

# CENTINEL SPINE®

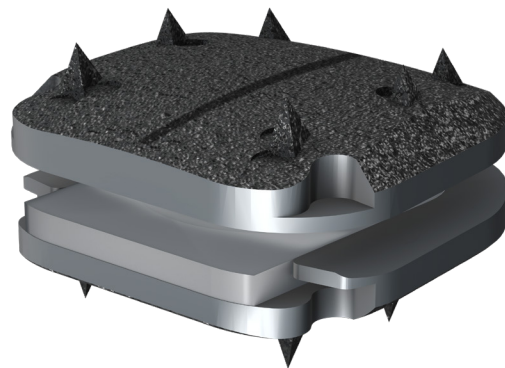


## prodisc® C Vivo

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

---

### SURGICAL TECHNIQUE GUIDE



This Surgical Technique Guide is  
For Use with the Silver Instrument Case



Silver

# prodisc® C Vivo

Cervical Total Disc Replacement System

## TABLE OF CONTENTS

Introductions	3
Features & Benefits	4
Kinematics	5
Indications, Warnings, & Precautions	6 - 9
Patient Positioning	10 - 11
Exposure	11
Discectomy, Decompression, & Remobilization	12 - 15
Implantation	16 - 21
Define the Implant Size	16 - 17
Implant Insertion: Preparation	18 - 19
Implant Insertion: Inserting the Implant	20 - 21
Implant Insertion: Releasing the Implant	21
Removal Procedure	22 - 23
Preparation	22 - 23
Implant Removal	23
Implants	24
Instruments	25 - 27
References	28

**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

## 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<sup>1</sup> devices implanted. **STALIF** still remains the only Stand-Alone device demonstrating biomechanical equivalence to anterior plate & cage in independent peer-reviewed publications.<sup>2,3</sup>

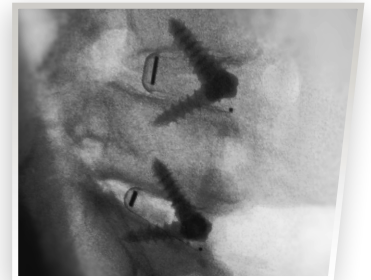
**STALIF** technology incorporates a proven design rationale based on AO principles of fracture fixation and Wolff’s Law of Bone Healing. The No Profile design utilizes unique integrated compressive lag fixation technology to enhance stability and compress endplates to the cage and graft material. The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

## Clinically-Proven Motion Preservation

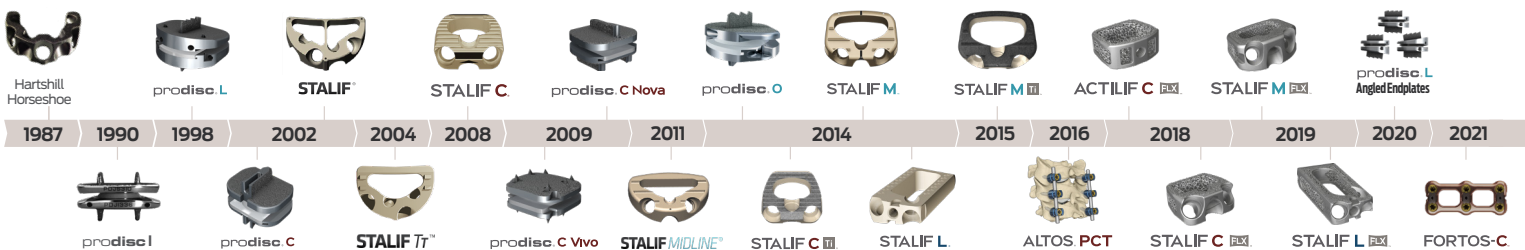
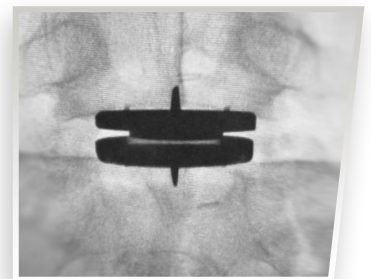
Centinel Spine couples its market-leading fusion portfolio with best-in-class prodisc Total Disc Replacement (TDR) technology. Centinel Spine offers an unmatched number of six cervical / lumbar TDR products, globally, and is the only company with both lumbar and cervical approval in the U.S. No other 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.<sup>6</sup>

**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%.<sup>7</sup>

## STALIF® For Fusion



## prodisc® For Motion



# prodisc® C Vivo

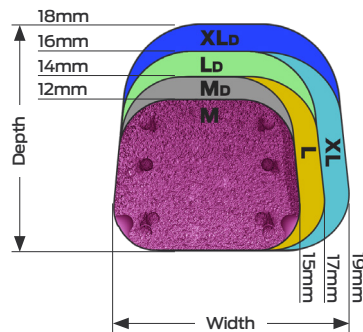
## Features & Benefits

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.



