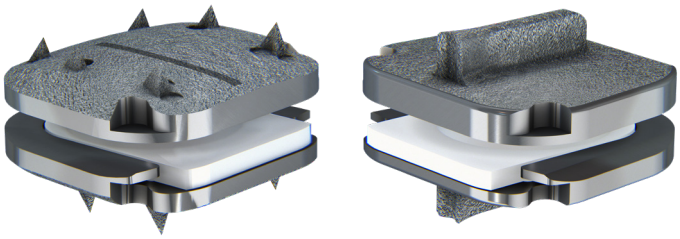
CENTINEL SPINE®

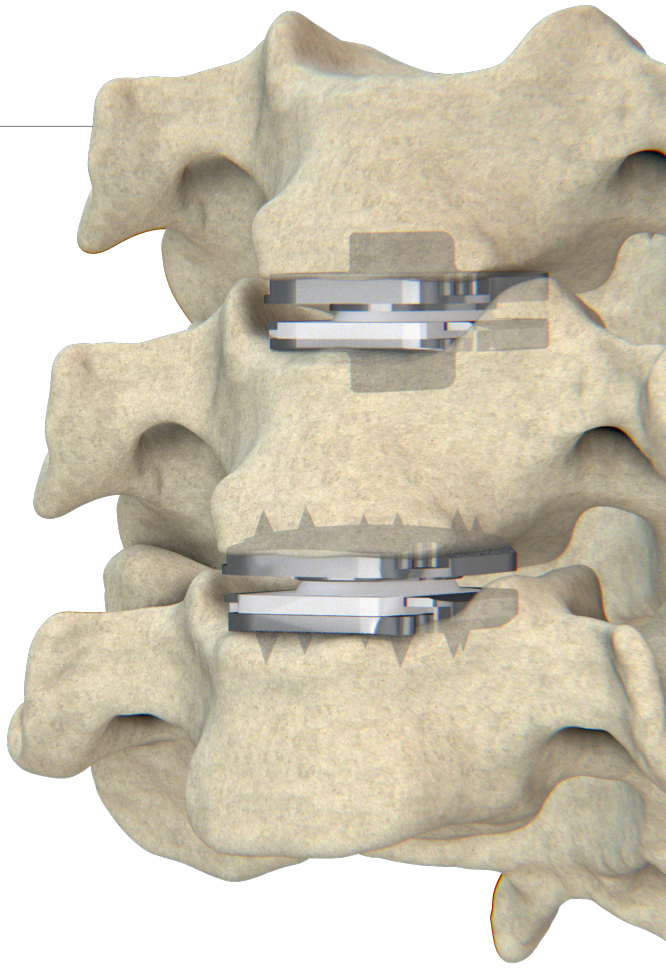
prodisc® C Vivo | prodisc® C SK

Cervical Total Disc Replacement System

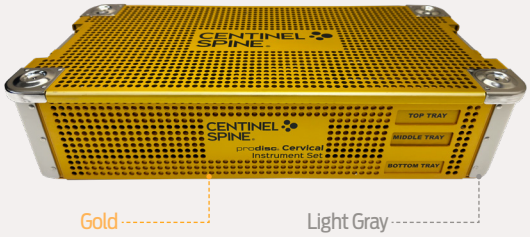
SURGICAL TECHNIQUE GUIDE

With prodisc Cervical Gen2 Instrument Set





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



prodisc® C Vivo | prodisc® C SK

Cervical Total Disc Replacement System

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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®

The leading global spine company focused exclusively on cervical and lumbar total disc replacement

ABOUT CENTINEL SPINE, LLC

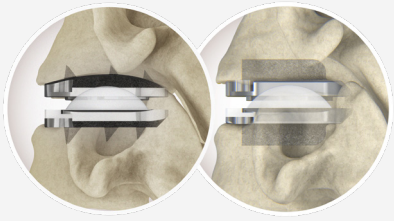
SINCE 1990 · 35+ YEARS OF CLINICAL SUCCESS

Centinel Spine®, LLC is the leading global medical device company exclusively focused on addressing cervical and lumbar spinal disease with prodisc®, the most complete and proven total disc replacement (TDR) technology platform in the world.

The Company's prodisc technology is the most studied and clinically-proven TDR system across the globe, validated by over 540 published papers[1] and more than 275,000 implantations[2]. Centinel Spine's prodisc is the only TDR technology with multiple motion-preserving cervical and lumbar anatomic solutions, allowing the surgeon to Match-the-Disc™ to each patient's anatomy. Additionally, prodisc is the only TDR technology in the U.S. approved for one-and two-level use in both the cervical* and lumbar spine.

prodisc® C CERVICAL PORTFOLIO

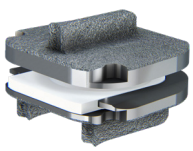
The Only Cervical Total Disc Replacement System that Allows **Matching the Disc** to the Needs of the Patient & Surgeon



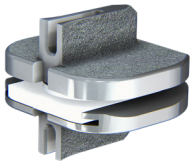
THE POWER OF 4 FDA-APPROVED cTDR DEVICES*

prodisc. C Vivo

prodisc. C SK



prodisc. C Nova



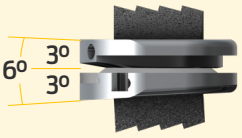
prodisc. C

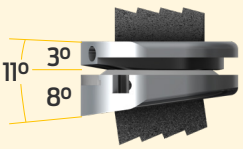
prodisc® L ANATOMIC ENDPLATES™

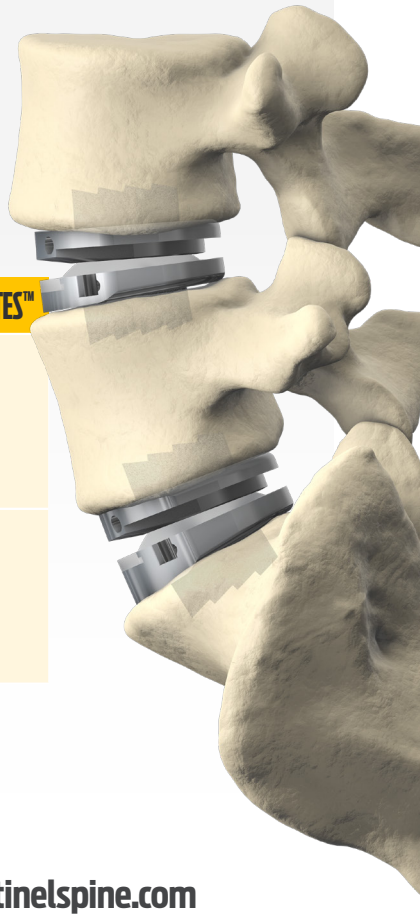
Designed to Better **Match Patient Anatomy**, Allowing a Customized Fit Throughout the Full Range of Indicated Levels (L3-S1)

prodisc. L

NOW AVAILABLE: ANATOMIC ENDPLATES™





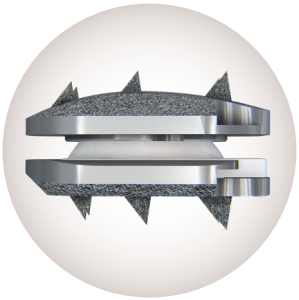


* prodisc C Vivo & prodisc C SK are approved for both 1- and 2-level usage. prodisc C Nova & prodisc C are approved for 1-level usage only.

MATCH THE DISC™

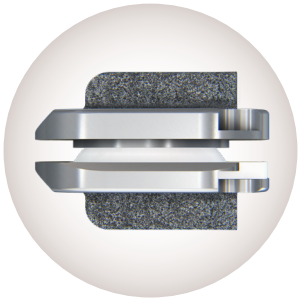
LEARN MORE:
match.centinelspine.com

Introduction to prodisc® C Vivo & prodisc® C SK



prodisc® C Vivo

- Anatomical domed, superior endplate shape for optimized implant positioning
- The unique combination of an anatomically-designed superior endplate with lateral spikes provides immediate fixation strength equivalent to prodisc C[3]

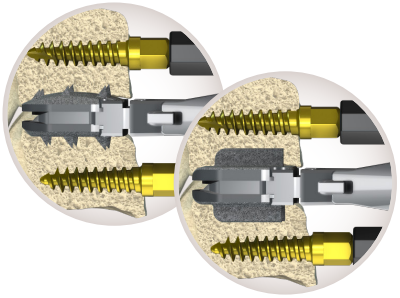


prodisc® C SK

- Proven flat endplate design for optimized implant positioning
- Low Profile central keels provides immediate fixation strength equivalent to prodisc C[3]

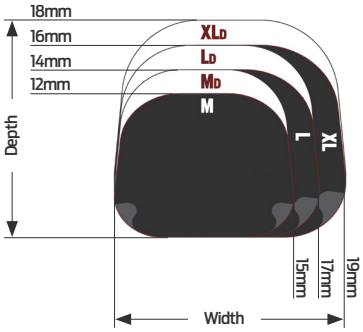
Powered by prodisc CORE

- The fixed core and optimized core radius together provide stability and controlled predictable motion[4,5]



Simple Surgical Technique

- **prodisc C Vivo**: Streamlined, One-Step Keel-less Implantation
- **prodisc C SK**: Low-Profile Keel Allows Streamlined Keel Preparation Technique



Anatomical Footprints

- Trapezoidal footprint to maximize endplate coverage & optimize fit within the uncinate process
- 36 options to accommodate anatomical variation: 2 endplates, 6 footprints and 3 heights (5-7mm)

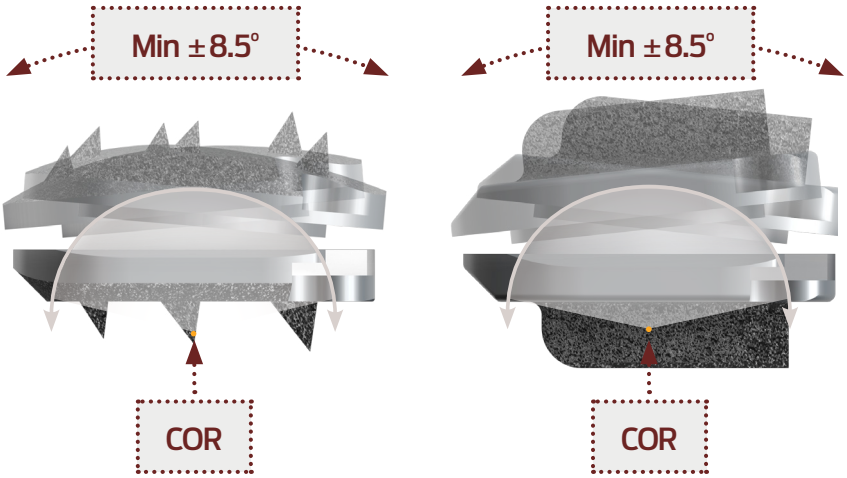
Proven Materials

- Proven articulating surfaces: UHMWPE on CoCrMo alloy
- Inlay made from ultra-high molecular weight polyethylene (UHMWPE)
- Secondary fixation from the plasma-sprayed titanium coating on bone contacting surfaces

prodisc C Vivo & prodisc C SK have a center of rotation which is located just below the inferior endplate of the prosthesis. Anteriorposterior (AP) translation occurs with flexion/extension rotation.

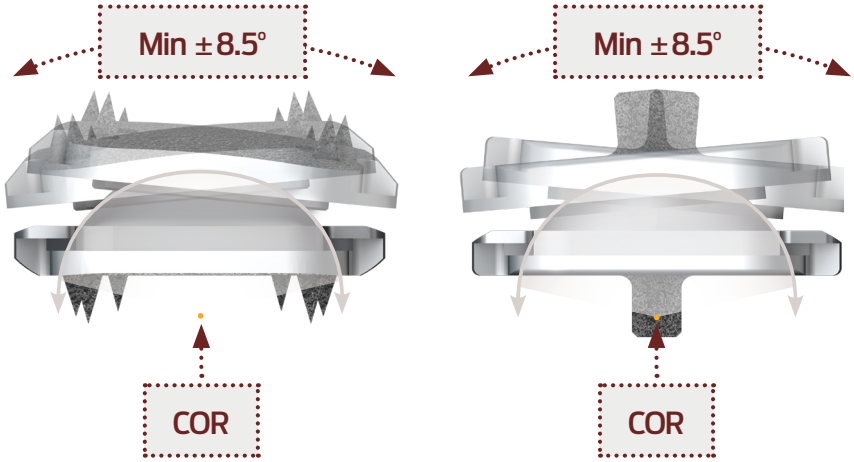
Flexion/Extension

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



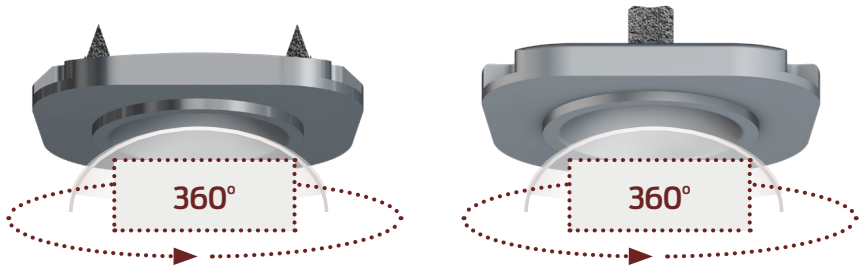
Lateral Bending

- 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



INSTRUCTIONS FOR USE

CAUTION ***Federal (USA) law restricts this device to sale by or on the order of a physician who has appropriate training or experience.***

Important Information:

The **prodisc C Vivo** & **prodisc C SK** Cervical Total Disc Replacement Implants are provided sterile. The instruments are provided non-sterile and must be sterilized using the validated instructions.

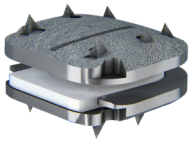
Safety Precautions:

Please read these instructions for use and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Contents

The **prodisc C Vivo** Cervical Total Disc Replacement Implant is made up of three components:

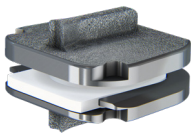
- **prodisc C Vivo** superior endplate
- **prodisc C Vivo** inferior endplate
- **prodisc C Vivo** inlay



prodisc. C Vivo

The **prodisc C SK** Cervical Total Disc Replacement Implant is made up of three components:

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



prodisc. C SK

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

Device Description

The **prodisc C Vivo** & **prodisc C SK** devices are indicated for use in skeletally mature subjects for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The **prodisc C Vivo** & **prodisc C SK** are implanted using an anterior approach. Subjects should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the **prodisc C Vivo** & **prodisc C SK**.

The **prodisc C Vivo** & **prodisc C SK** are manufactured with cobalt chromium molybdenum alloy (Co-28Cr-6Mo (CoCrMo)) endplates and an ultra-high molecular weight polyethylene (UHMWPE) inlay. The **prodisc C Vivo** features six pegs oriented anterior-posterior on the lateral edges that anchor the devices to the vertebral bodies, while the **prodisc C SK** device features a midline keel oriented anterior-posterior.

The **prodisc C Vivo** & **prodisc C SK** devices are designed to allow for the total replacement of the diseased and/or damaged cervical disc while restoring disc height and providing the potential for motion at the affected vertebral segment. These devices are a line extension to the **prodisc C** device family, which have been used in the United States since PMA Approval on December 17, 2007.

Components of prodisc C Vivo & prodisc C SK

	prodisc C Vivo	prodisc C SK
Inferior Endplate	An inferior cobalt chromium molybdenum alloy (Co-28Cr-6Mo (CoCrMo)) plate with six pegs oriented anterior-posterior on the lateral edges (3 each) that are anchored to the superior endplate of the inferior vertebral body.	An inferior cobalt chromium molybdenum alloy (Co-28Cr-6Mo (CoCrMo)) plate with a midline keel oriented anterior-posterior that is anchored to the superior endplate of the inferior vertebral body.
Inlay	An ultra-high molecular weight polyethylene (UHMWPE) inlay that is preassembled and snap-locked into a tray detail in the inferior CoCrMo alloy plate and provides the inferior convex bearing surface.	An ultra-high molecular weight polyethylene (UHMWPE) inlay that is preassembled and snap-locked into a tray detail in the inferior CoCrMo alloy plate and provides the inferior convex bearing surface.
Superior Endplate	A superior CoCrMo plate with six pegs oriented anterior-posterior on the lateral edges (3 each) that are anchored to the inferior endplate of the superior vertebral body, and a highly polished concave bearing surface that articulates with the convex UHMWPE spherical dome.	A superior CoCrMo plate with a midline keel, which anchors to the inferior endplate of the superior vertebral body, and a highly polished concave bearing surface that articulates with the convex UHMWPE spherical dome.

Intended Use

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

Indications

The prodisc C Vivo & prodisc C SK are indicated for use in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The prodisc C Vivo & prodisc C SK are implanted using an anterior approach. Subjects should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the prodisc C Vivo & prodisc C SK.

Contraindications

- Fractures, infections, tumors
- Spinal stenosis by hypertrophic spondylarthrosis
- Cervical instability on resting (neutral) lateral or flexion-extension radiographs; translation greater than or equal to 3.5mm and/or greater than 11º of angular difference from either adjacent level
- Ossification of posterior longitudinal ligament (OPLL)
- Cervical anatomical deformity or mal-alignment (e.g., ankylosing spondylitis, scoliosis, kyphosis) at the operative or adjacent levels or anatomical compromise of the vertebral bodies or vertebral endplates at the operative levels
- Osteoporosis or osteopenia defined as DEXA bone mineral density T-score less than -1.5
- Facet joint degeneration
- Acute or chronic systemic, spinal, or localized infections
- Allergy or sensitivity to cobalt, chromium, molybdenum, titanium, or polyethylene

Warnings

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

- Correct placement of the device is essential for optimal performance of the prodisc C Vivo & prodisc C SK Total Disc Replacement and should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics, has experience with anterior cervical spinal surgeries, and has received hands-on training in the use of this specific device. A lack of adequate experience and/or training may lead to higher incidence of adverse events, including neurological complications.
- Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device.
- The safety and effectiveness of the prodisc C Vivo & prodisc C SK have not been studied in the clinical situation of prior cervical fusion.

