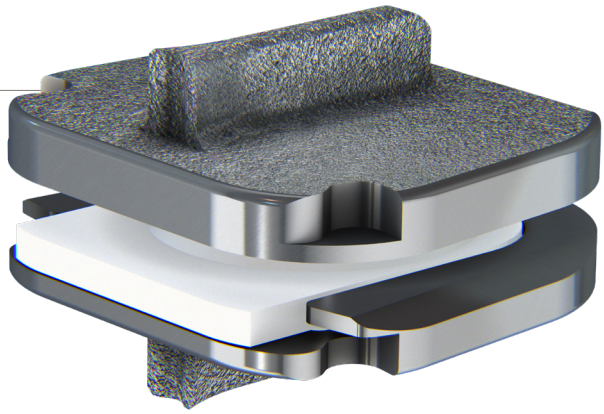
CENTINEL SPINE®

prodisc® C SK

Keel Fixation—Simplified Surgical Technique



SURGICAL TECHNIQUE GUIDE

With prodisc Cervical V2 Instrument Set

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

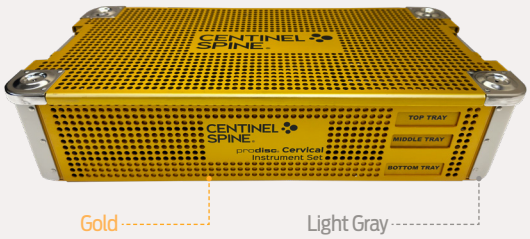


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TABLE OF CONTENTS

please NOTE *This guide alone does not provide sufficient background for direct use of Centinel Spine products. Instruction by a surgeon experienced in handling these products is mandatory.*

CENTINEL SPINE®

A dedicated spine company with a singular focus

30+ YEARS OF CLINICAL SUCCESS SINCE 1988

About Centinel Spine

Centinel Spine is a leading global medical device company addressing cervical and lumbar spinal disease through anterior surgical access. The company offers a continuum of trusted, brand-name, motion-preserving and fusion solutions backed by over 30 years of clinical success—providing the most robust and clinically-proven technology platforms in the world for total disc replacement (prodisc®) and Integrated Interbody™ fusion (STALIF®).

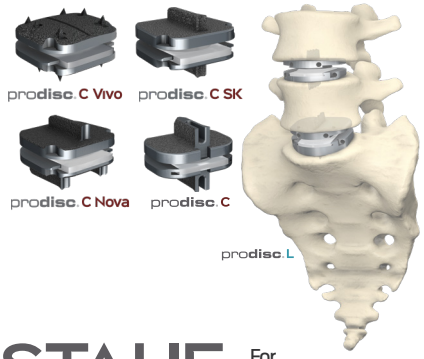
Clinically-Proven Motion Preservation

Centinel Spine offers an unmatched number of six cervical / lumbar total disc replacement (TDR) products, globally, and is the only company with both lumbar and cervical approval in the U.S. The prodisc technology is the most studied and clinically-proven TDR system in the world, validated after over 30 years of clinical use and by over 540 published papers.[1]

Centinel Spine's cervical TDR portfolio now includes four devices approved by the U.S. Food and Drug Administration for 1-level indications, offering the broadest spectrum of solutions to address surgeon preference and individual patient anatomy. Centinel Spine's prodisc L is the only TDR system in the U.S. approved for two-level use in the lumbar spine.

All prodisc products incorporate prodisc CORE technology, the basis behind the predictable clinical outcomes of every prodisc device in over 225,000 implantations worldwide.[2] The variety of cervical TDR endplate configurations, coupled with the proven and well-documented prodisc CORE technology, allows for optimization of implant fit and surgical outcomes.

prodisc® For Motion

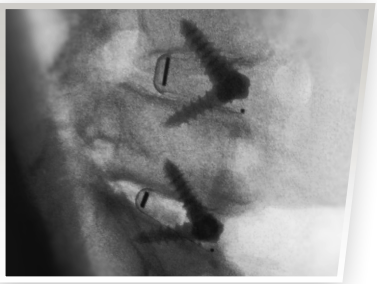


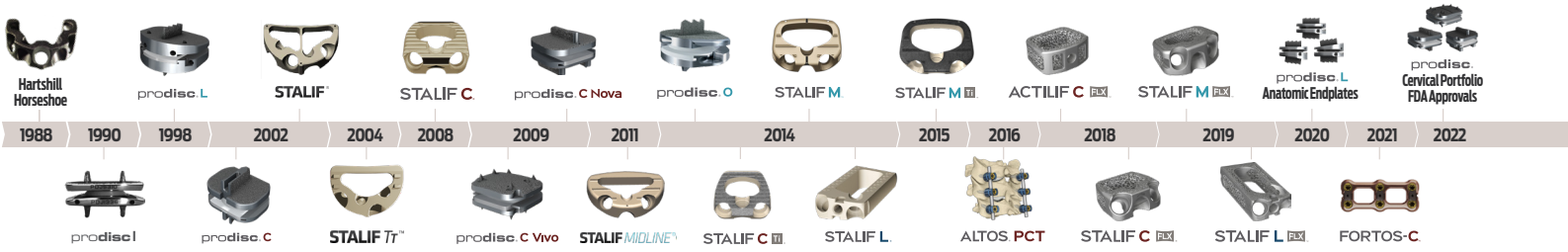
Pioneering Integrated Interbody Solutions

The Stand-Alone/No Profile® device category was founded in 1988 with the release of the Hartshill Horseshoe product, the foundation for the technology platform known today as STALIF. Centinel Spine remains a leader in Stand-Alone solutions today, with over 30 years of clinical history and over 75,000[3] devices implanted. STALIF is one of the few Stand-Alone devices with demonstrated biomechanical equivalence to anterior plate & cage in independent peer-reviewed publications.[4,5]

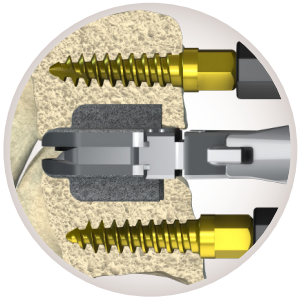
STALIF technology incorporates unique integrated compressive lag fixation technology to enhance stability and compress endplates to the cage and graft material. The system utilizes simple, elegant instrumentation—perfected over years of clinical use and proven to reduce surgical time by 40%, compared to reported alternatives.[6,7] STALIF technology is currently available in PEEK, Ti-ACTIVE™ microporous texturized titanium surface, and FLX™ proprietary 3D-Printed titanium trabecular scaffold.

STALIF® For Fusion



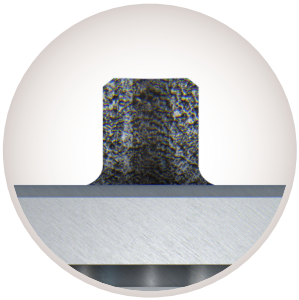


Introduction to prodisc® C SK



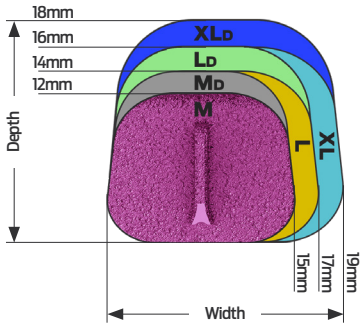
Simple Surgical Technique

- Low-Profile Keel Allows Streamlined Keel Preparation Technique



Implant Fixation

- Low Profile central keel provides immediate fixation
- Secondary fixation from the plasma-sprayed titanium coating on bone contacting surfaces



Anatomical Footprint & Sizes

- Trapezoidal footprint to maximize endplate coverage & optimize fit within the uncinate process
- 18 options to accommodate anatomical variation & a broad patient population: 6 footprints and 3 heights (5-7mm)

Proven Materials

- Proven articulating surfaces: ultra-high molecular weight polyethylene (UHMWPE) on Cobalt Chrome (CoCrMo) alloy

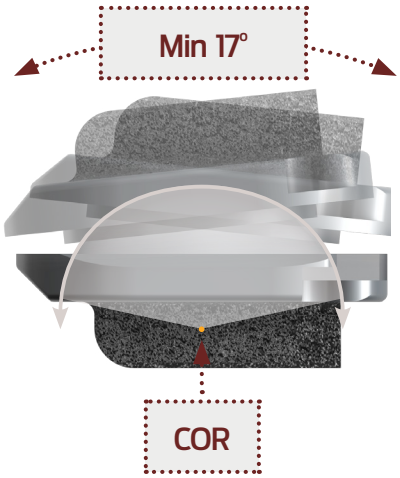
Powered by prodisc CORE

- The fixed core and optimized core radius together provide stability and controlled predictable motion[8,9]