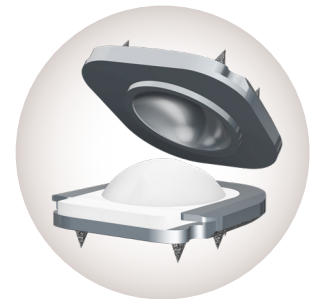
### Proven Materials

- 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



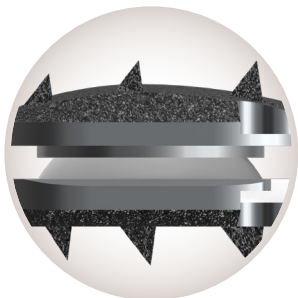
### Anatomical Sizing

- 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



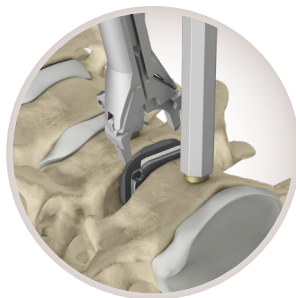
### Kinematics

- 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

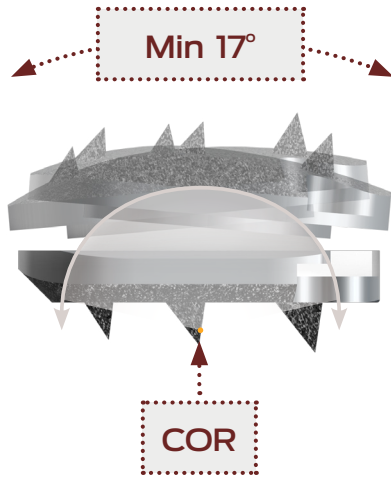
- Simple technique with two main steps: trial and implant insertion

# 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.

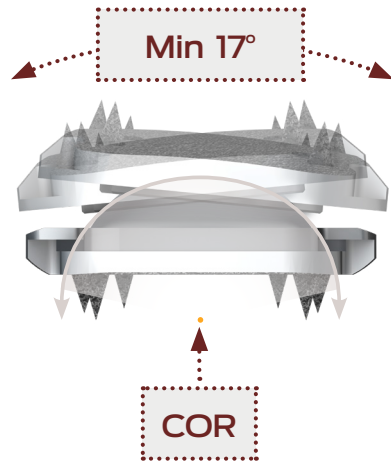
## Flexion/Extension

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



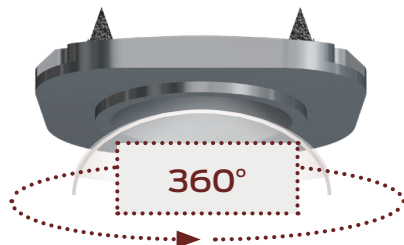
## Lateral Bending

- 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



## 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 prosthesis 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 2°C 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 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.*

