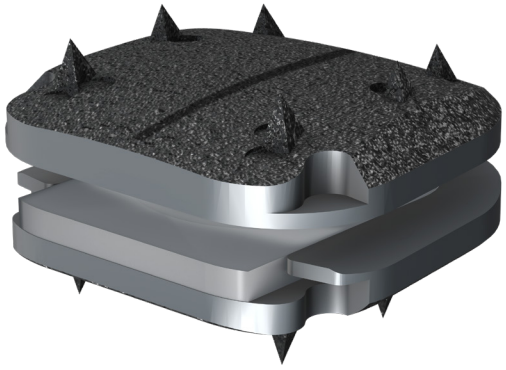
CENTINEL SPINE®

prodisc® C Vivo

Cervical Total Disc Replacement System
For Single Level Spinal Arthroplasty from C3 to C7

SURGICAL TECHNIQUE GUIDE



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®

30+ YEARS OF CLINICAL SUCCESS SINCE 1988

A dedicated spine company with a singular focus

About Centinel Spine

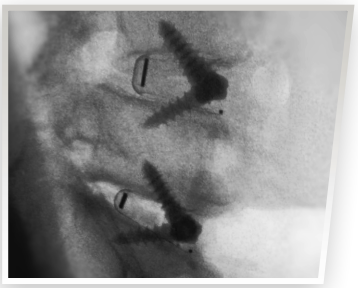
Centinel Spine was founded in 2008 through the merger-acquisition of two pioneering medical device companies (Raymedica, LLC and Surgicraft LTD.) and is the largest privately-held spine company focused on anterior column reconstruction. The company offers a continuum of motion-preserving and fusion solutions—providing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

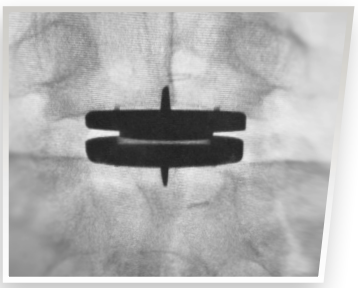


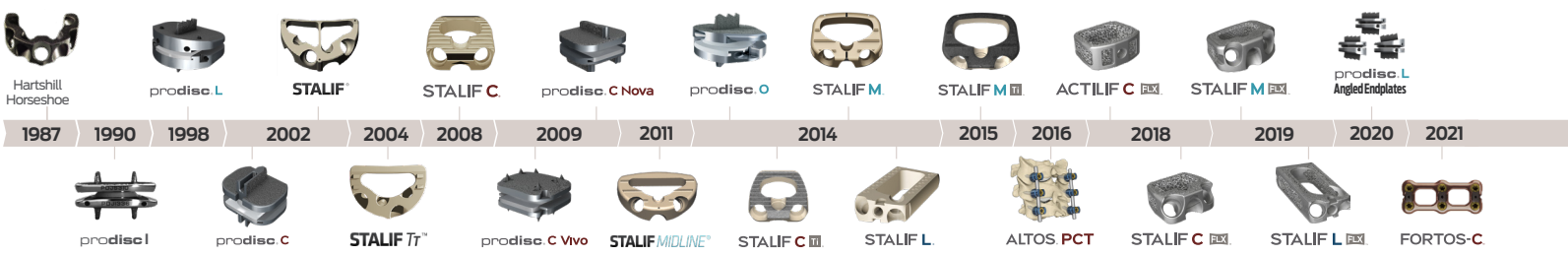
Clinically-Proven Motion Preservation

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





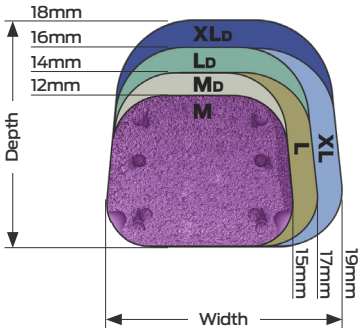
prodisc® C Vivo

Features & Benefits

The prodisc® **C Vivo** device is intended to replace a diseased and/or degenerated intervertebral disc of the cervical spine in patients with symptomatic cervical disc disease (SCDD). The prodisc® **C 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.

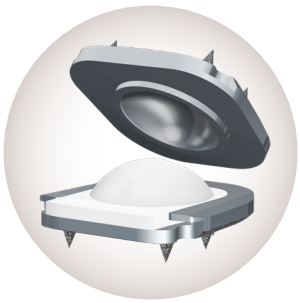
Proven Materials

- 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

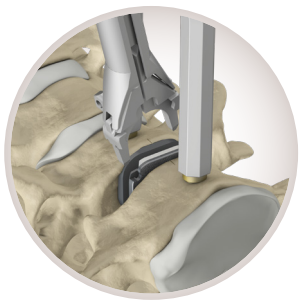


Kinematics

- 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

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



Simple Surgical Technique

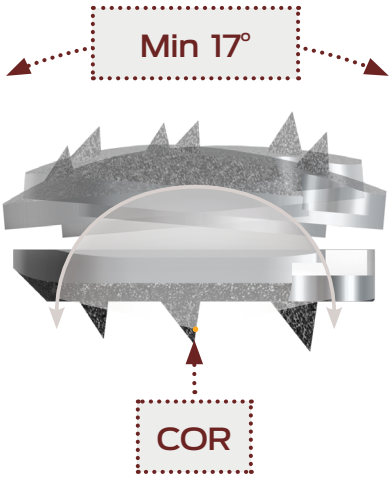
- Simple technique with two main steps: trial and implant insertion

