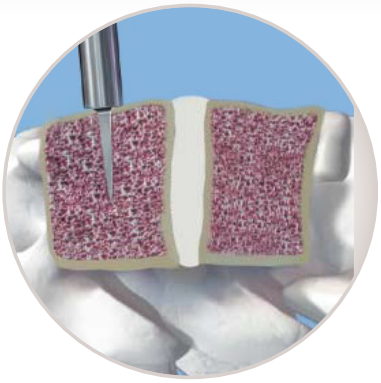
The technique for use is:

1. Perforate the anterior cortex with the awl, using lateral fluoroscopy to ensure its trajectory is parallel to the affected endplate **(Figure 7)**.
2. Estimate retainer screw length based on awl tip (12mm long).
3. Insert retainer screws with the self-retaining screwdriver **(Figure 8)**, using fluoroscopy to confirm trajectory and screw depth. The retainer screws should be inserted parallel to the operative disc space and within the central area of the vertebral body. Bicortical purchase is not necessary **(Figure 9)**.

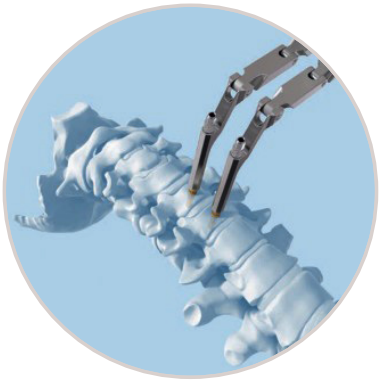
6. Ideal Positioning for Retainer Screw Insertion



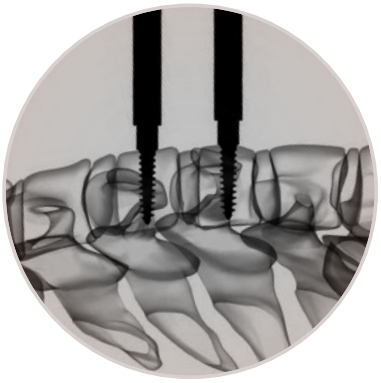
7. Perforating the Anterior Cortex with the Awl



8. Inserting the Retainer Screws into the Perforations



9. Confirming Retainer Screw Trajectory and Screw Depth with Fluoroscopy



please NOTE *Use only the 3.5 mm diameter, color-coded screws. The 4.5 mm diameter screws should only be used as "rescue" screws.*

Do not perforate the posterior cortex with the tip of the screw.

Discectomy, Decompression, & Remobilization (Cont'd)

Slide the vertebral body retainer over the screws; lock it in place with retainer nuts **(Figure 10)**.

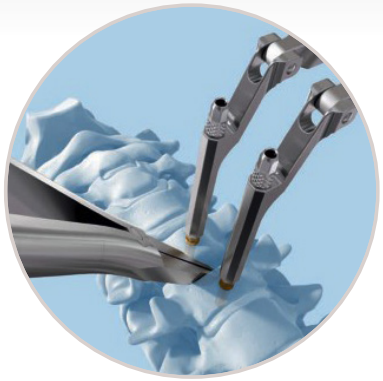
Apply light pretension to the operative disc space with the retainer—do not apply enough force to distract the segment. Create an anterior annulotomy centered on midline and wide enough to accommodate the implant. Perform the preliminary discectomy using standard rongeurs and curettes.

Insert the vertebral distractor to the posterior aspect of the disc space under lateral fluoroscopy. Ensure the distractor tips reach the posterior margin of the vertebral bodies to avoid penetration of the vertebral end plates **(Figures 11 & 12)**.

Manually distract the space with the vertebral distractor. Adjust the vertebral body retainer to maintain the distraction achieved with the vertebral distractor. Remove the vertebral distractor and complete the discectomy, decompression, and remobilization as indicated.

10. The Vertebral Body Retainer Locked on the Retainer Screws

11. Inserting the Vertebral Distractor



12. Ensuring Safe Distractor Tip Depth with Fluoroscopy

check POINT *To reduce the incidence of HO, refrain from using a burr to gain access to the posterior aspect of the disc space.*

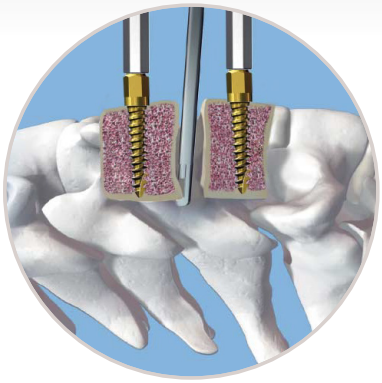
please NOTE *The vertebral body retainer is not intended to distract the segment as with a Caspar retractor. Distraction is achieved with the vertebral distractor.*

Avoid overdistraction with the vertebral distractor as this can lead to nerve root tension or improper implant selection.