## 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 on the upper extremities (**Figures 1, 2, 3**).

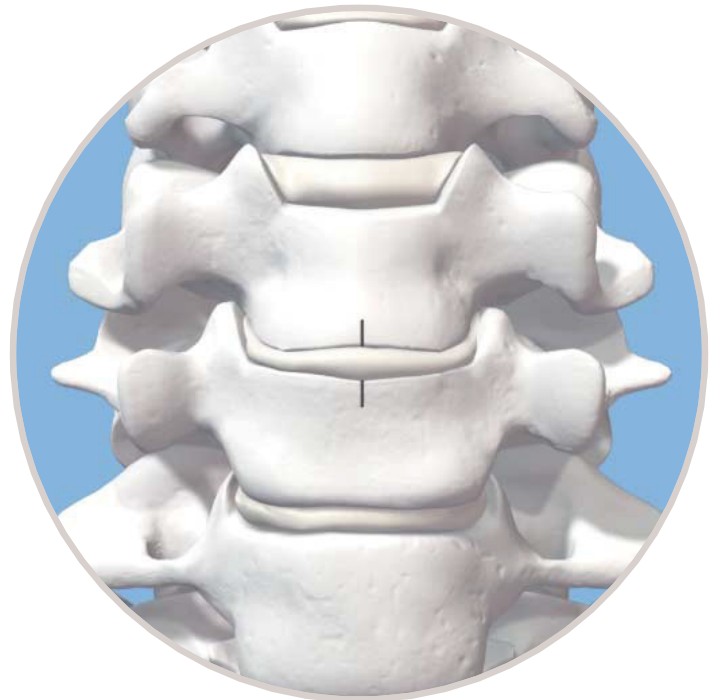
Expose the operative level via a standard transverse approach to the anterior cervical spine. Verify the operative level with fluoroscopy.

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

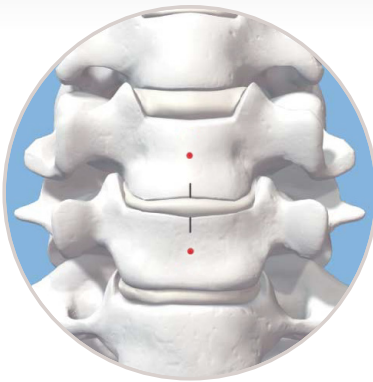
Performing a complete and meticulous discectomy, decompression, and remobilization of the disc space is critical to the success of the surgery. The surgeon must remobilize the diseased segment and restore the disc height prior to implantation of the prodisc C Vivo Total Disc Replacement.

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**).

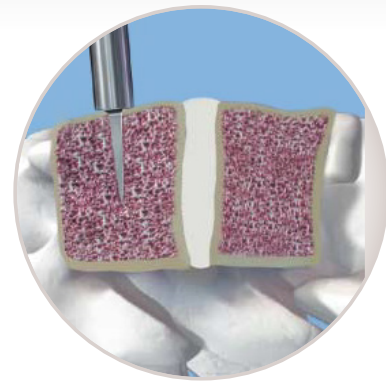
The technique for use is:

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**).

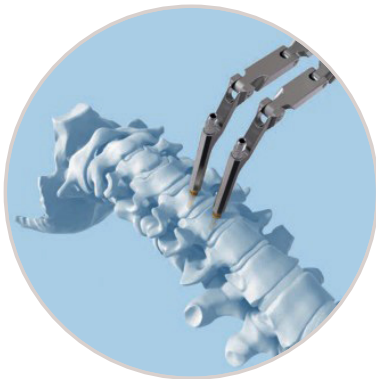
5. Ideal Positioning for Retainer Screw Insertion



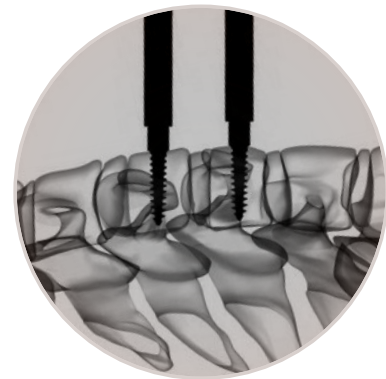
6. Perforating the Anterior Cortex with the Awl



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.

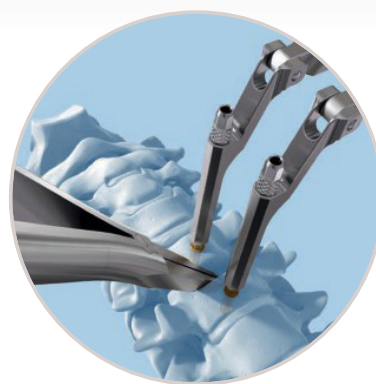
Insert the vertebral distractor to the posterior aspect of the disc space under lateral fluoroscopy. Ensure the distractor tips reach the posterior margin of the vertebral bodies to avoid penetration of the vertebral end plates (**Figures 10 & 11**).

