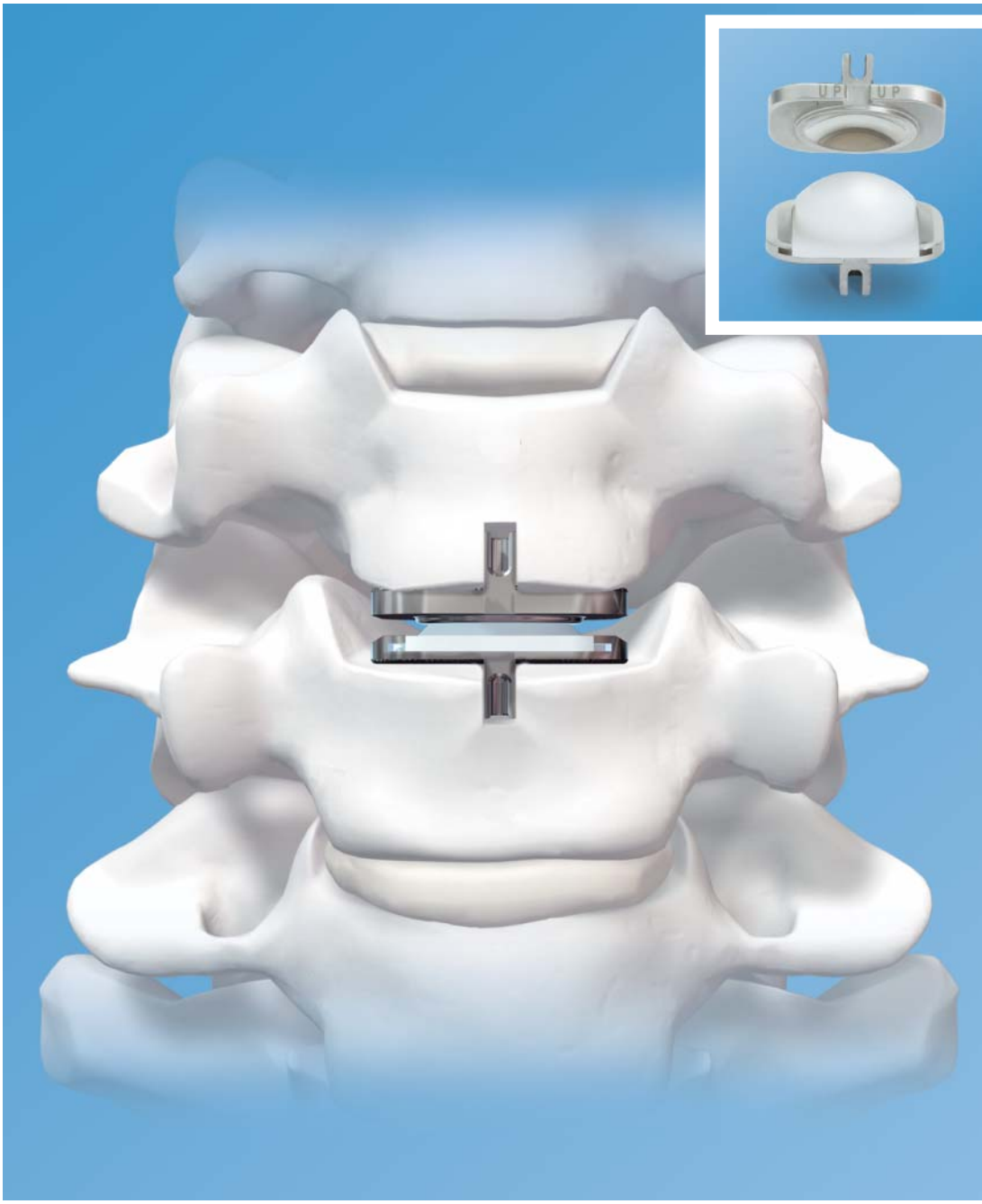
prodisc® C Total Disc Replacement.

For single level spinal arthroplasty from C3 to C7.

Technique Guide



CENTINEL SPINE®

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pro**disc C Total Disc Replacement**

The pro**disc C** Total Disc Replacement (Figure 1) is intended to replace a diseased and/or degenerated intervertebral disc of the cervical spine in patients with symptomatic cervical disc disease (SCDD). The pro**disc C** Total Disc Replacement 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.

Figure 1

The pro**disc C** Total Disc Replacement is a modular implant consisting of two CoCrMo (cobalt chromium molybdenum) endplates and one UHMWPE (ultra-high molecular weight polyethylene) inlay. The inferior CoCrMo alloy endplate has a midline keel that is anchored into the endplate of the inferior vertebral body. The UHMWPE insert is preassembled snap-locked into a tray detail in the inferior CoCrMo alloy endplate and provides the inferior convex bearing surface. The superior CoCrMo alloy endplate has a midline keel that anchors to the superior vertebral body and has a highly polished concave bearing surface that articulates with the convex UHMWPE spherical dome. Immediate anchoring of pro**disc C** Total Disc Replacement to the vertebral bodies is achieved through a midline keel that is oriented anterior-posterior on the surface of each of the two endplates. In addition, the bone-contacting surfaces of the inferior and superior endplates, as well as both keels, are titanium plasma spray coated to allow for long-term fixation (Figure 2).

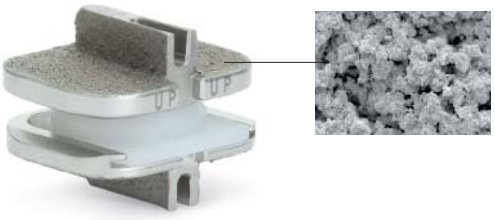


Figure 2

The plasma sprayed titanium surface texture also provides a high coefficient of friction to aid in immediate implant fixation. CoCrMo alloy was used in pro**disc C** Total Disc Replacement for its superior strength, proven biocompatibility, superior abrasion resistance, and superior wear characteristics when coupled with UHMWPE.

pro**disc C** Total Disc Replacement is labeled MR Conditional, where it has been demonstrated to pose no known hazards in a specified MR enviroment with specified conditions of use. Please refer to page 6 for further information.

Features and Potential Benefits

Ball and socket design
- Allows for the potential for motion in the treated segment
- Provides a fixed center of rotation
- Resists shear forces

Figure 3

Device design range of motion (as measured through in vitro testing)
- 20° flexion/extension (17.5° for 5 mm large, large deep, extra large, and extra large deep implants)
- 20° lateral bending (17.5° for 5 mm large, large deep, extra large, and extra large deep implants)
- Unconstrained in axial rotation

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

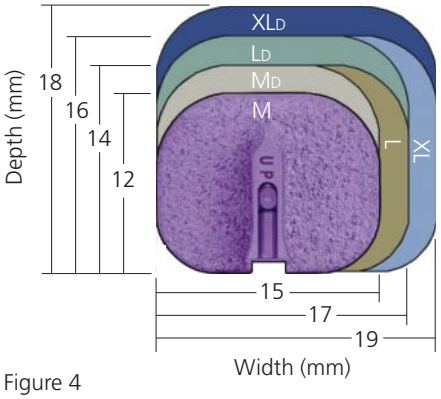


Figure 4

Dimensions—endplates

Implant Size	AP (mm)	Lateral (mm)	Disc heights (mm)
Medium	12	15	5, 6, 7
Medium Deep	14	15	5, 6, 7
Large	14	17	5, 6, 7
Large Deep	16	17	5, 6, 7
Extra Large	16	19	5, 6, 7
Extra Large Deep	18	19	5, 6, 7

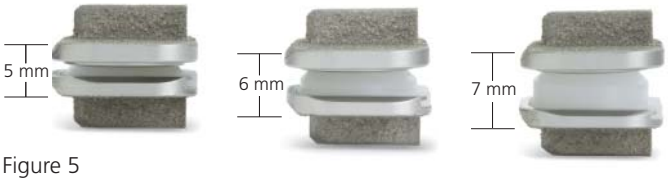


Figure 5

Stable fixation
- Patented central keels (oriented anterior-posterior) provide secure primary fixation
- Titanium porous coating aids in long-term fixation