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.

Patient Selection Considerations

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 levels 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 anterior posterior directions
- Severe abnormality of the endplate (e.g. large Schmorl nodes)

General Surgery Risks

General surgical risks include, but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Pain at surgical site
- Blood clots, including pulmonary emboli
- Medication and anesthesia reactions
- Phlebitis
- Pneumonia
- Atelectasis
- Soft tissue damage
- Septicemia
- Hemorrhage possibly requiring a blood transfusion, with possible transfusion reaction
- Myocardial infarction
- Paralysis
- Poor tissue healing
- Cerebrovascular accident (CVA)
- Death

Anterior Cervical Surgery Risks

Anterior cervical surgical risks include, but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Injury or damage to the trachea, esophagus, nerves or blood vessels
- Dysphagia
- Hoarseness
- Vocal cord paralysis
- Paresis
- Recurrent laryngeal nerve palsy
- Soft tissue damage
- Spinal cord damage
- Dural tear with cerebrospinal fluid leakage
- Arm weakness or numbness
- Bowel, bladder or sexual dysfunction
- Nerve root injury
- Airway obstruction
- Epidural hematoma or bleeding
- Epidural fibrosis
- Vertebral body fracture
- Dysesthesia or numbness
- Paresthesia
- Unresolved pain
- Surgical intervention at incorrect level
- Need for supplemental fixation
- Spinal instability
- Death

Cervical Artificial Disc Risks

Risks specific to cervical artificial discs, including the **prodisc C Vivo** & **prodisc C SK**, include but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Allergic reaction to the implant materials
- Implant failure
- Device migration
- Device subsidence
- Device fatigue or fracture or breakage
- Device instability
- Separation of device components
- Placement difficulties, device malposition
- Improper device sizing
- Excessive device height loss
- Wear debris
- Disc space collapse
- Material degradation
- Excessive facet loading
- Kyphosis or hyper-extension
- Loss of flexibility
- Asymmetric range of motion
- Vertebral body fracture
- Spinal cord damage,
- Dural tear with cerebrospinal fluid leakage
- Soft tissue damage
- Epidural fibrosis
- Nerve injury, paralysis or weakness that is temporary or permanent
- Injury or damage to the trachea, esophagus, or blood vessels
- Epidural hematoma or bleeding
- Dysesthesia or numbness
- Paresthesia
- Failure to relieve symptoms including unresolved pain
- Additional surgery due to loss of fixation, infection or injury
- Spontaneous fusion due to heterotopic ossification, development of bridging bone or osteophytes
- Periarticular calcification and fusion
- Development of spinal conditions, including but not limited to spinal stenosis, spondylolisthesis, or retrolisthesis
- Removal, revision, reoperation or supplemental fixation of the disc
- Osteolysis, bone loss, or bone resorption
- Death

Magnetic Resonance Environment

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

Non-clinical testing of the worst-case scenario has demonstrated that the articles of the **prodisc C Vivo** & **prodisc C SK** 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** & **prodisc C SK** produced a temperature rise of less than 2 ºC 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** & **prodisc C SK** devices.

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** or **prodisc C SK** 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** or **prodisc C SK** 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

For Further Information

If further information on this product is needed, please contact your local Centinel Spine representative or dealer or refer to:

https://guides.centinelspine.com

SURGICAL TECHNIQUE

Patient Positioning

AP and lateral fluoroscopy is used frequently throughout the prodisc C Vivo & prodisc C SK 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 **(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 AP orientation with spot fluoroscopy. Tape or strap the head in place to maintain this 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 **(Figures 1, 2, 3, 4)**.

Figure 1.

Figure 2.

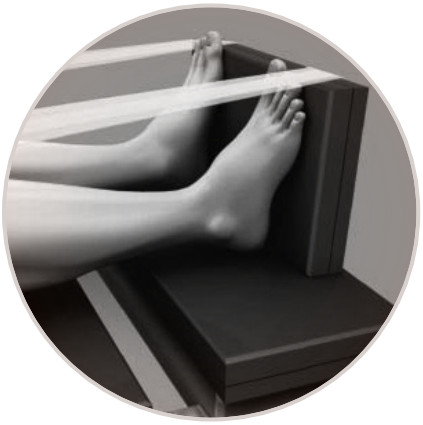


Figure 3.

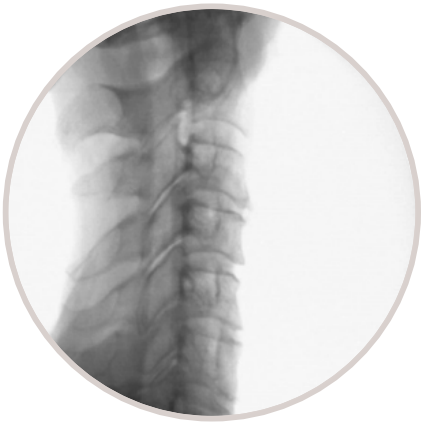


Figure 4.

PLEASE NOTE:

A fusion procedure may be necessary if adequate fluoroscopic visualization of the operative level cannot be achieved.

The use of head weights is not recommended.

Exposure

Expose the operative level via a standard anterior cervical approach. Verify the operative level with fluoroscopy **(Figure 5)**.

Use AP fluoroscopy to identify the midline of the operative level. Mark midline of the superior and inferior vertebral bodies so the mark is visible throughout the implantation procedure **(Figure 6)**.

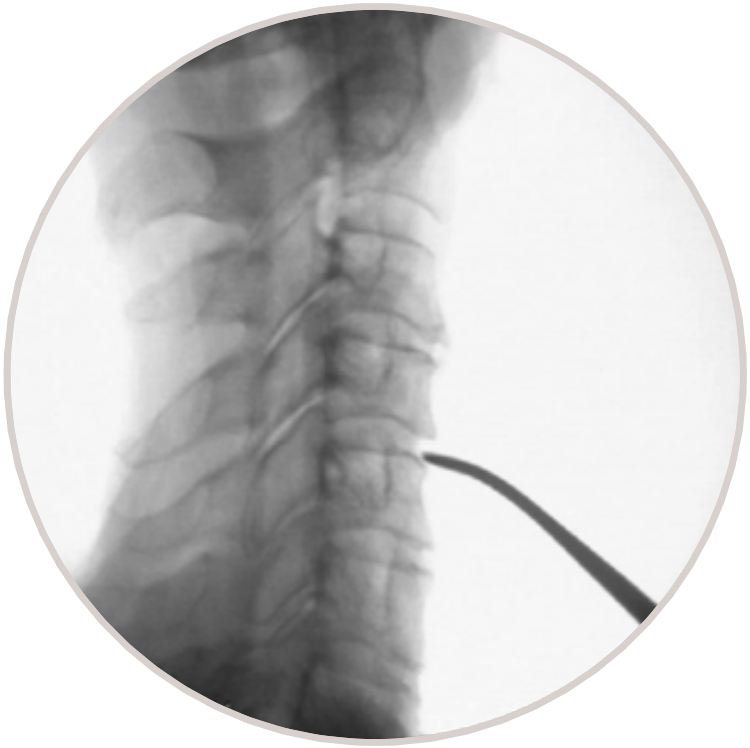


Figure 5.

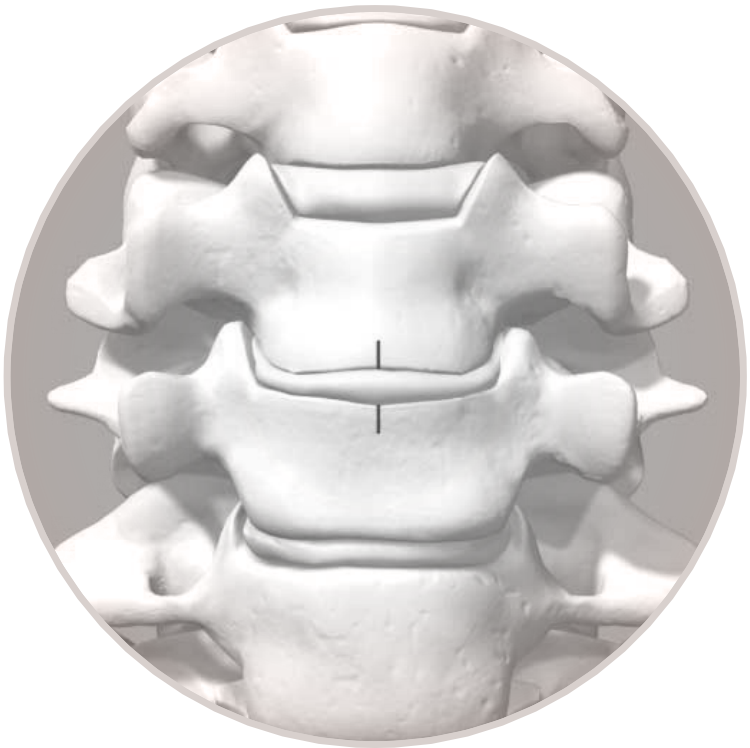


Figure 6.

Discectomy, Decompression, & Remobilization

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** or **prodisc C SK** Total Disc Replacement.

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

Instruments		
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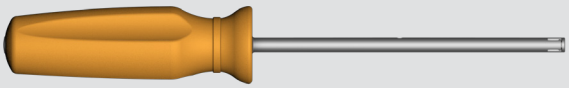
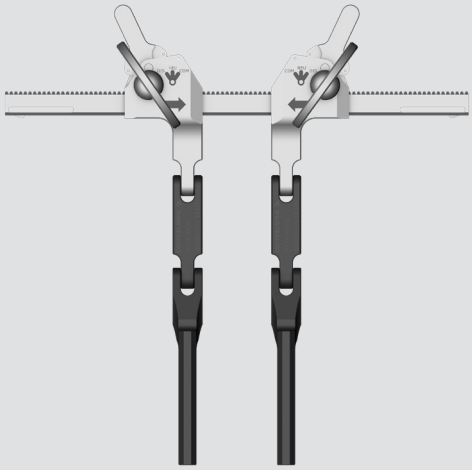
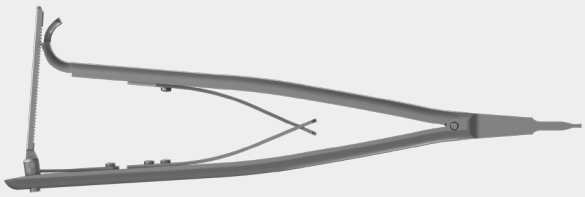
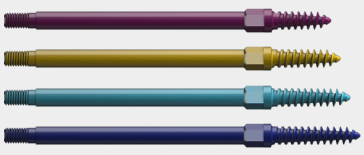
IN1444	Self-Retaining Screwdriver, Short	
03.820.110	Retainer Nut	
03.820.111/1	Vertebral Body Retainer	
03.820.112	Vertebral Distractor	
Standard Screws		
03.820.102 – 03.820.105	Retainer Screws, Ø3.5mm x 12mm, 14mm, 16mm, 18mm	
Rescue Screws		
03.820.106 – 03.820.109	Retainer Screws, Ø4.5mm x 13mm, 15mm, 17mm, 19mm	

With the awl, perforate the anterior cortex of the superior and inferior vertebra in the lateral midline and vertical center **(Figures 7 & 8)**.

Use lateral fluoroscopy to ensure its trajectory is parallel to endplates of the operative disc **(Figure 9)**.

The 12mm Awl tip can be used to estimate the desired Retainer Screw length.

The standard Ø3.5mm Retainer Screws are available in 12, 14, 16, 18mm lengths. Select a Retainer Screw length that will provide adequate purchase without breaching the posterior cortex.

The Ø4.5mm diameter "rescue" Retainer Screws are available in 13, 15, 17, 19mm lengths.

Insert retainer screws with the self-retaining screwdriver **(Figure 10)**, using fluoroscopy to confirm trajectory and screw depth.

2-LEVEL CONSIDERATION ***Refer to page 41 for guidance on retainer screw placement.***

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

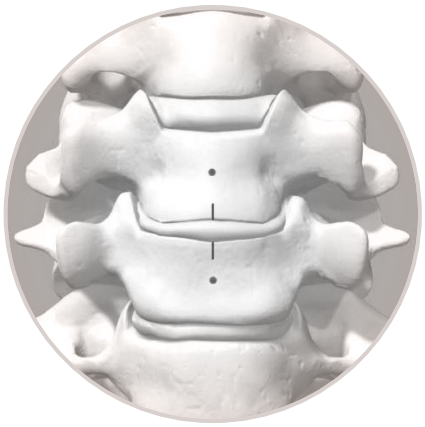


Figure 7.

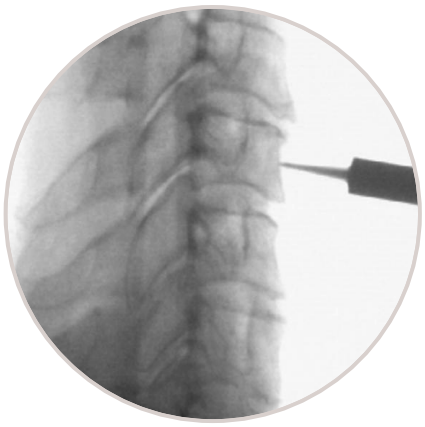


Figure 8.

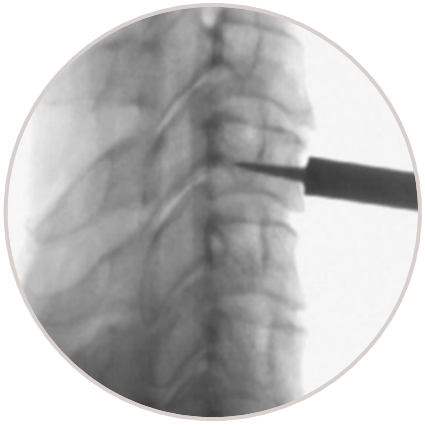


Figure 9.

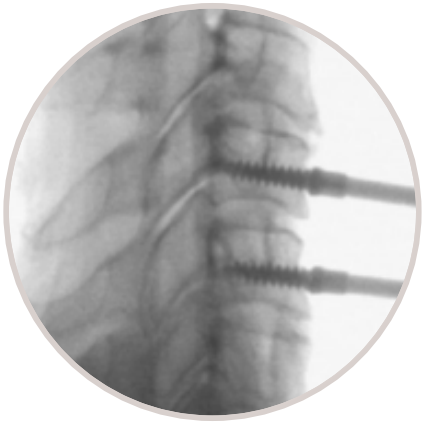


Figure 10.

Discectomy, Decompression, & Remobilization (Cont'd)

Assemble the vertebral body retainer **(Figure 11)**.

Slide the vertebral body retainer over the Retainer Screws. Secure the Vertebral Body Retainer with the Retainer Nuts **(Figure 12)**.

Apply light pretension to the operative disc space with the Vertebral Body Retainer.

Create an anterior annulotomy centered on midline and wide enough to accommodate the implant. Perform the preliminary discectomy using standard rongeurs and curettes.

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

Under lateral fluoroscopy, insert the vertebral distractor to the posterior aspect of the disc space. Ensure the distractor tips reach the posterior margin of the vertebral bodies to avoid penetration of the vertebral endplates **(Figure 13)**.

Figure 11.

Figure 12.

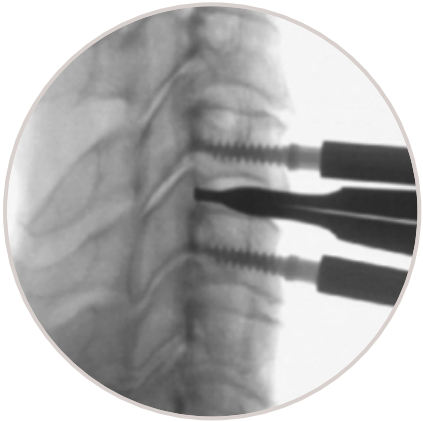


Figure 13.

Distract the intervertebral space with the vertebral distractor to restore the height and to gain access to the posterior intervertebral space **(Figure 14)**. Avoid over-distraction with the vertebral distractor as this can lead to nerve root tension or improper implant selection.

Readjust the Vertebral Body Retainer to the distracted height of the intervertebral space. This step should be repeated until adequate distraction has been achieved. Then release and withdraw the vertebral distractor and complete the discectomy, decompression, and remobilization as indicated.

NOTES:

Preserve the integrity of the bony endplates; only the cartilaginous endplate should be excised. Endplate remodeling should only be performed if posterior osteophytes interfere with implant positioning or excision is necessary for neural decompression. The 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. Use of a high speed burr is discouraged.

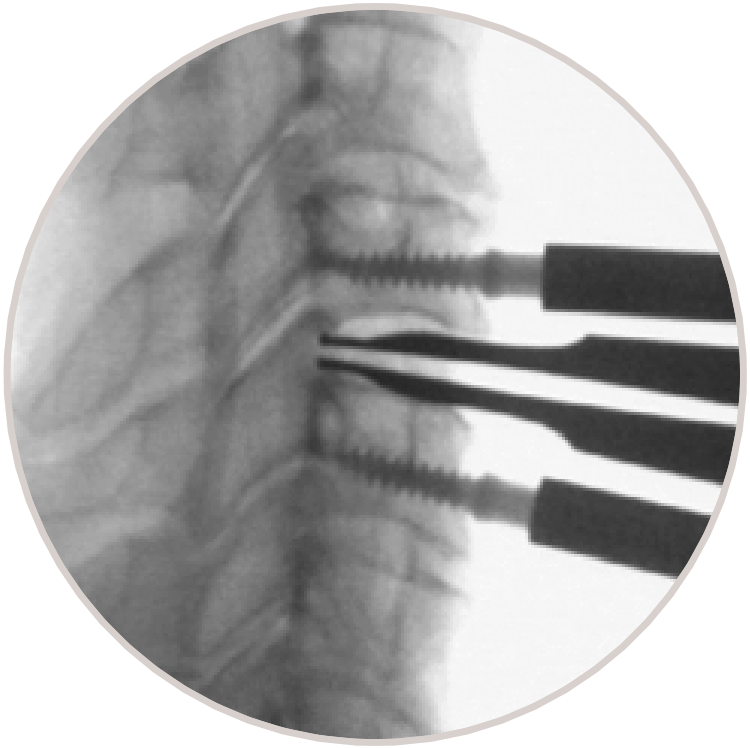


Figure 14.