Note: Preserve the integrity of the bony endplates; only the cartilaginous endplate should be excised. Endplate remodeling should only be performed if posterior osteophytes interfere with implant positioning or excision is necessary for neural decompression. The uncovertebral joints should be preserved, when possible—only the posterior 1/3 should be removed as needed for decompression. It is encouraged to use manual instruments, such as Kerrisons and curettes, when bony remodeling is necessary **(Figure 13)**.

More highly collapsed cervical disc spaces may require aggressive endplate remodeling and distraction for remobilization, which could create a highly osteogenic environment. Disc spaces that are not remobilized adequately may have limited motion, which may allow bone formation and possible fusion.

13. Endplate Remodeling with Kerrison



check POINT

There are two areas within the disc space endplate anatomy that may obstruct optimum, and preferably larger, implant footprint and positioning.

1. *Uncinate process along the posterolateral aspect of the inferior endplate*
   - *Flatten with Kerrison rongeurs or with careful use of a burr*
2. *Posterior central portion of the superior endplate*
   - *Avoid compromising the weight-bearing portion of the endplate*
   - *Remodel with Kerrison rongeurs or with careful use of a burr*

check POINT

Posteriorly, there should be no bony obstruction that would interfere with the trial and optimal placement of the device.

tech TIP

If any portion of PLL is removed for decompression, take down the whole ligament to achieve a bilateral symmetric posterior release.

Implantation

Implantation of the prodisc C Nova is performed in three steps:

1. Trial
2. Keel Preparation
3. Implant Insertion

Trial with prodisc C Nova to determine best endplate contact and proper position.

Select the largest footprint to maximize coverage of the vertebral bodies and the smallest appropriate height to match normal adjacent discs.

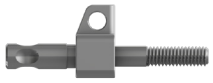
STEP 1: Trial

The system contains 18 trial implants that correspond to the 18 implant sizes. Trials are placed into the disc space intraoperatively to determine the appropriate implant footprint, disc height, and position.

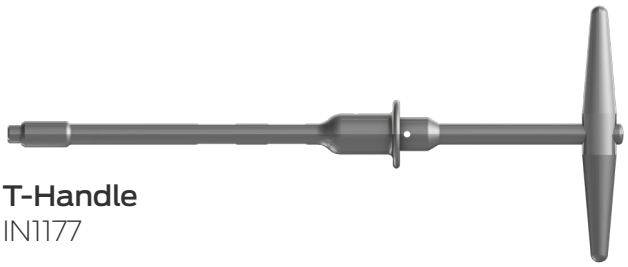
Assemble the trial stop to the trial of your choice. Attach the t-handle for the trials to the hexagonal end of the (central) shaft **(Figure 14)**. Ensure that the shaft is fully screwed (clockwise) and there is no gap between trial implant and trial stop.

Align the trial on midline with the trial stop pointing cranially and advance it under fluoroscopy into the disk space.

prodisc C Nova Trials (M, MD, L, LD, XL, XLD)
IN1248 - IN1265



Trial Stop
IN1284 - IN1286



T-Handle
IN1177

14. Fully Assembled Trial, Trial Stop, and T-Handle

please NOTE

Selecting an implant that is too tall may limit the segmental range of motion.

Avoid kyphotic position of the corresponding vertebrae. Select the next smaller size of trial implant instead.

In the lateral view of the fluoroscopic image, the optimal position of the center of the trial is to be aligned with the center of the vertebral body or slightly posterior (within 2mm), and a perfect circle in the trial should be visible **(Figure 15)**. In A/P, the trial implant should be centered on the midline **(Figure 16)**.

If the trial stop does not allow the trial implant to enter deep enough, it can be positioned deeper by turning the T-Handle counter-clockwise (1 rev = 0.5 mm). Ensure the proper axial orientation of the trial by rotating the trial handle.

