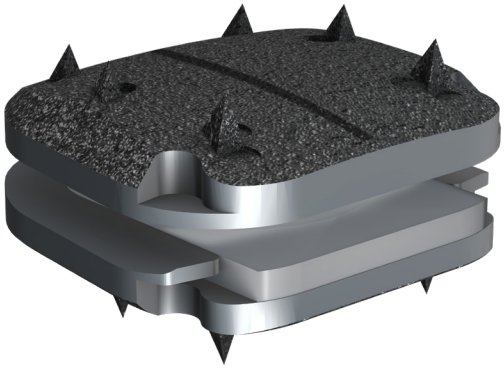
CENTINEL SPINE®

prodisc® C Vivo

Cervical Total Disc Replacement System

SURGICAL TECHNIQUE GUIDE



This Surgical Technique Guide is For Use with the Gold Instrument Case with Black Corners

prodisc® C Vivo

Cervical Total Disc Replacement System

TABLE OF CONTENTS

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

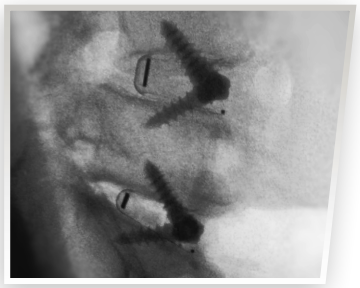
Centinel Spine was founded in 2008 through the merger-acquisition of two pioneering medical device companies (Raymedica, LLC and Surgicraft LTD.) and is the largest privately-held spine company focused on anterior column reconstruction. The company offers a continuum of motion-preserving and fusion solutions—providing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

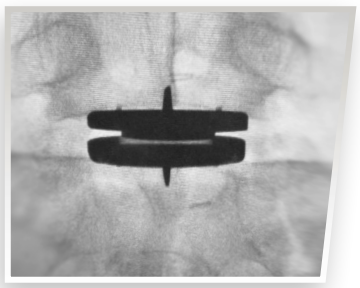


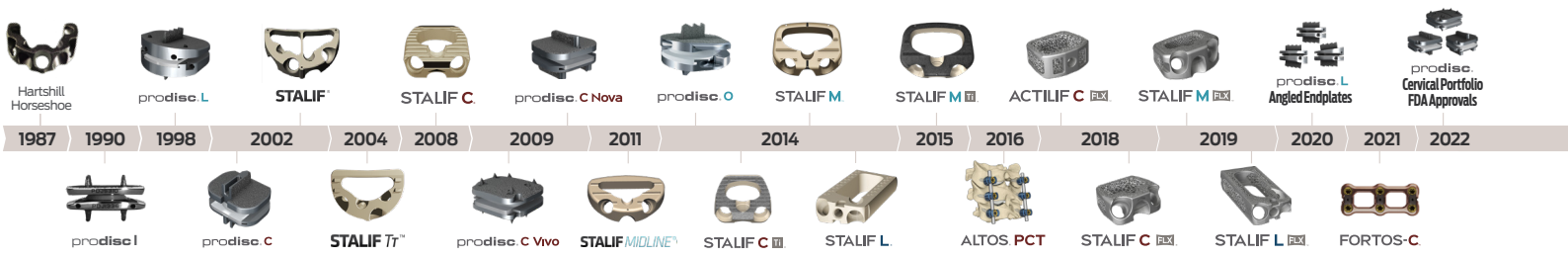
Clinically-Proven Motion Preservation

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



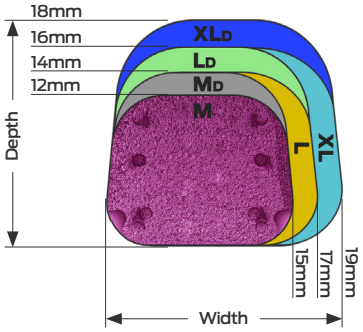


Introduction to prodisc® C Vivo

prodisc C Vivo 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 Vivo 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

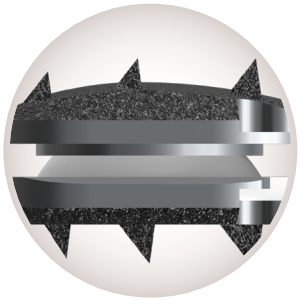


Anatomical Sizing

- 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

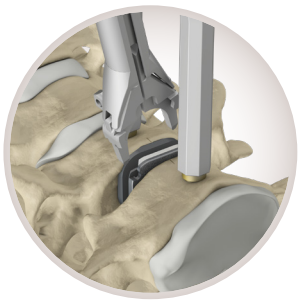
Powered by prodisc CORE

- 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

- Convex superior plate for anatomical fixation
- Trapezoidal footprint design for optimal anatomical fit and maximum endplate coverage