Implant Selection

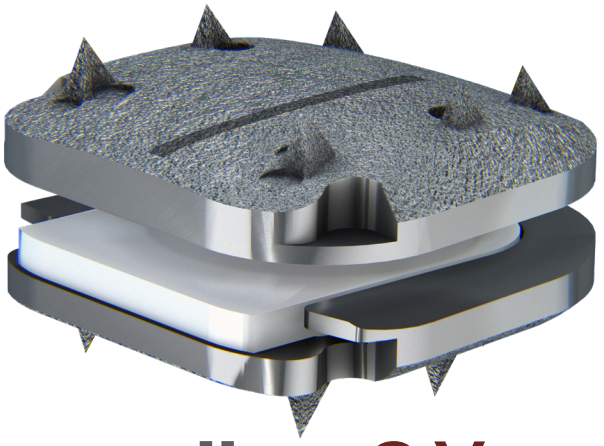
Trial with **prodisc C Vivo** and/or **prodisc C SK** to determine best implant fit and position. Select the largest footprint to maximize coverage of the vertebral body endplates and the smallest appropriate height to match healthy adjacent discs.

Implantation of the **prodisc C Vivo** is performed in two steps:

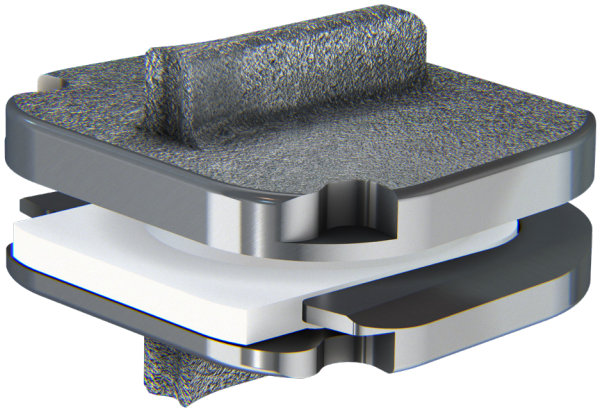
1. **Trial**
2. **Insert Implant**

Implantation of the **prodisc C SK** is performed in three steps:

1. **Trial**
2. **Chisel**
3. **Insert Implant**

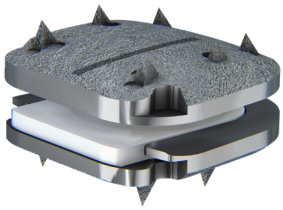


prodisc® C Vivo



prodisc® C SK

Implantation of prodisc® C Vivo



Implantation of the **prodisc C Vivo** is performed in two steps:

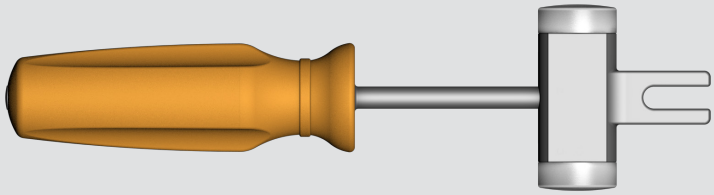
1. **Trial**
2. **Insert Implant**

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

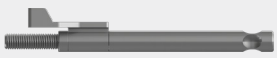
Select an implant with the best anatomical fit, using the largest footprint to maximize coverage of the vertebral bodies and the smallest appropriate height to match healthy adjacent discs.

STEP 1: Trial

Instruments

IN1617	T-Handle, for Trial Implants	
IN1564	**prodisc C Vivo** Trial Post Attachment	
IN1502 – IN1519	**prodisc C Vivo** Trials	
		Footprint: M | MD | L | LD | XL | XLD
		Width x Depth (mm): 15 x 12 | 15 x 14 | 17 x 14 | 17 x 16 | 19 x 16 | 19 x 18
03.820.113	Slotted Mallet	

Optional Instruments

IN1584 – IN1586	**prodisc C Vivo** Trial Stop - 5mm, 6mm, 7mm*	
IN1668	Remover/Repositioner Rod	

*7mm implants and instruments available by special request only.

Implantation of prodisc® C Vivo

STEP 1: Trial (Cont'd)

Each prodisc C Vivo trial is preassembled with a Trial Post Attachment. Attach the T-Handle to the end of the Trial Post Attachment **(Figure 15)**. Ensure that the Trial Post Attachment is fully seated before use.

Alternatively, if a straight Trial without the T-Handle is preferred, the Remover/Repositioner Rod may be used as a trial handle. Remove the Trial Post Attachment from the Trial and introduce the Remover/Repositioner Rod to the Trial and rotate clockwise to tighten **(Figure 16)**.

Alternatively, if a Trial Stop is preferred, remove the Trial Post Attachment from the Trial by rotating the T-Handle counterclockwise **(Figure 17)**. Introduce the appropriate height Trial Stop to the Trial using the T-Handle **(Figure 18)**. Confirm the Trial Stop is fully secured in the trial by rotating the T-Handle clockwise until the Trial Stop is in the "zero" position (in-line with the anterior margin of the Trial) **(Figure 19)**.

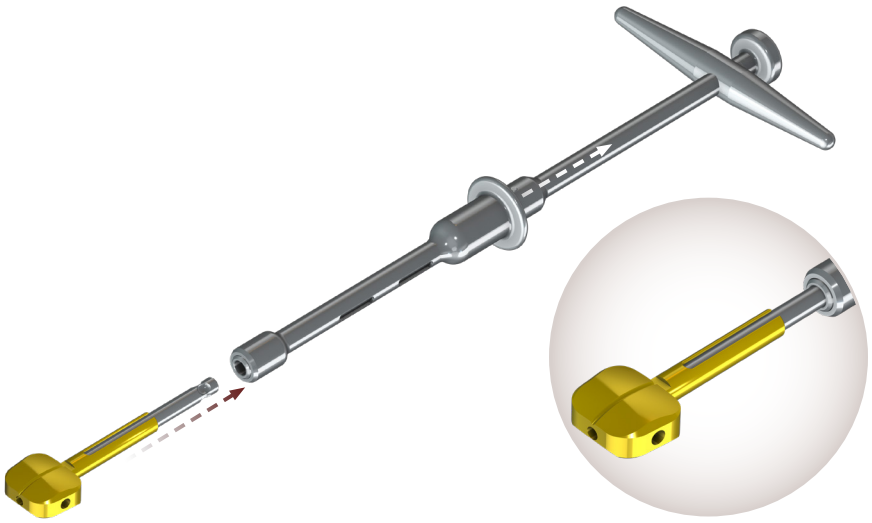


Figure 15.

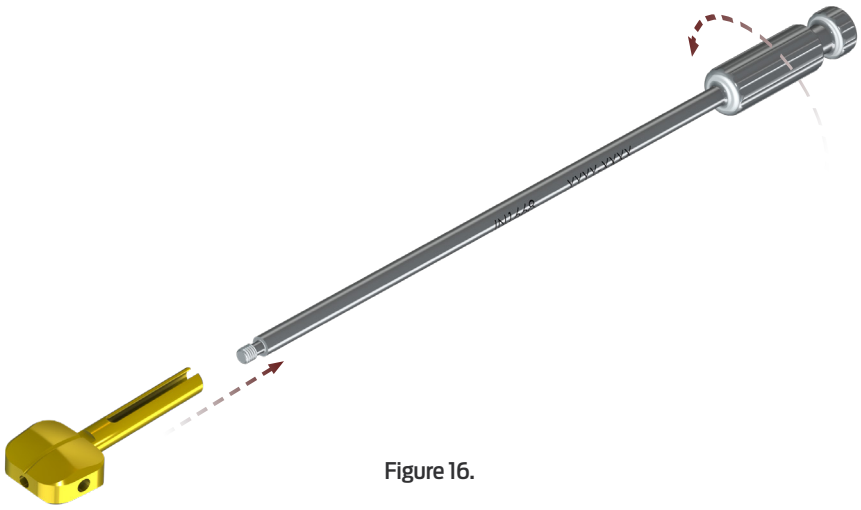


Figure 16.

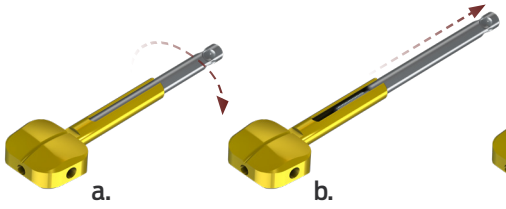


Figure 17.

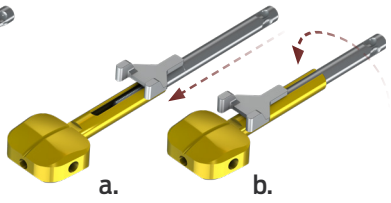


Figure 18.

Figure 19.

Orient the Trial with the domed surface cranially **(Figure 20)**, align the Trial on midline using the midline indicator groove on the trial as a guide **(Figure 21)**. Under lateral fluoroscopy, advance the Trial towards the posterior margin of the disc space.

If applicable, the Trial Stop can be retracted to allow the Trial to advance more posteriorly. Each counterclockwise revolution of the T-Handle will retract the Trial Stop 0.5mm.

CAUTION ***Do not impact the trial beyond the posterior margin of the disc space.***

Select the best possible anatomical fit with the vertebral bodies, using the largest footprint and the smallest appropriate height.

The center of the trial should be positioned at the midline of the vertebral body or slightly posterior, to align with the approximate center of rotation (COR) of the motion segment.

The lateral hole in the Trial may be used to help determine orientation of the Trial **(Figure 22)**.

NOTE: ***Release vertebral body distraction for final assessment of trial size and position.***

Selecting an implant that is too tall can limit the segmental range of motion and sagittal alignment at the operative and/or adjacent levels.

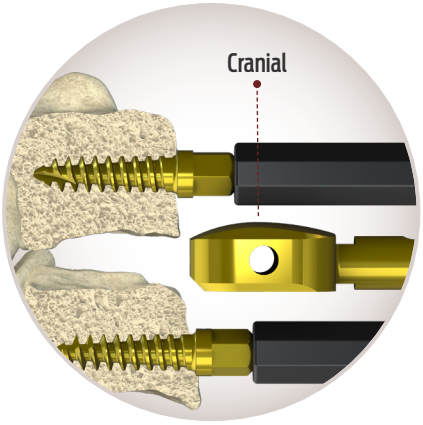


Figure 20.

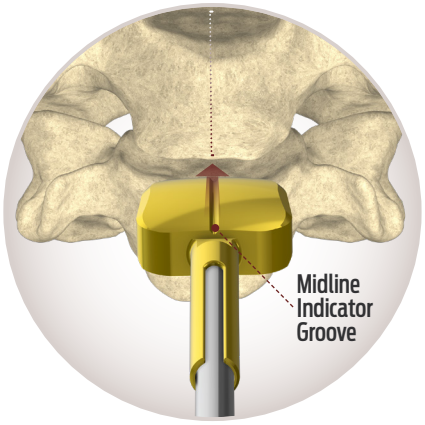


Figure 21.

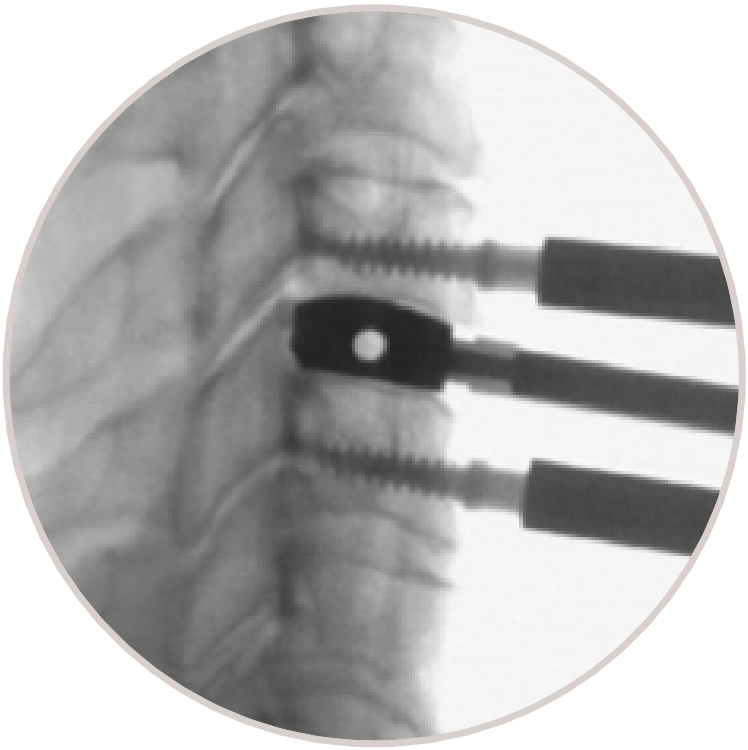


Figure 22.

Implantation of prodisc® C Vivo

STEP 1: Trial (Cont'd)

Apply compression with the vertebral body retainer and disengage the t-handle from the trial, leaving the trial in the disc space. AP fluoroscopy should be performed to assess the width of the trial and the midline position **(Figure 23)**.

Apply slight distraction with the vertebral body retainer and remove the trial with the t-handle **(Figure 24)**.

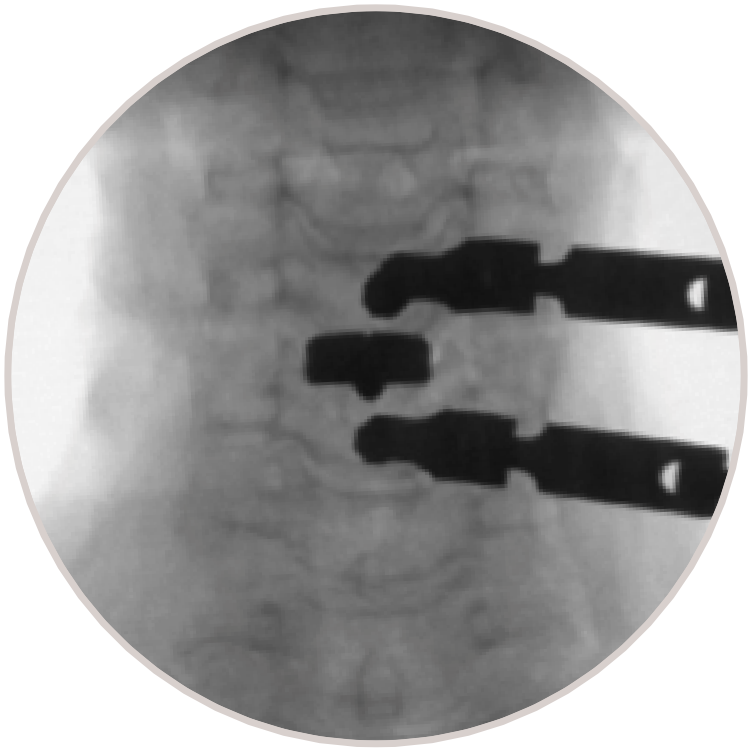


Figure 23.

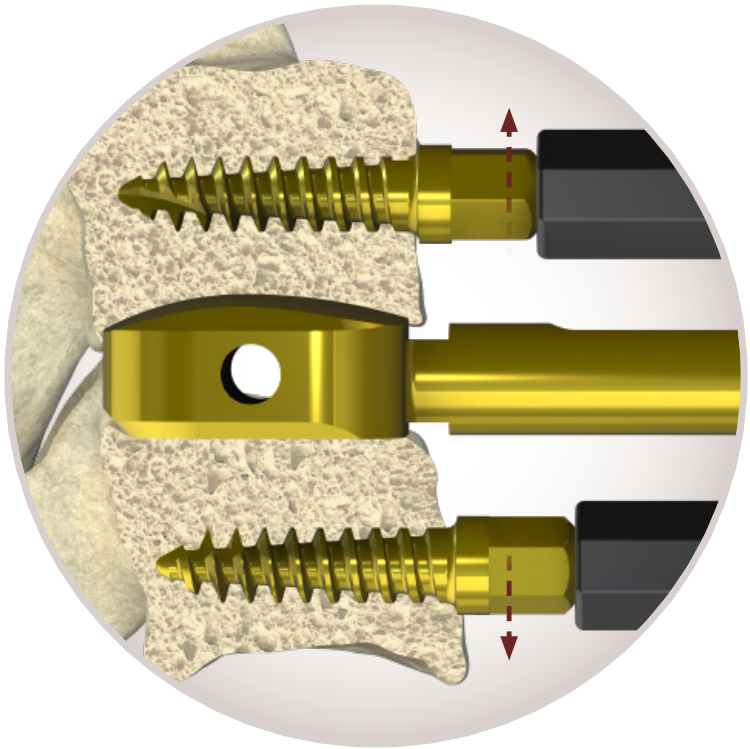
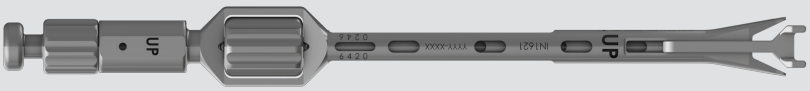
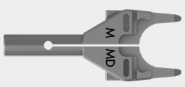
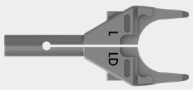
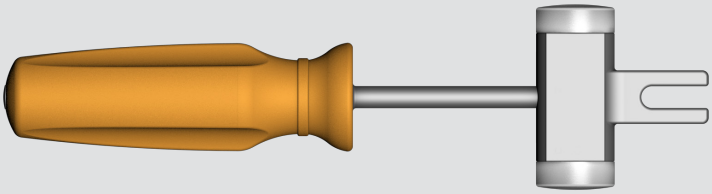


Figure 24.