Kinematics

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

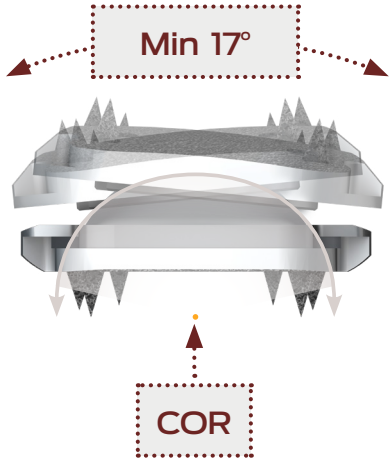
Flexion/Extension

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



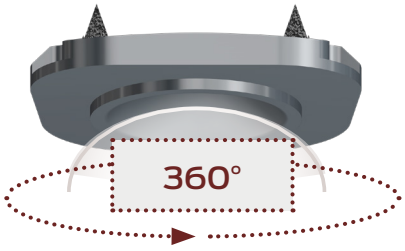
Lateral Bending

- 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 Vivo** Total Disc Replacement device consists of the following three components. The first is the inferior CoCrMo (cobalt chromium molybdenum) alloy plate with 6 endplate spikes that anchor to the inferior vertebral body. The second component is an Ultra High Molecular Weight Polyethylene (UHMWPE) inlay 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 6 endplate spikes 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 are titanium plasma spray coated, which may provide additional fixation through bony ingrowth.

The maximum range of motion allowed by the prodisc® **C Vivo** 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 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** Total Disc Replacement should have failed at least six weeks of nonoperative treatment prior to implantation of the prodisc® **C Vivo** Total Disc Replacement.

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 Vivo** Total Disc Replacement 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. 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
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 Vivo** Total Disc Replacement should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics, 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.

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

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
- 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 ≤ -2.5, as the patient may be osteoporotic.

Use aseptic technique when removing the prodisc® **C Vivo** Total Disc Replacement implant from the innermost packaging.

Use care when handling the prodisc® **C Vivo** 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 Vivo** 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.

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.

MRI information

Centinel Spine prodisc® **C Vivo** implants are labeled MR Conditional 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 Vivo** demonstrated that the implant is MR Conditional. A patient with a prodisc® **C Vivo** 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 Vivo** 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 Vivo** 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 Vivo** 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 Vivo** 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 consultant 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 please consult the Important Information leaflet or refer to:

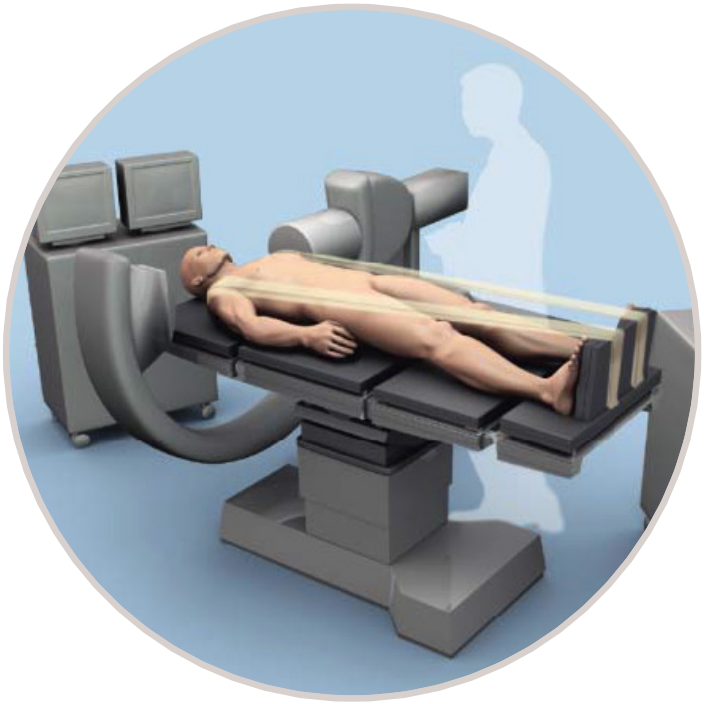
http://prodiscguides.centinelspine.com

Patient Positioning

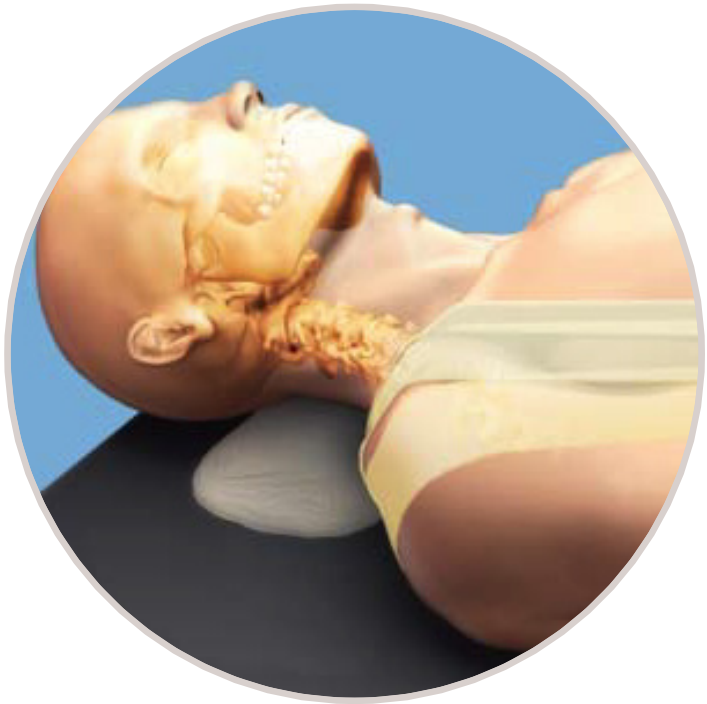
AP and lateral imaging is used frequently throughout the prodisc® C Vivo surgical procedure. Set up the OR table, patient and C-arm to allow for circumferential use of fluoroscopy at the operative level; and for unobstructed cranial and caudal movement of the C-arm, avoiding frequent passage in and out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

Position the patient supine on the operating table. Support the neck with a 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 AP orientation with spot fluoroscopy. Tape or strap the head in place to maintain this position.

1. Demonstrating Patient Positioning



2. Supporting the Neck with a Cushioned Neck Roll



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

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

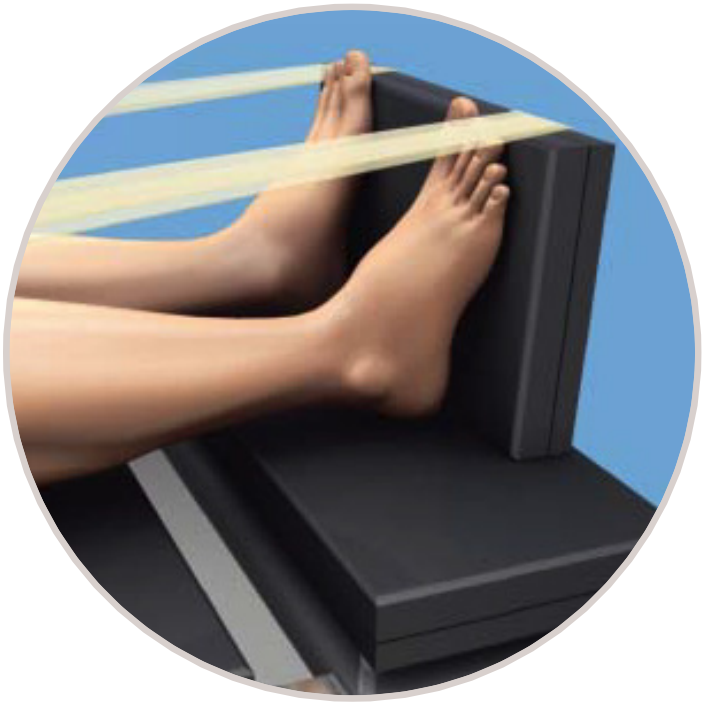
Both vertebral bodies of the affected level must be clearly visible on fluoroscopy before proceeding with surgery. If the shoulders obstruct the view of the operative level, depress the shoulder girdle using caudal traction on the upper extremities **(Figures 1, 2, 3)**.

Exposure

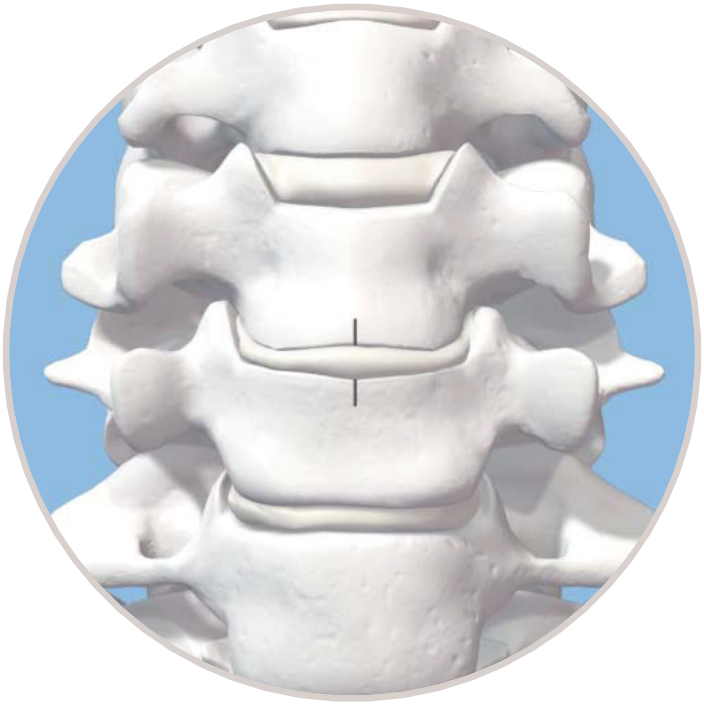
Expose the operative level via a standard transverse approach to the anterior cervical spine. Verify the operative level with fluoroscopy.

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 4)**.

3. Demonstrating Feet Placement



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



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

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.

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.