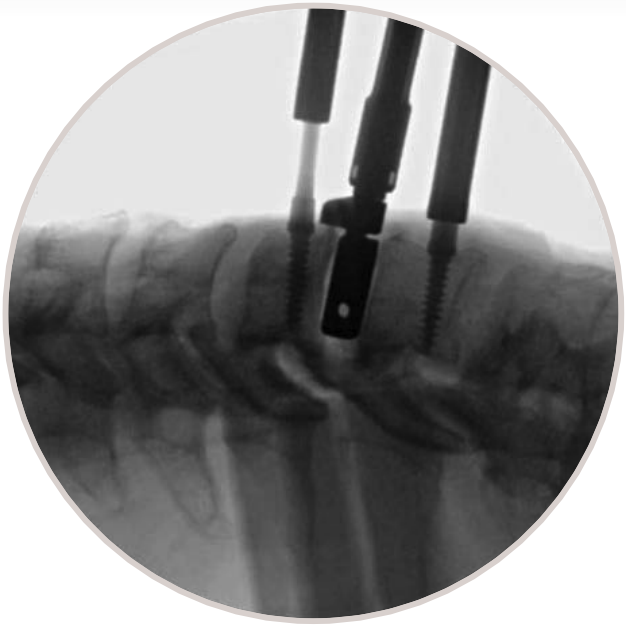
Note: If the trial fits well anteriorly, but is obstructing posteriorly, then one or both of the two endplate anatomical obstructions need to be addressed.

Release the distraction on the vertebral body retainer to determine the optimal height of the trial implant. Its height should be the smallest appropriate height. The vertebral bodies should stay in parallel position to each other.

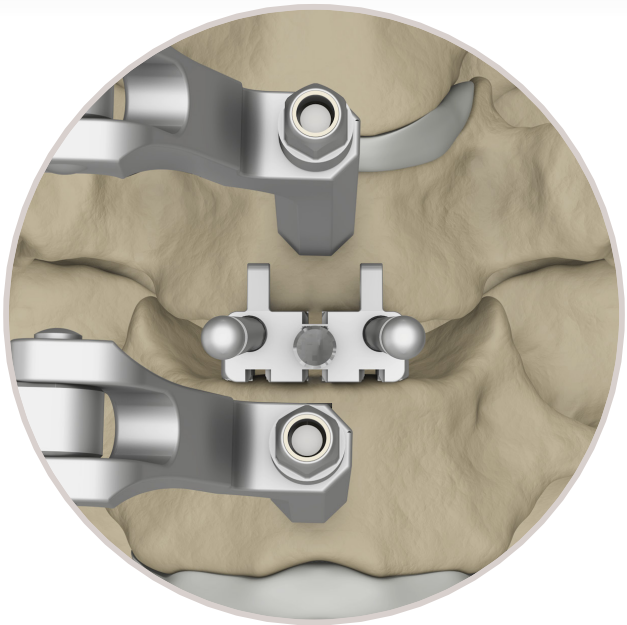
Ensure that the trial stop is fully seated against the vertebral bodies, apply compression with the vertebral body retainer, and remove the T-Handle from the trial. Leave the trial in the disc space.

Note: Facet joints will become distracted if too large of a trial / implant height is selected, and final range of motion may become compromised.

15. Verifying Trial Depth with Lateral Fluoroscopy



16. Centering Trial on the Vertebral Body Midline



please NOTE *If contact with trial is lost, simply reattach to trial body and rotate T-Handle clockwise.*

check POINT *In the lateral view of the fluoroscopic image, a perfect circle in the trial and perfectly superimposed facets should be visible **(Figure 15)**.*

*At this junction, A/P spot fluoroscopy should be performed, with the T-Handle removed, to check the width of the trial and midline position **(Figure 16)**.*

Implantation (Cont'd)

STEP 2: Keel Preparation

Compress the vertebral body retainer onto the trial. Slide the chisel of the appropriate height over the shaft of the trial and touch the anterior cortex **(Figure 17)**. Confirm the chisel is centered on midline and properly oriented in the A/P sagittal plane.

Under lateral fluoroscopy, advance the chisel into the vertebral bodies with the slotted mallet. The trajectory of the chisel should remain on midline while advancing. Continue advancing the chisel until it is fully seated on the trial **(Figure 18)**.