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

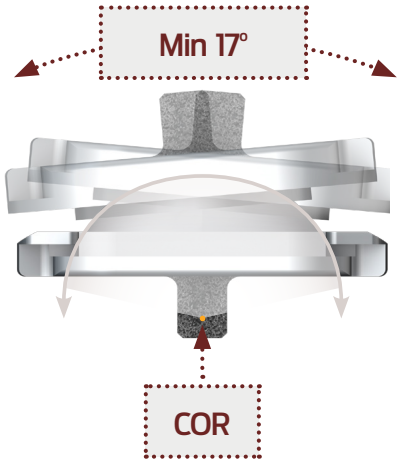
Flexion/Extension

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



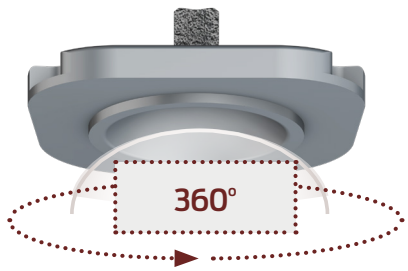
Lateral Bending

- 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



Contents

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

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

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

Description

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

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

Contents are supplied sterile.

Device Description

The prodisc C SK Total Disc Replacement device consists of the following three components. The first is the inferior CoCrMo (cobalt chromium molybdenum) alloy plate with a midline keel that anchors to the inferior vertebral body. The second component is an Ultra High Molecular Weight Polyethylene (UHMWPE) insert that is pre-assembled snap-locked into a tray detail in the inferior CoCrMo alloy plate and provides the inferior convex bearing surface. The third component is a CoCrMo alloy plate with a midline keel that anchors to the superior vertebral body endplate and has a highly polished concave bearing surface that articulates with the convex UHMWPE spherical dome.

The endplate footprints range from 15-19 mm wide (medial-lateral) x 12-18 mm deep (anterior-posterior). Each endplate size is available in three disc heights: 5, 6, and 7 mm. This allows for a wide range of sizing to accommodate individual patient anatomy.

The bone contacting surfaces of the inferior and superior plates, as well as both keels, are titanium plasma spray coated, which may provide additional fixation through bony ongrowth.

The maximum range of motion allowed by the prodisc C SK Total Disc Replacement device design is 20° in flexion/extension (17° for the 5mm Large, Large Deep, Extra Large, and Extra Large Deep implants), 20° in lateral bending (17° for the 5mm Large, Large Deep, Extra Large, and Extra Large Deep implants), and the device is unconstrained in axial rotation as measured through in vitro testing.

Intended Use

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

Indications for Use

The prodisc C SK Total Disc Replacement is indicated in skeletally mature patients for reconstruction of a single disc from C3-C7 following discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or loss of disc height.

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

Specific Contraindications

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

General Contraindications

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

Contraindications

The prodisc C SK Total Disc Replacement device should not be implanted in patients with the following conditions::

- Active systemic infection or infection localized to the site of implantation
- Osteoporosis defined as DEXA bone density measured T-score ≤ -2.5
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3 mm and/or > 11º of rotational difference to either adjacent level
- Allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
- Spondylosis within levels C1-C7
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion)

Patient Exclusion Recommendations

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

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

Warnings

Correct placement of the device is essential to optimal performance. Use of the prodisc C SK Total Disc Replacement 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 a 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.

Preoperative Considerations

Perform a thorough review of patient history, physical exam, and imaging studies to identify possible contraindications to total disc replacement and to identify the appropriate symptomatic level. Upon reviewing all pertinent information, determine whether a bone density scan is appropriate.

Precautions

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

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

The safety and effectiveness of this device has not been established in patients with the following conditions:

- Not skeletally mature
- Patients under the age of 18 or over the age of 69
- More than one vertebral level with SCDD
- Prior fusion surgery at an adjacent vertebral level
- Prior surgery at the level to be treated
- Advanced facet joint disease or degeneration at the level to be treated
- Neck or arm pain of unknown etiology
- Paget's disease, osteomalacia, or other metabolic bone disease
- Pregnancy
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids)
- Rheumatoid arthritis or other autoimmune disease
- Severe diabetes mellitus requiring daily insulin treatment
- Systemic disease including AIDS, HIV, and hepatitis
- Active malignancy
- Patients with progressive symptoms and signs of spinal cord/nerve root compression with less than six weeks of conservative treatment

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all comorbidities, past and present medications, previous treatments, etc. A screening questionnaire for osteoporosis, i.e. SCORE (Simple Calculated Osteoporosis Risk Estimation), may be used to screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, the patient should be excluded from receiving the device (per the contraindications listed above) if the DEXA bone density measured T-score is ≤ -2.5, as the patient may be osteoporotic.

Use care when handling the prodisc C SK Total Disc Replacement implant to ensure that it does not come in contact with objects that could damage the implant. Exercise care to ensure that implantation instruments do not contact the highly polished articulating surfaces of the endplates. Damaged implants are no longer functionally reliable.

To prevent unnecessary damage to the bearing surfaces, ensure that blood or other debris is not trapped within the device.

prodisc C SK Total Disc Replacement implants should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique guide for step-by-step instructions.

Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. This includes the avoidance of heavy lifting, repetitive bending, and prolonged or strenuous activity initially and for a period of weeks to months depending on the individual patient's progress and the stability and functioning of the implant.

Procedure

The prodisc C SK cervical disc prosthesis must be implanted with the prodisc C SK instruments only.

Magnetic Resonance Environment

MR Conditional

Non-clinical testing of the worst-case scenario has demonstrated that the articles of the 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 SK produced a temperature rise of less than 2ºC at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3 Tesla MR scanner.

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

Processing, Reprocessing, Care, & Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://prodiscguides.centinelspine.com

For general information about reprocessing, care, and maintenance of Centinel Spine reusable devices, instrument trays, and cases, please refer to:

http://prodiscguides.centinelspine.com

SURGICAL TECHNIQUE

Patient Positioning

A/P and lateral imaging is used frequently throughout the 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, avoiding frequent passage in and out of the sterile field **(Figure 1)**.

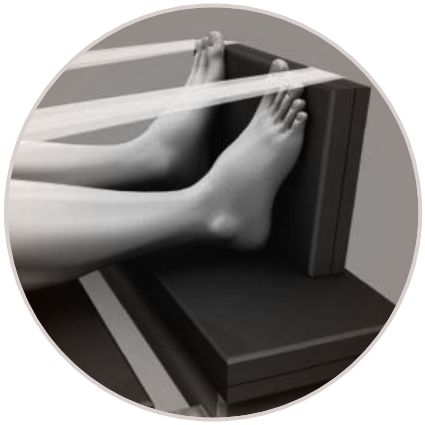
Position the patient supine on the operating table. Support the neck with a radiolucent cushioned neck roll to keep the neck in a normal lordotic ("neutral") position **(Figure 2)**. Correct any malrotation of the neck and head. Confirm true A/P orientation with spot fluoroscopy. Tape or strap the head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

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

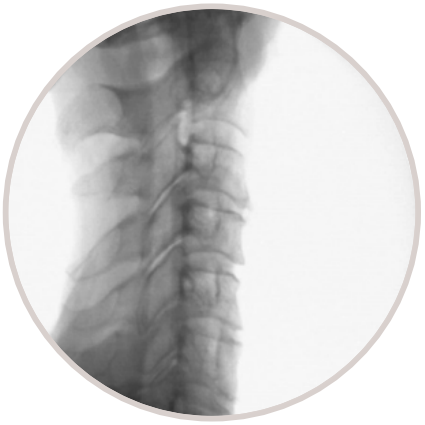
Use A/P spot fluoroscopy to look at rotation and lateral fluoroscopy to line up and perfectly superimpose the facets **(Figure 4)**.