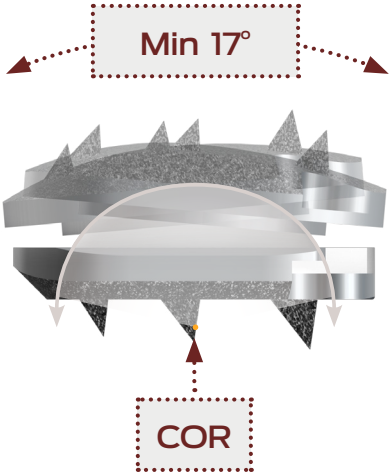
Simple Surgical Technique

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

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

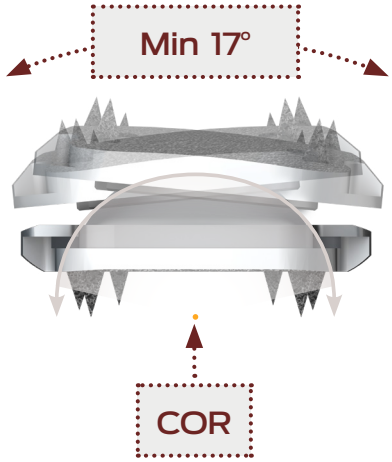
Flexion/Extension

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



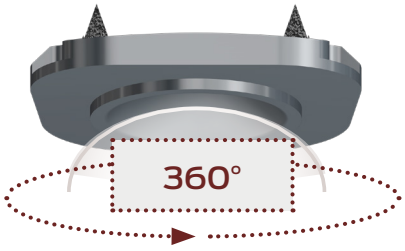
Lateral Bending

- 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



Contents

The prodisc **C Vivo** cervical disc prosthesis is made up of three components:

- prodisc **C Vivo** superior endplate
- prodisc **C Vivo** inferior endplate
- prodisc **C Vivo** inlay

All implant components (the superior endplate and the inferior endplate with the PE inlay snapped in) are packaged together using a double sterile barrier method.

Description

The components of the prodisc **C Vivo** cervical disc prosthesis are made from:

1. **Superior and inferior endplate: CoCrMo (Co-28Cr-6Mo) per ISO 5832-12 with pure titanium coating per ASTM F1580**
2. **Inlay: UHMWPE per ISO 5834-2**

Contents are supplied sterile.

Intended Use

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

Indications for Use

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

Specific Contraindications

- Fractures, infections, tumours
- Spinal stenosis by hypertrophic spondylarthrosis
- Facet joint degeneration
- Increased segmental instability
- Ossification of posterior longitudinal ligament (OPLL)
- Advanced cervical anatomical deformity (e.g., ankylosing spondylitis, scoliosis) at the operative or adjacent levels
- Osteopenia
- Advanced cervical degenerative facet joint changes, and
- Cervical spine mal-alignment conditions (e.g. scoliosis or kyphosis.)

General Contraindications

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

Patient Exclusion Recommendations

Patient selection is one of the most important factors contributing to the outcome of the total disc replacement procedure. The following may affect clinical outcomes:

- A condition of senility or mental illness, alcoholism or smoking
- Dependency on pharmaceutical drugs or drug abuse
- The patient's occupation or activity level
- Compromised vertebral bodies at affected level due to current or past trauma (fractures)
- Disc height less than 3mm measured from the center of the disc in a neutral position and disc height less than 20% of the anterior-posterior width of the inferior vertebral body
- Involved vertebral endplate dimensionally smaller than the minimum implant footprint size in both the medial-lateral and the anteriorposterior directions
- Severe abnormality of the endplate (e.g. large Schmorl nodes)

Precautions

Proper surgical performance of the implantation is the responsibility of the operating surgeon.

- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- Assembling and implanting the implant components is the responsibility of the operating surgeon.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- Under no circumstances may implant components from different suppliers be combined.
- The implant components applied (name, article number, lot number) must be documented in each patient's record.
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed.
- Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as to other grave complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the cervical disc prosthesis must be checked periodically post operative, using appropriate techniques.
- prodisc **C Vivo** device has not been studied in the clinical situation of prior cervical fusion.

Procedure

The prodisc **C Vivo** cervical disc prothesis must be implanted with the prodisc **C Vivo** instruments only.

Magnetic Resonance Environment

MR Conditional

Non-clinical testing of the worst-case scenario has demonstrated that the articles of the prodisc **C Vivo** system are MR conditional. These articles can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla
- Spatial gradient field of 90 mT/cm (900 Gauss/cm)
- Maximum whole body averaged specific absorption rate (SAR) of
  2 W/kg for 15 minutes of scanning

In non-clinical testing, the prodisc **C Vivo** produced a temperature rise of less than 2ºC at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or close to the position of the prodisc **C Vivo** device.

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

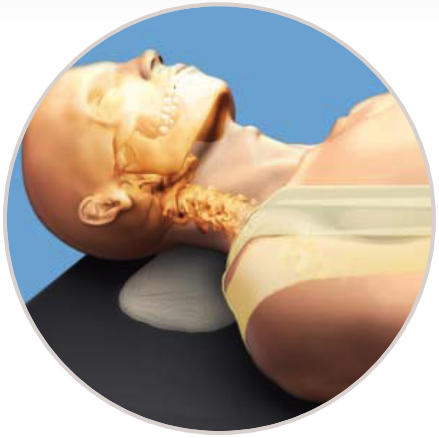
Patient Positioning

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

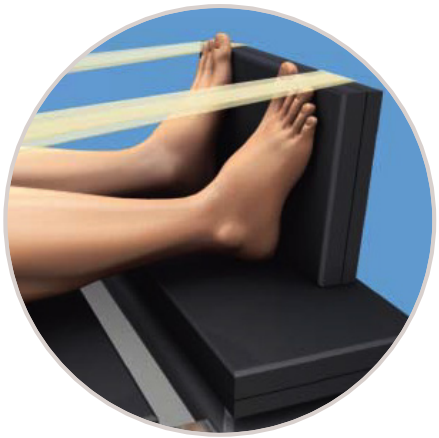
Position the patient supine on the operating table. Support the neck with a radiolucent cushioned neck roll to keep the neck in a normal lordotic ("neutral") position **(Figure 2)**. Correct any malrotation of the neck and head. Confirm true A/P orientation with spot fluoroscopy. Tape or strap the head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