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

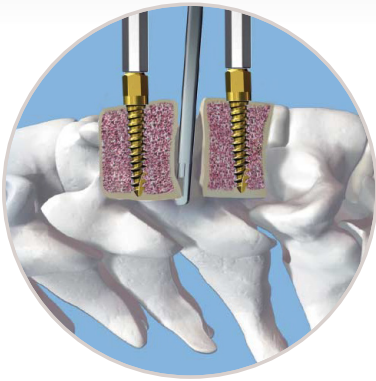
The vertebral body retainer is not intended to distract the segment as with a Caspar retractor. Distraction is achieved with the vertebral distractor.

Avoid overdistract 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 weight-bearing portion of the endplate
  - Remodel with Kerrison rongeurs or with careful use of a burr

**tech TIP**

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

**check POINT**

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

## Implantation

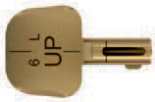
### Define the Implant Size

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

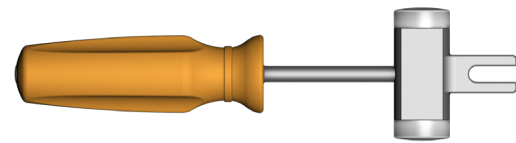
**The goal is to select a prosthesis with the best possible anatomical fit, using the largest footprint and the smallest height needed to restore the natural disc.**

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

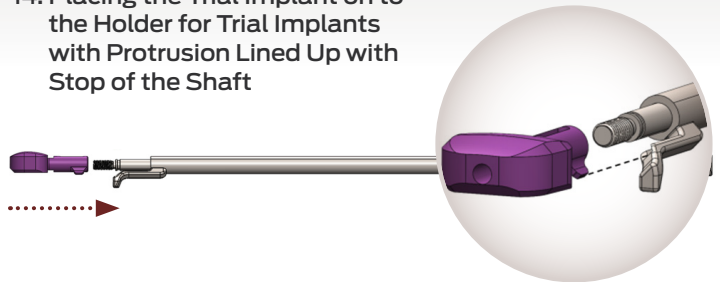


**Holder for Trial Implants**  
03.670.204

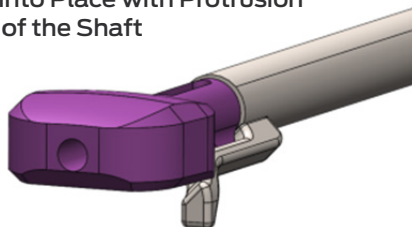
13. Inserting the Inner Shaft of the Holder for Trial Implants into the Corresponding Sleeve



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.

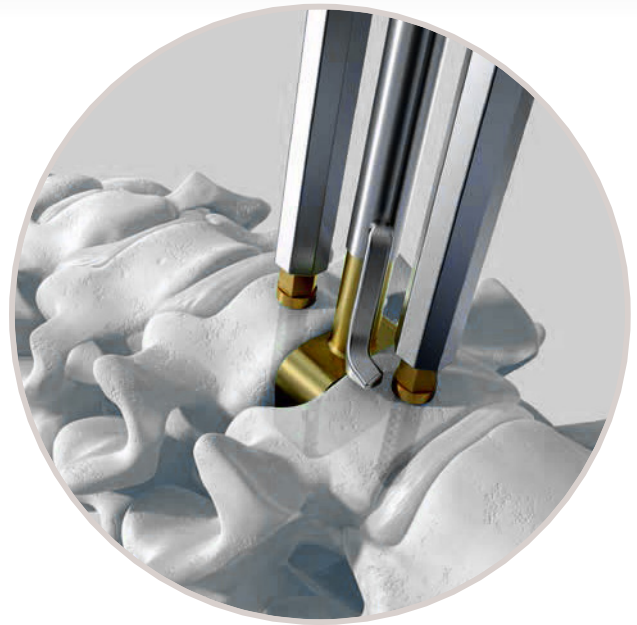
In the lateral fluoroscopy view, the optimal position of the trial implant is given by the best possible anatomical fit (**Figure 16**). If the stop does not allow the trial implant to go deep enough, the stop can be adjusted by turning the trial shaft counter clockwise (1 rev = 0.5 mm), enabling the 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. Use two fingers to rotate the Shaft of the Implant Holder clockwise to tighten Spacer Clamp into Implant Holder.  
**CAUTION: Do not over-tighten.**
5. Pull the implant en-bloc out of the packaging tray.