1. Taping Shoulder to the Foot Board

2. Supporting the Neck with a Radiolucent Cushioned Neck Roll



3. Demonstrating Use of Foot Board



4. Fluoroscopy Demonstrating Final Patient Positioning

PLEASE NOTE:

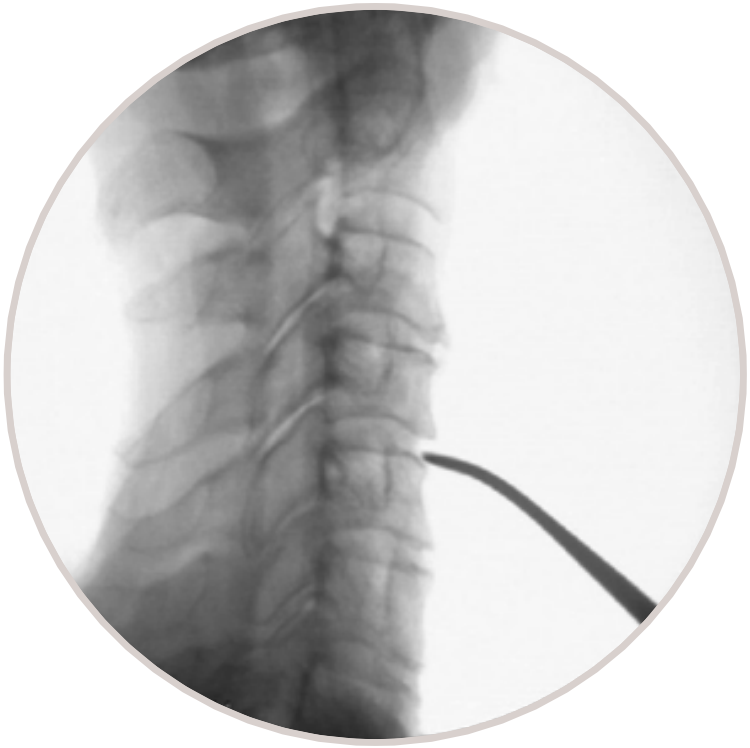
A fusion procedure may be necessary if visualization of the target disc space does not allow for an optimal lateral view.

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

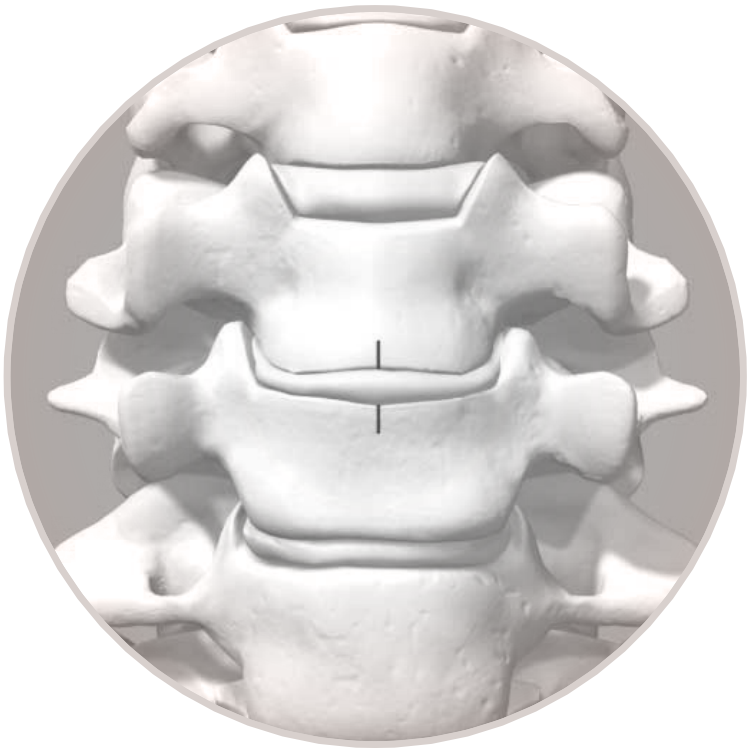
Exposure

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

Use A/P fluoroscopy to identify the midline of the operative level. Mark both the superior and inferior bodies at the disc so the mark is visible throughout the implantation procedure **(Figure 6)**.



5. Verifying Operative Level Under Fluoroscopy



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

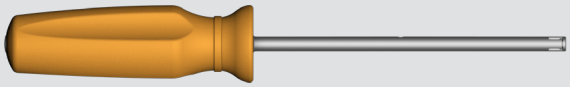
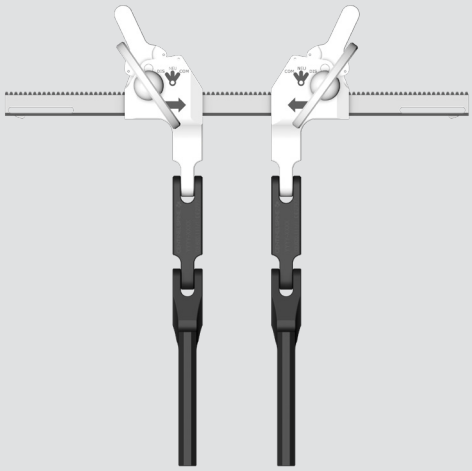
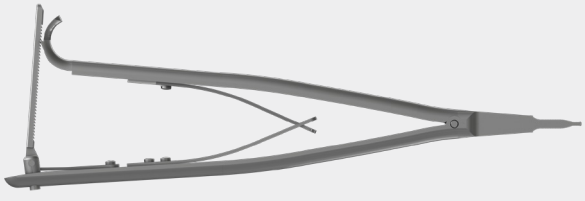
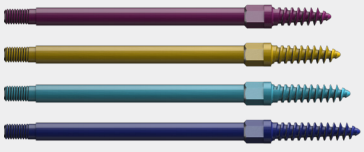
Discectomy, Decompression, & Remobilization

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

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

To avoid the risk of migration or subsidence, it is critical that greater than 90% of the weight-bearing surface of the bone endplate is not violated with a burr or curettes.

Retainer screws maintain parallel distraction of the disc space. Screws should be inserted parallel to the operative disc space of the vertebral body to allow adequate working window for implant insertion.

Instruments		
03.820.100	Awl, 12mm	
IN1444	Self-Retaining Screwdriver, Short	
03.820.110	Retainer Nut	
03.820.111/1	Vertebral 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	

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

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

Estimate retainer screw length based on awl tip (12mm long).

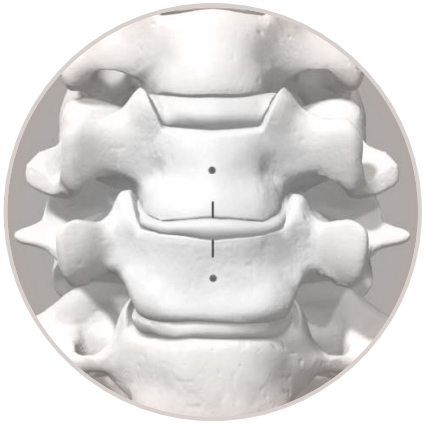
Insert retainer screws with the self-retaining screwdriver **(Figure 10)**, using fluoroscopy to confirm trajectory and screw depth.

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

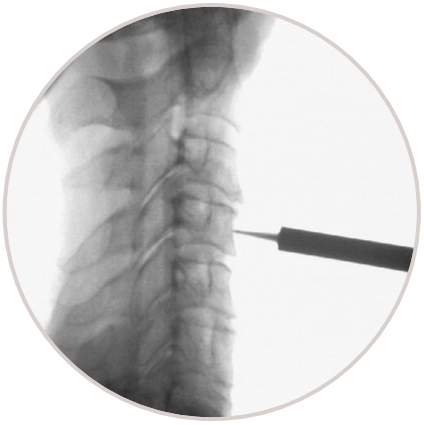
The retainer screws should be inserted parallel to the operative disc space and within the central area of the vertebral body.

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

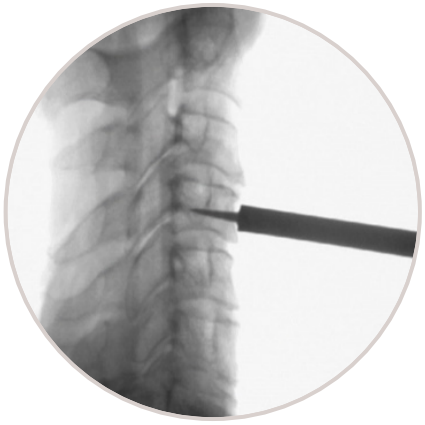
Bicortical purchase is not necessary.