STEP 2: Insert Implant

Instruments

IN1620	prodisc C Vivo / prodisc C SK Introducer, No Stop						
IN1621	prodisc C Vivo / prodisc C SK Introducer						
IN1655 – IN1663	Introducer Tips						
		Footprints	*M*	*MD*	*L*	*LD*	*XL*	*XLD*
		Heights	*5, 6, 7mm**		*5, 6, 7mm**		*5, 6, 7mm**	
03.820.113	Slotted Mallet							

Optional Instrument

03.670.207	prodisc C Vivo One-Piece Positioner	

*7mm implants and instruments available by special request only.

Implantation of prodisc® C Vivo

STEP 2: Insert Implant (Cont'd)

The implant is loaded onto the Introducer Tip "en-bloc" directly from the packaging.

Choose the Introducer Tip corresponding to the selected implant footprint and height. The Introducer Tips are compatible with both the prodisc C Vivo and prodisc C SK implants.

Align the laser marked side of the Introducer Tip with the superior endplate of the prodisc C Vivo implant, as indicated by the black midline marker and the domed shape of the implant endplate **(Figure 25)**.

Advance the Introducer Tip onto the implant until the Introducer Tip's attachment arms engage with the holding features on both implant endplates. A subtle tactile click may be felt as the Introducer Tip attachment arms engage with the implant's holding features.

Both introducers (with and without stops) are compatible with all Introducer Tips.

Align the "UP" laser marking on the Introducer with the laser marked side of the Introducer Tip. Advance the Introducer over the Introducer Tip, ensuring the alignment tabs on the Introducer Tip are captured within the Introducer before tightening **(Figure 26)**.

Use two fingers to rotate the proximal knob of the Introducer clockwise to tighten the connection with the Introducer Tip **(Figure 27)**. The Introducer Tip should now be secured to the implant. There will still be some toggle of the implant endplates on the Introducer Tip, per the design.

CAUTION ***Do not over-tighten Introducer onto the Introducer Tip.***

Remove the implant "en-bloc" out of the packaging.

If the Introducer with Stop is being utilized, the center knob of the Introducer can be used to adjust the position of the stop. Ensure the stop is in the "zero" position **(Figure 28)**.

Figure 25.

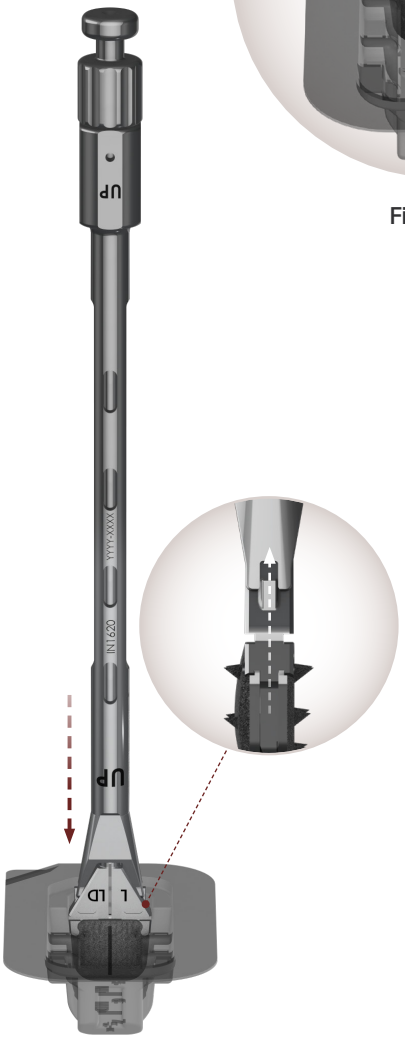


Figure 26.

Figure 27.

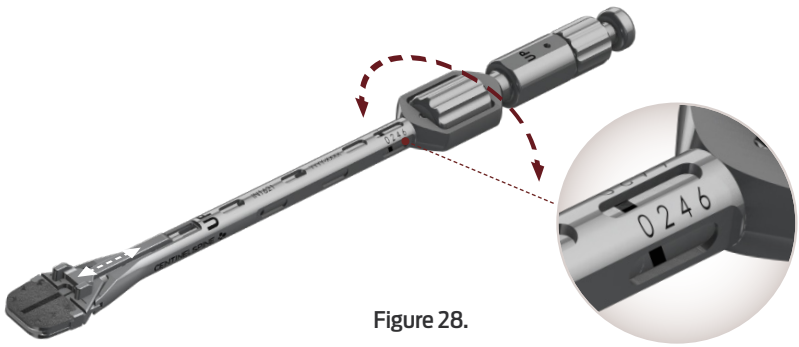


Figure 28.

With the implant oriented cranially, align the implant on midline. Under lateral fluoroscopy, advance the implant towards the posterior margin of the vertebral bodies. Use the two grooves on the Introducer Tip to visually confirm that the anterior edge of the implant is within the anterior edge of the vertebral body **(Figure 29)**.

If applicable, the Introducer stop can be retracted to allow the implant to advance more posteriorly. Each counterclockwise revolution of the central knob of the Introducer will retract the Introducer stop 1.0mm.

CAUTION ***Do not impact the implant beyond the posterior margin of the disc space.***

NOTE: ***Avoid excessive cranial-caudal or medial-lateral rocking during insertion. Aggressive rocking may cause the Introducer Tip to disengage from the holding features of the implant endplate.***

Before removing the Introducer, ensure satisfactory positioning of the implant using AP fluoroscopy **(Figure 30)**. When the desired position of the implant is confirmed, apply slight compression with the Vertebral Body Retainer to help the implant gain primary fixation.

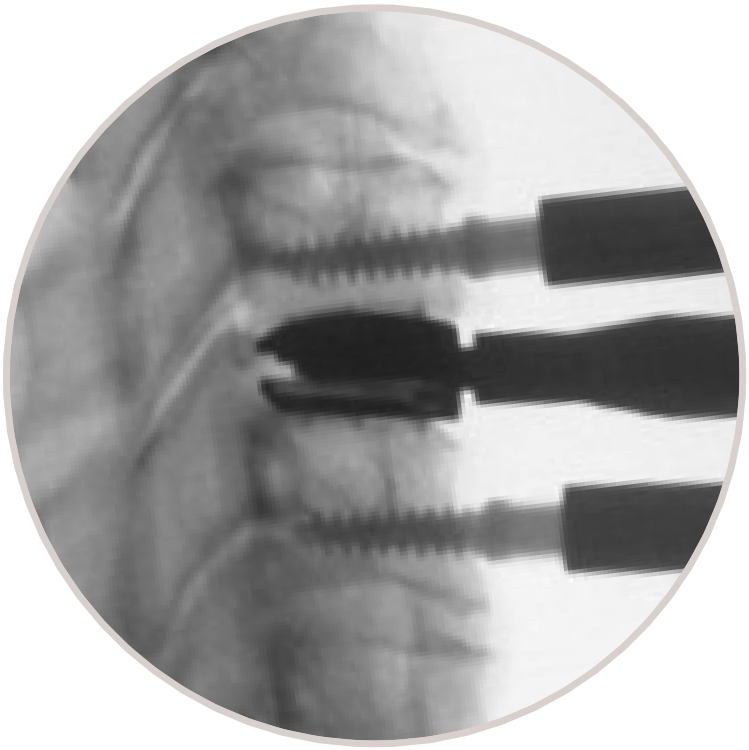


Figure 29.

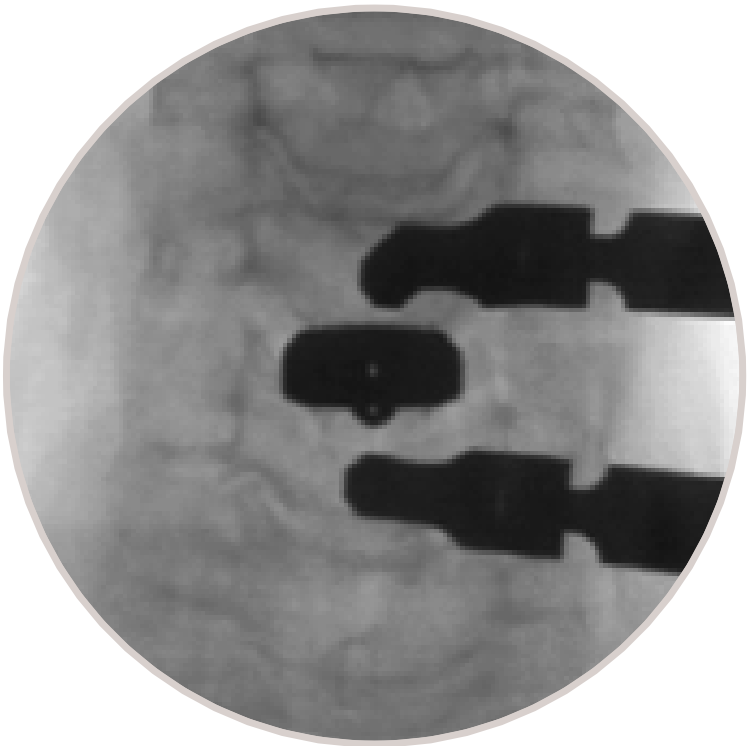


Figure 30.

Implantation of prodisc® C Vivo

STEP 2: Insert Implant (Cont'd)

Loosen the introducer tip from the implant by rotating the proximal knob of the Introducer three (3) counterclockwise revolutions **(Figure 31)**.

Rock the Introducer in a medial-lateral motion to approximately 30 degrees off midline and pull up until implant release occurs **(Figure 32)**.

Confirm final implant position with lateral and AP fluoroscopy **(Figures 33 & 34)**.

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

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

Close the surgical wound in a routine fashion.

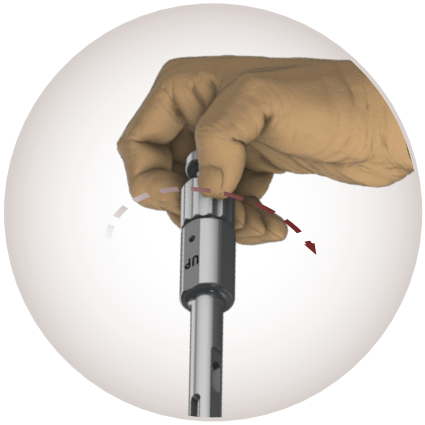


Figure 31.

Figure 32.

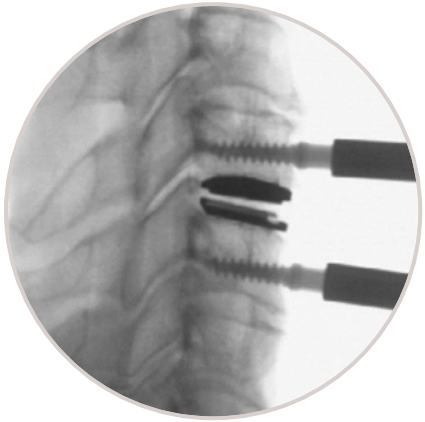


Figure 33.

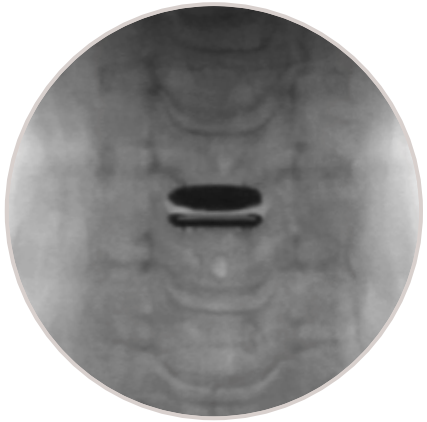
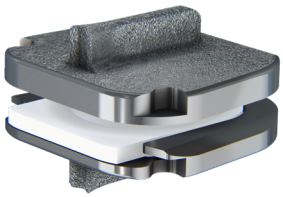


Figure 34.

Implantation of prodisc® C SK



Implantation of the **prodisc C SK** is performed in three steps:

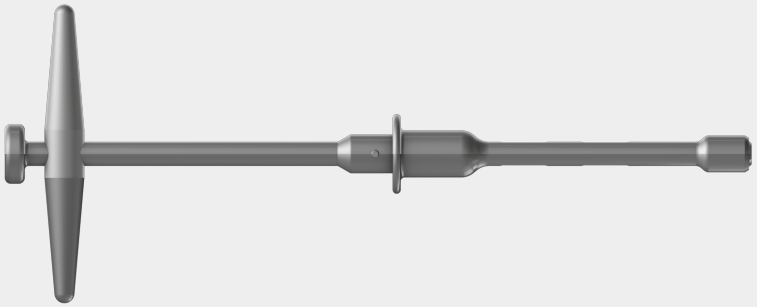
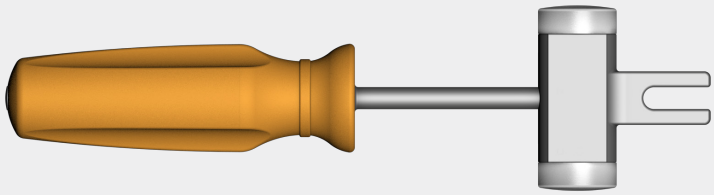
1. **Trial**
2. **Chisel**
3. **Insert Implant**

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

Select an implant with the best anatomical fit, using the largest footprint to maximize coverage of the vertebral bodies and the smallest appropriate height to match healthy adjacent discs.

STEP 1: Trial

Instruments

IN1617	T-Handle, for Trial Implants							
IN1520 – IN1538	**prodisc C SK** Trials							
		Footprint	M	MD	L	LD	XL	XLD
		Width x Depth (mm)	15 x 12	15 x 14	17 x 14	17 x 16	19 x 16	19 x 18
03.820.113	Slotted Mallet							

Implantation of prodisc® C SK

STEP 1: Trial (Cont'd)

Attach the T-Handle to the end of the Trial shaft **(Figure 35)**.

The T-Handle can be used to adjust the position of the Trial Stop. Ensure the Trial Stop is in the "zero" position (in-line with the anterior margin of the Trial) **(Figure 36)**.

With the Trial Stop oriented cranially, align the Trial on midline. Under lateral fluoroscopy, advance the Trial towards the posterior margin of the disc space **(Figure 37)**.

The Trial Stop can be retracted to allow the Trial to advance more posteriorly. Each counterclockwise revolution of the T-Handle will retract the Trial Stop 0.5mm.

CAUTION ***Do not impact the trial beyond the posterior margin of the disc space.***

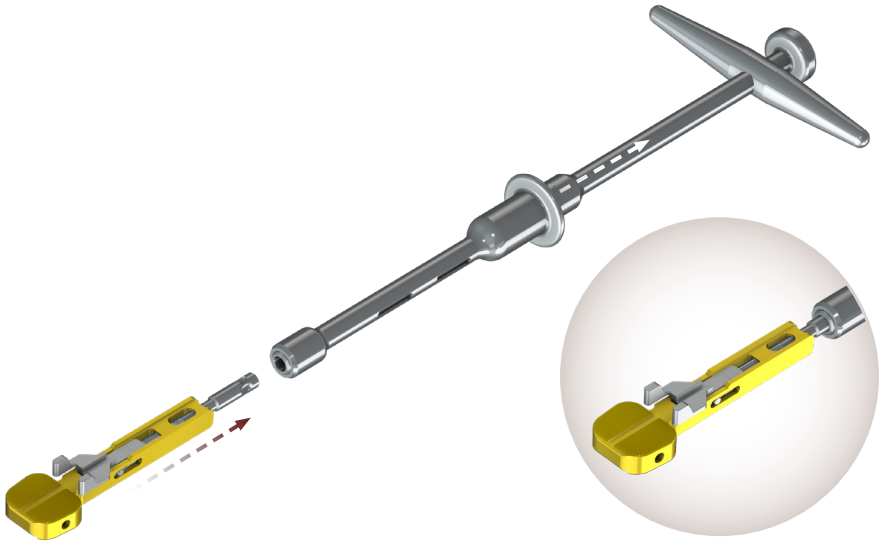


Figure 35.

Figure 36.

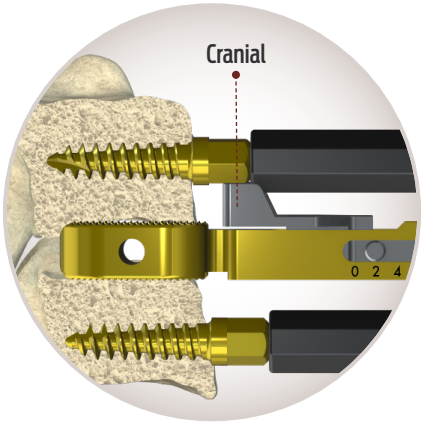


Figure 37.

Select the best possible anatomical fit with the vertebral bodies, using the largest footprint and the smallest appropriate height.

The center of the trial should be positioned at the midline of the vertebral body or slightly posterior, to align with the approximate center of rotation (COR) of the motion segment.

The lateral hole in the Trial may be used to help determine orientation of the Trial **(Figure 38)**.

NOTE: ***Release vertebral body distraction for final assessment of trial size and position.***

Selecting an implant that is too tall can limit the segmental range of motion and sagittal alignment at the operative and/or adjacent levels.

Apply compression with the vertebral body retainer and disengage the t-handle from the trial, leaving the trial in the disc space. AP fluoroscopy should be performed to assess the width of the trial and the midline position **(Figure 39)**.