Awl/Punch
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

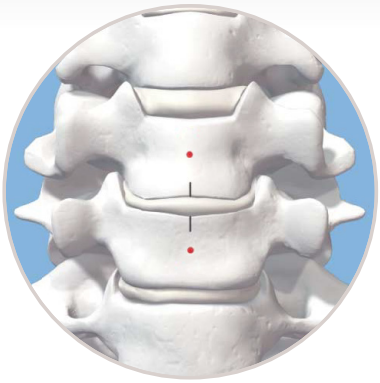
please NOTE *Performing a complete and meticulous discectomy, decompression, and remobilization of the disc space is critical to the success of the surgery. The surgeon must remobilize the diseased segment and restore the disc height prior to implantation of the prodisc C Vivo Total Disc Replacement.*

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 5)**.

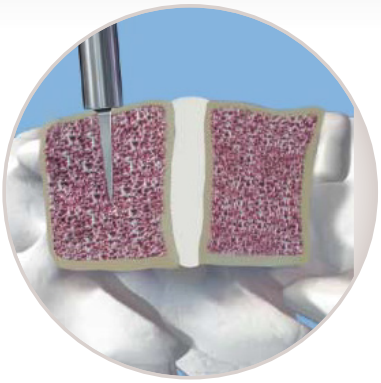
The technique for use is:

1. Perforate the anterior cortex with the awl, using lateral fluoroscopy to ensure its trajectory is parallel to the affected endplate **(Figure 6)**.
2. Estimate retainer screw length based on awl tip (12mm long).
3. Insert retainer screws with the self-retaining screwdriver **(Figure 7)**, 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 8)**.

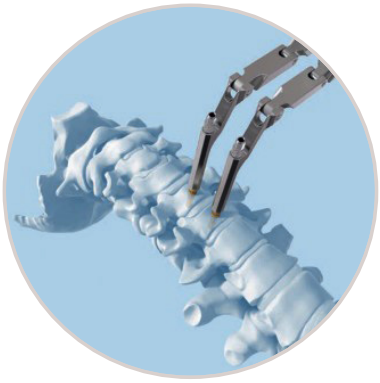
5. Ideal Positioning for Retainer Screw Insertion



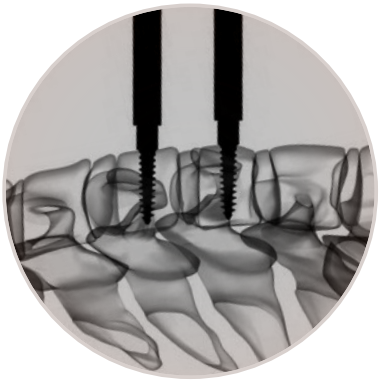
6. Perforating the Anterior Cortex with the Awl



7. Final Construct of the Retainer Over the Screws



8. 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 retainer screws; lock it in place with retainer nuts **(Figure 9)**.

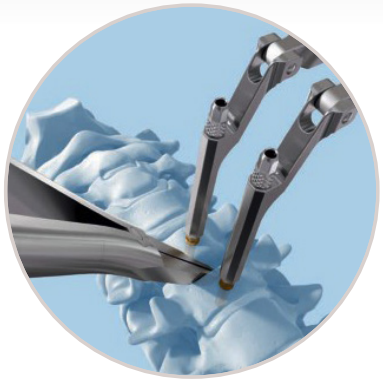
Apply light pretension to the operative disc space with the retainer—do not apply enough force to distract the segment. Create an anterior annulotomy centered on midline and wide enough to accommodate the implant. Perform the preliminary discectomy using standard rongeurs and curettes.

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 10 & 11)**.

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.

9. The Vertebral Body Retainer Locked on the Retainer Screws

10. Inserting the Vertebral Distractor



11. 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.*

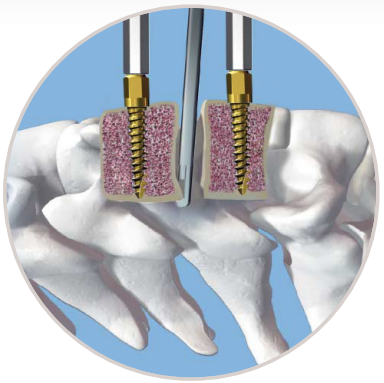
please NOTE *The vertebral body retainer is not intended to distract the segment as with a Caspar retractor. Distraction is achieved with the vertebral distractor.*

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 12)**.

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.

12. 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 wieght-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

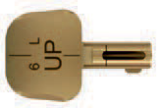
Define the Implant Size

After completing discectomy and decompression, use the trial implants to determine the appropriate disc height and size of footprint.

The goal is to select a prosthesis with the best possible anatomical fit, using the largest footprint and the smallest height needed to restore the natural disc.

Prosthesis center of rotation (COR) should be positioned at the midline of the vertebral body or slightly posterior. The implant should cover the majority of the vertebral body endplate.

Insert the inner shaft of the holder for trial implants into the corresponding sleeve and push it until it snaps into place **(Figure 13)**. Select the appropriate trial implant and make sure that its protrusion is captured in the stop of the shaft before assembling **(Figures 14 & 15)**. Ensure that the shaft is fully screwed in before use.