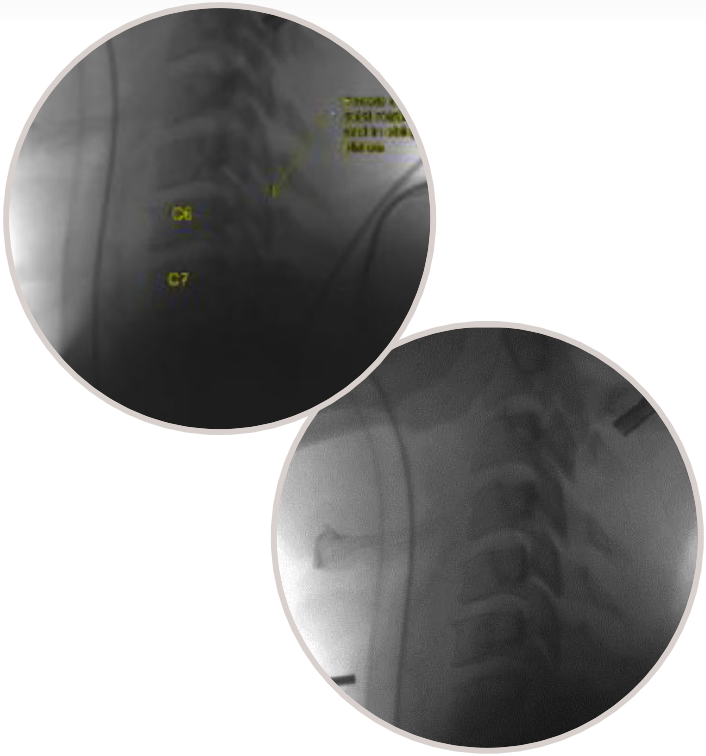
Both vertebral bodies of the affected level must be clearly visible on fluoroscopy before proceeding with surgery. If the shoulders obstruct the view of the operative level, depress the shoulder girdle using caudal traction **(Figures 1, 2, 3)**.

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

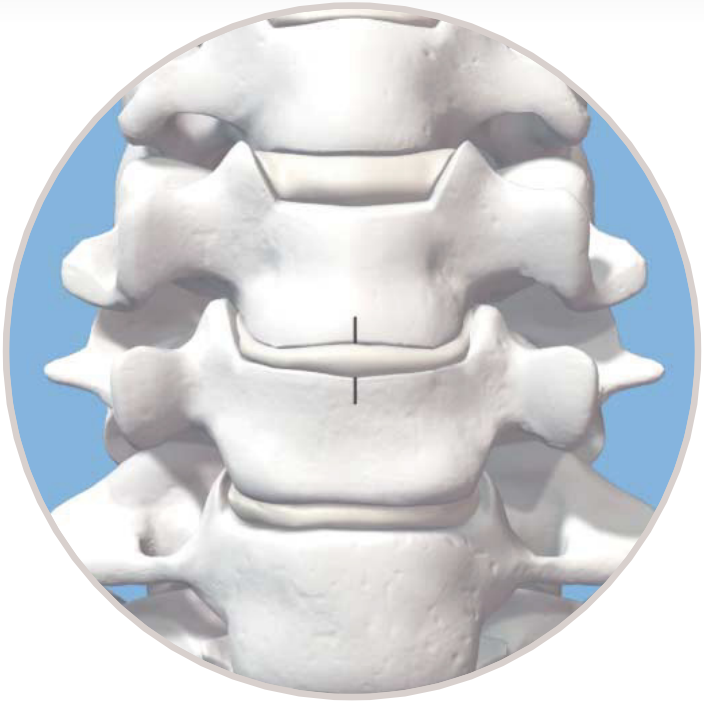
Expose the operative level via a standard transverse approach to the anterior cervical spine. Verify the operative level with fluoroscopy.

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

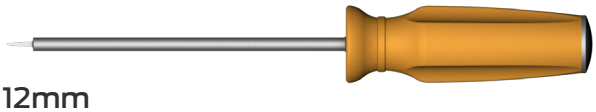


Discectomy, Decompression, & Remobilization

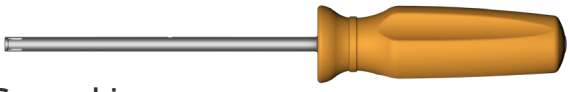
Thorough disc space preparation is best performed with controlled, parallel distraction of the operative level. Distraction should be obtained using the vertebral distractor and then maintained with the vertebral body retainer system.

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 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

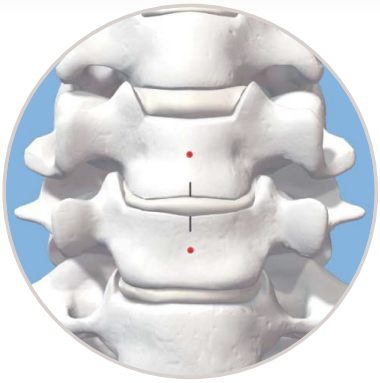
Vertebral Distractor
03.820.112

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 Vivo Total Disc Replacement.*

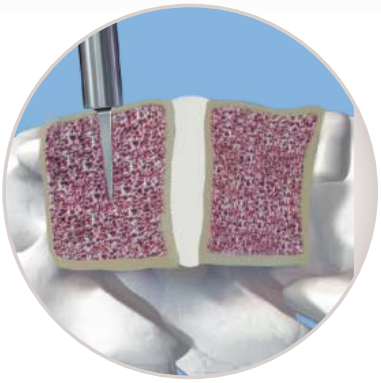
The technique for use is:

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)**.