Chisel, 5-7mm
IN1233 - IN1235

Slotted Mallet
03.820.113

Keel Cleaner
IN1404

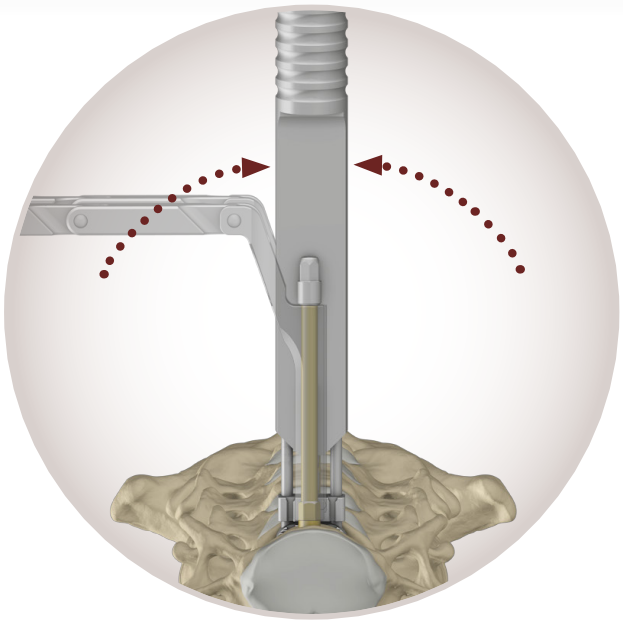
Hemi Chisel, 5-7mm (Optional)
IN1406 - IN1408

Ensure that the depth and height of the keel channels are equal in the superior and inferior vertebral bodies.

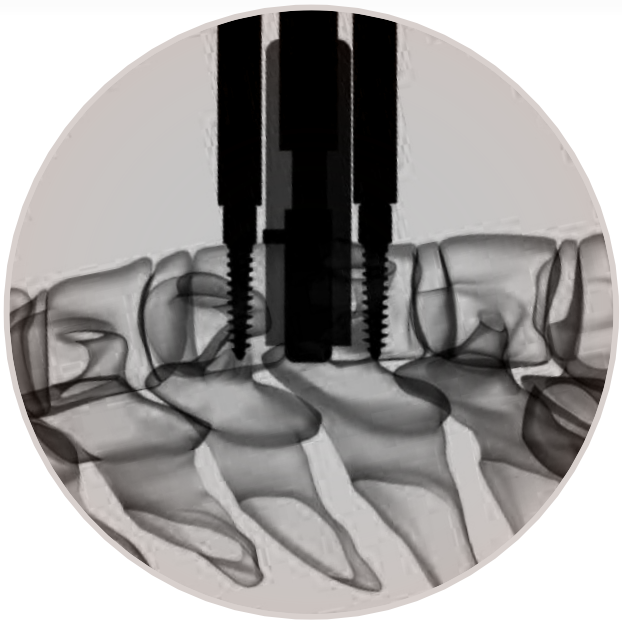
Optional: If the superior vertebral body keel channel is not as deep as the inferior vertebral body keel channel, a 5, 6, or 7mm Hemi Chisel may be used. The appropriate height Hemi Chisel can cut 1mm deeper into the Superior Vertebral Body after using the appropriate height Nova Chisel. Use of the Hemi Chisel is limited to the channel in the superior vertebral body.

Remove the chisel and trial. Under fluoroscopic control, use the the keel cut cleaner to verify the depth of the keel channels and to remove any bony debris from both the superior and inferior vertebral bodies. Irrigate the wound to ensure the disc space is clear of debris.

17. Ensuring Correct Axial Rotation and Orientation of the Trial and Chisel



18. Advancing the Chisel Under Fluoroscopy



check POINT *Swap the image to the 2nd screen on the fluoroscope to use as a guide for permanent implant positioning.*

Implantation (Cont'd)

STEP 3: Implant Insertion

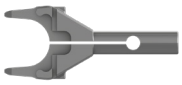
Open the packaging of the implant. Keep the implant in the plastic packaging tray for easier assembly of the Introducer Tip. Choose the Introducer Tip corresponding to the implant footprint (M/MD, L/LD or XL/XLD).

Attach the appropriate Introducer Tip to the prosthesis until the arms snap into the holding features on both endplates of the implant **(Figure 19)**.

Connect the Introducer Tip to the Introducer **(Figure 20)**. Align the Introducer (postitive) stop with the superior side of the implant. Lightly tighten the Introducer and Introducer Tip, holding the implant by turning the proximal knob clockwise. **CAUTION: Do not over-tighten.**

Pull the implant en-bloc out of the packaging tray.

Note: The positive stop can be added or removed from the Introducer as desired by adjusting the distal knob to remove or add the stop.