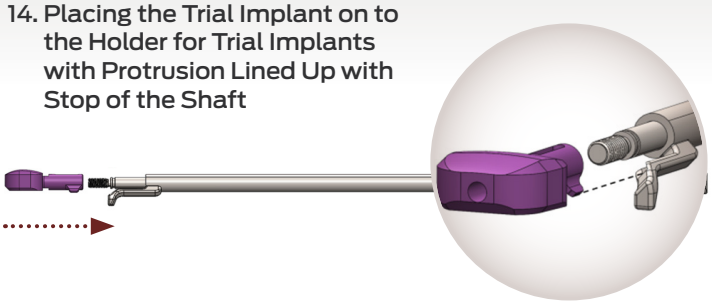
prodisc® C Vivo Trials (M, MD, L, LD, XL, XLD)
03.670.925 - 03.670.977

Mallet
03.820.113

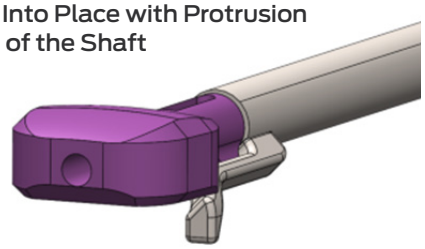
Holder for Trial Implants
03.670.204

13. Inserting the Inner Shaft of the Holder for Trial Implants into the Corresponding Sleeve

14. Placing the Trial Implant on to the Holder for Trial Implants with Protrusion Lined Up with Stop of the Shaft



15. Trial Implant Seated Into Place with Protrusion Captured in the Stop of the Shaft



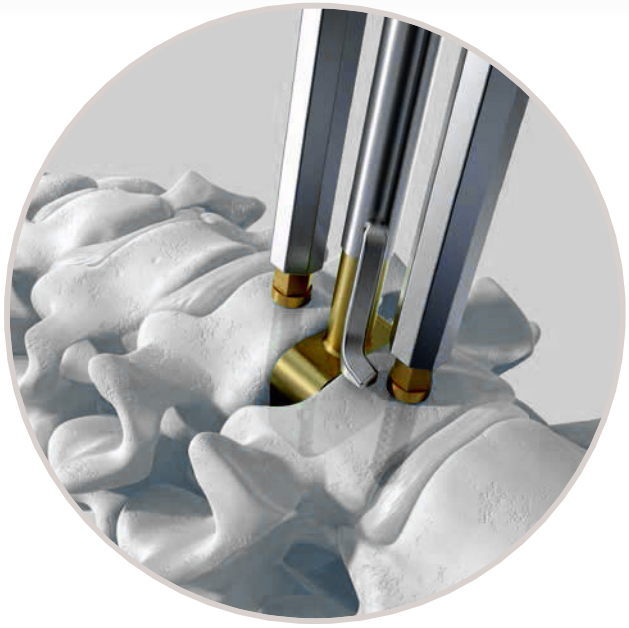
Align the trial implant with the midline and advance it under fluoroscopic control into the disc space by tapping it cautiously.

In the lateral fluoroscopy view, the optimal position of the trial implant is given by the best possible anatomical fit **(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 **(Figure 17)**.

Now release the distraction to determine if the trial implant height is appropriate for the patient. Its height should be the smallest height to match normal adjacent discs. When the correct size for the implant is determined, the trial implant is removed (apply slight distraction with the vertebral retainer if necessary).

16. Verifying Trial Depth and Fit with Lateral Fluoroscopy

17. Trial Centered on the Vertebral Body Midline



please NOTE

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

Avoid kyphotic position of the corresponding vertebrae.

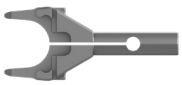
Do not unscrew stop more than 4 mm or contact to trial implant may be lost. Use next size trial implant instead.

Implantation (Cont'd)

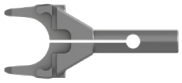
Implant Insertion: Preparation

Assemble the shaft for the Implant Holder. Open the packaging of the implant and follow these steps:

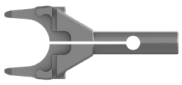
1. Choose Spacer Clamp size M/MD, L/LD or XL/XLD corresponding to the implant.
2. Attach the appropriate Spacer Clamp to the prosthesis until the arms snap into the holding features in the implant **(Figure 18)**.
3. Attach the corresponding Implant Holder (M/MD, L/LD or XL/XLD) to the Spacer Clamp, making sure that the lateral projections of the Spacer Clamp are captured in the arms of the Implant Holder.
4. Tighten the Implant Holder to the Spacer Clamp turning the head of the inner shaft clockwise.
5. Pull the implant en-bloc out of the packaging tray.