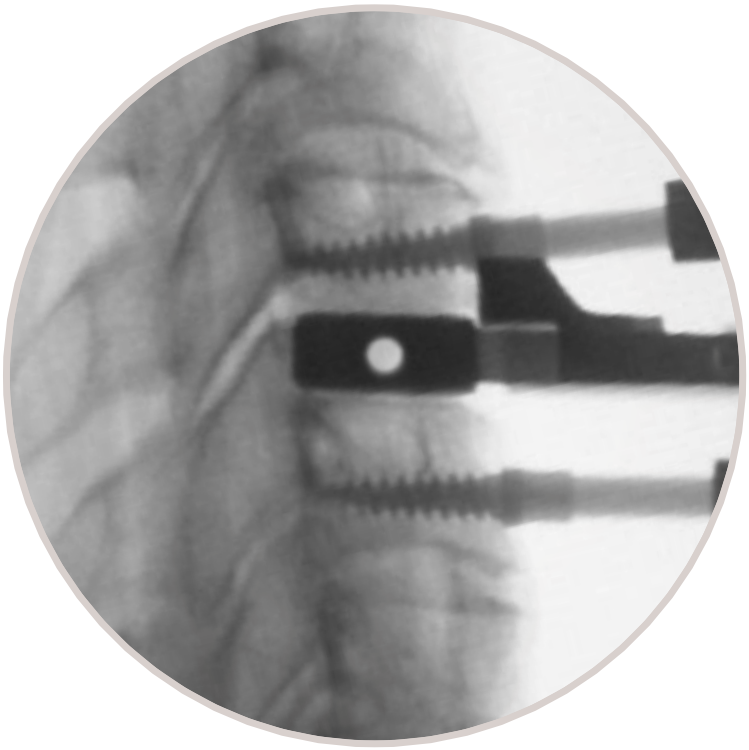


Figure 38.

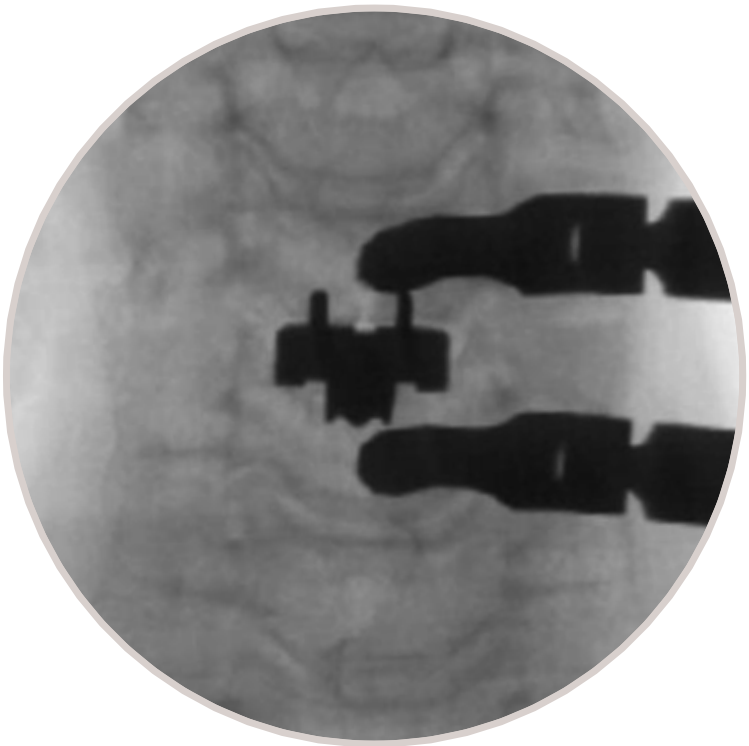
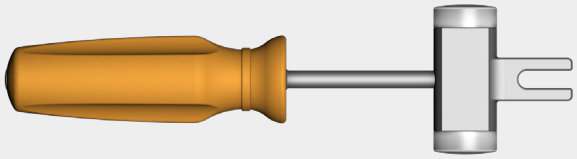
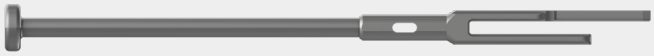
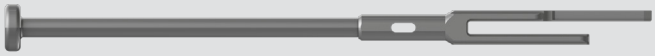


Figure 39.

Implantation of prodisc® C SK

STEP 2: Chisel

Instruments		
03.820.113	Slotted Mallet	
IN1541 – IN1543	prodisc C SK Chisels (5mm, 6mm, 7mm*)	
Optional Instruments		
IN1587 - IN1589	Hemi Chisels +1 (5mm, 6mm, 7mm*)	
IN1590 - IN1592	Hemi Chisels +2** (5mm, 6mm, 7mm*)	
IN1404	prodisc C SK Small Keel Cut Cleaner	

Apply compression to the Trial with the Vertebral Body Retainer. Using a Chisel of the appropriate height, engage the Chisel with the Trial shaft **(Figure 40)**. Advance the Chisel until the Chisel contacts the anterior cortex.

Confirm the Trial and Chisel are centered on midline. Under lateral fluoroscopy, advance the Chisel until it is fully seated on the Trial. The posterior edge of the Chisel will be 2.3mm from the posterior edge of the Trail when the Chisel is fully seated **(Figure 41)**.

Ensure that the depth and height of the keel channels are equal in the superior and inferior vertebral bodies. Remove the Chisel using the Slotted Mallet.

CAUTION ***Do not attempt to cephalize hand with the chisel to achieve deeper cut.***

Hemi chisels may be used as needed if the superior vertebral body keel channel needs to be extended by 1mm or 2mm**. Use of the Hemi Chisels is limited to the superior keel channel.

Apply slight distraction with the Vertebral Body Retainer and remove the Trial with the T-Handle. Irrigate to ensure the disc space is clear of debris.

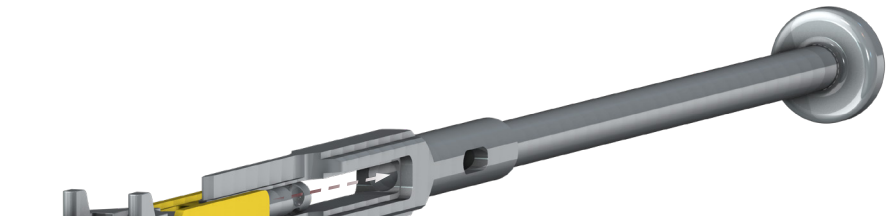


Figure 40.

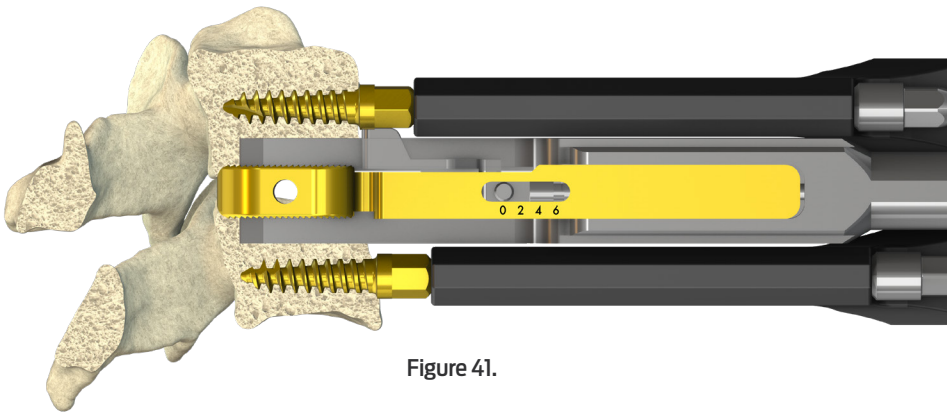


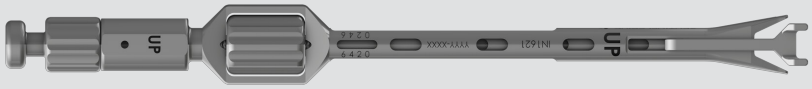
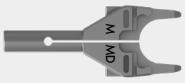
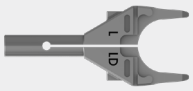
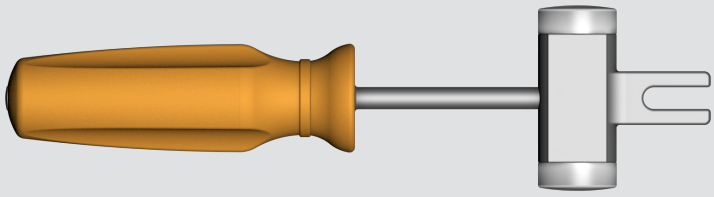
Figure 41.

*7mm implants and instruments available by special request only. ** Available by special request only.

Implantation of prodisc® C SK

STEP 3: Insert Implant

Instruments

IN1620	prodisc C Vivo / prodisc C SK Introducer, No Stop						
IN1621	prodisc C Vivo / prodisc C SK Introducer						
IN1655 – IN1663	Introducer Tips						
		Footprints	*M*	*MD*	*L*	*LD*	*XL*	*XLD*
		Heights	*5, 6, 7mm**		*5, 6, 7mm**		*5, 6, 7mm**	
03.820.113	Slotted Mallet							

*7mm implants and instruments available by special request only.

Implantation of prodisc® C SK

STEP 3: Insert Implant (Cont'd)

The implant is loaded onto the Introducer Tip "en-bloc" directly from the packaging.

Choose the Introducer Tip corresponding to the selected implant footprint and height. The Introducer Tips are compatible with both the prodisc C Vivo and prodisc C SK implants.

Align the laser marked side of the Introducer Tip with the superior endplate of the prodisc C SK implant, as indicated by the "UP" laser mark on the anterior face of the superior endplate **(Figure 42)**.

Advance the Introducer Tip onto the implant until the Introducer Tip's attachment arms engage with the holding features on both implant endplates. A subtle tactile click may be felt as the Introducer Tip attachment arms engage with the implant's holding features.

Both introducers (with and without stops) are compatible with all Introducer Tips.

Align the "UP" laser mark on the Introducer with the laser marked side of the Introducer Tip. Advance the Introducer over the Introducer Tip, ensuring the alignment tabs on the Introducer Tip are captured within the Introducer before tightening **(Figure 43)**.

Use two fingers to rotate the proximal knob of the Introducer clockwise to tighten the connection with the Introducer Tip **(Figure 44)**. The Introducer Tip should now be secured to the implant. There will still be some toggle of the implant endplates on the Introducer Tip, per the design.

CAUTION ***Do not over-tighten Introducer onto the Introducer Tip.***

Remove the implant "en-bloc" out of the packaging.

If the Introducer with Stop is being utilized, the center knob of the Introducer can be used to adjust the position of the stop. Ensure the stop is in the "zero" position **(Figure 45)**.

Figure 42.

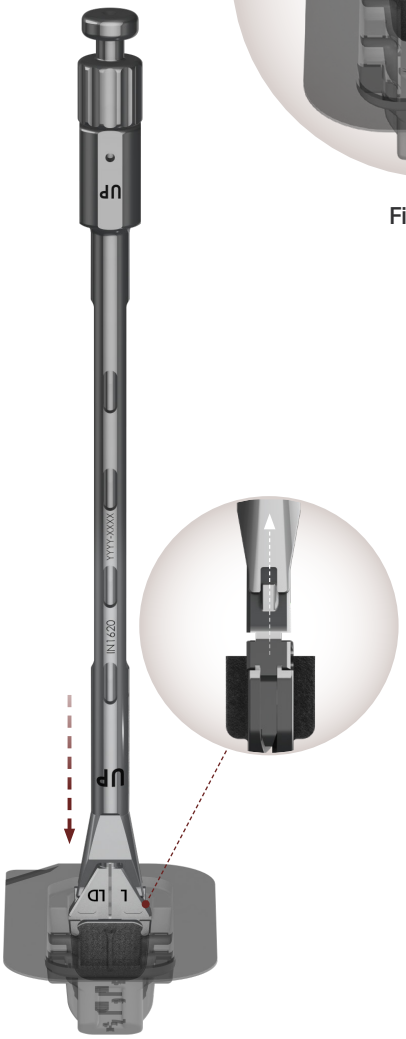


Figure 43.

Figure 44.

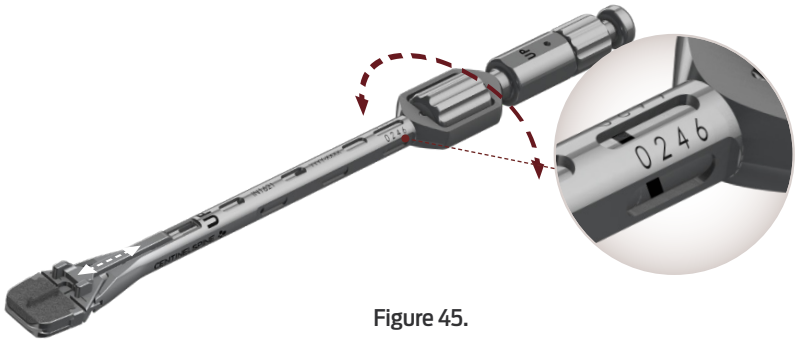


Figure 45.

Align the keels of the implant with the prepared keel channels in the vertebral bodies. Ensure the "UP" laser mark on the Introducer and the dome of the implant's polyethylene inlay are oriented cranially **(Figure 46)**.

Under lateral fluoroscopy, advance the implant towards the posterior margin of the vertebral bodies **(Figure 47)**.

Use the two grooves on the Introducer Tip to visually confirm that the anterior edge of the implant is within the anterior edge of the vertebral body.

If applicable, the Introducer Stop can be retracted to allow the implant to advance more posteriorly. Each counterclockwise revolution of the central knob of the Introducer will retract the Introducer Stop 1.0mm.

CAUTION ***Do not impact the implant beyond the posterior margin of the disc space.***

NOTE: ***Avoid excessive cranial-caudal or medial-lateral rocking during insertion. Aggressive rocking may cause the Introducer Tip to disengage from the holding features of the implant endplate.***

When the desired position of the implant is confirmed, apply slight compression with the Vertebral Body Retainer.

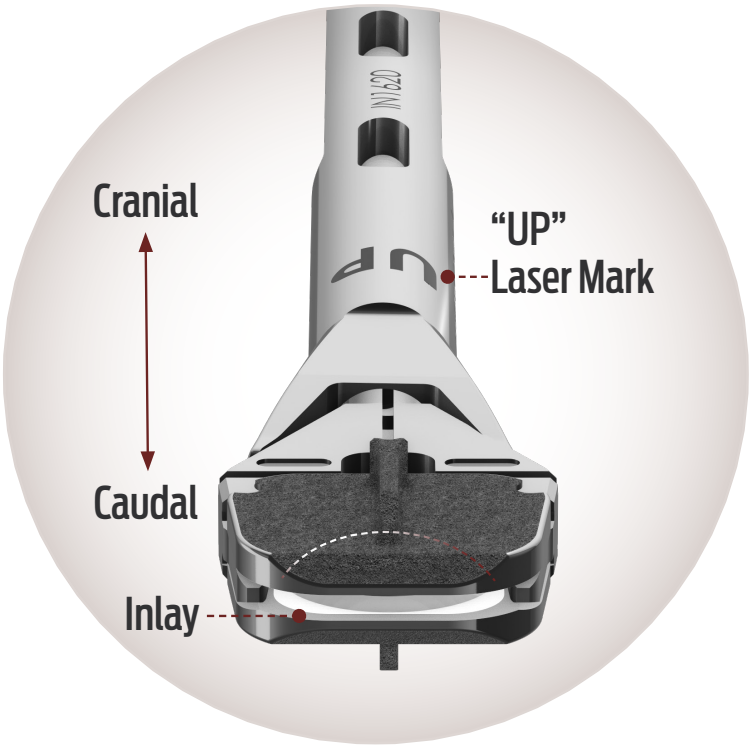


Figure 46.

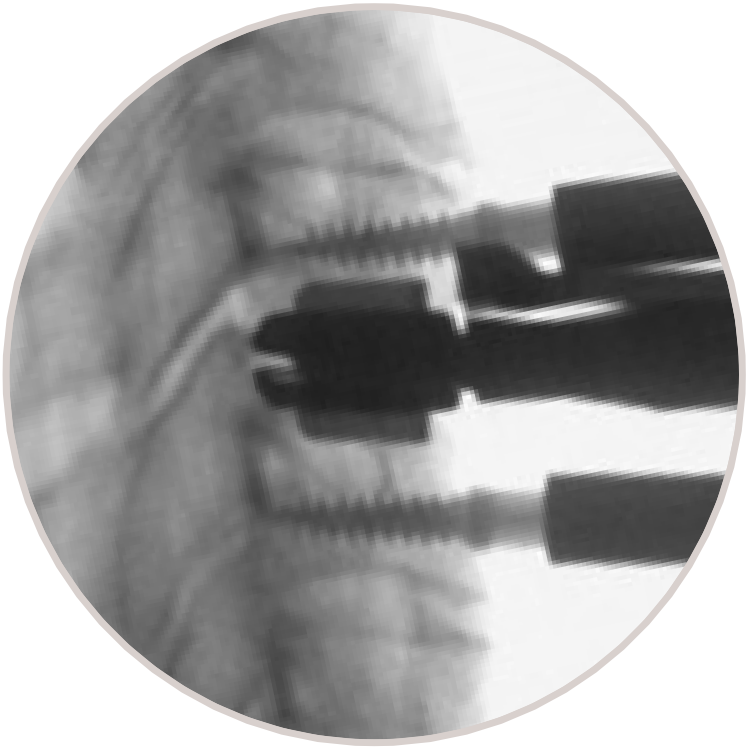


Figure 47.

Implantation of prodisc® C SK

STEP 3: Insert Implant (Cont'd)

Loosen the introducer tip from the implant by rotating the proximal knob of the Introducer three (3) counterclockwise revolutions **(Figure 48)**.

Rock the Introducer in a medial-lateral motion to approximately 30 degrees off midline and pull up until implant release occurs **(Figure 49)**.

Confirm final implant position with lateral and AP fluoroscopy **(Figures 50 & 51)**.

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

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

Close the surgical wound in a routine fashion.

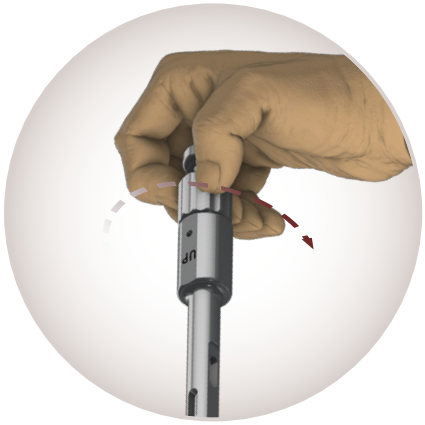


Figure 48.