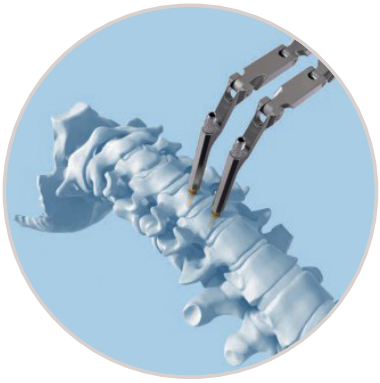
6. Ideal Positioning for Retainer Screw Insertion



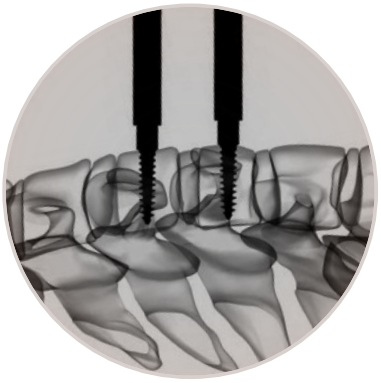
7. Perforating the Anterior Cortex with the Awl



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)**.

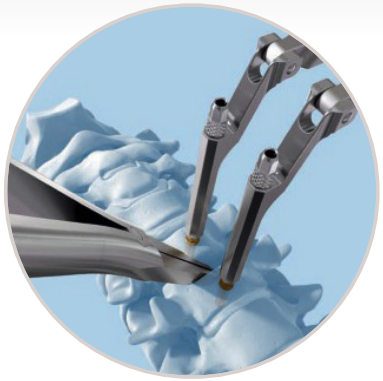
Apply light pretension to the operative disc space with the retainer—do not apply enough force to distract the segment. Create an anterior annulotomy centered on midline and wide enough to accommodate the implant. Perform the preliminary discectomy using standard rongeurs and curettes.

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.*

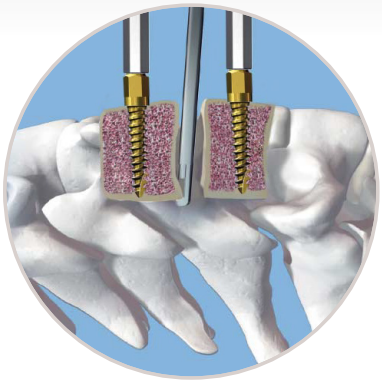
please NOTE *The vertebral body retainer is not intended to distract the segment as with a Caspar retractor. Distraction is achieved with the vertebral distractor.*

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 Vivo is performed in two steps:

1. Trial
2. Implant Insertion

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

Select the largest footprint to maximize coverage of the vertebral bodies and the smallest appropriate height.

STEP 1: Trial

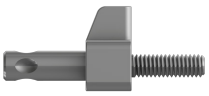
The system contains 18 trial implants that correspond to the 18 implant sizes. Trials are placed into the disc space intraoperatively to determine the appropriate implant footprint, disc height, and position.

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 stop.

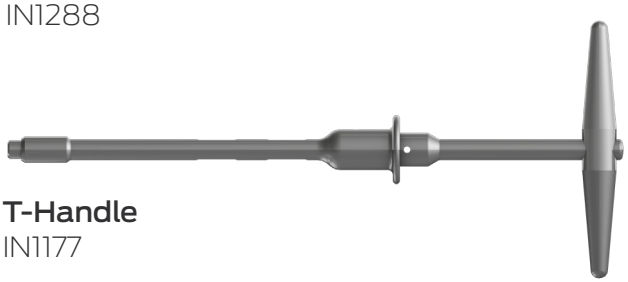
Align the trial on midline with the stops pointing cranially and advance it under fluoroscopy into the disk space.

prodisc C Vivo Trials (M, MD, L, LD, XL, XLD)
IN1266 - IN1283

prodisc C Vivo Trial Post Attachment
IN1288



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 can 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) **(Figure 15)**. In A/P, the trial implant should be centered on the midline **(Figure 16)**.

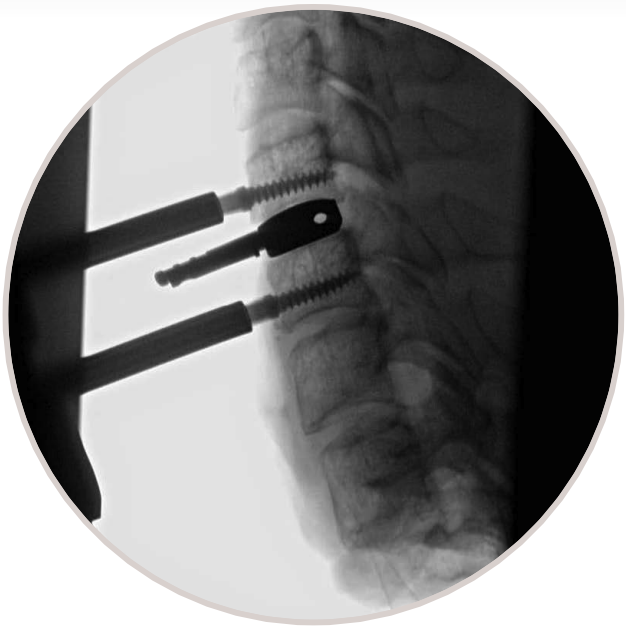
If the stop does not allow the trial implant to go deep enough, the stop can be adjusted by turning the trial shaft counter-clockwise (1 rev = 0.5 mm), enabling the trial implant to be advanced slightly deeper. At the same time, the trial implant should be kept centered on the midline.