**Note: When tightened, there will still be some toggle of the implant on the Spacer Clamp, per the design (especially on the superior endplate).**



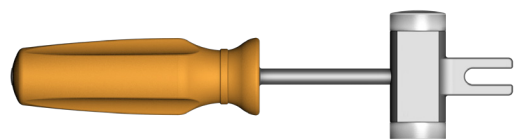
**Spacer Clamp M/MD (Heights 5mm - 7mm)**  
03.670.305 - 03.670.307



**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



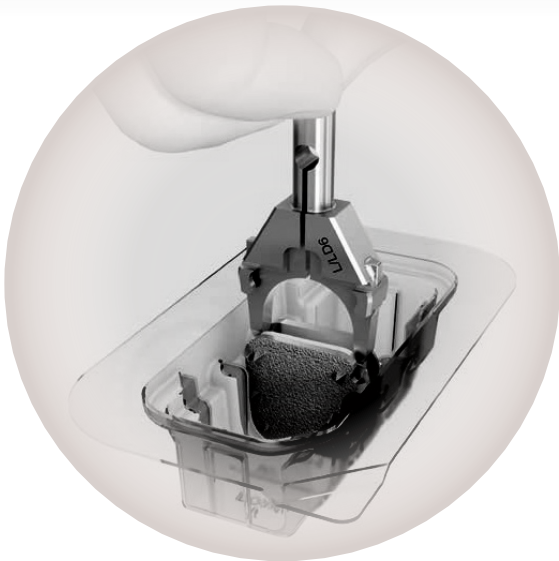
**Positioner (Optional)**  
03.670.207

**please  
NOTE**

**When tightened, there will still be some toggle of the implant on the Spacer Clamp, per the design (especially on the superior endplate).**

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

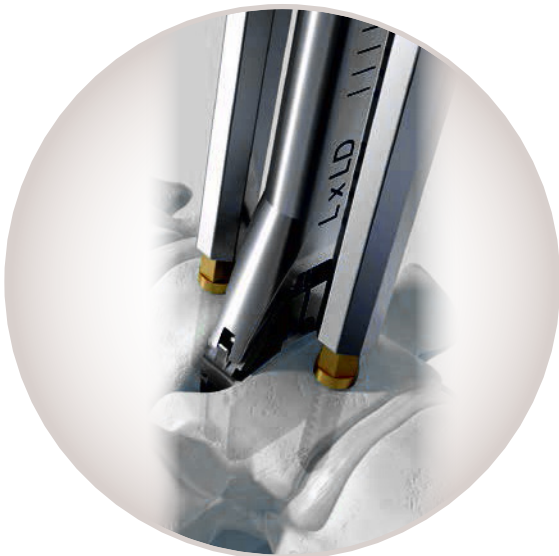
18. Attaching the Spacer Clamp to the Implant



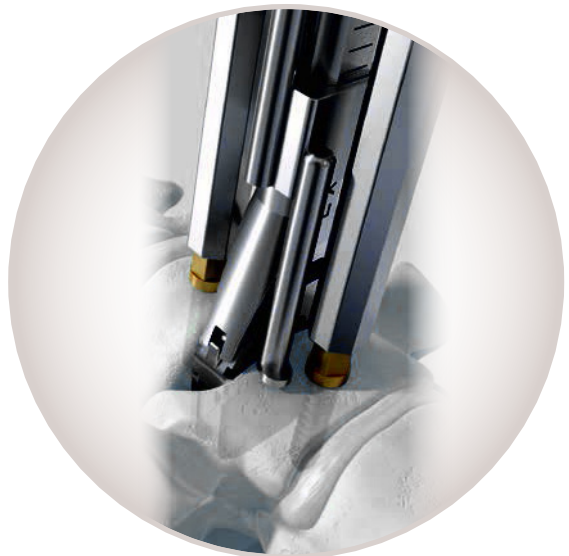
19. Fully Assembled Implant Holder with Shaft, Spacer Clamp, and Implant