Indications and Contraindications

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

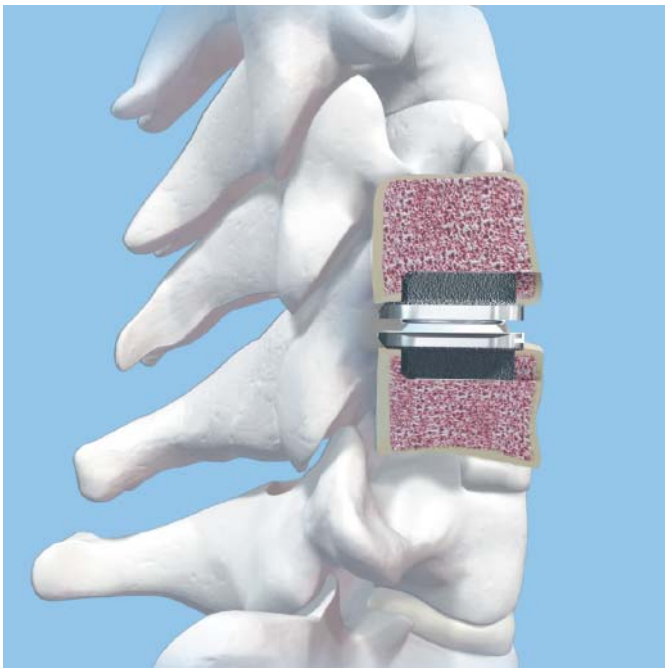


Figure 6

Contraindications
The pro**disc C** Total Disc Replacement should not be implanted in patients with the following conditions:

- Active systemic infection or infection localized to the site of implantation
- Osteoporosis defined as DEXA bone density measured T-score $\leq$ -2.5
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3 mm and/or > 11° of rotational difference to either adjacent level
- Allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
- Severe spondylosis characterized by bridging osteophytes or a loss of disc height > 50% or an absence of motion (< 2°). The treatment of patients with more advanced cervical degeneration with this device has many potential implications on outcomes and the potential for heterotopic ossification. For example, from a surgical standpoint, more highly collapsed cervical disc spaces require more aggressive endplate resection and distraction in order to restore disc height. The surgical release of these more collapsed disc spaces can lead to a highly osteogenic environment. Extremely collapsed disc spaces can lead to the placement of a "tight" implant that would limit motion and further encourage bone formation and possible fusion
- 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)

Patient Exclusion Recommendations

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

Warnings
Correct placement of the device is essential to optimal performance. Use of the pro**disc C** Total Disc Replacement should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biome-chanics, has had experience with anterior cervical spinal surgeries, and has had 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.

There were no patients in the pivotal study who were less than 22 years of age. The safety and effectiveness of this device has not been studied in the pediatric or adolescent age group (< 22 years old).

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.

Precautions
Patient selection is extremely important. In selecting patients for a total disc replacement the following factors can be of importance to the success of the procedure: the patient's occupation or activity level, a condition of senility, mental illness, alcoholism, or drug abuse. In addition, certain degenerative diseases may be so advanced at the time of implantation that the expected useful life of the device is substantially decreased.

Furthermore, correct selection of the appropriate implant size is extremely important to assure the placement and function of the device. Please refer to this technique guide for step-by-step instructions on the required surgical technique, including determining the correct implant size.

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 22 or over the age of 60
- more than one vertebral level with SCDD
- prior fusion surgery at an adjacent vertebral level
- prior surgery at the level to be treated
- when implanted at more than one cervical spinal level and/or adjacent to an anterior cervical discectomy and fusion (ACDF)
- patients with progressive symptoms and signs of spinal cord/nerve root compression with less than six weeks of conservative treatment
- 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

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, 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 $\leq$ -2.5, as the patient may be osteoporotic.

Use aseptic technique when removing the pro**disc C** Total Disc Replacement implant from the innermost packaging.

Use care when handling the pro**disc C** Total Disc Replace-ment 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 Total Disc Replacement implant should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique guide for step-by-step instructions.

Surgical implants must never be reused or reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

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, including 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.

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.

MRI information
Centinel Spine prodisc C implants are labeled MR Conditional according to the terminology specified in ASTM F 2503-05, Standard Practice for Marketing Medical Devices and Other Items for Safety in the Magnetic Resonance Enviroment.

Nonclinical testing of the prodisc C demonstrated that the implant is MR Conditional. A patient with a prodisc C 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 1.1°C for 1.5 T and a maximum observable heating of 1.9°C 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 2°C. 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 implants may have the potential to cause artifact 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 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 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 15°, 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 70°, worstcase artifact will extend approximately 2.5 cm from the implant

Patient positioning

AP and lateral imaging is used frequently throughout the prodisc C 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 7).

Position the patient supine on the operating table. Support the neck with a cushioned neck roll to keep the neck in a normal lordotic ("neutral") position (Figure 8). Correct any malrotation of the neck and head. Confirm true AP orientation with spot fluoroscopy. Tape or strap the head in place to maintain this position.

Note: The use of head weights is not recommended. Adjacent disc spaces are also distracted, giving false impression of disc height.

Caution: The inability to reproduce neutral alignment in the sagittal plane may result in improper implant position.

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 on the upper extremities (Figures 7, 8 and 9).

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

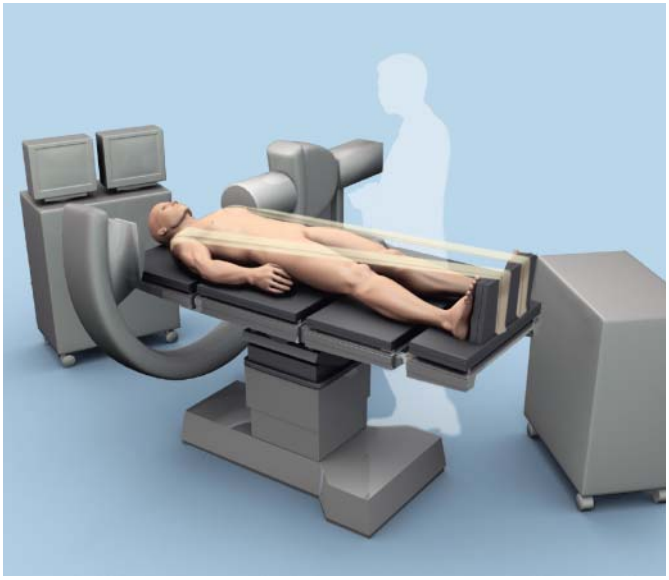


Figure 7

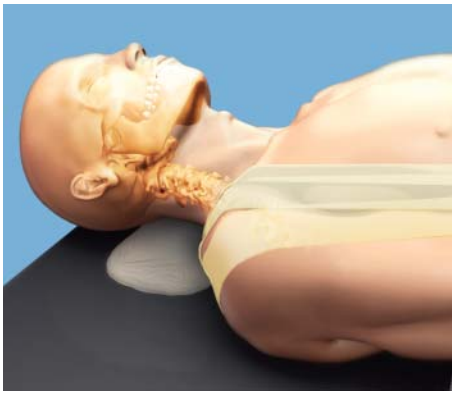


Figure 8

Figure 9

Exposure

Exposure

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

Note: The presence of anatomical abnormalities and/or deformities, such as the presence of scoliosis, kyphosis or abnormal segmentation, may reduce the ability to ensure proper placement of the instrumentation and/or prosthesis and may require that a fusion procedure be performed.

Marking the midline

Use AP 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 10).