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.

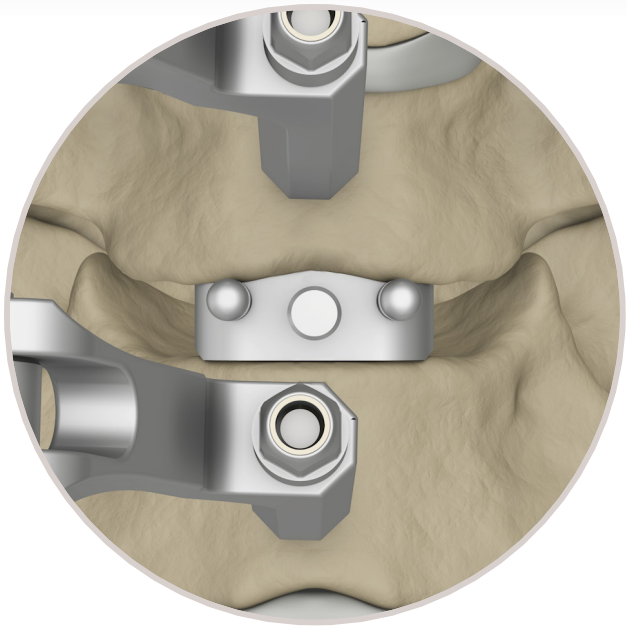
Release the distraction on the vertebral body retainer to determine the optimal height of the trial implant. The trial height should be the smallest appropriate height. The vertebral bodies should stay in parallel position to each other.

Note: Facet joints can become overdistracted 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 *Optimally, the largest footprint, the smallest height trial, and implant will be used without sacrificing COR positioning.*

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 to check the width of the trial and midline position ***(Figure 16)****.*

Implantation (Cont'd)

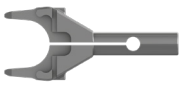
STEP 2: Implant Insertion

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).

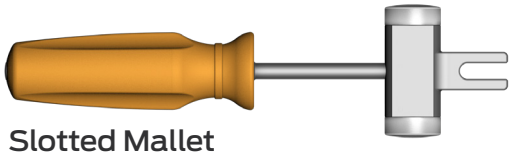
Attach the appropriate Introducer Tip to the prosthesis until the arms snap into the holding features on both endplates of the implant **(Figure 17)**.

Connect the Introducer Tip to the Introducer. Align the Introducer (postitive) stop with the superior side of the implant. Use two fingers to rotate proximal knob clockwise to tighten Introducer Tip. When tightened, there will still be some toggle of the implant on the Introducer Tip, per the design (especially on the superior endplate). **CAUTION: Do not over-tighten.**

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



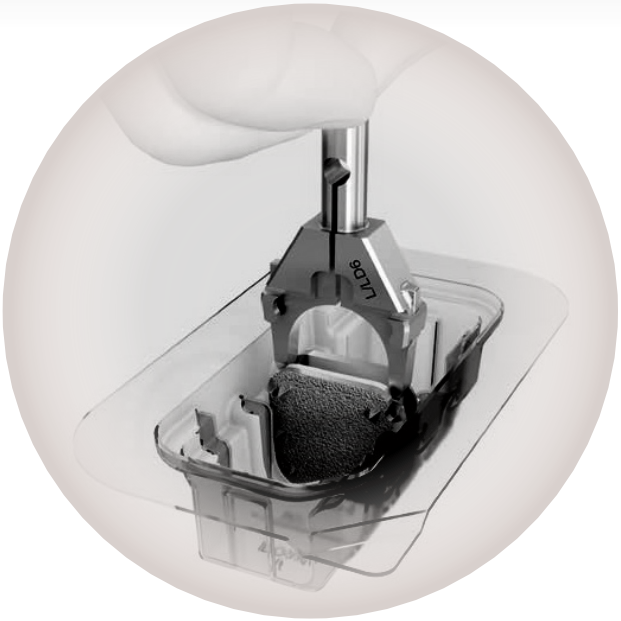
Introducer Tip (M/MD, L/LD, XL/XLD)
IN1236/1 - IN1244/1



Slotted Mallet
03.820.113

Introducer
IN1190/1

17. Attaching the Introducer Tip to the Implant



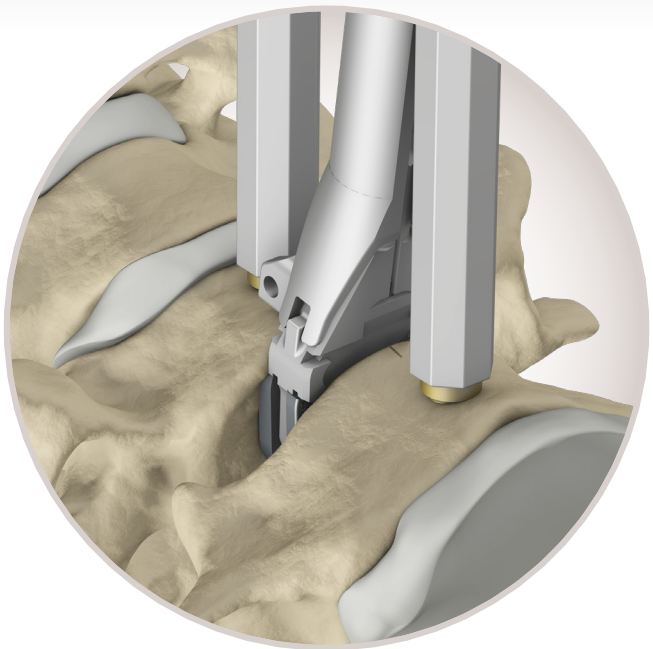
Add a few clicks of distraction with the vertebral body retainer to allow removal of the trial implant. Apply distraction as necessary, to facilitate the insertion of the implant.