20. Implant Holder without Stop



21. Implant Holder with Stop



## Implantation (Cont'd)

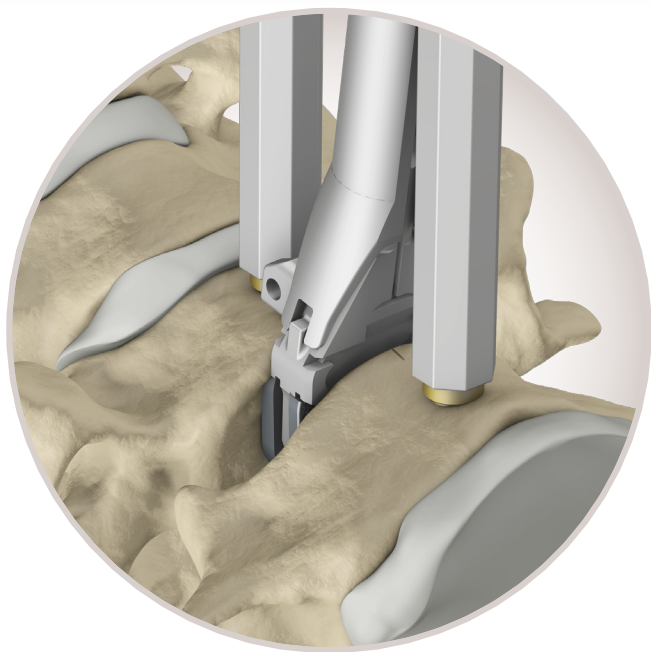
### Implant Insertion: Inserting the Implant

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 in a left-to-right (or right-to-left) motion to approximately 30 degrees off midline and pull up until implant release occurs (**Figures 24 & 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).

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

## 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

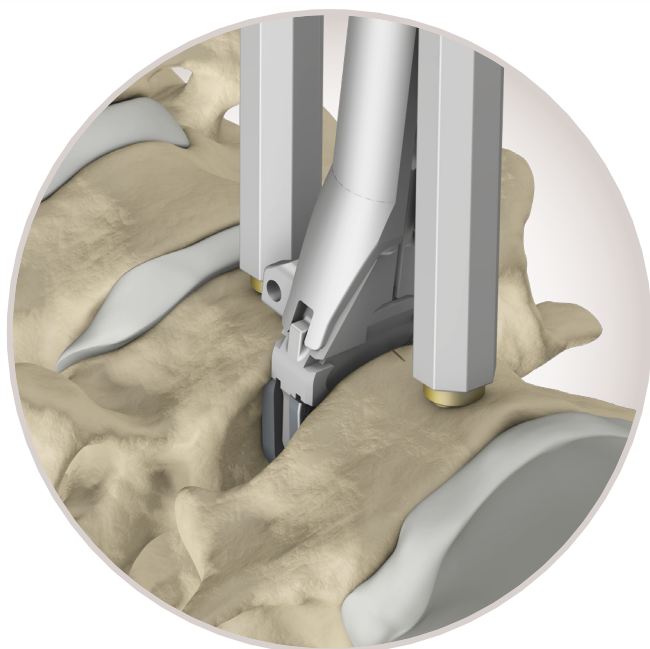


**Implant Holder**  
03.670.201 - 03.670.203



**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.**

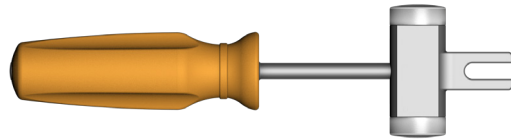
### Implant Removal

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.