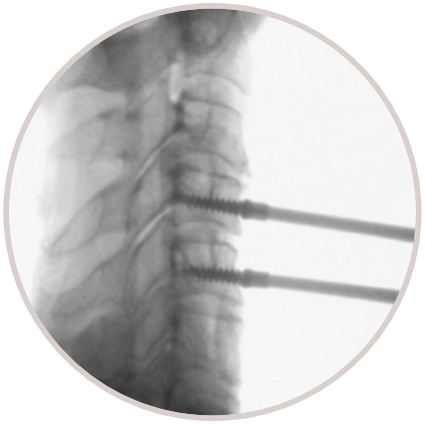
7. Ideal Positioning for Retainer Screw Insertion



8. Perforating the Anterior Cortex with the Awl



9. Verifying Awl Trajectory Under Lateral Fluoroscopy



10. Verifying Screw Depth and Trajectory Under Lateral Fluoroscopy

Discectomy, Decompression, & Remobilization (Cont'd)

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

Slide the vertebral body retainer over the screws; lock it in place with retainer nuts **(Figure 12)**.

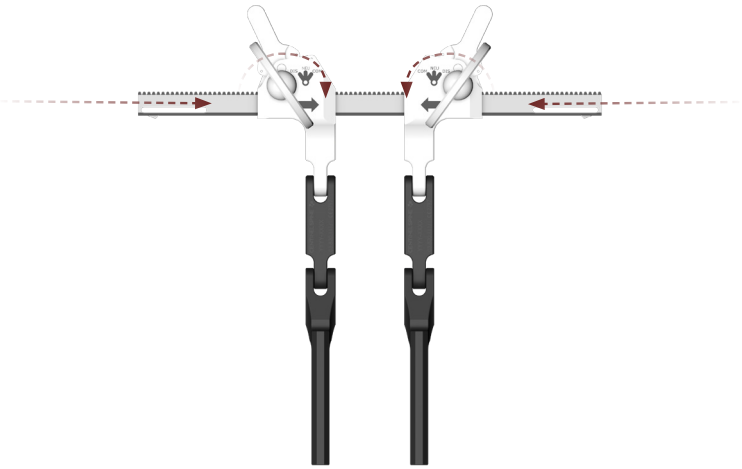
Start the discectomy using standard instruments.

Remove as much disc material as possible to allow the vertebral distractor tips to be placed as posteriorly as possible into the intervertebral space.

Apply light pretension to the operative disc space with the retainer—do not apply enough force to distract the segment.

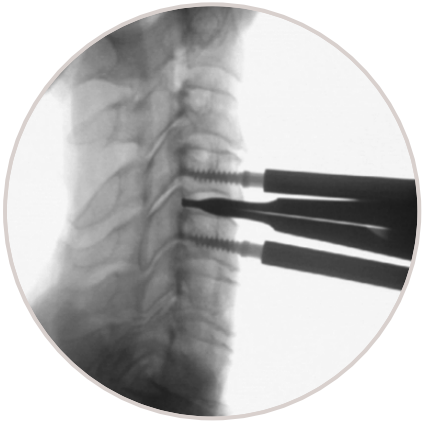
NOTE: ***The vertebral body retainer is not intended to distract the segment as with a Caspar-type retractor. Distraction is achieved with the vertebral distractor.***

Under lateral fluoroscopy, insert the vertebral distractor to the posterior aspect of the disc. Ensure the distractor tips reach the posterior margin of the vertebral bodies to avoid penetration of the vertebral end plates **(Figure 13)**. Avoid over-distraction with the vertebral distractor as this can lead to nerve root tension or improper implant selection.



11. Assembling the Vertebral Body Retainer

12. Sliding Vertebral Body Retainer Over Retainer Screws & Locking with Retainer Nuts



13. Observing Vertebral Distractor Depth Under Lateral Fluoroscopy

Manually distract the space with the vertebral distractor. Distract the intervertebral space with the vertebral distractor to restore the height and to gain access to the posterior intervertebral space **(Figure 14)**.

Readjust the retainer to the distracted height of the intervertebral space. This step should be repeated until maximum distraction has been achieved. Then release and withdraw the vertebral distractor and complete the discectomy, decompression, and remobilization as indicated. Disc spaces that are not remobilized adequately may have limited motion, which may allow bone formation and possible fusion.

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

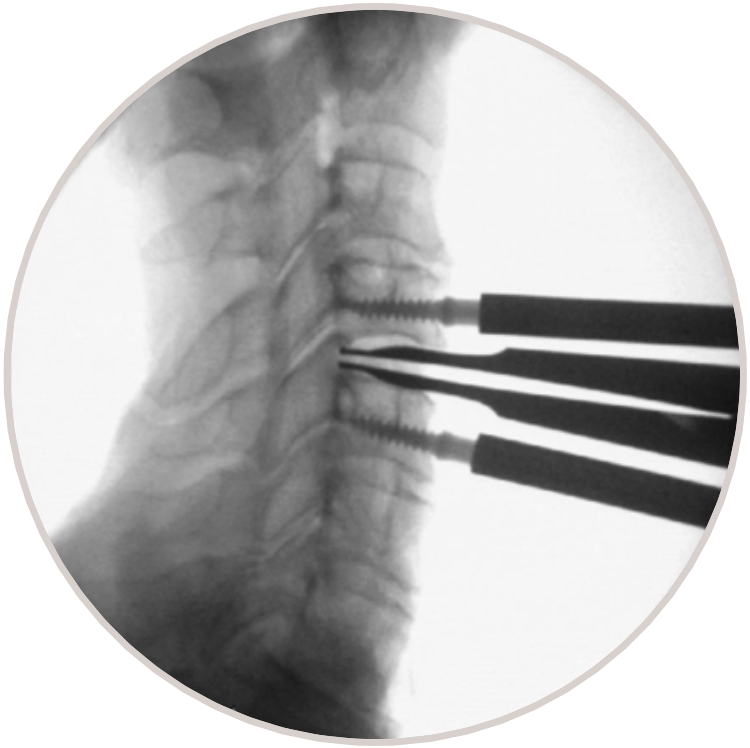
It is encouraged to use manual instruments, such as Kerrisons and curettes, when bony remodeling is necessary.

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

To reduce the incidence of HO, refrain from using a burr to gain access to the posterior aspect of the disc space.

There are two areas within the disc space endplate anatomy that may obstruct optimum, and preferably larger, implant footprint and positioning:

1. ***Uncinate process along the posterolateral aspect of the inferior endplate***
   - ***Flatten with Kerrison rongeurs or with careful use of a burr***
2. ***Posterior central portion of the superior endplate***
   - ***Avoid compromising the weight-bearing portion of the endplate***
   - ***Remodel with Kerrison rongeurs or with careful use of a burr***



14. Observing Distraction of Intervertebral Space Under Lateral Fluoroscopy

Implantation

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

1. **Trial**
2. **Keel Preparation**
3. **Implant Insertion**

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.

The goal is to 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 normal adjacent discs.

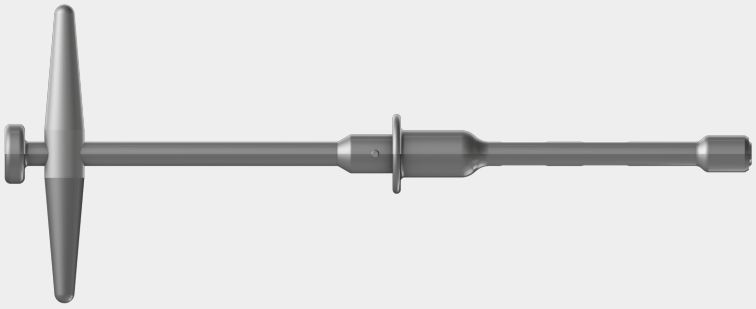
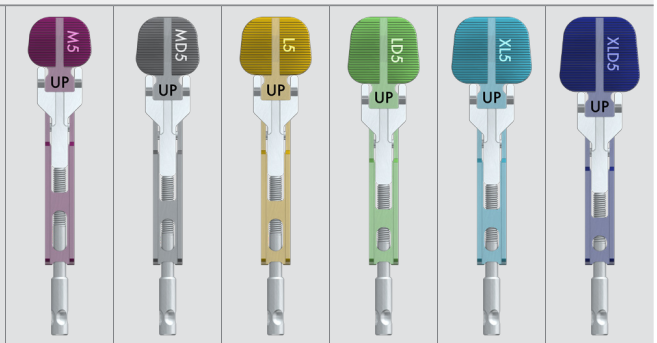
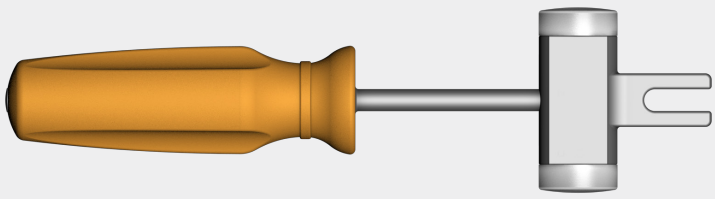
PLEASE NOTE:

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

Avoid kyphotic position of the corresponding vertebrae. Select the next smaller size of trial implant instead.