Figure 49.

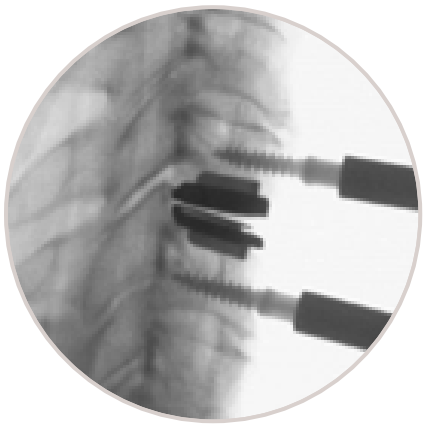


Figure 50.

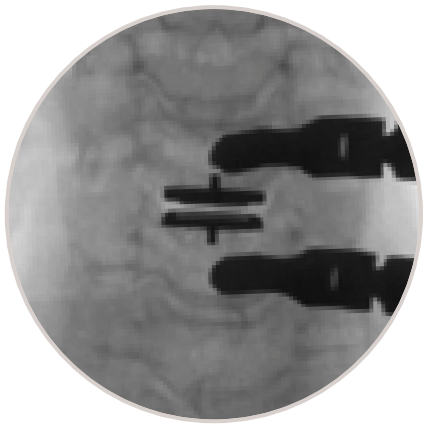
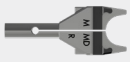
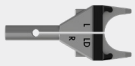
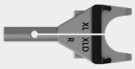
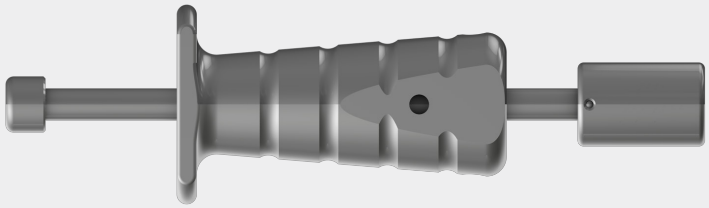


Figure 51.

Optional Steps: Intra-Operative Implant Repositioning or Removal

To reposition or remove a prodisc C Vivo or prodisc C SK implant intraoperatively, follow the instructions on page 34 for repositioning and page 37 for removing. To explant a prodisc C Vivo or prodisc C SK, refer to page 42 for instructions.

Remover/Repositioner Instruments

IN1665 – IN1667	Remover/Repositioner Tips							
		Footprints	*M*	*MD*	*L*	*LD*	*XL*	*XLD*
IN1668	Remover/Repositioner Rod							
IN1621	prodisc C Vivo / prodisc C SK Introducer							
IN1620	prodisc C Vivo / prodisc C SK Introducer, No Stop							
03.820.282	Slide Hammer							

Intra-Operative Implant Repositioning or Removal (Cont'd)

Intra-Operative Implant Repositioning

Information:

The remover/repositioner tips are compatible with both the prodisc C Vivo and prodisc C SK implants.

The remover/repositioner tips are intended to attach to **either** the superior or the inferior endplate of the implant as desired. Only one implant endplate can be attached at a time.

Holding features on the bone contacting surfaces of the superior and inferior implant endplates are used as the attachment location for the laser marked attachment arms of the remover/repositioner tip **(Figures 52 & 53)**.

NOTE: ***The holding features are also used for attachment of the introducer tip attachment arms during initial implantation.***

The guide rails of the remover/repositioner tip are designed to lead the remover/repositioner tip between the implant endplates and facilitate engagement of the laser marked attachment arms of the remover/repositioner tip with the holding features of the implant endplate.

See **Figures 54 & 55** for visual guidance on correct engagement of the remover/repositioner tip to the implant endplate.

Preparation:

Slight distraction of the disc space may be required for visualization of the implant and attachment of the remover/repositioner tip.

See instructions for distraction using the vertebral distractor and vertebral body retainer on page 14.

Choose the remover/repositioner tip corresponding to the implant footprint: M/MD, L/LD, or XL/XLD. Attach the remover/repositioner tip to the remover/repositioner rod by rotating the remover/repositioner rod clockwise until it is secure **(Figure 56)**.

Choose the desired implant endplate to capture.

NOTE: ***For most repositioning needs it is recommended to attach the remover/repositioner instrument assembly to the superior implant endplate.***

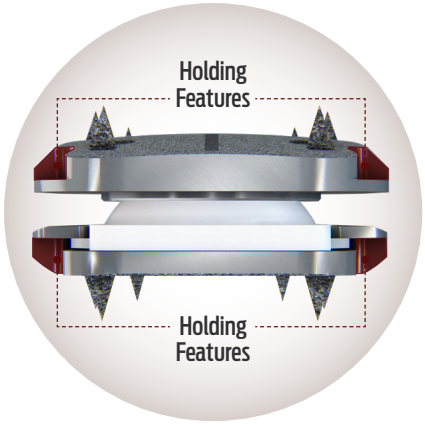


Figure 52.

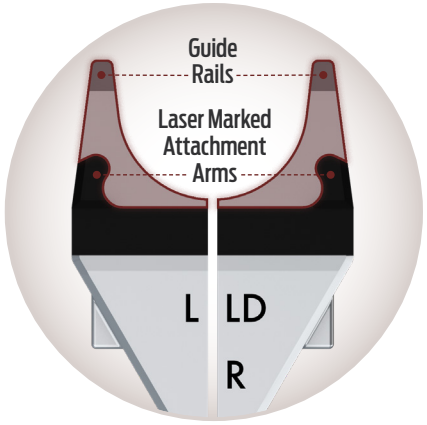


Figure 53.

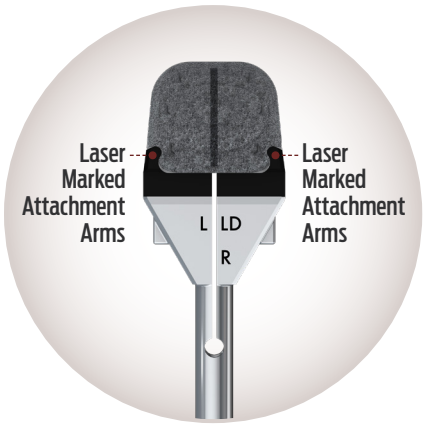


Figure 54.

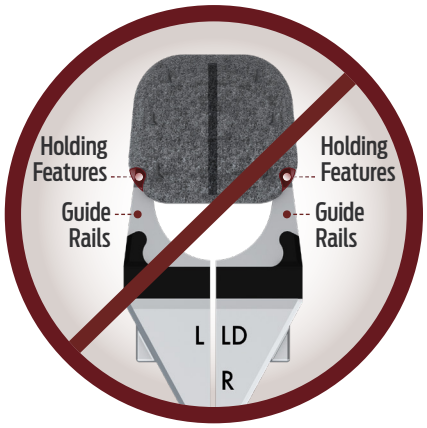


Figure 55.

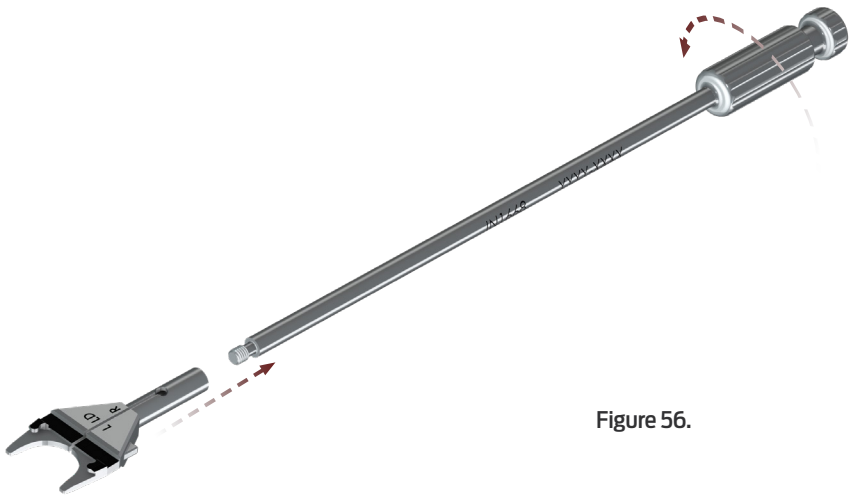


Figure 56.

Provisional Attachment of the Superior Endplate for Repositioning:

With the remover/repositioner tip attachment arms facing the superior implant endplate, introduce the lead in guide rails between the superior and inferior implant endplates with the remover/repositioner rod at a slight caudal angulation **(Figure 57)**.

The guide rails will straddle the polyethylene inlay laterally and contact the inner surface of the implant endplate **(Figure 57)**.

Rotate the remover/repositioner rod cranially until the axis of the implant endplate and the remover/repositioner rod are parallel **(Figure 58)**.

The attachment arms will now be in the correct orientation to capture the holding features on the bone contacting surface of the implant endplate.

Advance the remover/repositioner instrument assembly posteriorly (towards the implant) until the remover/repositioner tip attachment arms engage with the holding features on the implant endplate **(Figure 59)**.

A subtle tactile click may be felt as the remover/repositioner tip attachment arms engage with the implant endplate's holding features.

CAUTION ***When properly aligned, only minimal force is required to attach the remover/repositioner tip attachment arms to the holding features of the implant endplate. Excessive force increases the risk of advancing the implant endplate posteriorly.***

NOTE: ***The remover/repositioner tip is only provisionally attached to the implant endplate. The Introducer is used to firmly secure the remover/repositioner tip attachment arms to the implant endplate's holding features.***

Remove the remover/repositioner rod by rotating counterclockwise. The remover/repositioner tip should remain provisionally attached to the implant endplate **(Figure 60)**.

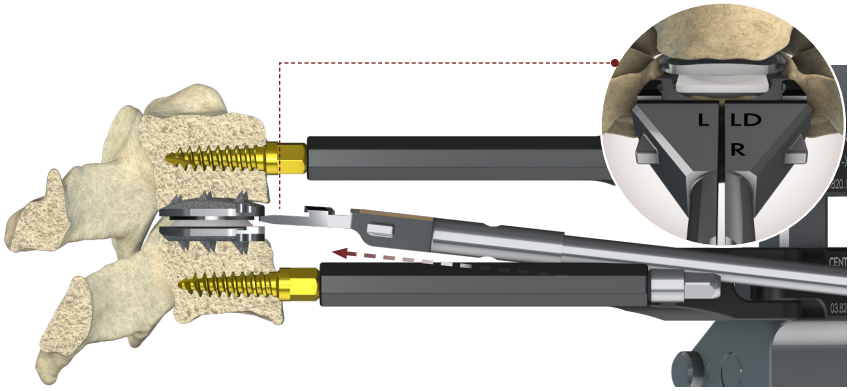


Figure 57.

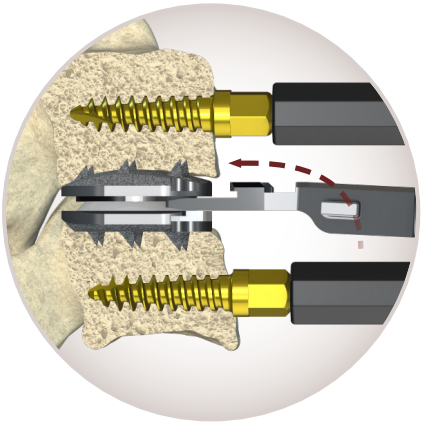


Figure 58.

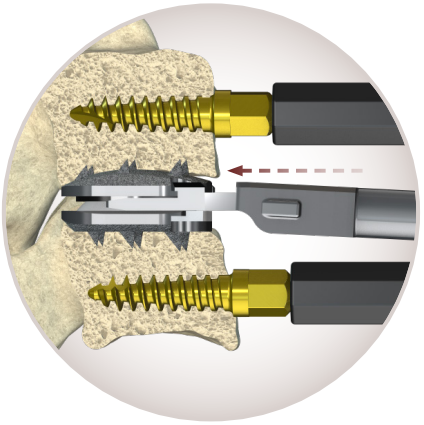


Figure 59.

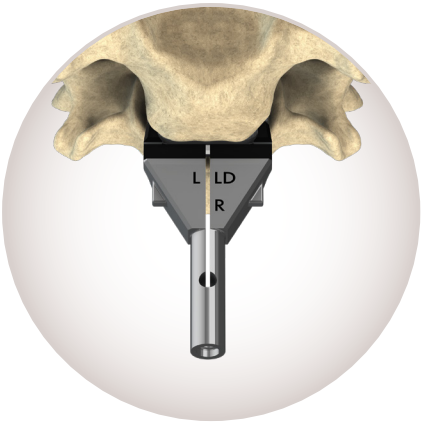


Figure 60.

Intra-Operative Implant Repositioning or Removal (Cont'd)

Secure Attachment of the Superior Endplate for Repositioning:

Both introducers (with and without stops) are compatible with all remover/repositioner tips. Advance the Introducer over the remover/repositioner tip **(Figure 61)**.

NOTE: ***Up-Down orientation of the Introducer is not required.***

Ensure the alignment tabs on the remover/repositioner tip are captured within the Introducer before tightening **(Figure 62)**.

Use two fingers to rotate the proximal knob of the Introducer clockwise to tighten the connection with the remover/repositioner tip **(Figure 62)**.

The remover/repositioner tip should now be firmly attached to the superior implant endplate.

Gently reposition the implant endplate by hand or with the aid of the slide hammer, as desired.

NOTE: ***Repositioning of the prodisc C Vivo may require slight medial-lateral rocking to aid in repositioning the implant endplate. Repositioning of the prodisc C SK may require slight cranial-caudal rocking to aid in repositioning the implant endplate.***

Aggressive rocking may cause the Remover/Repositioner Tip to disengage from the holding features of the implant endplate.

CAUTION ***Applying excessive force increases the risk of further advancing the implant endplate posteriorly.***

Endplate Release:

Loosen the remover/repositioner tip from the implant endplate by rotating the proximal knob of the Introducer three (3) full turns in the counterclockwise direction **(Figure 63)**.

Rock the Introducer in a medial-lateral motion to approximately 30 degrees off midline and pull up until implant endplate release occurs **(Figure 64)**.

Confirm final implant position with lateral and A/P imaging.

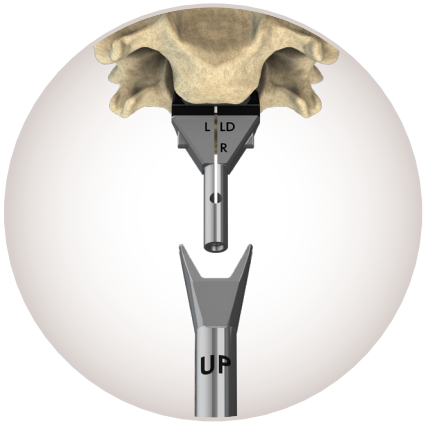


Figure 61.

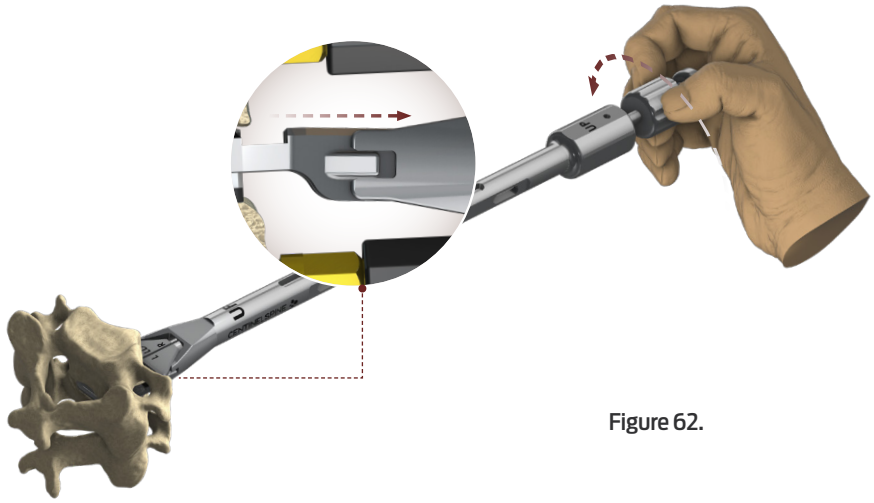


Figure 62.

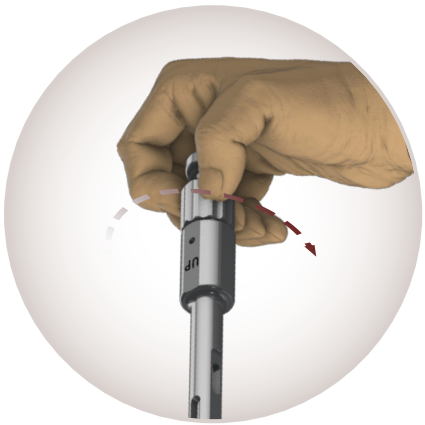


Figure 63.

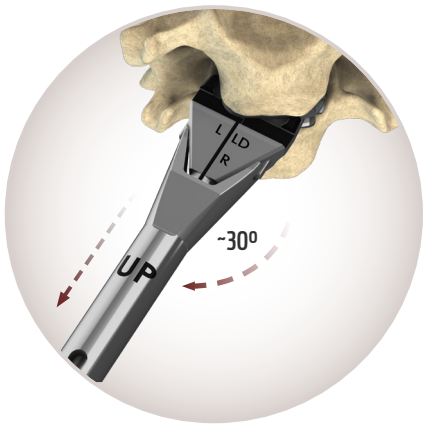


Figure 64.

Intra-Operative Implant Removal

Information:

The remover/repositioner tips are compatible with both the prodisc C Vivo and prodisc C SK implants.

The remover/repositioner tips are intended to attach to **either** the superior or the inferior endplate of the implant as desired. Only one implant endplate can be attached at a time.