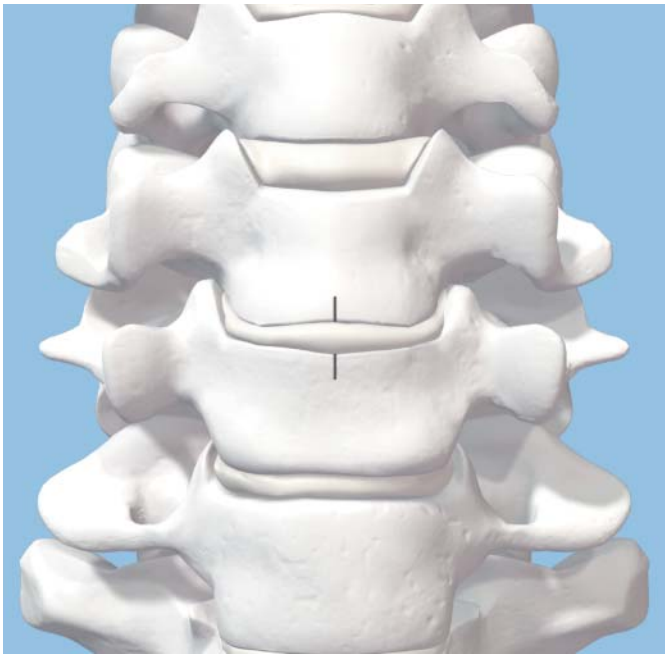


Figure 10

Discectomy, Decompression, and Remobilization

Instruments	
03.820.100	Awl, 12 mm
03.820.101	Self-Retaining Screwdriver
03.820.110-CS	Retainer Nut
03.820.111 Or 03.820.111/1	Vertebral Body Retainer
03.820.112	Vertebral Distractor

Standard Screws	
03.820.102-CS – 03.820.105-CS	Retainer Screws, 3.5 mm x 12 mm, 14 mm, 16 mm, and 18 mm

Rescue Screws	
03.820.106-CS – 03.820.109-CS	Retainer Screws, 4.5 mm x 13 mm, 15 mm, 17 mm, and 19 mm

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 pro**disc C Total Disc Replacement.**

Thorough disc space preparation is best performed with controlled, parallel distraction of the operative level. Distraction should be obtained using the vertebral distractor and maintained with the specially-designed screw-and-retainer device. Technique for use is:

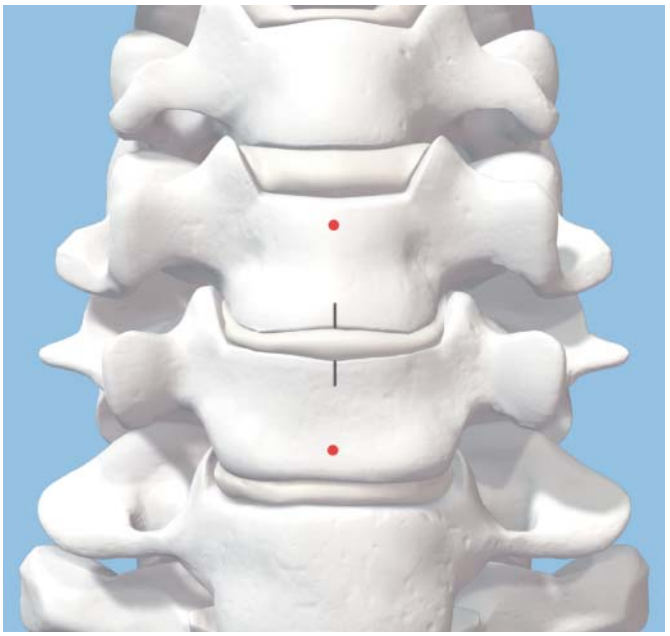
1. Insert retainer screws in the vertebral bodies;
2. Attach the retainer to the screws, apply initial predistraction to the disc space and perform preliminary discectomy;
3. Insert the vertebral distractor and apply parallel distraction; and
4. Complete the discectomy, decompression and remobilization of the space.

Retainer screws maintain parallel distraction of the disc space. Screws should be inserted parallel to the operative disc space and within the "distal" 1/3 of the vertebral body to allow adequate working room for keel preparation and implant insertion (Figure 11).

- Perforate the anterior cortex with the awl, using lateral fluoroscopy to ensure its trajectory is parallel to the affected endplate (Figure 12).

- Insert retainer screws which are long enough to engage the posterior cortex. Engage the screw into the awl track with the self-retaining screwdriver, using fluoroscopy to confirm trajectory and screw depth (Figure 13).

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



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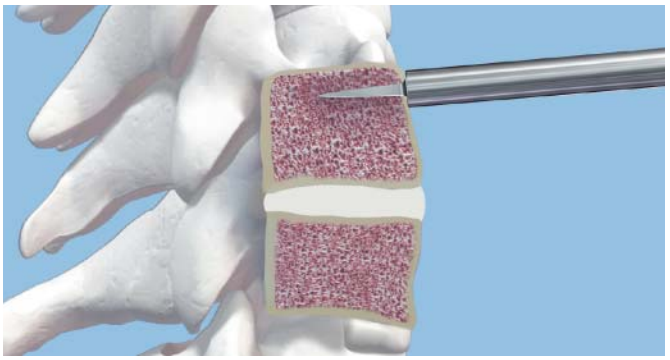

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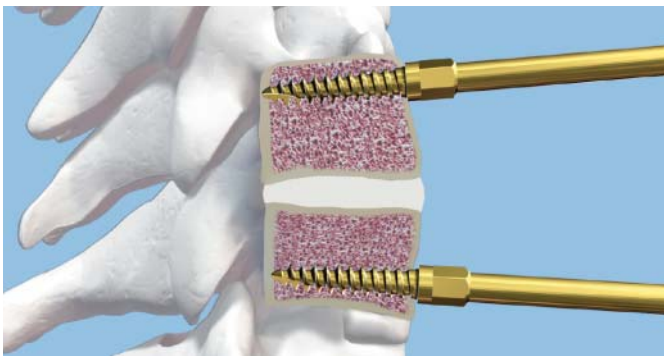

Figure 13

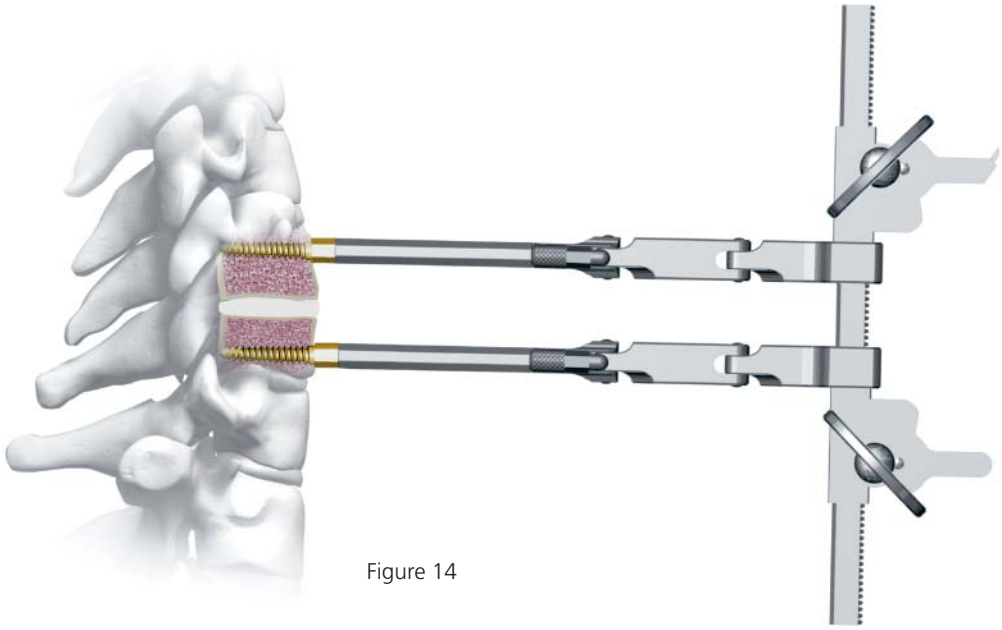

Figure 14

Slide the vertebral body retainer over the screws; lock it in place with retainer nuts (Figure 14).