STEP 1: Trial

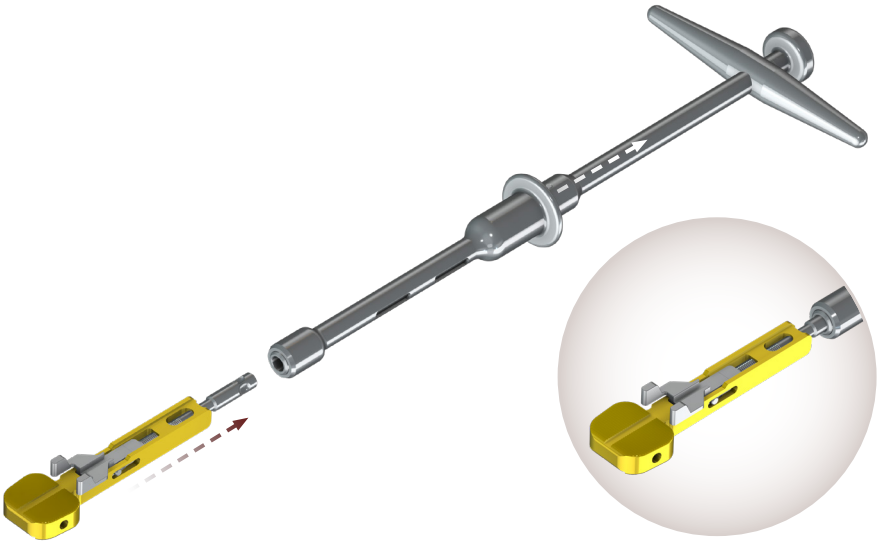
Instruments

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						

Attach the t-handle for the trials to the hexagonal end of the (central) trial shaft **(Figure 15)**.

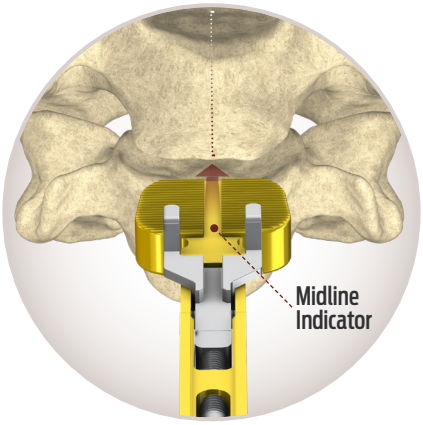
Ensure that the trial stop is fully seated by turning the T-handle clockwise until it will not advance any further **(Figure 16)**.

Align the trial on midline with the stop pointing cranially **(Figures 17 & 18)** and advance it under lateral fluoroscopy into the disc space using the slotted mallet.

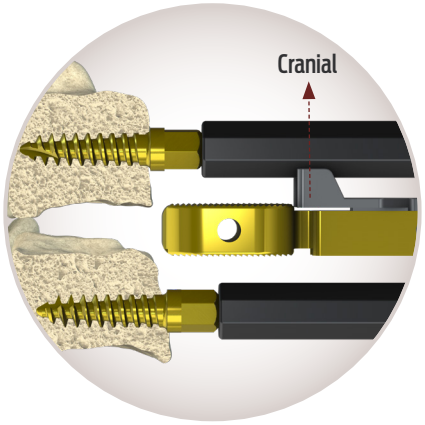


15. Attaching Trial to the T-Handle

16. Trial Stop Fully Seated



17. Aligning Trial on Midline



18. Verifying Trial Stop is Pointing Cranially

Implantation (Cont'd)

Under lateral fluoroscopy, advance the trial to the posterior margin of the disc space.

Two factors should be considered when determining the optimal position of the trial:

1. The best possible anatomical fit with the vertebral bodies.
2. The center of the trial should be positioned mid-body to slightly posterior in order to align with the approximate center of rotation (COR) of the motion segment. This position can be confirmed via lateral fluoroscopy.

CAUTION ***Do not impact the trial beyond the posterior margin of the disc space—confirmed using lateral fluoroscopy.***

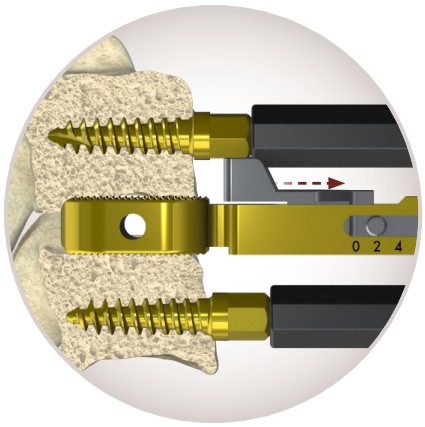
The trial stop can be backed out to allow the trial to advance more posteriorly **(Figure 19)**. Each full counterclockwise rotation of the handle allows the trial to be advanced 0.5mm.

To ensure the trial is not axial rotated, a perfect circle in the trial and perfectly superimposed facets should be visible in the lateral view of the fluoroscopic image **(Figure 20)**.

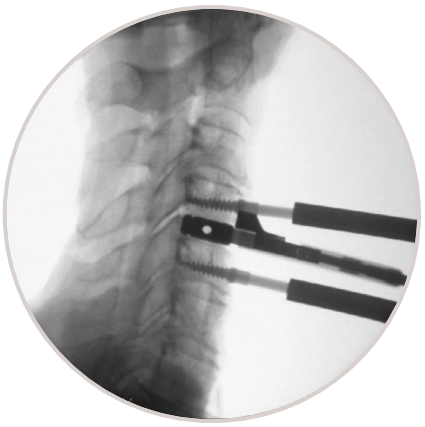
Release the distraction on the vertebral body retainer to determine the optimal height of the trial implant using lateral fluoroscopy. The trial height should be the smallest appropriate height to match normal adjacent discs. Facet joints can become over distracted if too large of a trial/implant height is selected, and final range of motion may become compromised.

Ensure that the trial stop is fully seated against the vertebral body, apply compression with the vertebral body retainer, and remove the T-Handle from the trial. Leave the trial in the disc space **(Figure 21)**.

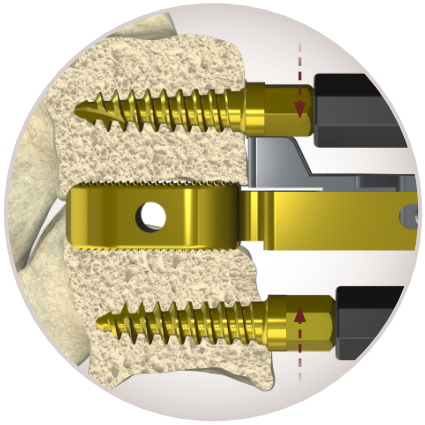
A/P fluoroscopy should be performed to check the width of the trial and midline position **(Figure 22)**.



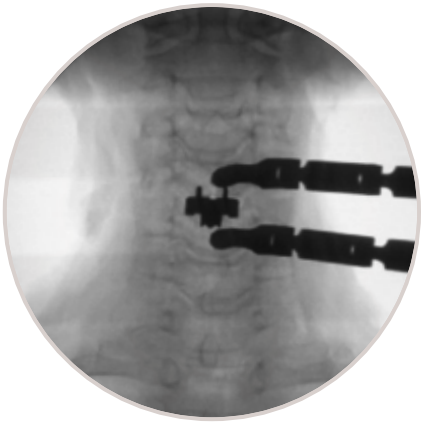
19. Backing Out the Trial Stop to Advance the Trial Posteriorly



20. Verifying Proper Axial Rotation of Trial Under Lateral Fluoroscopy

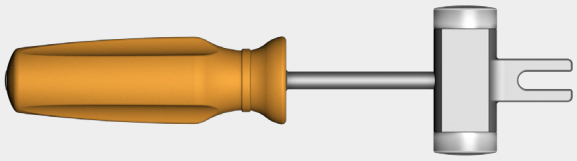
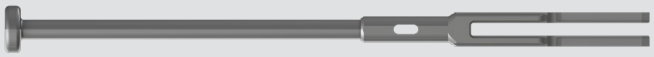
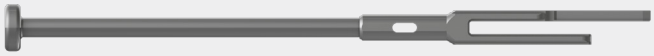
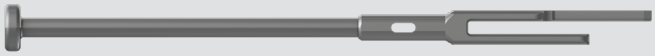


21. Applying Slight Compression with Retainer While Trial Stop is Fully Seated



22. Verifying Width and Midline Positioning of Trial Under A/P Fluoroscopy

STEP 2: Keel Preparation

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

Compress the vertebral body retainer onto the trial. Slide the prodisc C SK chisel of the appropriate height over the shaft of the trial and touch the anterior cortex **(Figure 23)**.