Spacer Clamp M/MD (Heights 5mm - 7mm)
03.670.305 - 03.670.307



Spacer Clamp L/LD (Heights 5mm - 7mm)
03.670.315 - 03.670.317



Spacer Clamp XL/XLD (Heights 5mm - 7mm)
03.670.325 - 03.670.327

Mallet
03.820.113

Implant Holder
03.670.201 - 03.670.203

Shaft for Implant Holder
03.670.213

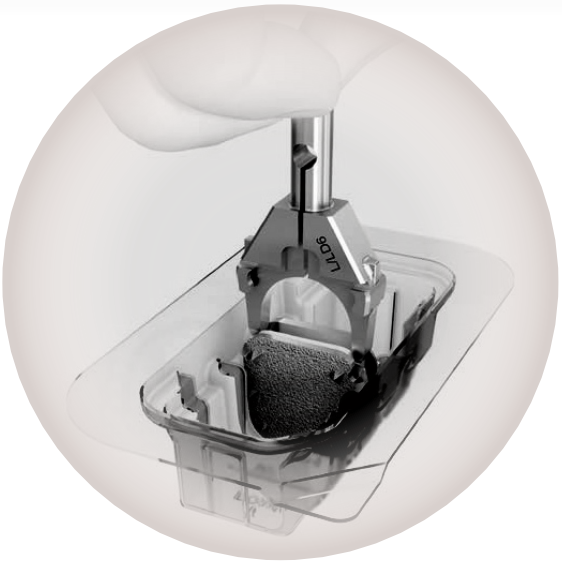
Stop for Implant Holder (Optional)
03.670.212

Short Screwdriver
IN1444

Positioner (Optional)
03.670.207

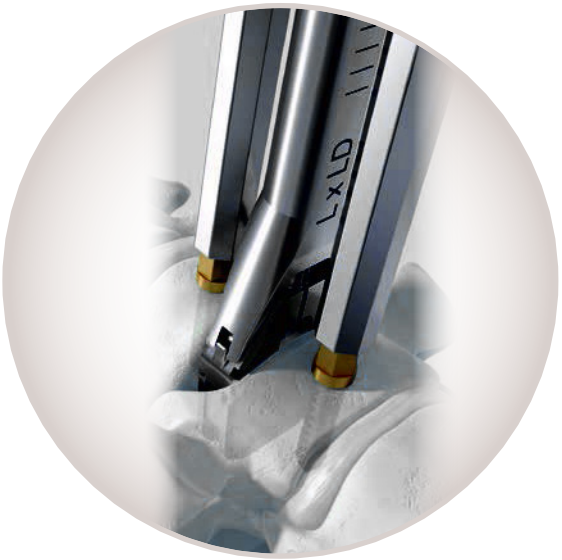
Optionally, the stop can be attached to the implant holder **(Figures 20 & 21)**.

18. Attaching the Spacer Clamp to the Implant

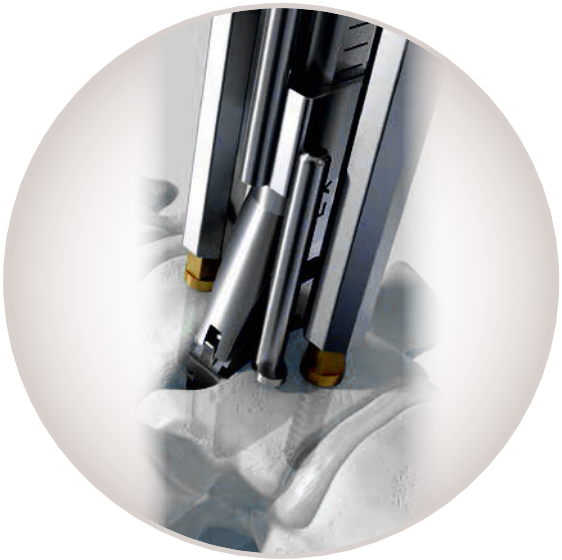


19. Fully Assembled Implant Holder with Shaft, Spacer Clamp, and Implant

20. Implant Holder without Stop



21. Implant Holder with Stop



Implantation (Cont'd)

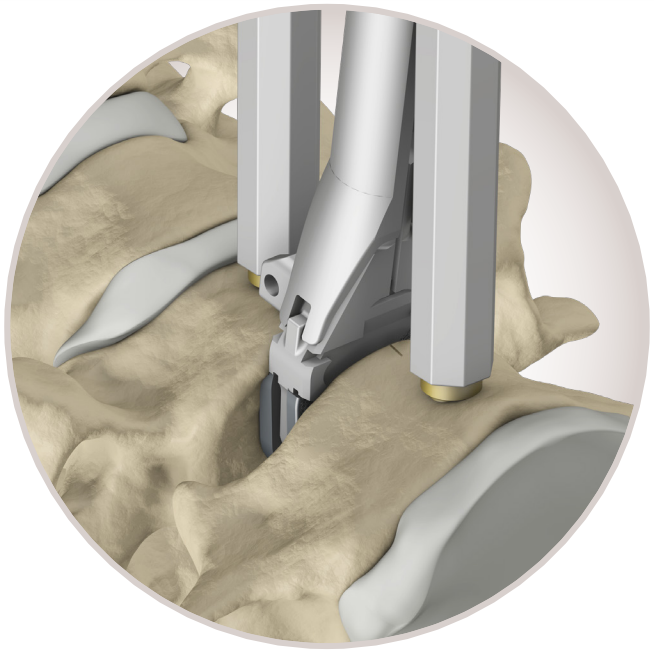
Implant Insertion: Inserting the Implant

Apply distraction as necessary, to facilitate the insertion of the implant.

Ensure that the black midline on the superior endplate faces cranially and align it with the midline marking of the vertebral body **(Figure 22)**.

Under lateral fluoroscopic control, advance the implant into its final position providing the best possible anatomical fit with the vertebral bodies **(Figure 23)**. 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.