Holding features on the bone contacting surfaces of the superior and inferior implant endplates are used as the attachment location for the laser marked attachment arms of the remover/repositioner tip **(Figures 65 & 66)**.

NOTE: ***The holding features are also used for attachment of the introducer tip attachment arms during initial implantation.***

The guide rails of the remover/repositioner tip are designed to lead the remover/repositioner tip between the implant endplates and facilitate engagement of the laser marked attachment arms of the remover/repositioner tip with the holding features of the implant endplate.

See **Figures 67 & 68** for visual guidance on correct engagement of the remover/repositioner tip to the implant endplate.

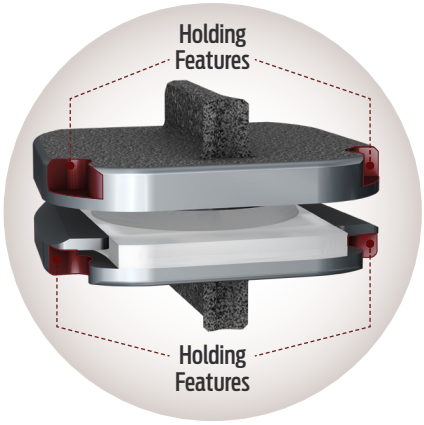


Figure 65.

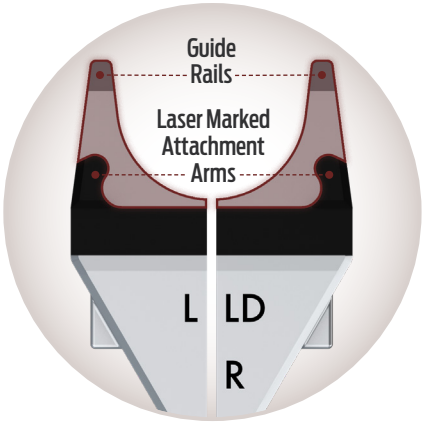


Figure 66.

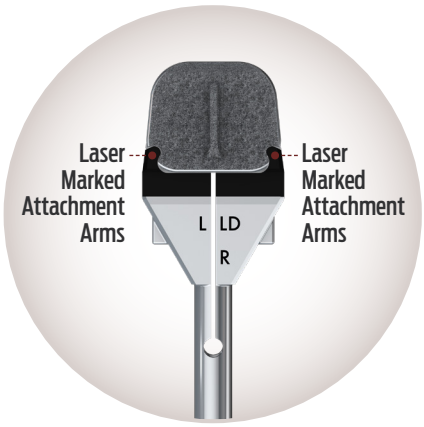


Figure 67.

Figure 68.

Intra-Operative Implant Repositioning or Removal *(Cont'd)*

Preparation:

Slight distraction of the disc space may be required for visualization of the implant and attachment of the remover/repositioner tip.

See instructions for distraction using the vertebral distractor and vertebral body retainer on page 14.

Choose the remover/repositioner tip corresponding to the implant footprint: M/MD, L/LD, or XL/XLD. Attach the remover/repositioner tip to the remover/repositioner rod by rotating the remover/repositioner rod clockwise until it is secure **(Figure 69)**.

NOTE: ***For removal needs attach the remover/repositioner tip to the inferior implant endplate.***

Provisional Attachment of the Inferior Endplate for Removal:

With the remover/repositioner tip attachment arms facing the inferior implant endplate, introduce the lead in guide rails between the superior and inferior implant endplates with the remover/repositioner rod at a slight cranial angulation **(Figure 70)**.

The guide rails will straddle the polyethylene inlay laterally and contact the inner surface of the implant endplate **(Figure 70)**.

Rotate the remover/repostioner rod caudally until the axis of the implant endplate and the remover/repositioner rod are parallel **(Figure 71)**.

The attachment arms will now be in the correct orientation to capture the holding features on the bone contacting surface of the implant endplate.

Advance the remover/repositioner instrument assembly posteriorly (towards the implant) until the remover/repositioner tip attachment arms engage with the holding features on the implant endplate **(Figure 72)**.

A subtle tactile click may be felt as the remover/repositioner tip attachment arms engage with the implant endplate's holding features.

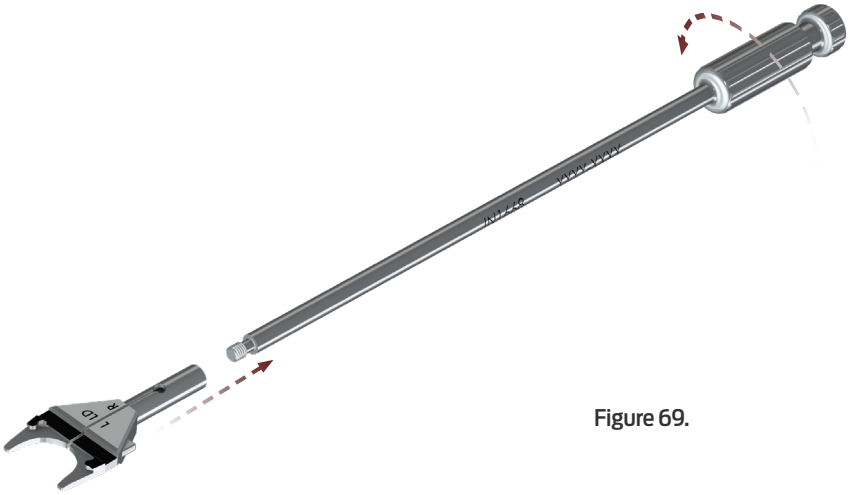


Figure 69.

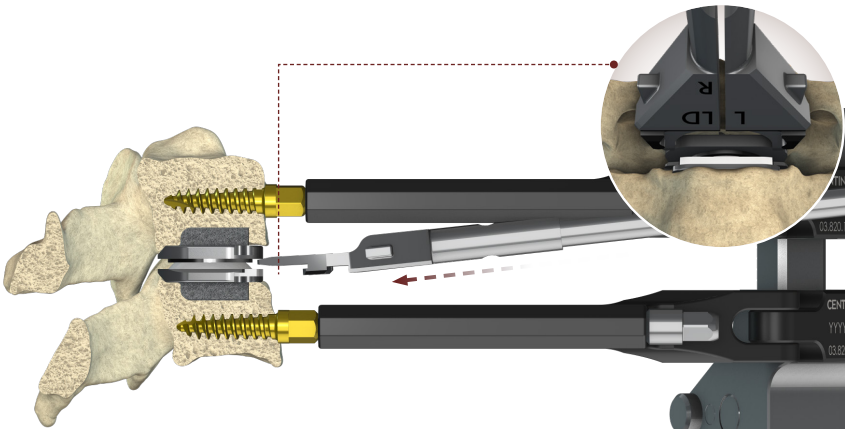


Figure 70.

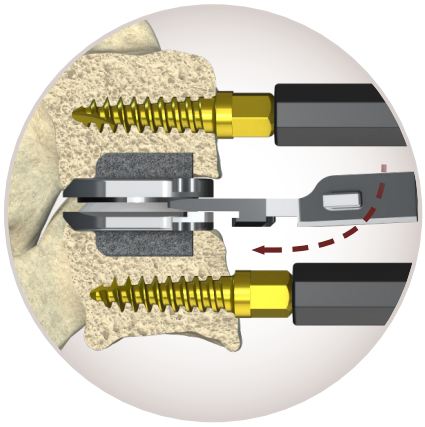


Figure 71.

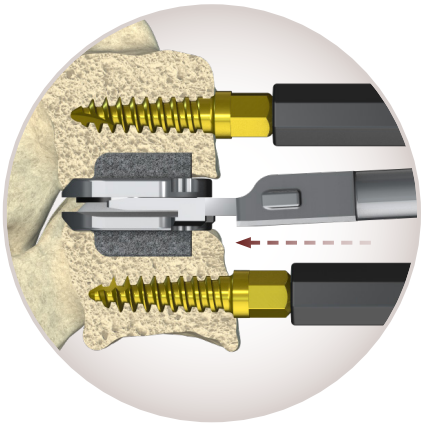


Figure 72.

CAUTION ***When properly aligned, only minimal force is required to attach the remover/repositioner tip attachment arms to the holding features of the implant endplate. Excessive force increases the risk of advancing the implant endplate posteriorly.***

NOTE: *The remover/repositioner tip is only provisionally attached to the implant endplate. The Introducer is used to firmly secure the remover/repositioner tip attachment arms to the implant endplate's holding features.*

Remove the remover/repositioner introducer rod by rotating counterclockwise. The remover/repositioner tip should remain provisionally attached to the implant endplate **(Figure 73)**.

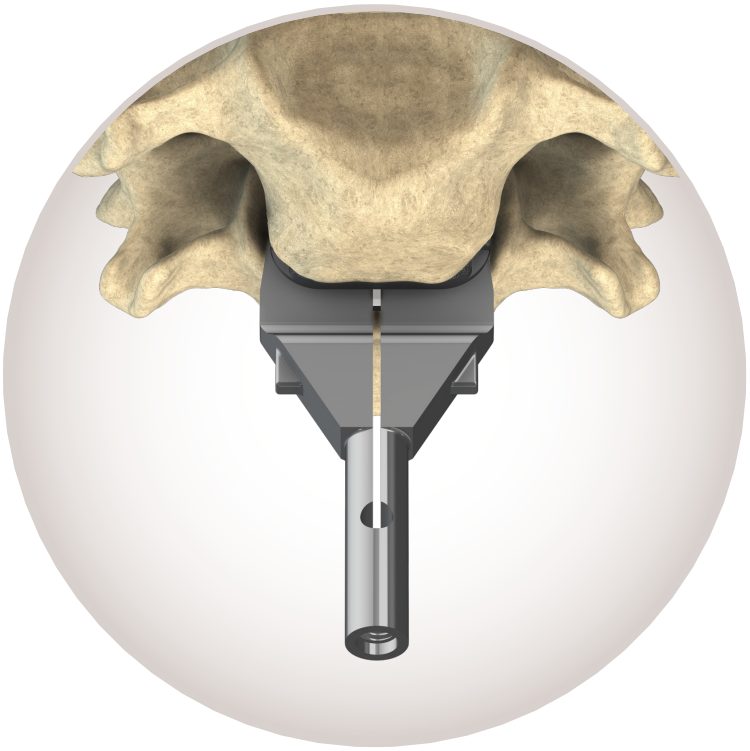


Figure 73.

Intra-Operative Implant Repositioning or Removal (Cont'd)

Secure Attachment of the Inferior Endplate for Removal:

Both Introducers (with and without stops) are compatible with all remover/repositioner tips. Advance the Introducer over the remover/repositioner tip **(Figure 74)**.

NOTE: ***Up-Down orientation of the Introducer is not required.***

Ensure the alignment tabs on the remover/repositioner tip are captured within the Introducer before tightening **(Figure 75)**.

Use two fingers to rotate the proximal knob of the Introducer clockwise to tighten the connection with the remover/repositioner tip **(Figure 75)**.

The remover/repositioner tip should now be firmly attached to the inferior implant endplate.

Remove the implant endplate by hand or with the aid of the slide hammer, as desired **(Figure 76)**.

NOTE: ***Removing the prodisc C Vivo may require slight medial-lateral rocking to aid in removing the implant endplate. Removing the prodisc C SK may require slight cranial-caudal rocking to aid in removing the implant endplate.***

Aggressive rocking may cause the Remover/Repositioner Tip to disengage from the holding features of the implant endplate.

CAUTION ***Applying excessive force increases the risk of further advancing the implant endplate posteriorly.***

Utilize standard surgical instruments to remove the superior endplate, such as a Kocher clamp or other grasping instrument.

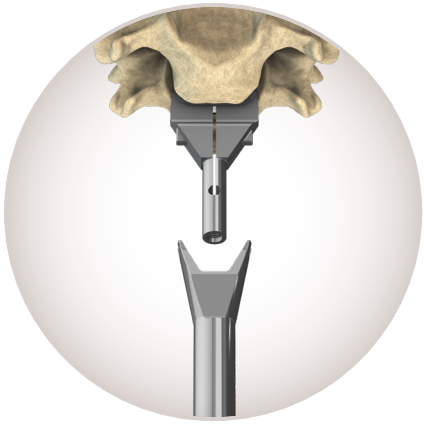


Figure 74.

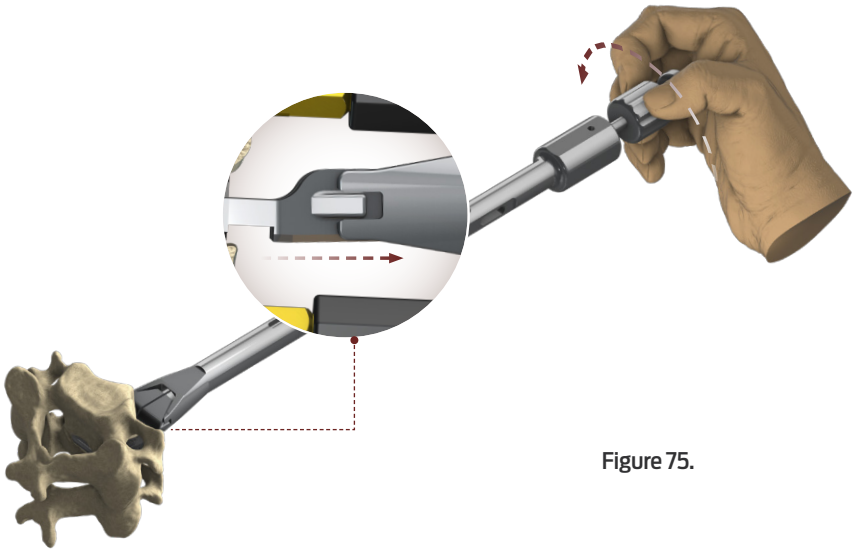


Figure 75.

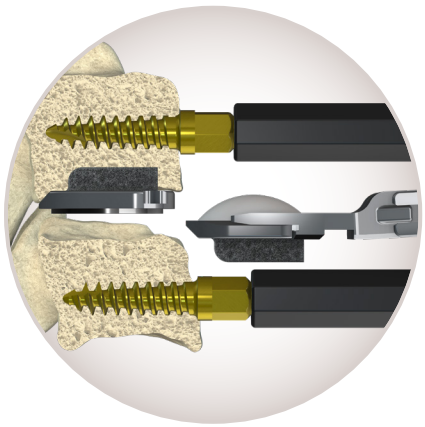


Figure 76.

Surgical Technique Considerations for Implantation of prodisc C Vivo *and/or* prodisc C SK *at Two Contiguous Levels*

Initial Level Selection:

Either the superior or inferior operative level may be addressed first, at the discretion of the operating surgeon.

Retainer Screw Placement:

Be sure to use the Vertebral Body Retainer for each level independently. Do not span the intermediate level with the Vertebral Body Retainer.

Place one Retainer Screw at the midpoint of the intermediate vertebral body, approximately parallel to the endplates **(Figure 77)**.

Care should be taken to ensure clearance for the prodisc C Vivo & prodisc C SK instrumentation.

Place the second Retainer Screw per the instructions detailed on page 13.

After implantation of the first operative level, remove the cephalad or caudal most Retainer Screw and place an appropriately sized Retainer Screw above or below the remaining operative level, following the instructions detailed on page 13.

Implant Selection:

Follow the implant sizing and positioning guidelines on page 19-20 for prodisc C Vivo and page 35 for prodisc C SK.

Care should be taken to avoid excessive distraction of each motion segment.

Selecting an implant that is too tall can limit the segmental range of motion and sagittal alignment at the operative and/or adjacent levels.

Confirm final positioning of both implants with lateral and AP fluoroscopy (Figures 78 & 79).

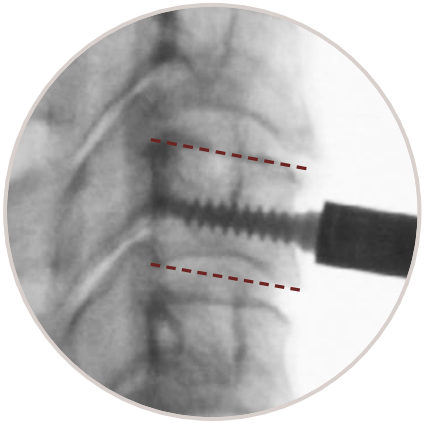


Figure 77.

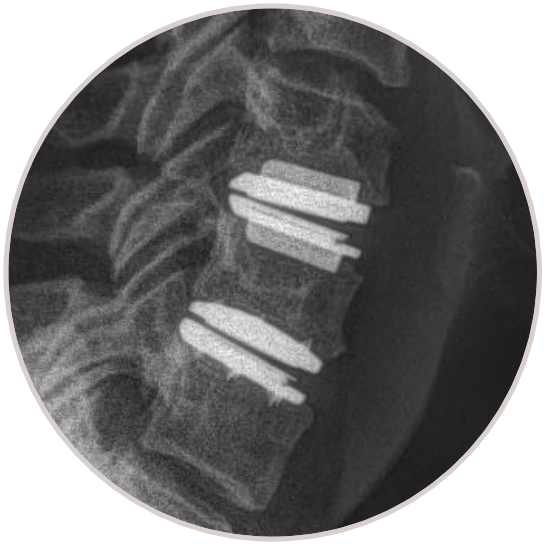


Figure 78.

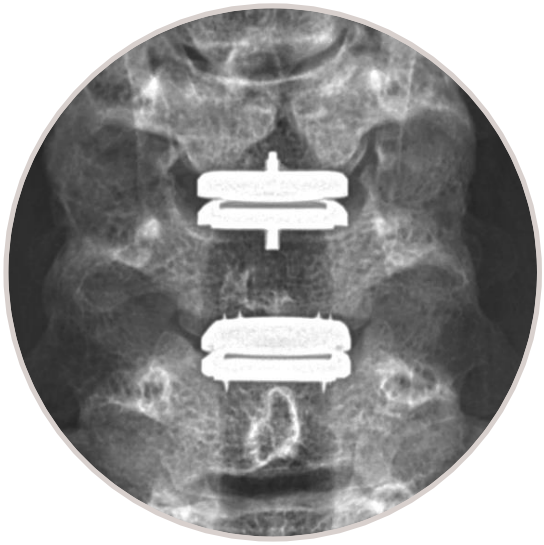


Figure 79.