Under A/P fluoroscopy, confirm the chisel is centered on midline and oriented in the A/P sagittal plane. Under lateral fluoroscopy, advance the chisel into the vertebral bodies with the slotted mallet. The trajectory of the chisel should remain on midline while advancing. Continue advancing the chisel until it is fully seated on the trial **(Figure 24)**.

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

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

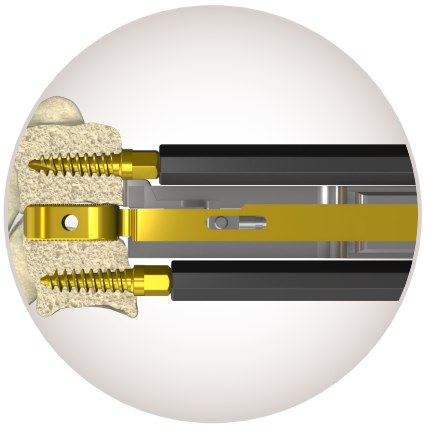
Hemi chisels may be used as needed if the superior vertebral body keel channel needs to be extended by 1mm or 2mm*. Use of the Hemi Chisels is limited to the channel in the superior vertebral body.

Remove the chisel using the slotted mallet **(Figure 25)**.

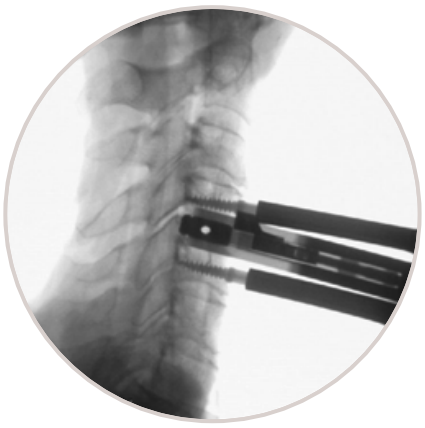
Apply slight distraction to the vertebral body retainer and remove the trial.

Under lateral fluoroscopy, use the keel cut cleaner to verify the depth of the keel channels and to remove any bony debris from both the superior and inferior vertebral bodies **(Figure 26)**.

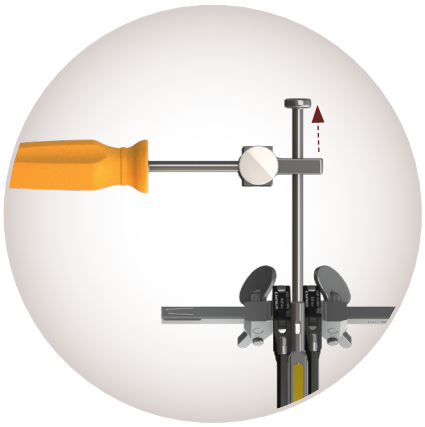
Irrigate the wound to ensure the disc space is clear of debris.



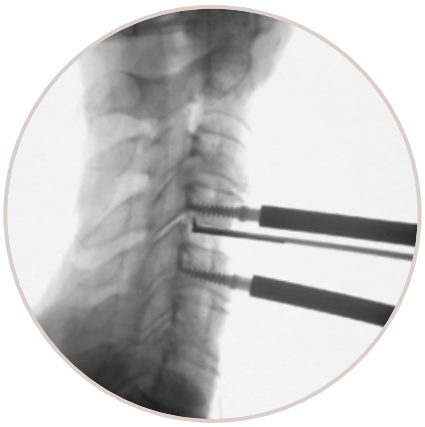
23. Sliding the Chisel Over the Trial Shaft to Touch the Anterior Cortex



24. Advancing the Chisel Until Full Seating on the Trial Under Lateral Fluoroscopy



25. Removing the Chisel with the Slotted Mallet



26. Verifying Keel Channel Depth with Keel Cut Cleaner Under Lateral Fluoroscopy

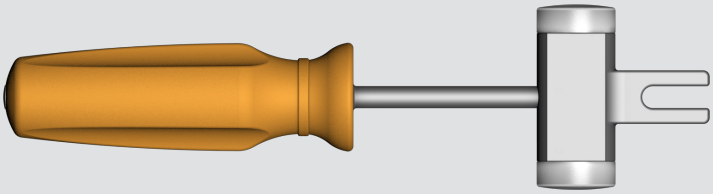
*** Only available in the optional prodisc Cervical Auxiliary Instrument Set.**

**** Available by special request only.**

Implantation (Cont'd)

STEP 3: Implant Insertion

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							

* Only available in the optional prodisc Cervical Auxiliary Instrument Set.

Preparation:

Open the packaging of the implant. Keep the implant in the plastic packaging tray for easier attachment to the Introducer Tip. The implant is loaded onto the Introducer Tip "en-bloc" directly from the package tray.

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 color coded side of the Introducer Tip with the superior side of the implant.

Attach the Introducer Tip to the implant until the arms snap into the holding features on both endplates of the implant **(Figure 27)**.

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

Align the "UP" etching on the Introducer with the superior endplate without the polyethylene inlay **(Figure 28)**.

Connect the Introducer Tip to the Introducer, ensuring the alignment tabs on the Introducer Tip are captured when connecting the Introducer.

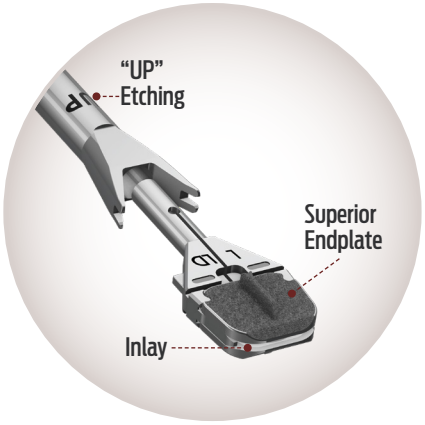
Use two fingers to rotate the proximal knob of the Introducer clockwise to tighten the connection with the Introducer Tip. When tightened, there will still be some toggle of the implant on the Introducer Tip, per the design—especially on the superior endplate **(Figure 29)**.

CAUTION ***Do not over-tighten Introducer Tip on to the Introducer!***

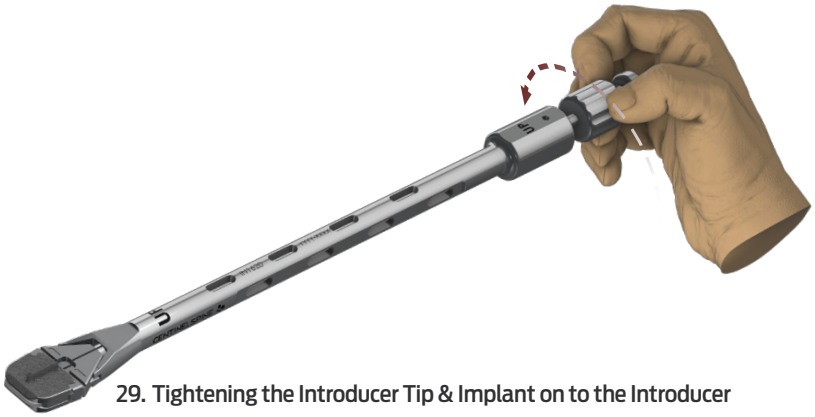
Pull the implant "en-bloc" out of the packaging tray **(Figure 30)**.

If the Introducer with Stop is being utilized, ensure that the Introducer stop is in the "0" position by rotating the stop adjuster knob **(Figure 31)**.