22. Inserting the Implant with the Assembled Implant Holder and Spacer Clamp



23. Advancing the Implant Under Fluoroscopy

The Spacer Clamp includes two grooves that visualize the anterior margin of the implant under lateral fluoroscopy.

Once the correct position of the implant is confirmed under fluoroscopy, release the retainer and apply slight compression with the retainer. Slight compression from the retainer will help the spikes on the implant to penetrate into the vertebral bodies.

Implant Insertion: Releasing the Implant

To release the connection between the Spacer Clamp and implant, follow the two steps below:

1. Rotate the shaft of the implant holder two full turns in the counterclockwise direction.
2. Move the implant holder laterally—left-to-right a few times **(Figure 24)**—until the spacer clamp disconnects from the implant **(Figure 25)**.

Step by step remove the locking nuts, the vertebral body retainer and the retainer screws. Close surgical wound in a routine fashion.

24. **Removing the Assembled Implant Holder and Spacer Clamp from the Implant**

25. **Assembled Implant Holder and Spacer Clamp Released from the Implant**

please NOTE *Copious saline lavage is recommended to remove osteogenic stimuli (blood/bone marrow).*

Removal Procedure

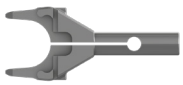
If a prodisc® **C Vivo** implant must be removed, the following technique is recommended.

Preparation

Start the procedure by distracting the prosthesis index level by using the vertebral distractor and the retainer system.

Attach the appropriate Remover Clamp to the corresponding Implant Holder with minimal thread engagement without tightening the head of the inner shaft of the implant holder.

Note: If the thread of the shaft is fully engaged and tightened, the Remover Clamp cannot be attached to the implant in the next step.

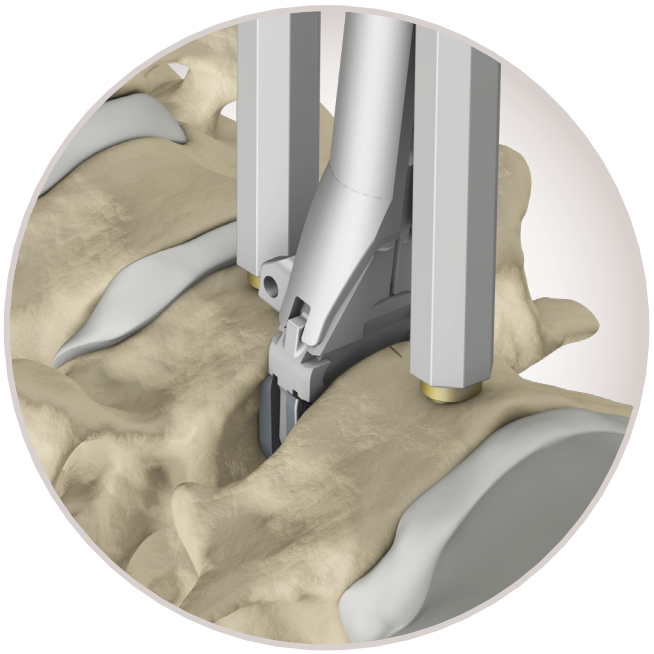


Remover Clamp (M/MD, L/LD, XL/XLD)
03.670.400, 03.670.410, 03.670.420

Implant Holder
03.670.201 - 03.670.203

Shaft for Implant Holder
03.670.213

26. Attaching the Assembled Implant Holder and Remover Clamp to the Inferior Endplate of the Implant



27. Verifying Implant Attachment Under Fluoroscopy

Attach the Remover Clamp assembly to the inferior endplate of the implant **(Figures 26 & 27)** and securely attach it by turning the head of the Implant Holder Shaft in clockwise direction.

Note: The surface edged with "inside" must be oriented towards the center of the disc space with respect to the implant endplate being removed.

Implant Removal

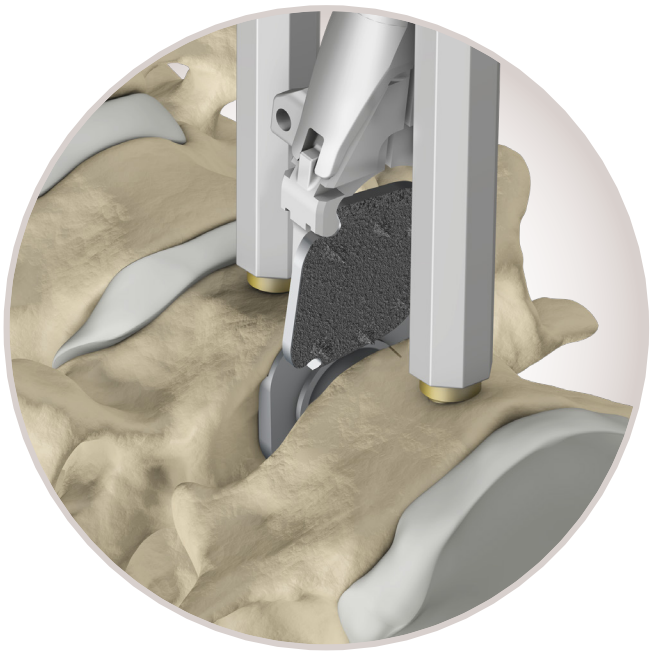
Remove the inferior endplate of the implant by cautiously pulling the Implant Holder **(Figure 28)**. Alternatively, the Slotted Mallet or Slide Hammer can be used to aid implant removal.