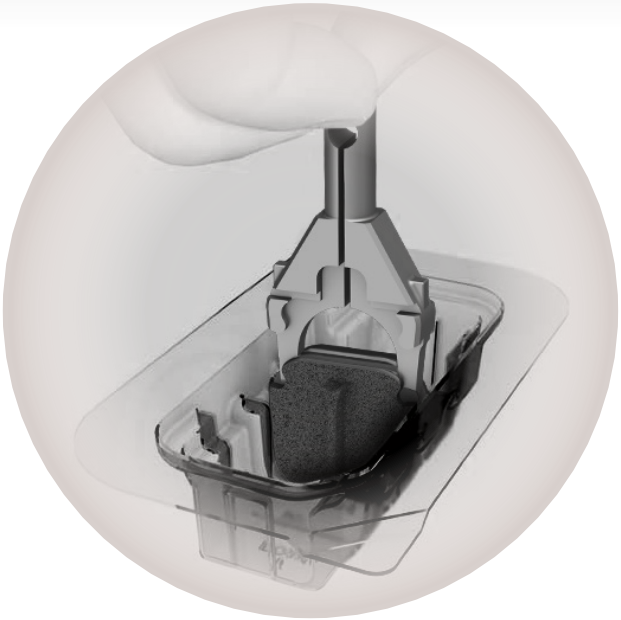


Introducer Tip (M/MD, L/LD, XL/XLD)
IN1236/1 - IN1244/1

Slotted Mallet
03.820.113

Introducer
IN1190/1

19. Attaching the Introducer Tip to the Implant



20. The Assembled Introducer with Introducer Tip and Implant

Reopen the vertebral body retainer slightly to allow removing the trial implant. Apply distraction as necessary, to facilitate the insertion of the implant.

Before inserting, ensure that the keel surfaces are oriented cranially by observing "UP" etched on the superior endplate of the prodisc C Nova. Align the implant with the keel slot of the vertebral body **(Figure 21)**.

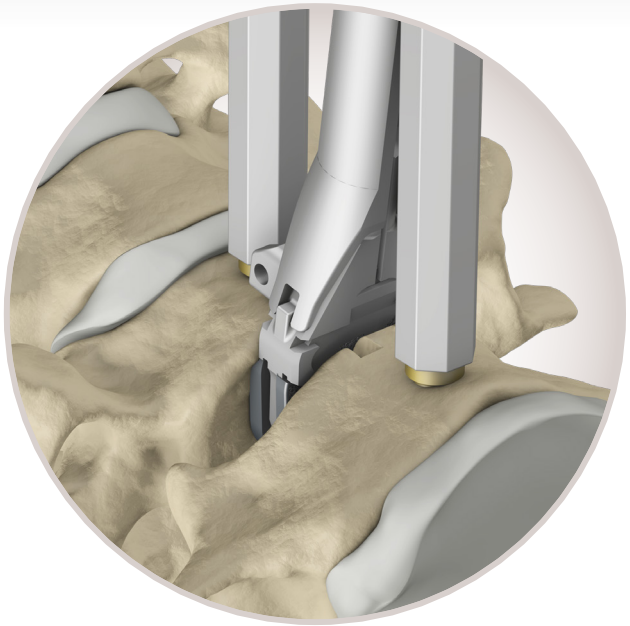
Under lateral fluoroscopic control, advance the implant into its final position providing the best possible anatomical fit with the vertebral bodies **(Figure 22)**.

The center of rotation (COR) of the prosthesis should be positioned at the midline of the vertebral body or slightly posterior. Avoid excessive cranial, caudal, or lateral corrections during insertion and ensure that the implant doesn't exceed the posterior margin of the vertebral body.

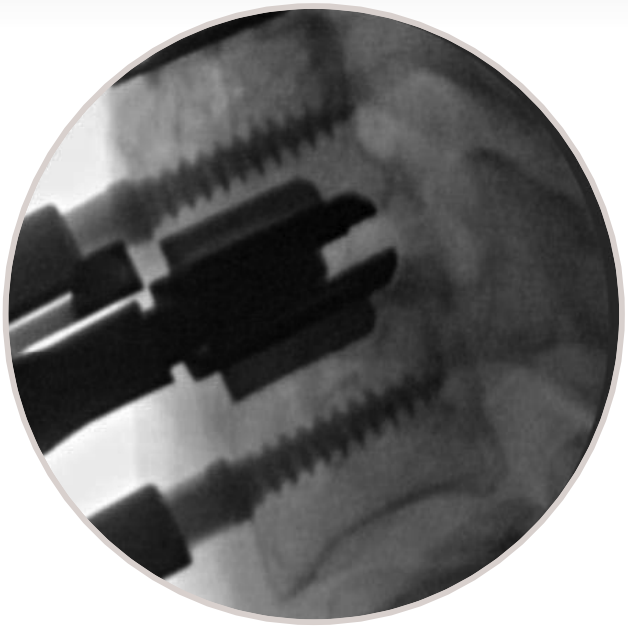
The prodisc C Nova should be positioned so as to match the prepared keel cut, with the endplate typically positioned to the posterior margin of the vertebral body.