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

Implant Removal Procedure

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 or prodisc C SK implant from any overlying scar tissue. Excise any bone tissue from the anterior aspect of the endplates to expose the implant-bone junction.

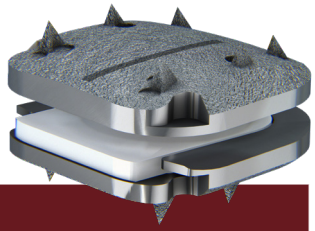
Use an interbody distractor or retainer device to distract the disc space. Using a fine osteotome, pry the superior implant endplate from the vertebral body and extract the superior implant endplate from the space with a Kocher clamp or other grasping instrument. Repeat this technique on the inferior implant endplate. If distraction is not achievable, it may be necessary to pry the polyethylene insert from the inferior implant endplate first, before removing the superior and inferior implant endplates.

Should it be necessary to remove a prodisc C Vivo or prodisc C SK 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 by emailing* **explant@centinelspine.com.**

prodisc C Vivo *Implants*

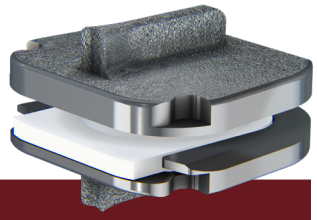


prodisc C Vivo Total Disc Replacement Implants, Sterile

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

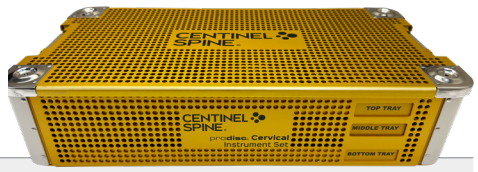
prodisc C SK *Implants*

prodisc C SK Total Disc Replacement Implants, Sterile

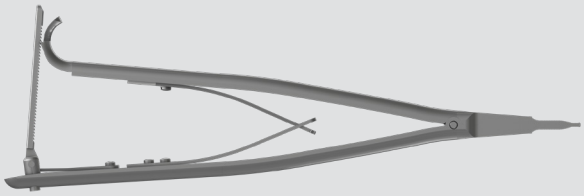
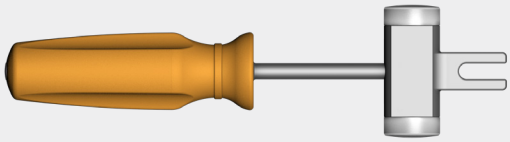
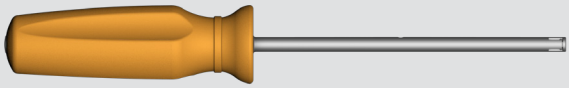
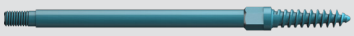
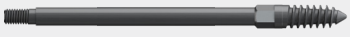
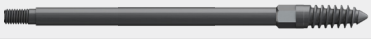


Implant Footprints			Part Numbers		
	Depth (mm)	Width (mm)	5 mm Height	6 mm Height	7 mm Height (available by special request only)
M	12	15	PDSM5	PDSM6	PDSM7
MD	14	15	PDSMD5	PDSMD6	PDSMD7
L	14	17	PDSL5	PDSL6	PDSL7
LD	16	17	PDSLD5	PDSLD6	PDSLD7
XL	16	19	PDSXL5	PDSXL6	PDSXL7
XLD	18	19	PDSXLD5	PDSXLD6	PDSXLD7

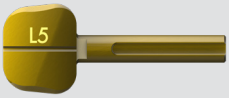
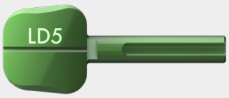
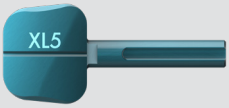
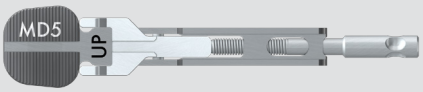
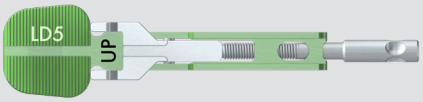
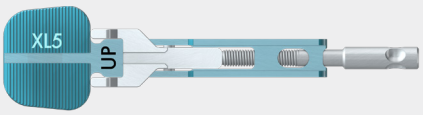
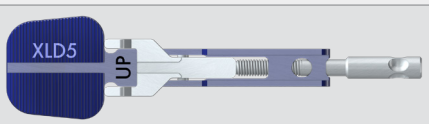
prodisc Cervical Gen2 Instrument Set



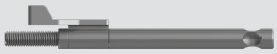
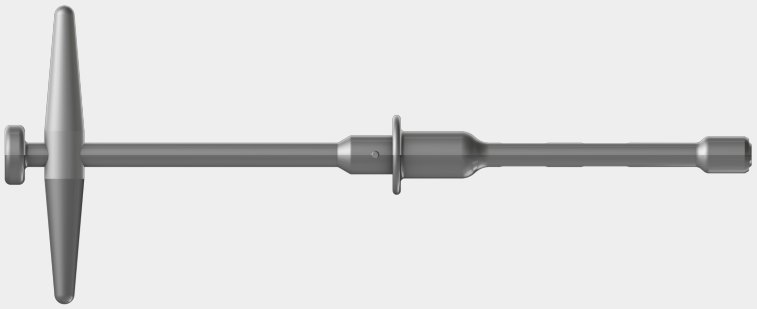
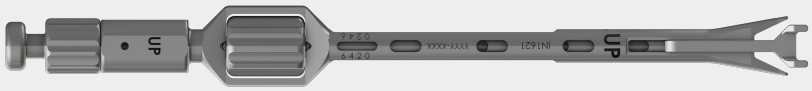
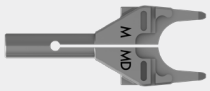
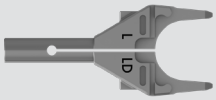
TOP TRAY | Instruments

03.820.100	Awl, 12mm	
03.820.110	Retainer Nut	
03.820.111/1	Vertebral Body Retainer	
03.820.112	Vertebral Distractor	
03.820.113	Slotted Mallet	
IN1444	Self-Retaining Screwdriver, Short	
	Retainer Screws	
03.820.102	Ø3.5mm x 12mm	
03.820.103	Ø3.5mm x 14mm	
03.820.104	Ø3.5mm x 16mm	
03.820.105	Ø3.5mm x 18mm	
03.820.106	Ø4.5mm x 13mm	
03.820.107	Ø4.5mm x 15mm	
03.820.108	Ø4.5mm x 17mm	
03.820.109	Ø4.5mm x 19mm	

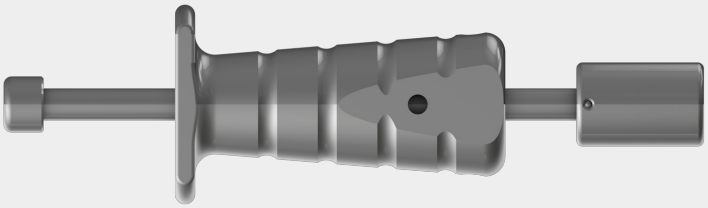
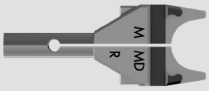
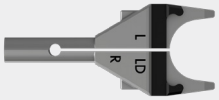
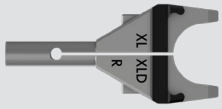
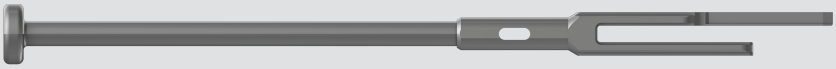
MIDDLE TRAY | Instruments

03.670.207	prodisc C Vivo One-Piece Positioner		
IN1404	prodisc C SK Small Keel Cut Cleaner		
	prodisc C Vivo Trials		
IN1502	Medium	5mm	
IN1503		6mm	
IN1505	Medium, Deep	5mm	
IN1506		6mm	
IN1508	Large	5mm	
IN1509		6mm	
IN1511	Large, Deep	5mm	
IN1512		6mm	
IN1514	Extra-Large	5mm	
IN1515		6mm	
IN1517	Extra-Large, Deep	5mm	
IN1518		6mm	
	prodisc C SK Trials		
IN1520	Medium	5mm	
IN1521		6mm	
IN1523	Medium, Deep	5mm	
IN1524		6mm	
IN1526	Large	5mm	
IN1527		6mm	
IN1529	Large, Deep	5mm	
IN1530		6mm	
IN1532	Extra-Large	5mm	
IN1533		6mm	
IN1535	Extra-Large, Deep	5mm	
IN1536		6mm	

MIDDLE TRAY | Instruments (cont'd)

IN1564	prodisc C Vivo Trial Post Attachment		
IN1584	prodisc C Vivo Trial Stop	5mm	
IN1585		6mm	
IN1617	T-Handle, for Trial Implants		
IN1620	prodisc C Vivo / prodisc C SK / Introducer, No Stop		
IN1621	prodisc C Vivo / prodisc C SK / Introducer		
	Introducer Tips		
IN1655	Medium / Medium, Deep	5mm	
IN1656		6mm	
IN1658	Large / Large, Deep	5mm	
IN1659		6mm	
IN1661	Extra-Large / Extra-Large, Deep	5mm	
IN1662		6mm	

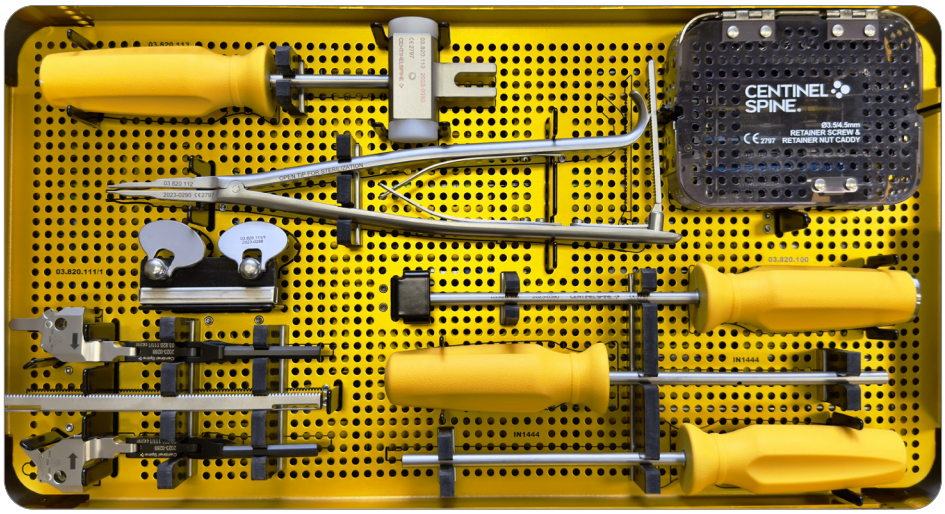
BOTTOM TRAY | Instruments

03.820.282	Slide Hammer		
IN1668	Remover/Repostioner Rod		
	Remover/Repostioner Tips		
IN1665	Medium / Medium, Deep		
IN1666	Large / Large, Deep		
IN1667	Extra-Large / Extra-Large, Deep		
	prodisc C SK Chisels		
IN1541	**SK** Chisel	5mm	
IN1542		6mm	
	Hemi Chisels + 1		
IN1587	Hemi Chisel + 1mm	5mm	
IN1588		6mm	
	Hemi Chisels + 2		
IN1590	Hemi Chisel + 2mm*	5mm	
IN1591		6mm	

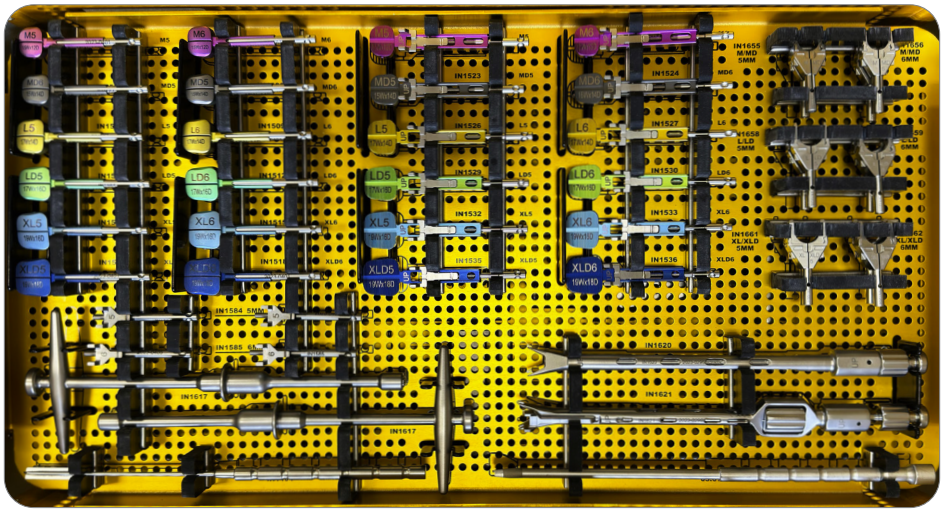
* Available by special request only.

Instrument Set Configuration

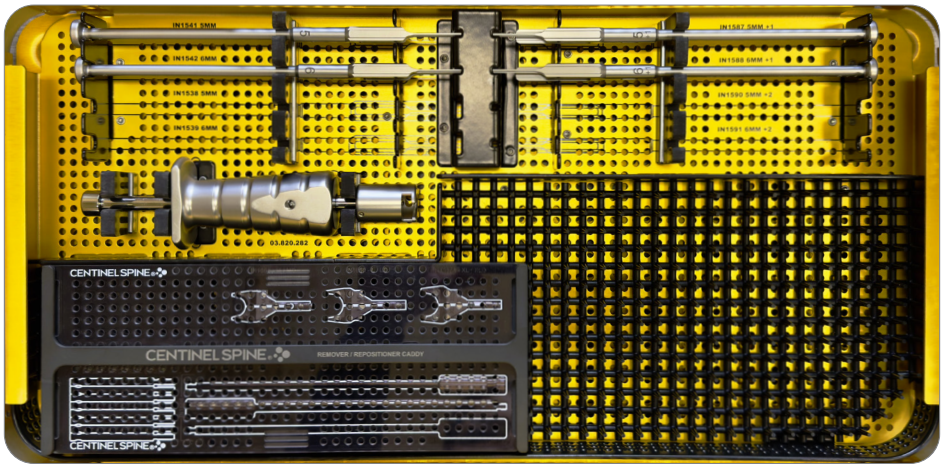
TOP TRAY | Instrument Set Configuration



MIDDLE TRAY | Instrument Set Configuration



BOTTOM TRAY | Instrument Set Configuration

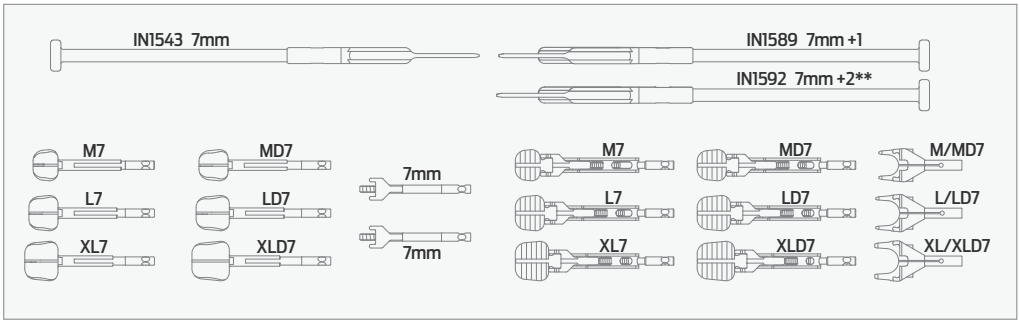


prodisc *Cervical Auxiliary Instrument Set**

Instruments

	prodisc C Vivo Trials
IN1504	Medium, 7mm
IN1507	Medium, Deep, 7mm
IN1510	Large, 7mm
IN1513	Large, Deep, 7mm
IN1516	Extra-Large, 7mm
IN1519	Extra-Large, Deep, 7mm
	prodisc C SK Trials
IN1522	Medium, 7mm
IN1525	Medium, Deep, 7mm
IN1528	Large, 7mm
IN1531	Large, Deep, 7mm
IN1534	Extra-Large, 7mm
IN1537	Extra-Large, Deep, 7mm
IN1543	prodisc C SK Chisel, 7mm
IN1564	prodisc C Vivo Trial Post Attachment
IN1586	prodisc C Vivo Trial Stop, 7mm
IN1589	Hemi Chisel +1mm, 7mm
IN1592	Hemi Chisel +2mm, 7mm**
	Introducer Tips
IN1657	Medium / Medium, Deep, 7mm
IN1660	Large / Large, Deep, 7mm
IN1663	Extra-Large / Extra-Large, Deep, 7mm

Auxiliary Instrument Set Configuration



*7mm implants and instruments available by special request only. ** Available by special request only.

References

[1] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2024.

[2] Data on file at Centinel Spine.

[3] DiAngelo D, Chung C, Hoyer D, Carson T, Foley K. Biomechanical Analysis of the Endplate Fixation Methods of Cervical Total Disc Replacement (TDR) Prostheses to Shear Force Expulsion. Presented at NASS Annual conference. Sept 29-Oct 2, 2021, Boston, USA.

[4] Sears, R., et al., Kinematics of Cervical and Lumbar Total Disc Replacement, Semin Spine Surg, 2006, 18:117-129.

[5] Bertagnoli, R., Marnay, T., Mayer, H.M., The PRODISC Book, 2003.

CENTINEL SPINE
US Headquarters: 900 Airport Rd, Ste. 3B, West Chester, PA 19380 USA
Email (US): info@centinelspine.com
Web: www.centinelspine.com