Ensure that the implant is inserted with the black markings on the superior endplate of the prodisc **C Vivo**. Align the implant with the midline marking of the vertebral body **(Figure 18)**.

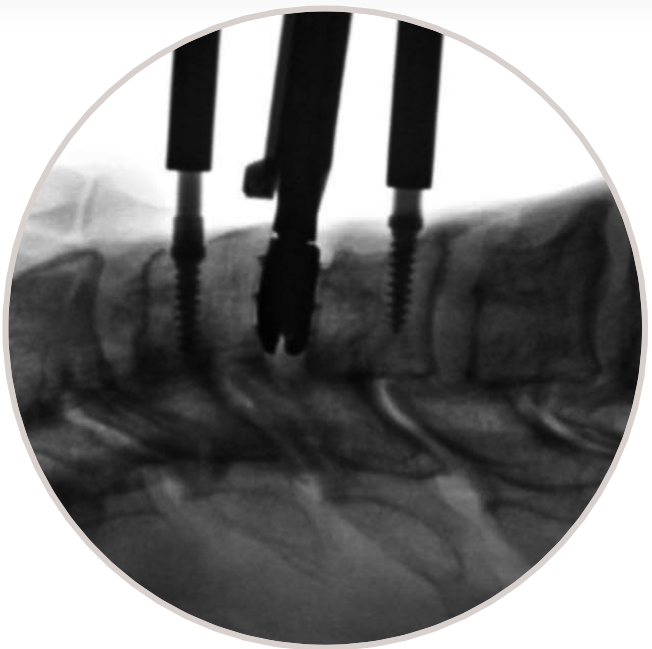
Under lateral fluoroscopic control, advance the implant into its final position providing the best possible anatomical fit with the vertebral bodies **(Figure 19)**. The center of rotation (COR) of the prosthesis should be positioned at the midline of the vertebral body or slightly posterior. Avoid excessive cranial, caudal, or lateral corrections during insertion and ensure that the implant doesn't exceed the posterior margin of the vertebral body.

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

18. Inserting the Implant with the Introducer



19. 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 seat the spikes to 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.

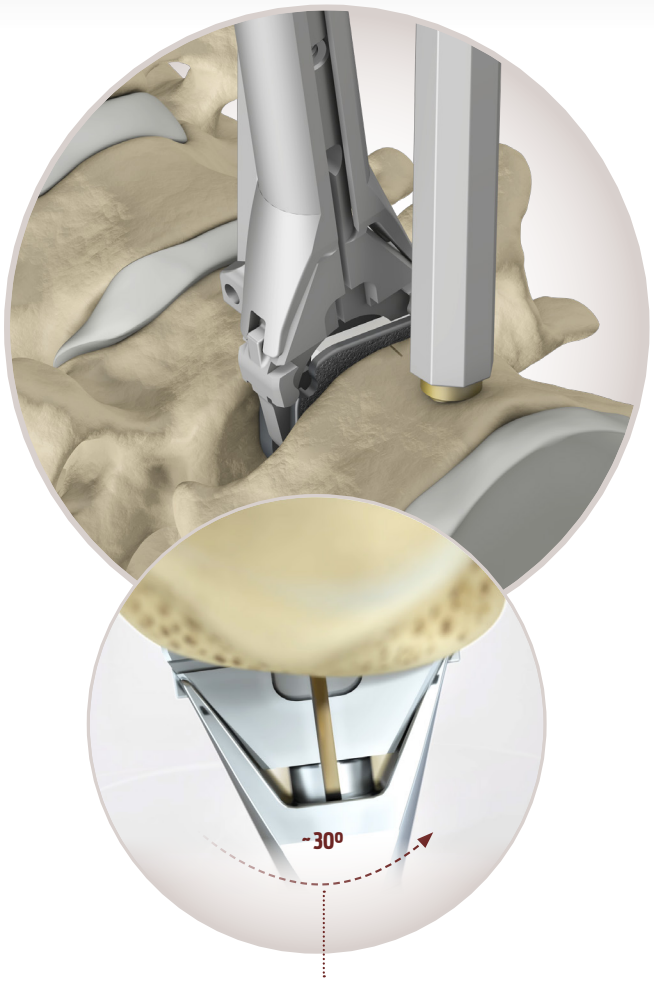
To disconnect the loosened Introducer Tip from the implant, move the Introducer in a left-to-right (or right-to-left) motion to approximately 30 degrees off midline and pull up until implant release occurs. **(Figures 20 & 21)**.

Confirm final implant position with lateral and A/P imaging **(Figures 22 & 23)**.