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

Apply light pretension to the operative disc space with the retainer—do not apply enough force to distract the segment, as with a Caspar-type distractor. Create an anterior annulotomy centered on midline and wide enough to accommodate the pro**disc C** 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 (Figure 15). Manually distract the space with the distractor. Adjust the retainer to maintain the distraction achieved with the distractor. Remove the distractor and complete the discectomy, decompression and remobilization as indicated.

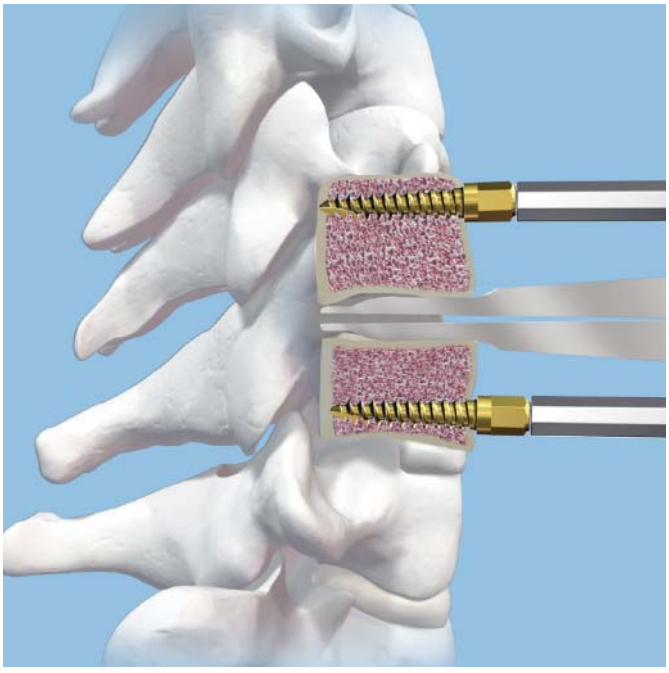

Figure 15

Notes:
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 uncinatus process should be preserved, when possible—only the posterior 1/3 should be removed as needed for decompression. Use manual instruments, such as Kerrisons and curettes, when bony remodeling is necessary (Figure 16).

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 encourage bone formation and possible fusion.

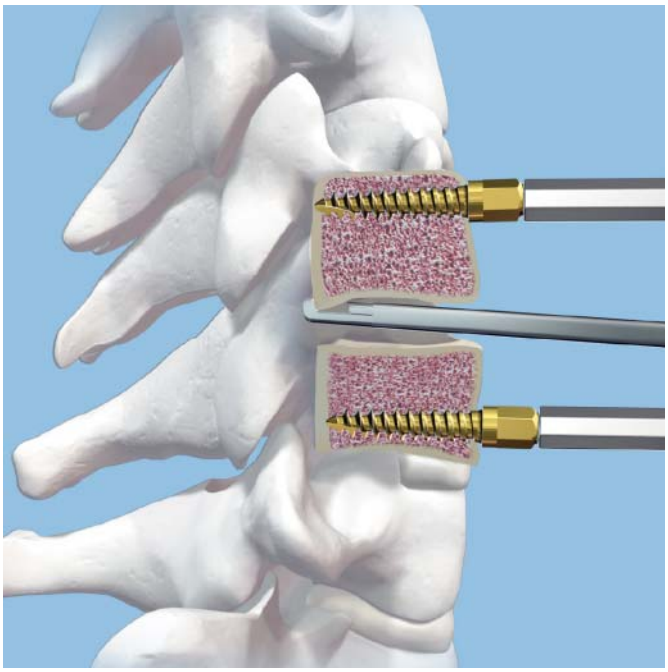

Figure 16

Implantation

Implantation of the prodisc C total disc replacement implant is performed in three steps:

1. Trial
2. Keel preparation
3. Implant insertion

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

1
Trial

Instruments	
03.820.000	Handle, for Trial Implants
03.820.025– 03.820.077	Trial Implants (medium, medium deep, large, large deep, extra large, extra large deep)
03.820.113	Slotted Mallet

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

Connect the trial handle to the trial implant (Figures 17 and 18). Ensure that the trial stop is fully seated by turning the trial handle clockwise until it will not advance any further.

Figure 17

Figure 18

1

Trial continued

Under lateral fluoroscopic control, insert the trial into the disc space using the mallet (Figure 19). The trial stop can be backed out to allow the trial to advance more posteriorly (Figure 20). Each full counterclockwise rotation of the handle allows the trial to be advanced 0.5 mm. The optimal position of the trial is at the posterior margin of the vertebral bodies, centered on the midline (Figures 21 and 22).

Note: Ensure that distraction is released while assessing the trial height.

Release the distraction while assessing the trial height. Trial height should be the smallest appropriate height to match normal adjacent discs. Selecting an implant that is too tall can limit the segmental range of motion. Correct sizing and placement are critical for optimal implant performance. If the implant footprint is too small and does not cover the entire vertebral endplate it may lead to exposed bone surfaces that will predispose to bone formation and potential fusion. It is important to carefully select the height of the implant to be tight enough to provide initial stability while still allowing motion. If the implant is positioned too far anteriorly the implant will act as a wedge and inhibit motion at the segment, which may encourage bone formation and possibly fusion.

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

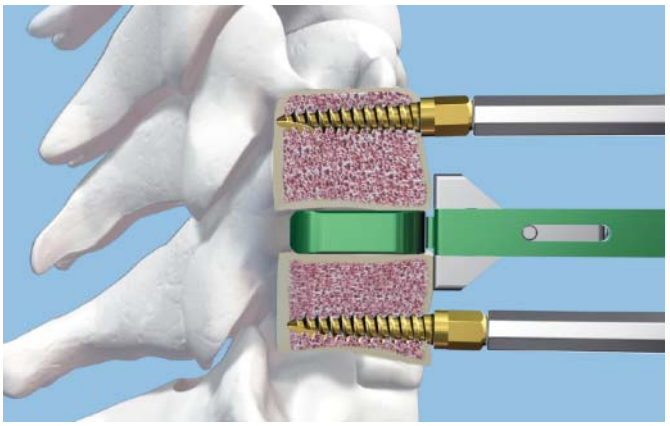

Figure 19

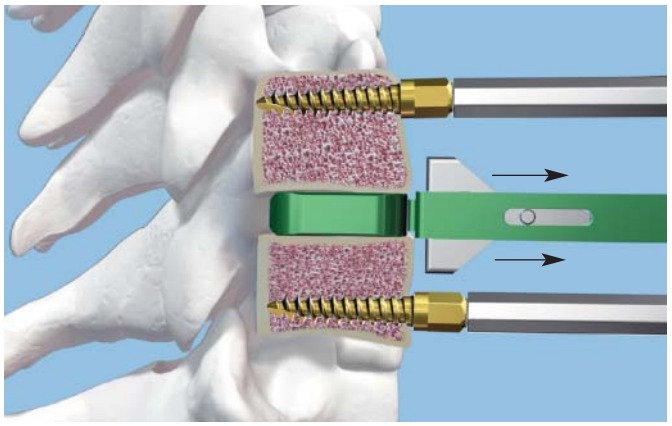

Figure 20

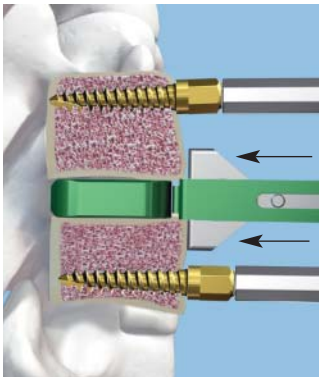

Figure 21

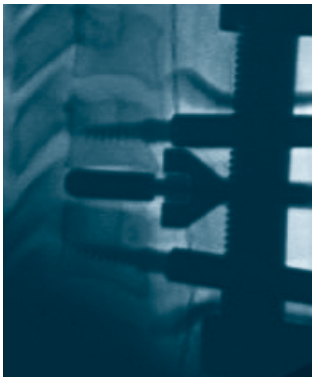

Figure 22

2

Keel preparation

There are two surgical options for keel preparation of the vertebral bodies: milling or chiseling.