The Introducer Tip includes superior and inferior surface grooves that align with the anterior margin of the implant under lateral fluoroscopy.

21. Inserting the Implant with the Introducer



22. Advancing the Implant Under Fluoroscopy



Implantation (Cont'd)

When the correct position of the implant is confirmed using fluoroscopy, apply slight compression with the retainer. Slight compression from the retainer will help the implant gain primary fixation.

To release the connection between the Introducer Tip and implant, first, rotate the shaft of the Introducer three full turns by adjusting the proximal knob in the counterclockwise direction.

To disconnect the loosened Introducer Tip from the implant, gently articulate the Introducer laterally (left - right).

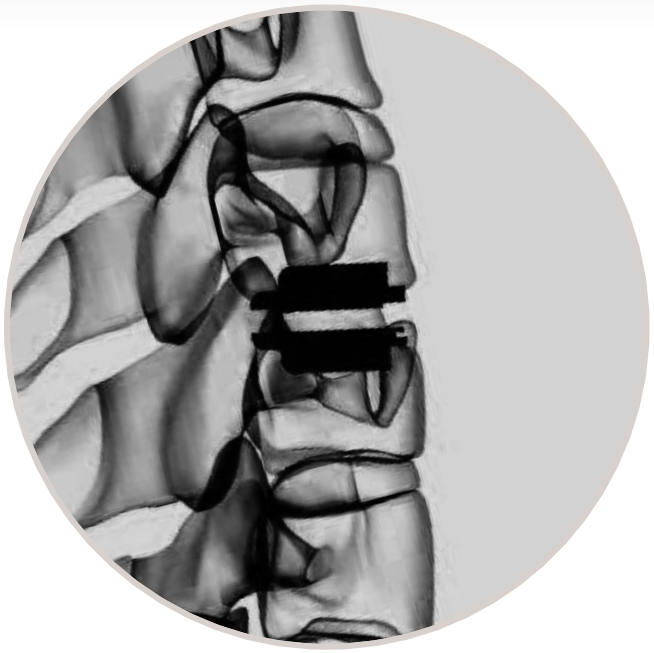
Once the Introducer and Introducer Tip are disengaged from the implant, step-by-step remove the retainer nuts, the vertebral body retainer and the retainer screws.

Confirm final implant position with lateral and A/P imaging **(Figures 23 & 24)**.

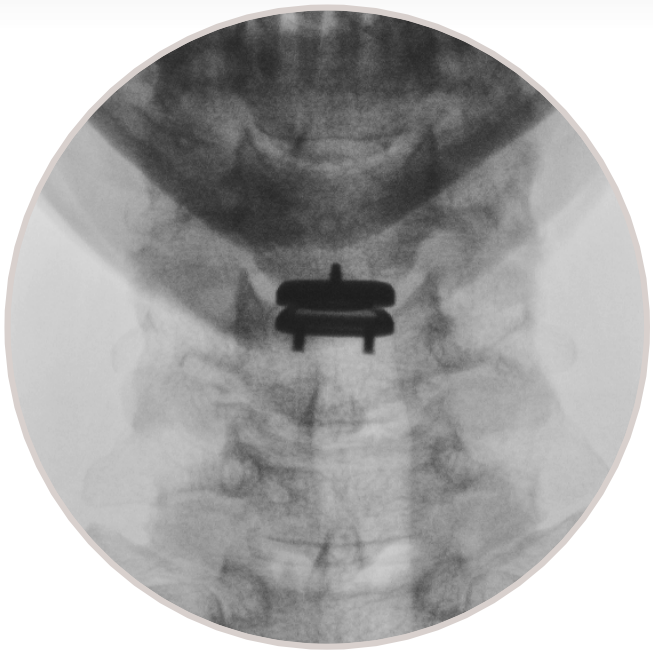
Copious saline lavage is recommended to remove osteogenic stimuli (blood/bone marrow). Apply bone wax to close cavities in the bone (retainer screw holes , keel channels, and open bone surfaces).

Close the surgical wound in a routine fashion.

23. Final Implant Position in Lateral View



24. Final Implant Position in A/P View



Optional Introducer Tip Removal Technique Using Shaft of the Introducer:

Fully unthread the shaft from the Introducer by turning counterclockwise. Reconnect Introducer Shaft to Introducer Tip and gently tighten by turning clockwise. Apply easy lateral (left-right) articulation force on the Introducer Shaft to release the implant from the Introducer Tip.