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

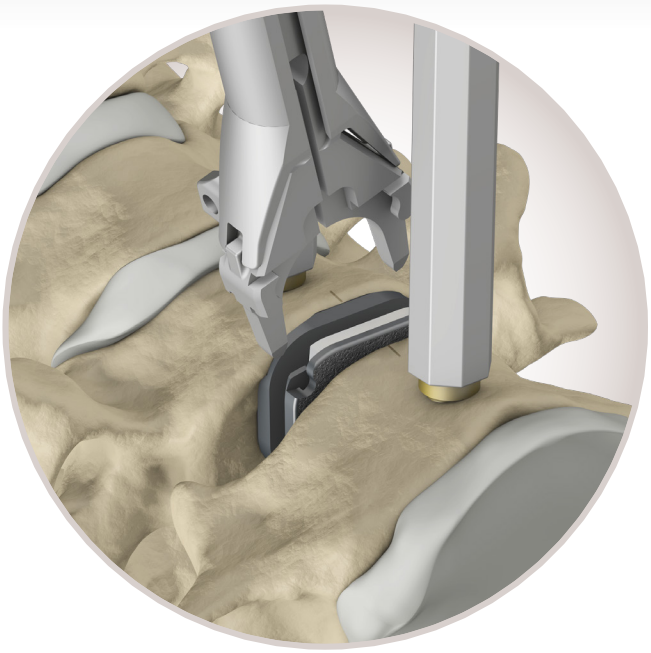
Close the surgical wound in a routine fashion.

20. Removing the Introducer from the Implant



Moving Introducer Laterally from Left to Right (or Right to Left), about 30° for Implant Release

21. Introducer Released from the Implant



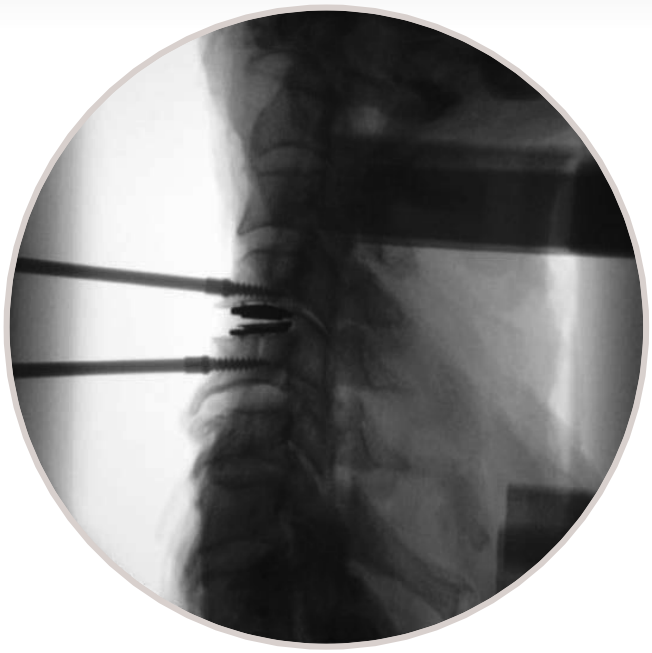
Optional Introducer Tip Removal Technique Using Shaft of the Introducer:

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.

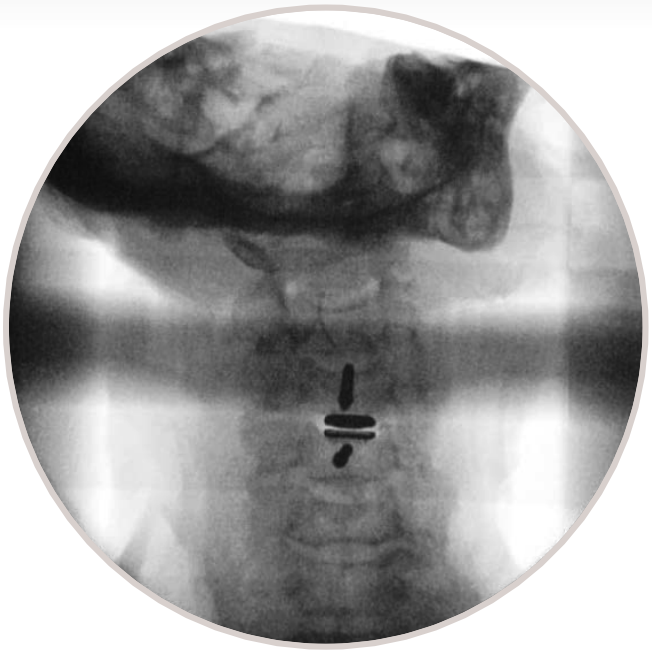
Post-Operative Care

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.

22. Final Implant Position in Lateral View



23. Final Implant Position in A/P View



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.

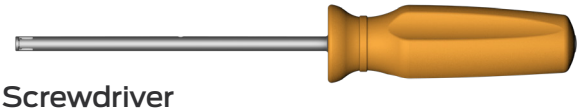
Approach the level through the original anterior incision. Expose, identify, and isolate the prodisc **C Vivo** implant from any overlying scar tissue. Excise any bone tissue from the anterior aspect of the endplates and keels to expose the implant-bone junction.

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.

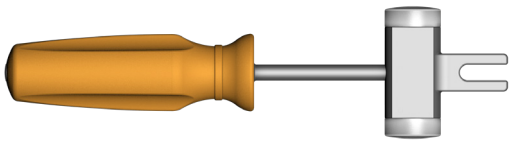
Re-attach the Endplate Remover to the 2nd Endplate. Tighten the speed nut. Apply extraction force to the Endplate Remover.

Should it be necessary to remove a prodisc **C Vivo** 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.