Option A*: *Milling

Instruments	
03.820.114– 03.820.116	Milling Guides, 5 mm–7 mm
IN1545S IN1546S 03.820.153S, 03.820.163S, 03.820.157S, 03.820.167S, 03.820.117S, 03.820.161S, 03.820.159S, 03.820.169S	Milling Bits, sterile
03.820.126	Keel Cut Cleaner
03.820.136	Temporary Fixation Pin, sharp
03.820.137	Temporary Fixation Pin, blunt

- Slide the appropriate milling guide over the shaft of the trial and tighten the locking nut. Under AP fluoroscopy, confirm that the guide and trial are centered on the midline and oriented in the AP sagittal plane (Figure 23).

  To ensure construct stability, place the sharp temporary fixation pin through the inferior hole in the guide and manually drive the pin into the bone (Figure 24).

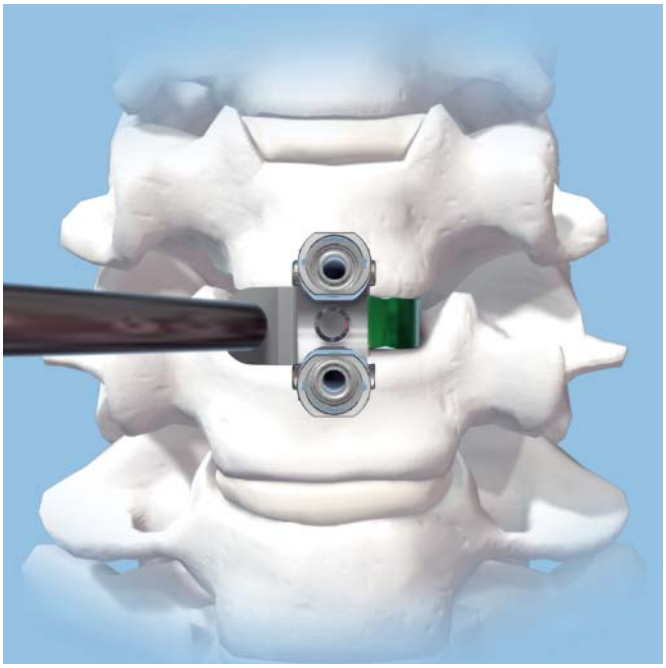

Figure 23

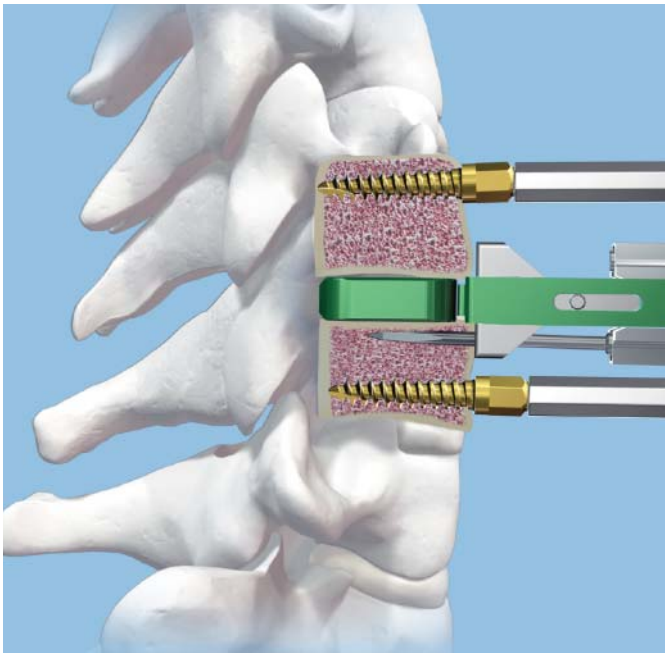

Figure 24

2

Keel preparation continued

Option A*: *Milling* *continued

Under lateral fluoroscopy, insert the appropriate milling bit into the superior hole of the guide until the tip of the mill touches the anterior cortex (Figure 25).

Note: Do not power on the device until the mill is at the cortex.

Under full power, plunge the bit into the vertebral body until it reaches the positive stop in the guide (Figure 26). Keeping the drill at full power, sweep the mill bit toward the trial until it reaches the inner limit of the guide, then away from the trial to the full outer limit (Figure 27). Remove the bit and insert the blunt temporary fixation pin into the superior hole of the guide.

Remove the sharp temporary fixation pin from the inferior hole of the guide. Repeat the milling procedure in the inferior body.

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

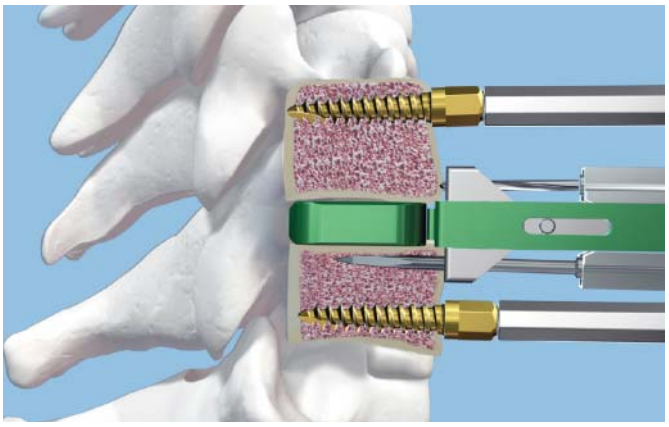

Figure 25

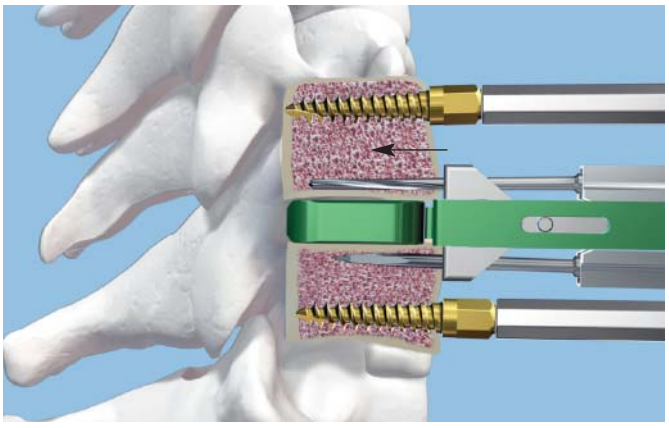

Figure 26

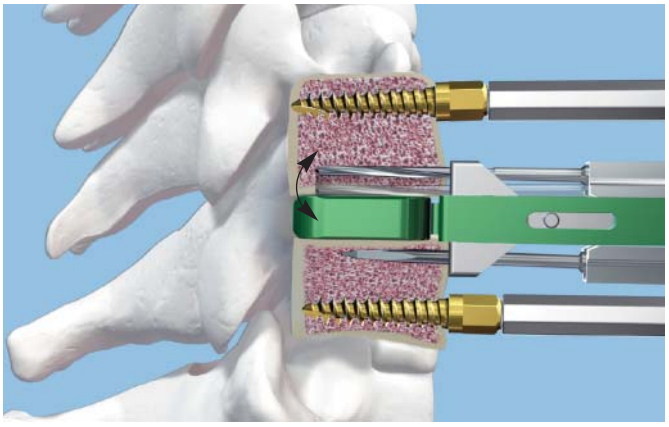

Figure 27

Remove the guide and trial. Under fluoroscopic control, use 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 (Figure 28). Irrigate the wound to ensure the disc space is clear of debris.