The superior endplate of the implant can be removed using the Remover Clamps **(Figure 29)** or alternatively suitable forceps.

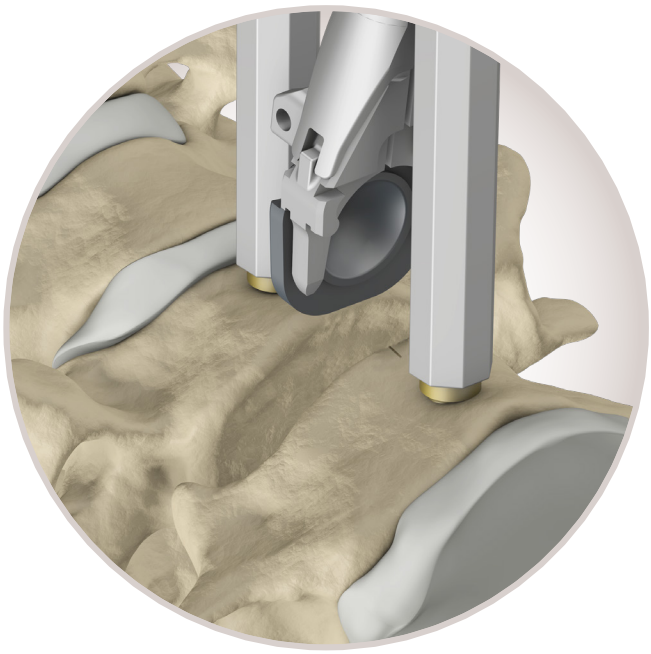
Slide Hammer
03.820.282

Mallet
03.820.113

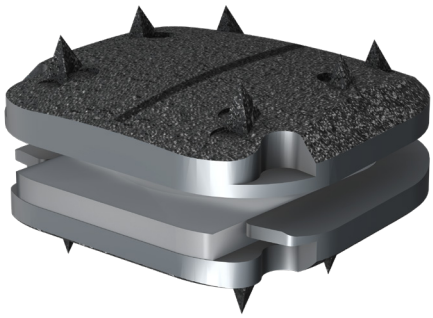
28. Removing the Inferior Endplate of the Implant with the Assembled Implant Holder and Remover Clamp



29. Removing the Superior Endplate of the Implant with the Assembled Implant Holder and Remover Clamp



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

Instruments: Retainer Screw System

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

Awl/Punch
03.820.100

Short Screwdriver
IN1444

Locking Nut
03.820.110

Vertebral Body Retainer
03.820.111/1

The vertebral body retainer is used to maintain the distraction achieved with the vertebral distractor.

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

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

Vertebral Distractor
03.820.112

Instruments: Trial Implants

Trial implants are used to define the correct size of the implants (height, width and depth).

Trial Implant M, 15mm x 12mm
5mm Height 03.670.925
6mm Height 03.670.926
7mm Height 03.670.927

Trial Implant MD, 15mm x 14mm
5mm Height 03.670.935
6mm Height 03.670.936
7mm Height 03.670.937

Trial Implant L, 17mm x 14mm
5mm Height 03.670.945
6mm Height 03.670.946
7mm Height 03.670.947

Trial Implant LD, 17mm x 16mm
5mm Height 03.670.955
6mm Height 03.670.956
7mm Height 03.670.957

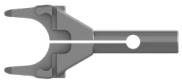
Trial Implant XL, 19mm x 16mm
5mm Height 03.670.965
6mm Height 03.670.966
7mm Height 03.670.967

Trial Implant XLD, 19mm x 18mm
5mm Height 03.670.975
6mm Height 03.670.976
7mm Height 03.670.977

Depth	Width		
	15mm	17mm	19mm
18mm			
16mm			
14mm			
12mm			

Holder for Trial Implants
03.670.204

Instruments: For Insertion



Spacer Clamp, M/MD

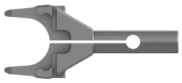
5mm Height	03.670.305
6mm Height	03.670.306
7mm Height	03.670.307

Spacer Clamp, L/LD

5mm Height	03.670.315
6mm Height	03.670.316
7mm Height	03.670.317

Spacer Clamp, XL/XLD

5mm Height	03.670.325
6mm Height	03.670.326
7mm Height	03.670.327



Removal Clamp

M/MD	03.670.400
L/LD	03.670.410
XL/XLD	03.670.420

The preassembled and sterile packed prodisc® C Vivo prosthesis can be easily secured on the implant holder. The spacer clamp can be easily attached onto the preassembled and sterile packed prodisc® C Vivo prosthesis.

Implant Holder

M/MD	03.670.201
L/LD	03.670.202
XL/XLD	03.670.203

Shaft for Implant Holder
03.670.213

Stop for Implant Holder
03.670.212

Slide Hammer for Cervical Spine
03.820.282

Mallet
03.820.113

Positioner
03.670.207

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.

CENTINEL SPINE

PA Operations: 900 Airport Rd, Ste. 3B, West Chester, PA 19380 USA
EMEA Office: Grafenauweg 8, 6300 Zug, Switzerland

Email: csemea@centinelspine.com
Web: www.centinelspine.com