Post-Operative Care

Patients may begin ambulating immediately postoperatively. A soft or hard collar may be used, if deemed necessary. Patients should be instructed to avoid prolonged or strenuous activity; heavy physical activity should not be resumed untl the surgeon is confident, based on review of postoperatiive radiographs, that the implant is stable and functioning. Patients should be instructed to immediately report any change in their pain or neurologic status.

Removal Procedure

Contact explant@centinelspine.com or customerservice@centinelspine.com to request an explant kit.

If the implant must be removed, the following technique is recommended.

Approach the level through the original anterior incision. Expose, identify, and isolate the prodisc **C Nova** implant from any overlying scar tissue. Excise any bone tissue from the anterior aspect of the endplates and keels to expose the implant-bone junction.

Perforate the anterior cortex of the vertebral bodies with the awl, using lateral fluroscopy to ensure its trajectory is parallel to the affected endplate. Estimate the retainer screw length based on awl (12 mm long).

Insert retainer screws with the self-retaining screwdriver, using fluoroscopy to confirm trajectory and screw depth. Bicortical purchase is not necessary.

Slide the vertebral body retainer over the retainer screws; lock it in place with the retainer nuts. Apply distraction to the operative disc space with the vertebral body retainer.

Awl, 12mm
03.820.100

Short Screwdriver
IN1444

Vertebral Body Retainer
03.820.111/1

Retainer Screw (3.5mm or 4.5mm)
03.820.102-03.820.109

Retainer Nut
03.820.110

Attach the Endplate Remover tips to both mating recesses on the anterior face of the Superior Endplate or Inferior Endplate. Tighten the speed nut against the handles of the Endplate Remover.

Apply extraction force to the Endplate Remover. You may also attach the Slide-Hammer to the Endplate Remover to apply extraction force. Remove the 1st Endplate. Release the Endplate Remover.

Re-attach the Endplate Remover to the 2nd Endplate. Tighten the speed nut. Apply extraction force to the Endplate Remover.

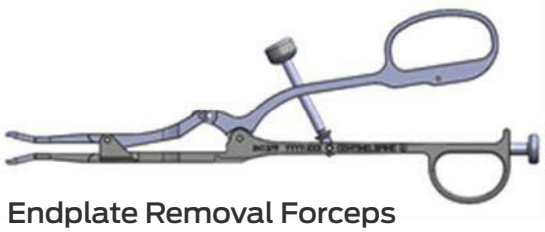
Should it be necessary to remove a prodisc **C Nova** Total Disc Replacement, please contact Centinel Spine to receive instructions regarding data collection. All explanted devices must be returned to Centinel Spine for analysis.

Please note that the prodisc® implant should be removed as carefully as possible in order to keep the implant and surrounding tissue intact. Also, please provide descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal methods, i.e., intact or in pieces.

Note: All implant removals must be reported immediately to Centinel Spine.

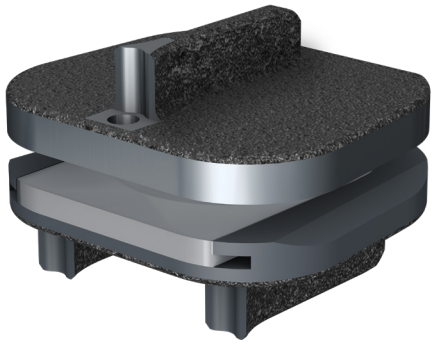
Slide Hammer
03.820.282

Slotted Mallet
03.820.113



Endplate Removal Forceps
IN1379

Implants



Implant Footprints			Part Numbers		
	Depth	Width	Height 5 mm	Height 6 mm	Height 7 mm
M	12mm	15mm	PDNM5	PDNM6	PDNM7
MD	14mm	15mm	PDNMD5	PDNMD6	PDNMD7
L	14mm	17mm	PDNL5	PDNL6	PDNL7
LD	16mm	17mm	PDNLD5	PDNLD6	PDNLD7
XL	16mm	19mm	PDNXL5	PDNXL6	PDNXL7
XLD	18mm	19mm	PDNXLD5	PDNXLD6	PDNXLD7

Instruments: Retainer Screw System

Awl, 12mm
03.820.100

Short Screwdriver
IN1444

Retainer Nut
03.820.110

Vertebral Body Retainer
03.820.111/1

Vertebral Distractor
03.820.112

Retainer Screw, 3.5mm Ø

12mm Thread	03.820.102
14mm Thread	03.820.103
16mm Thread	03.820.104
18mm Thread	03.820.105