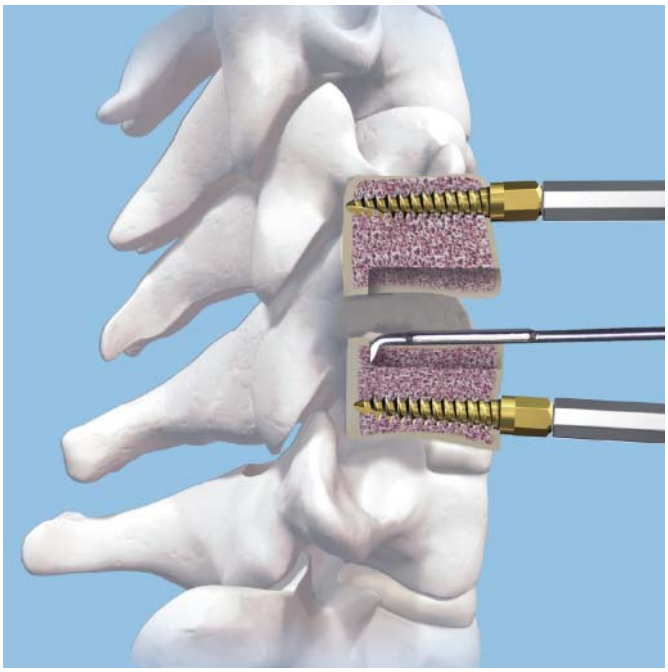

Figure 28

2

Keel preparation continued

Option B: Chiseling

Instruments	
03.820.113	Slotted Mallet
03.820.119– 03.820.121	Primary Chisels, 5 mm–7 mm
03.820.122– 03.820.124	Secondary Chisels, 5 mm–7 mm
03.820.126	Keel Cut Cleaner

Compress the vertebral body retainer onto the trial. Slide the primary chisel over the shaft of the trial. Under AP fluoroscopy, confirm the chisel is centered on midline and oriented in the AP 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 29).

Ensure that the depth and height of the keel channels are equal in the superior and inferior vertebral bodies. Repeat the chisel procedure with the secondary chisel (Figure 30).

Remove the chisel and trial. Under fluoroscopic control, use 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 (see Figure 28 on page 17). Irrigate the wound to ensure the disc space is clear of debris.

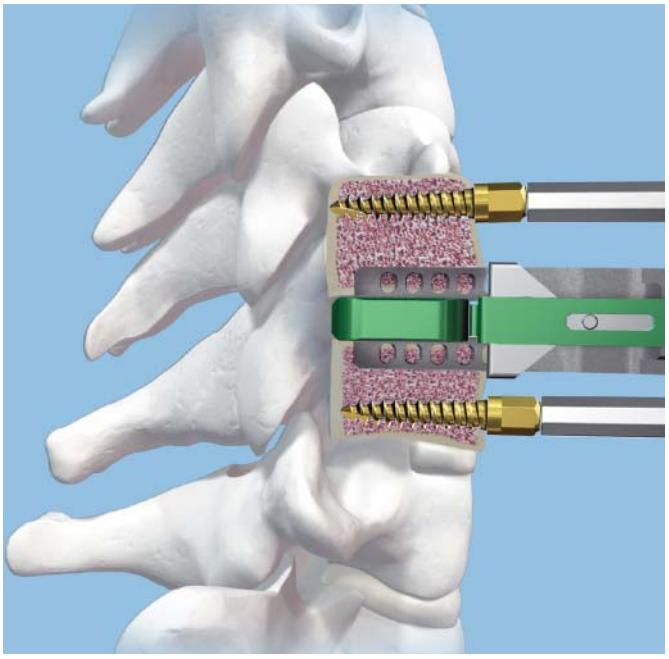

Figure 29

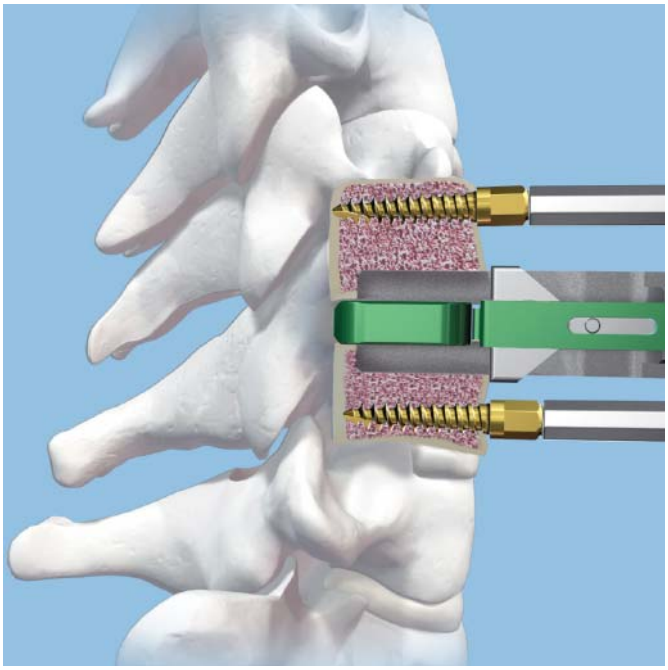

Figure 30

3
Implant insertion

Instruments	
03.820.129	Implant Inserter
03.820.130S– 03.820.142S	Inserter Tips, Sterile

The prodisc C implant is loaded onto the implant inserter "en-bloc" directly from the package tray. Insert the appropriate inserter tip into the distal end of the inserter and prepare it for loading (Figure 31).

Engage the implant inserter onto the prodisc C implant (Figure 32). Confirm that the "UP" indicator on the implant is attached to the inserter arm marked "UP". Visually confirm the inferior endplate with the polyethylene inlay is attached to the inserter arm marked "DOWN". Tighten the locking nut firmly to lock the implant to the inserter.

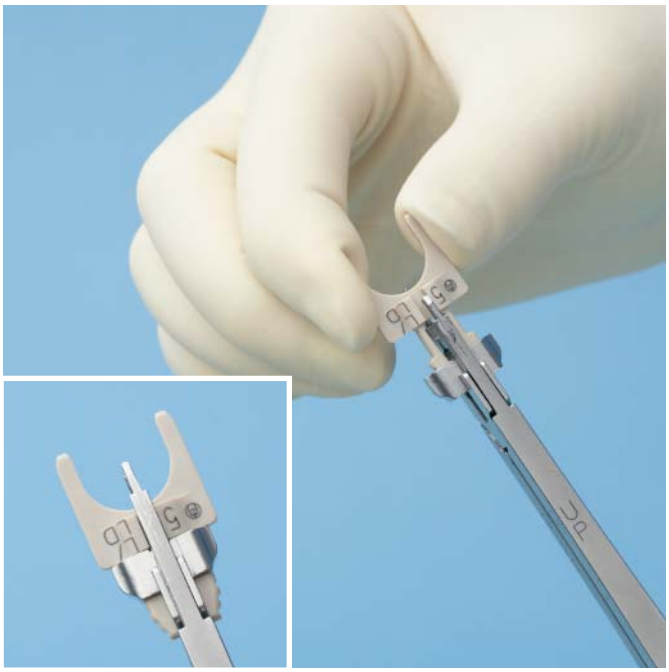

Figure 31

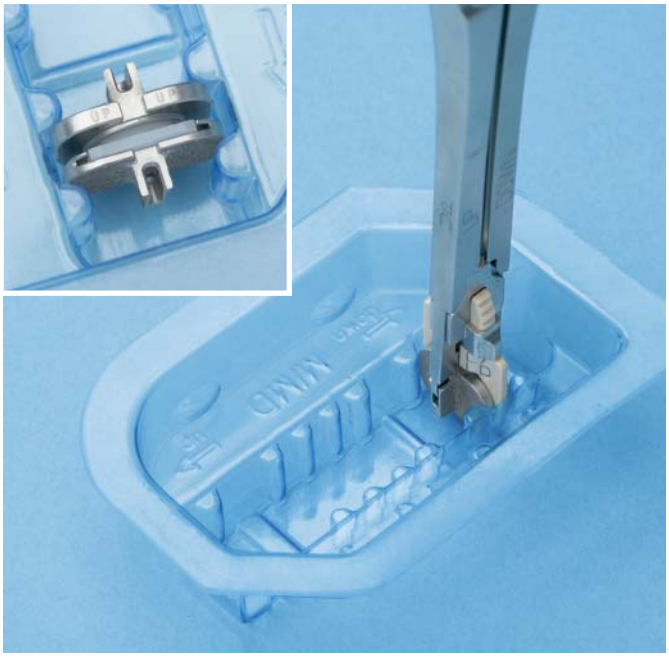

Figure 32

3

Implant insertion continued

- Align the keels of the prodisc C implant with the keel channels. Ensure the "UP" sides of the inserter and implant are oriented cranially. Under lateral fluoroscopic control, advance the prodisc C implant to the posterior margin of the vertebral bodies (Figure 33).