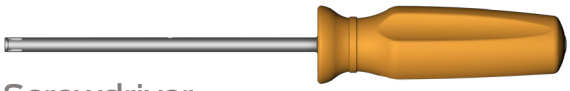
Slide Hammer
03.820.282



Slotted Mallet
03.820.113

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

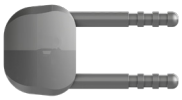
12mm Thread	03.820.102
14mm Thread	03.820.103
16mm Thread	03.820.104
18mm Thread	03.820.105

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 Vivo Trials



Trial Implant M, 15mm x 12mm

5mm Height	IN1266
6mm Height	IN1267
7mm Height	IN1268

Trial Implant MD, 15mm x 14mm

5mm Height	IN1269
6mm Height	IN1270
7mm Height	IN1271

Trial Implant L, 17mm x 14mm

5mm Height	IN1272
6mm Height	IN1273
7mm Height	IN1274

Trial Implant LD, 17mm x 16mm

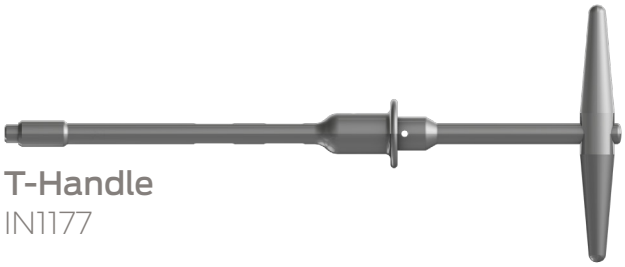
5mm Height	IN1275
6mm Height	IN1276
7mm Height	IN1277

Trial Implant XL, 19mm x 16mm

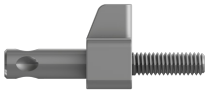
5mm Height	IN1278
6mm Height	IN1279
7mm Height	IN1280

Trial Implant XLD, 19mm x 18mm

5mm Height	IN1281
6mm Height	IN1282
7mm Height	IN1283



T-Handle
IN1177



Trial Stop

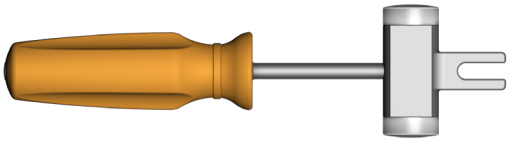
5mm Height	IN1284
6mm Height	IN1285
7mm Height	IN1286

prodisc C Vivo Trial Post Attachment
IN1288

Instruments: For Insertion

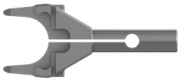
Introducer
IN1190

Slide Hammer for Cervical Spine
03.820.282



Slotted Mallet
03.820.113

Positioner
03.670.207



Introducer Tip, M/MD

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

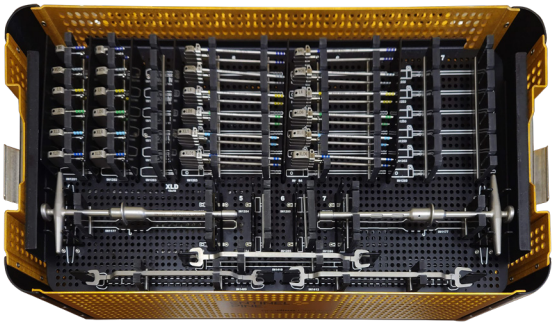
Introducer Tip, L/LD

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

Introducer Tip, XL/XLD

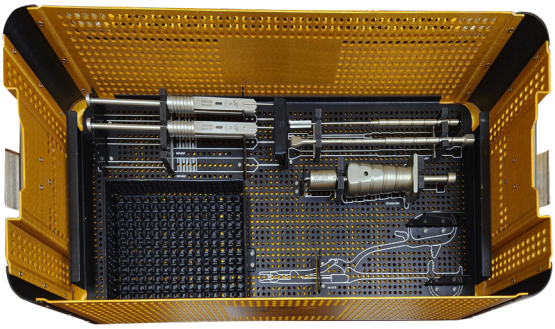
5mm Height	IN1242
6mm Height	IN1243
7mm Height	IN1244

Instrument Set Maps

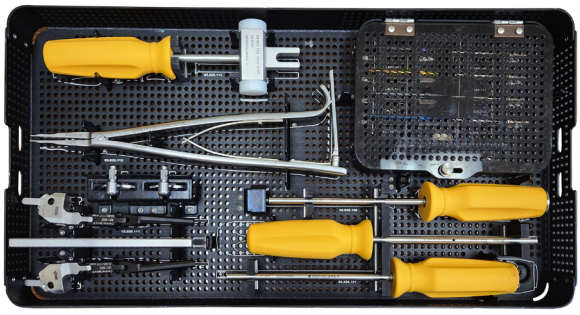


Cervical Instrument Set
Top Level

Cervical Instrument Set
Middle Level

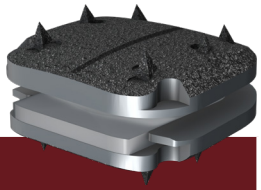


Cervical Instrument Set
Bottom Level



Cervical Retainer Set

Implants



Implant Footprints			Part Numbers		
	Depth	Width	Height 5 mm	Height 6 mm	Height 7 mm
M	12mm	15mm	PDVM5	PDVM6	PDVM7
MD	14mm	15mm	PDVMD5	PDVMD6	PDVMD7
L	14mm	17mm	PDVL5	PDVL6	PDVL7
LD	16mm	17mm	PDVLD5	PDVLD6	PDVLD7
XL	16mm	19mm	PDVXL5	PDVXL6	PDVXL7
XLD	18mm	19mm	PDVXLD5	PDVXLD6	PDVXLD7

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 – 2021.*

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

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