Retainer Screw, 4.5mm Ø

13mm Thread	03.820.106
15mm Thread	03.820.107
17mm Thread	03.820.108
19mm Thread	03.820.109

Instruments: Trials

prodisc C Nova Trials

Trial Implant M, 15mm x 12mm

5mm Height	IN1248
6mm Height	IN1249
7mm Height	IN1250

Trial Implant MD, 15mm x 14mm

5mm Height	IN1251
6mm Height	IN1252
7mm Height	IN1253

Trial Implant L, 17mm x 14mm

5mm Height	IN1254
6mm Height	IN1255
7mm Height	IN1256

Trial Implant LD, 17mm x 16mm

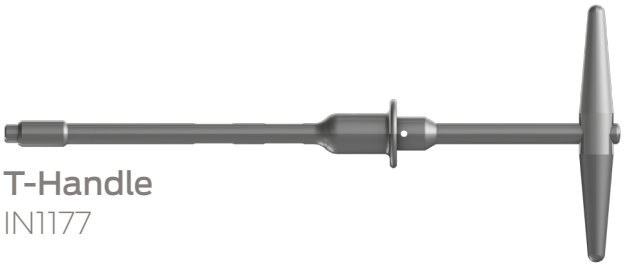
5mm Height	IN1257
6mm Height	IN1258
7mm Height	IN1259

Trial Implant XL, 19mm x 16mm

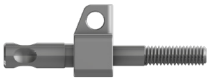
5mm Height	IN1260
6mm Height	IN1261
7mm Height	IN1262

Trial Implant XLD, 19mm x 18mm

5mm Height	IN1263
6mm Height	IN1264
7mm Height	IN1265



T-Handle
IN1177



Trial Stop

5mm Height	IN1284
6mm Height	IN1285
7mm Height	IN1286

Instruments: Keel Preparation

Chisel, 5-7mm

5mm Chisel	IN1233
6mm Chisel	IN1234
7mm Chisel	IN1235

Hemi Chisel, 5-7mm

5mm Hemi Chisel	IN1406
6mm Hemi Chisel	IN1407
7mm Hemi Chisel	IN1408

Keel Cleaner

IN1404

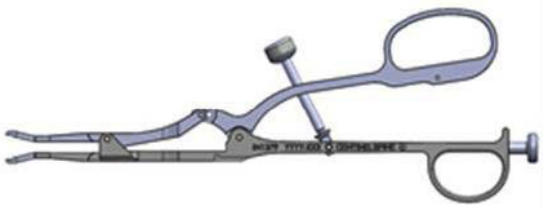
Instruments: For Insertion

Introducer
IN1190/1

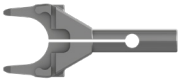
Slide Hammer for Cervical Spine
03.820.282

Slotted Mallet
03.820.113

Positioner
03.670.207



Endplate Removal Forceps
IN1379



Introducer Tip, M/MD

5mm Height	IN1236/1
6mm Height	IN1237/1
7mm Height	IN1238/1

Introducer Tip, L/LD

5mm Height	IN1239/1
6mm Height	IN1240/1
7mm Height	IN1241/1

Introducer Tip, XL/XLD

5mm Height	IN1242/1
6mm Height	IN1243/1
7mm Height	IN1244/1

References

[1] *Since 1991, Hartshill Horseshoe, STALIF®, STALIF TT®, STALIF C®, STALIF MIDLINE®, STALIF L™*

[2] *Stein MI, et al. The Spine Journal, 14(1): 128-136, 2014.*

[3] *A.N. Nayak, et al. The Spine Journal, 2014.*

[4] *Interim Report of Prospective STALIF C Study – Protocol SC-001.*

[5] *Represents single-level fusion data presented as part of IDE Clinical Study for Mobi-C cervical disc, including the Mobi-C experimental arm and the ACDF control arm. ACDF's were treated using an anterior cervical plate with screws [SLIM-LOC™ Anterior Cervical Plate System (DePuy Spine) and ATLANTIS™ or ATLANTIS™ VISION Anterior Cervical Plate Systems (Medtronic)] and corticocancellous allograft bone. Reference: Hisey, MS, et al. Multi-center, Prospective, Randomized, Controlled Investigational Device Exemption Clinical Trial Comparing Mobi-C Cervical Artificial Disc to Anterior Discectomy and Fusion in the Treatment of Symptomatic Degenerative Disc Disease in the Cervical Spine. International Journal of Spine Surgery. 8(7), doi: 10.14444/1007, 2014.*

[6] *Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2017.*

[7] *Based upon US complaint handling units for prodisc since launch in 2006.*

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