Visually confirm that the anterior edge of the implant is within the anterior edge of the vertebral body.

Release the locking nut on the inserter and squeeze gently to remove the inserter from the prodisc C implant.

Remove the retainer nuts, vertebral body retainer, and screws.

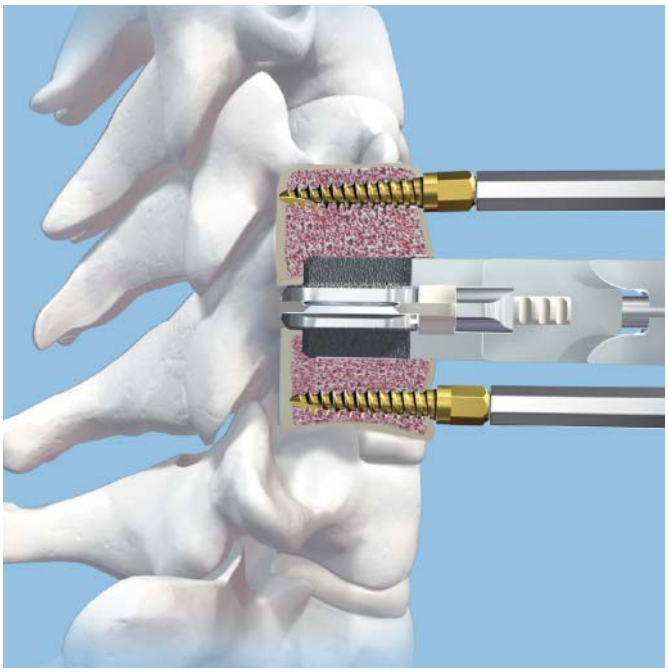

Figure 33

Confirm final implant position with lateral and AP imaging (Figures 34 and 35).

Copious saline lavage is recommended to remove osteogenic stimuli (blood/bone marrow). Apply standard homeostatic techniques to control bleeding.

Close the surgical wound in a routine fashion.

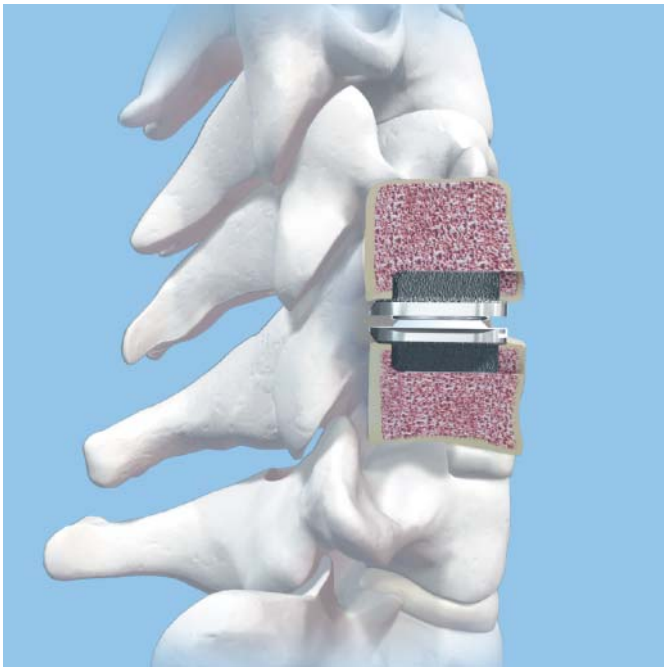

Figure 34

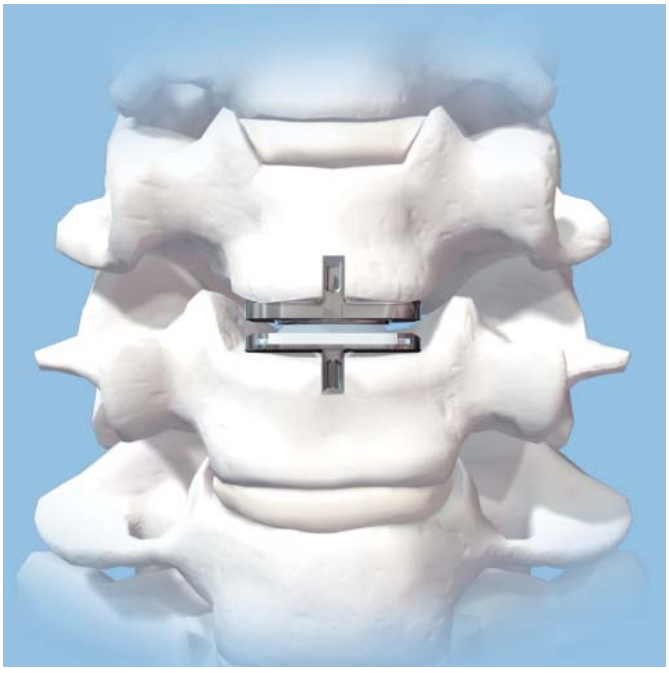

Figure 35

Postoperative Care and Implant Removal

Postoperative care

Patients can 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 until the surgeon is confident, based on review of postoperative radiographs, that the implant is stable and functioning. Patients should be instructed to immediately report any change in their pain or neurologic status.

Implant removal

Approach the level through the original anterior incision. Expose, identify and isolate the prodisc C implant from any overlying scar tissue. Excise any bony tissue from the anterior aspect of the endplates and keels to expose the implant-bone junction. Use an interbody distractor or retainer device to distract the disc space. Using a fine osteotome, pry the superior endplate from the vertebral body and extract the superior endplate from the space with a Kocher clamp or other grasping instrument. Repeat this technique on the inferior endplate. If distraction is not achievable, it may be necessary to pry the polyethylene insert from the inferior endplate first, before removing the superior and inferior endplates.

Should it be necessary to remove a prodisc C Total Disc Replacement, please contact Centinel Spine to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information. All explanted devices must be returned to Centinel Spine for analysis.

Please note that the prodisc C Total Disc Replacement 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.

Implants

pro**disc C Total Disc Replacement Implants, sterile**

09.820.025S Medium, 5 mm
09.820.026S Medium, 6 mm
09.820.027S* Medium, 7 mm

09.820.035S Medium, deep, 5 mm
09.820.036S Medium, deep, 6 mm
09.820.037S* Medium, deep, 7 mm

09.820.045S Large, 5 mm
09.820.046S Large, 6 mm
09.820.047S* Large, 7 mm

09.820.055S Large, deep, 5 mm
09.820.056S Large, deep, 6 mm
09.820.057S* Large, deep, 7 mm

09.820.065S Extra large, 5 mm
09.820.066S Extra large, 6 mm
09.820.067S* Extra large, 7 mm

09.820.075S Extra large, deep, 5 mm
09.820.076S Extra large, deep, 6 mm
09.820.077S* Extra large, deep, 7 mm

* Also available

Instruments

03.820.000	Handle, for Trial Implants

	Trial Implants, medium
03.820.025	5 mm
03.820.026	6 mm
03.820.027*	7 mm

	Trial Implants, medium, deep
03.820.035	5 mm
03.820.036	6 mm
03.820.037*	7 mm

	Trial Implants, large
03.820.045	5 mm
03.820.046	6 mm
03.820.047*	7 mm

	Trial Implants, large, deep
03.820.055	5 mm
03.820.056	6 mm
03.820.057*	7 mm

	Trial Implants, extra large
03.820.065	5 mm
03.820.066	6 mm
03.820.067*	7 mm

	Trial Implants, extra large, deep
03.820.075	5 mm
03.820.076	6 mm
03.820.077*	7 mm