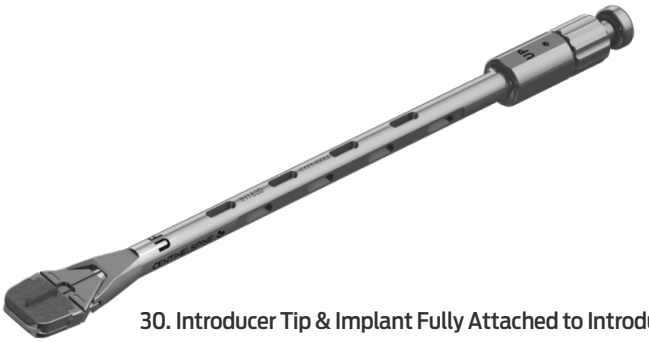
27. Attaching the Introducer Tip to the Implant



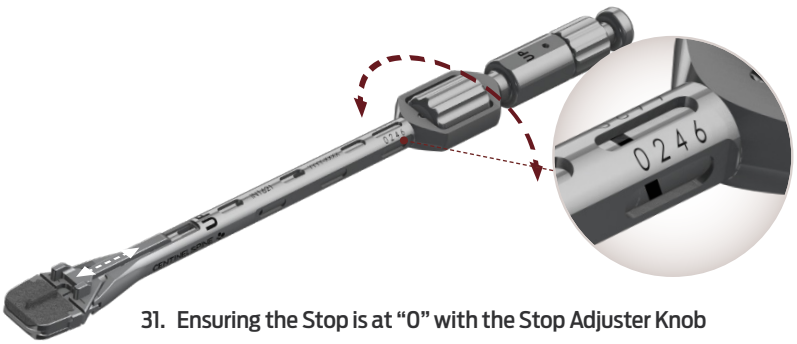
28. Aligning the "UP" Etching on the Introducer to the Superior Endplate without Inlay



29. Tightening the Introducer Tip & Implant on to the Introducer



30. Introducer Tip & Implant Fully Attached to Introducer



31. Ensuring the Stop is at "0" with the Stop Adjuster Knob

Implantation (Cont'd)

Implant Insertion:

Before inserting, ensure the polyethylene inlay core is on the inferior endplate and "UP" markings on the inserter are oriented cranially **(Figure 32)**.

Align the keels of the prodisc C SK implant with the keel channels in the vertebral bodies **(Figure 33)**.

Under lateral fluoroscopy confirm alignment and trajectory of the implant with the disc space.

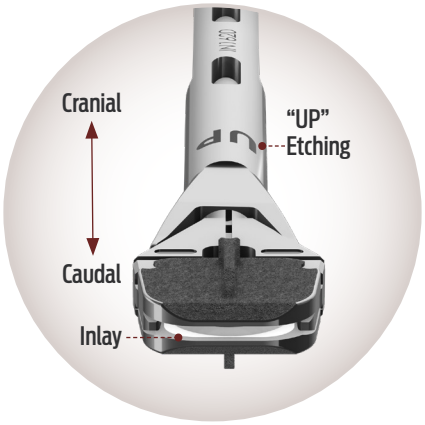
Under lateral fluoroscopy, advance the implant into its final position **(Figure 34)**. The prodisc C SK should be positioned so as to match the prepared keel cuts.

Avoid excessive cranial, caudal, or lateral corrections during insertion and ensure that the implant doesn't exceed the posterior margin of the vertebral body.

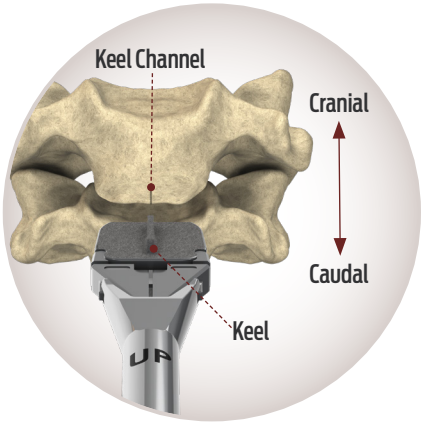
If applicable, the Introducer stop can be backed out to allow the implant to advance more posteriorly. Each full counter-clockwise rotation of the inserter stop adjuster allows the implant to be advanced 1.0mm **(Figure 35)**.

The Introducer Tip includes two grooves that visualize the anterior margin of the implant under lateral fluoroscopy.

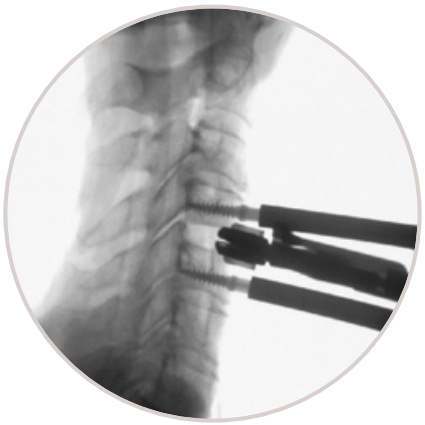
Before removing the introducer, ensure satisfactory positioning of the implant using A/P fluoroscopy. When the desired position of the implant is confirmed using fluoroscopy, apply slight compression with the retainer **(Figure 36)**.



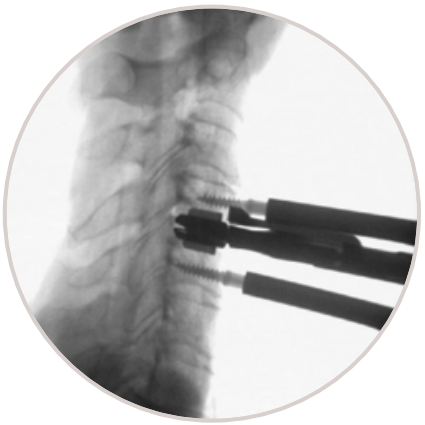
32. Ensuring the Inlay Core is in Place and "UP" Markings are Oriented Cranially



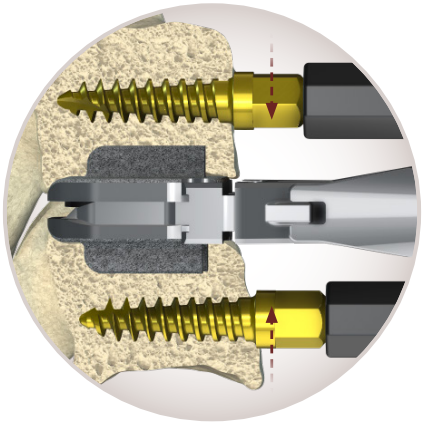
33. Aligning Keels with Keel Channels on the Vertebral Bodies



34. Advancing the Implant to Final Positioning Under Lateral Fluoroscopy



35. Advancing Introducer More Posteriorly with Introducer Stop Adjustment



36. Applying Slight Compression to the Vertebral Bodies with the Retainer

Implant Release:

First loosen the introducer tip from the implant by rotating the proximal knob of the Introducer three (3) full turns in the counter-clockwise direction **(Figure 37)**.

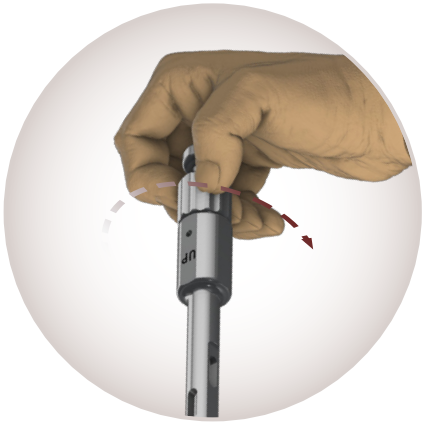
Then move the Introducer in a left-to-right (or right-to-left) motion to approximately 30 degrees off midline and pull up until implant release occurs **(Figure 38)**.

Confirm final implant position with lateral and A/P imaging **(Figures 39 & 40)**.

Step-by-step remove the retainer nuts, vertebral body retainer, and screws.

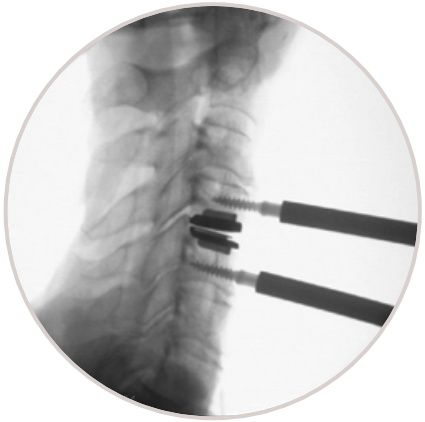
Copious saline lavage is recommended to remove osteogenic stimuli (blood/bone marrow). Apply bone wax to close cavities in the bone (retainer screw holes , keel channels, and open bone surfaces).

Close the surgical wound in a routine fashion.