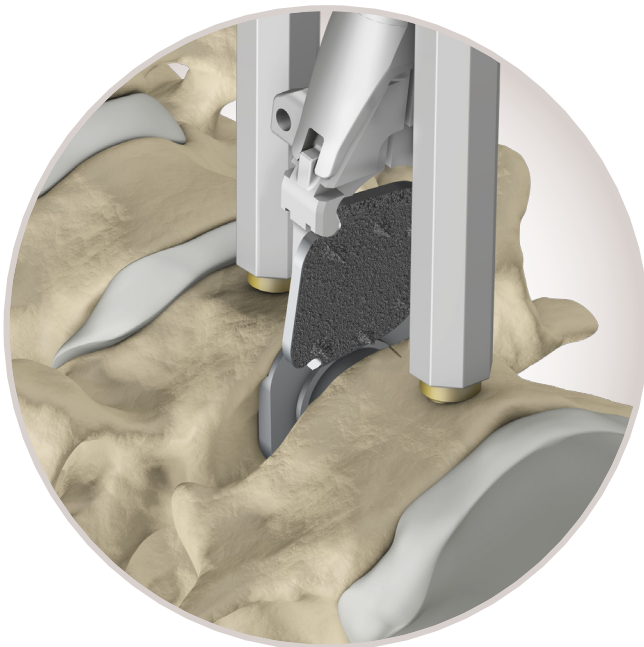


**Slide Hammer**  
03.820.282

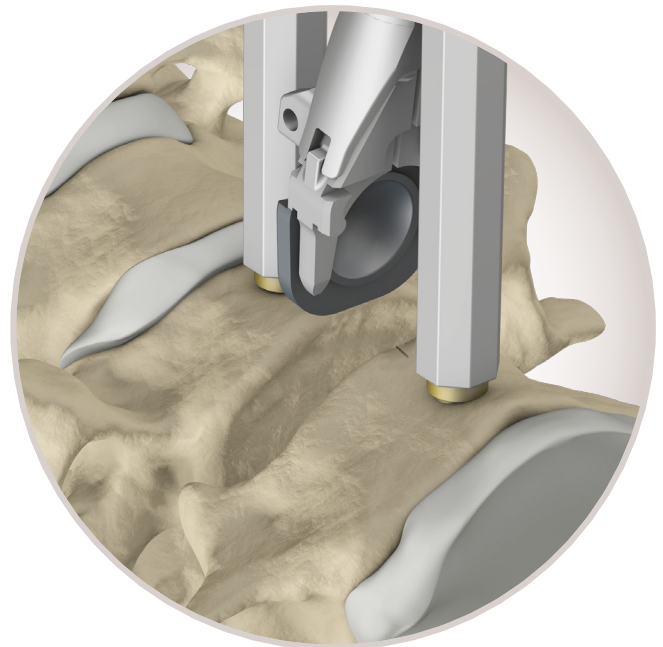


**Mallet**  
03.820.113

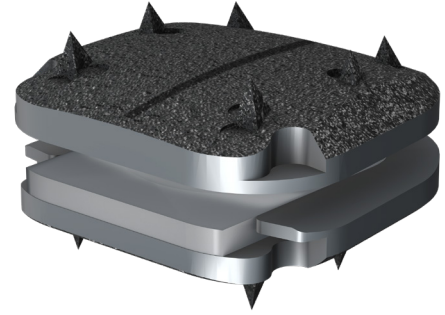
28. Removing the Inferior Endplate of the Implant with the Assembled Implant Holder and Remover Clamp



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
<b>M</b>	12mm	15mm	PDVM5	PDVM6	PDVM7
<b>MD</b>	14mm	15mm	PDVMD5	PDVMD6	PDVMD7
<b>L</b>	14mm	17mm	PDVL5	PDVL6	PDVL7
<b>LD</b>	16mm	17mm	PDVLD5	PDVLD6	PDVLD7
<b>XL</b>	16mm	19mm	PDVXL5	PDVXL6	PDVXL7
<b>XLD</b>	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

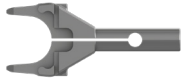
Depth	Width		
	15mm	17mm	19mm
18mm			
16mm			
14mm			
12mm			



### Holder for Trial Implants

03.670.204

## Instruments: For Insertion



### Spacer Clamp, M/MD

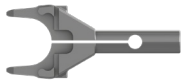
5mm Height	03.670.305
6mm Height	03.670.306
7mm Height	03.670.307

### 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



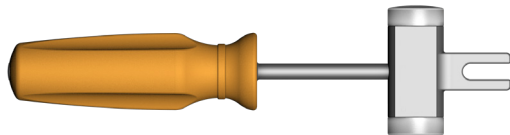
### Stop for Implant Holder

03.670.212



### Slide Hammer for Cervical Spine

03.820.282



### Mallet

03.820.113



### Positioner

03.670.207

## References

<sup>1</sup> Since 1991, Hartshill Horseshoe, STALIF®, STALIF TT®, STALIF C®, STALIF MIDLINE®, STALIF L™

<sup>2</sup> Stein MI, et al. *The Spine Journal*, 14(1): 128-136, 2014.

<sup>3</sup> A.N. Nayak, et al. *The Spine Journal*, 2014.

<sup>4</sup> Interim Report of Prospective STALIF C Study – Protocol SC-001.

<sup>5</sup> 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.

<sup>6</sup> Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2017.

<sup>7</sup> Based upon US complaint handling units for prodisc since launch in 2006.