03.820.100	Awl, 12 mm

*Also available

03.820.101	Self-Retaining Screwdriver

	Retainer Screws
03.820.102-CS	3.5 mm x 12 mm
03.820.103-CS	3.5 mm x 14 mm
03.820.104-CS	3.5 mm x 16 mm
03.820.105-CS	3.5 mm x 18 mm
03.820.106-CS	4.5 mm x 13 mm
03.820.107-CS	4.5 mm x 15 mm
03.820.108-CS	4.5 mm x 17 mm
03.820.109-CS	4.5 mm x 19 mm

03.820.110-CS	Retainer Nut

03.820.111 Or 03.820.111/1	Vertebral Body Retainer

03.820.112	Vertebral Distractor

Instruments continued

03.820.113	Slotted Mallet

	Milling Guides
03.820.114	5 mm
03.820.115	6 mm
03.820.116*	7 mm

IN1545S	Milling Bit, sterile
IN1546S	Milling Bit, sterile
03.820.117S	Milling Bit, sterile
03.820.153S	Milling Bit, sterile
03.820.163S	Milling Bit, sterile
03.820.157S	Milling Bit, sterile
03.820.167S	Milling Bit, sterile
03.820.161S	Milling Bit, sterile
03.820.159S*	Milling Bit, sterile
03.820.169S*	Milling Bit, sterile

	Primary Chisels
03.820.119	5 mm
03.820.120	6 mm
03.820.121*	7 mm

	Secondary Chisels
03.820.122	5 mm
03.820.123	6 mm
03.820.124*	7 mm

03.820.126	Keel Cut Cleaner

03.820.128	Chisel Cleaner

*Also available

03.820.129	Implant Inserter

	Inserter Tips, sterile
	for Medium and Medium Deep Implants,
03.820.130S	5 mm height
03.820.131S	6 mm height
03.820.132S*	7 mm height
	for Large and Large Deep Implants
03.820.133S	5 mm height
03.820.134S	6 mm height
03.820.135S*	7 mm height
	for Extra Large and Extra Large Deep Implants
03.820.140S	5 mm height
03.820.141S	6 mm height
03.820.142S*	7 mm height

	Temporary Fixation Pins
03.820.136	sharp
03.820.137	blunt

03.820.143	2.0 mm Hexagonal Screwdriver

03.820.144	Tamp

*Also available

pro**disc C Instrument and Implant Set (01.820.003)**

Graphic Case

60.820.001	Graphic Case, for pro**disc C** Instruments

Instruments (in graphic case)

03.820.000	Handle, for Trial Implants, 2 ea.
	Trial Implants
03.820.025	Medium, 5 mm
03.820.026	Medium, 6 mm
03.820.035	Medium, deep, 5 mm
03.820.036	Medium, deep, 6 mm
03.820.045	Large, 5 mm
03.820.046	Large, 6 mm
03.820.055	Large, deep, 5 mm
03.820.056	Large, deep, 6 mm
03.820.065	Extra large, 5 mm
03.820.066	Extra large, 6 mm
03.820.075	Extra large, deep, 5 mm
03.820.076	Extra large, deep, 6 mm
03.820.100	Awl, 12 mm
03.820.101	Self-Retaining Screwdriver, 2 ea.
	Retainer Screws
03.820.102-CS	3.5 mm x 12 mm, 2 ea.
03.820.103-CS	3.5 mm x 14 mm, 2 ea.
03.820.104-CS	3.5 mm x 16 mm, 2 ea.
03.820.105-CS	3.5 mm x 18 mm, 2 ea.
03.820.106-CS	4.5 mm x 13 mm
03.820.107-CS	4.5 mm x 15 mm
03.820.108-CS	4.5 mm x 17 mm
03.820.109-CS	4.5 mm x 19 mm
03.820.110-CS	Retainer Nut, 6 ea.
03.820.111 Or 03.820.111/1	Vertebral Body Retainer
03.820.112	Vertebral Distractor
03.820.113	Slotted Mallet
03.820.114	Milling Guide, 5 mm
03.820.115	Milling Guide, 6 mm
03.820.119	Primary Chisel, 5 mm
03.820.120	Primary Chisel, 6 mm
03.820.122	Secondary Chisel, 5 mm
03.820.123	Secondary Chisel, 6 mm
03.820.126	Keel Cut Cleaner
03.820.128	Chisel Cleaner
03.820.129	Implant Inserter
03.820.136	Temporary Fixation Pin, sharp, 2 ea.
03.820.137	Temporary Fixation Pin, Blunt
03.820.143	2.0 mm Hexagonal Screwdriver
03.820.144	Tamp

Note: For additional information, please refer to package insert.
For detailed cleaning and sterilization instructions, please refer to guides.centinelspine.com or to the below listed inserts, which will be included in the shipping container:
– Processing Centinel Spine Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305

Instruments (supplied sterile packaged)

	Milling Bits, sterile
IN1545S	Milling Bit, sterile
IN1546S	Milling Bit, sterile
03.820.117S	Milling Bit, sterile
03.820.153S	Milling Bit, sterile
03.820.163S	Milling Bit, sterile
03.820.157S	Milling Bit, sterile
03.820.167S	Milling Bit, sterile
03.820.161S	Milling Bit, sterile
03.820.159S	Milling Bit, sterile
03.820.169S	Milling Bit, sterile
	Inserter Tips, for Medium and Medium Deep Implants, sterile
03.820.130S	5 mm height
03.820.131S	6 mm height
	Inserter Tips, for Large and Large Deep Implants, sterile
03.820.133S	5 mm height
03.820.134S	6 mm height
	Inserter Tips, for Extra Large and Extra Large Deep Implants, sterile
03.820.140S	5 mm height
03.820.141S	6 mm height

Implants (supplied sterile packaged)

prodisc C Total Disc Replacement Implants, sterile

09.820.025S	Medium, 5 mm
09.820.026S	Medium, 6 mm
09.820.035S	Medium, deep, 5 mm
09.820.036S	Medium, deep, 6 mm
09.820.045S	Large, 5 mm
09.820.046S	Large, 6 mm
09.820.055S	Large, deep, 5 mm
09.820.056S	Large, deep, 6 mm
09.820.065S	Extra large, 5 mm
09.820.066S	Extra large, 6 mm
09.820.075S	Extra large, deep, 5 mm
09.820.076S	Extra large, deep, 6 mm

Also Available

Implants

prodisc C Total Disc Replacement Implants, sterile

09.820.027S	Medium, 7 mm
09.820.037S	Medium, deep, 7 mm
09.820.047S	Large, 7 mm
09.820.057S	Large, deep, 7 mm
09.820.067S	Extra Large, 7 mm
09.820.077S	Extra Large, deep, 7 mm

Instruments

	Trial Implants
03.820.027	Medium, 7 mm
03.820.037	Medium, deep, 7 mm
03.820.047	Large, 7 mm
03.820.057	Large, deep, 7 mm
03.820.067	Extra large, 7 mm
03.820.077	Extra large, deep, 7 mm
03.820.116	Milling Guide, 7 mm
03.820.121	Primary Chisel, 7 mm
03.820.124	Secondary Chisel, 7 mm
03.820.132S	Inserter Tip, for Medium and Medium Deep Implants, 7 mm height, sterile
03.820.135S	Inserter Tip, for Large and Large Deep Implants, 7 mm height, sterile
03.820.142S	Inserter Tip, for Extra Large and Extra Large Deep Implants, 7 mm height, sterile

	Retainer Screws, sterile, 2/pkg.
03.820.102.02S-CS	3.5 mm x 12 mm
03.820.103.02S-CS	3.5 mm x 14 mm
03.820.104.02S-CS	3.5 mm x 16 mm
03.820.105.02S-CS	3.5 mm x 18 mm
03.820.110.02S	Retainer Nut, sterile, 2/pkg.

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