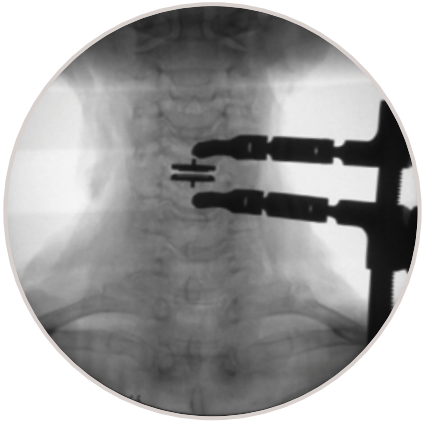


37. Loosening the Introducer Tip from the Implant with Proximal Knob Rotation

38. Removing the Introducer from the Implant



39. Verifying Final Implant Positioning Under Lateral Fluoroscopy



40. Verifying Final Implant Positioning Under A/P Fluoroscopy

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

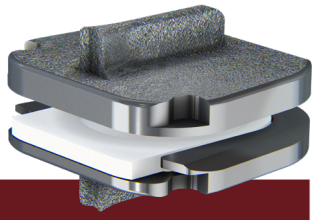
Use an interbody distractor or retainer device to distract the disc space. Using a fine osteotome, pry the superior endplate from the vertebral body and extract the superior endplate from the space with a Kocher clamp or other grasping instrument. Repeat this technique on the inferior endplate. If distraction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

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

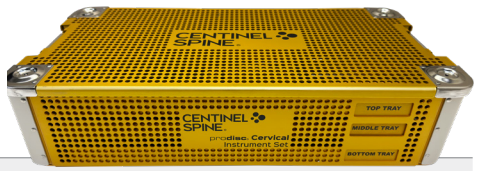
Implants



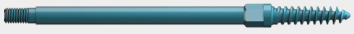
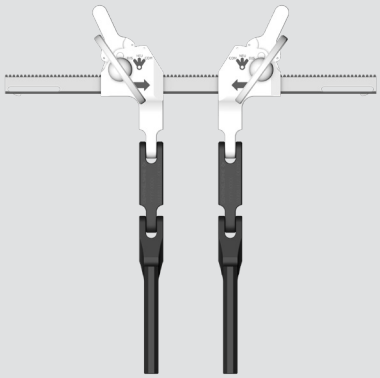
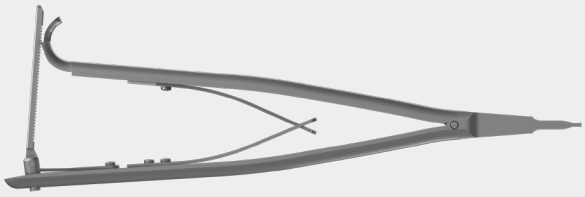
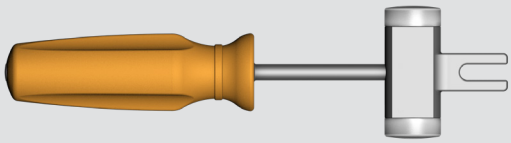
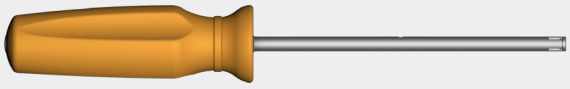
prodisc C SK Total Disc Replacement Implants, Sterile

Implant Footprints			Part Numbers		
	Depth (mm)	Width (mm)	5 mm Height	6 mm Height	7mm 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

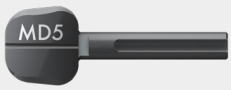
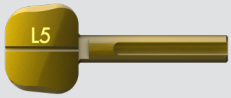
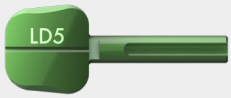
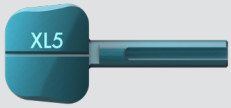
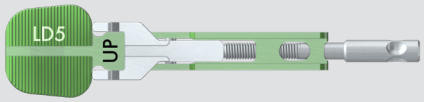
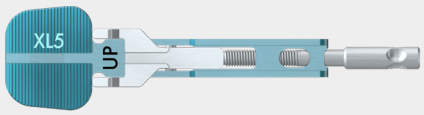
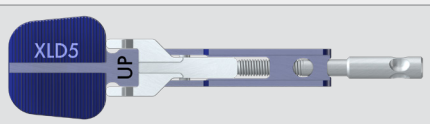
prodisc *Cervical V2 Instrument Set*



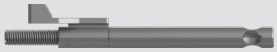
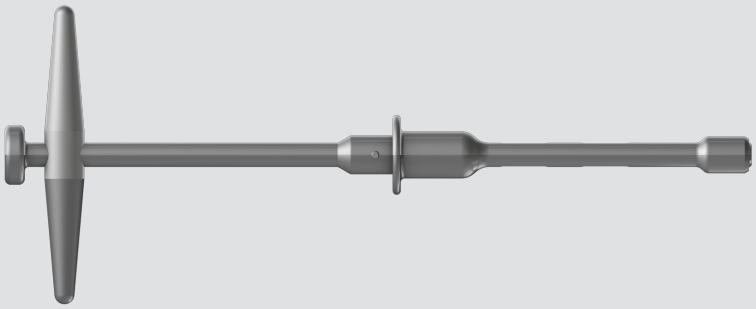
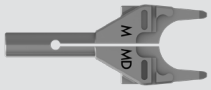
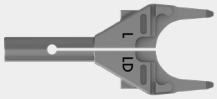
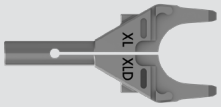
TOP TRAY | Instruments

03.820.100	Awl, 12mm	
	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	
03.820.110	Retainer Nut	
03.820.111/1	Vertebral Retainer	
03.820.112	Vertebral Distractor	
03.820.113	Slotted Mallet	
IN1444	Self-Retaining Screwdriver, Short	

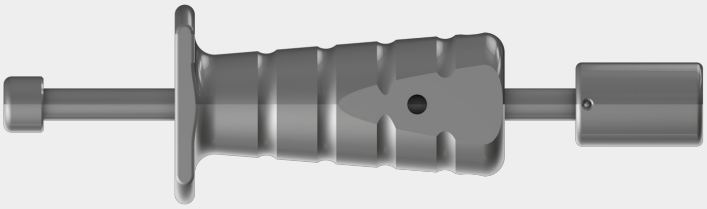
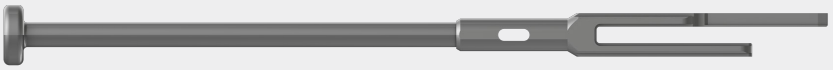
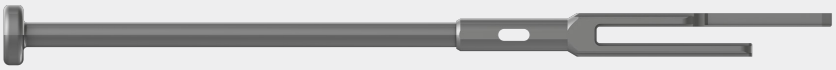
MIDDLE TRAY | Instruments

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	prodisc C Vivo Trial Stop, 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	

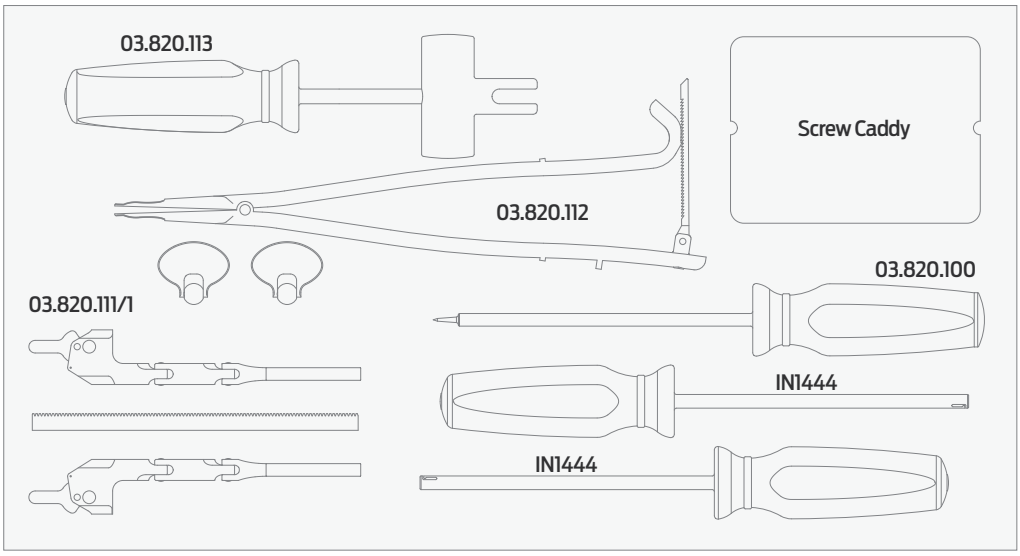
BOTTOM TRAY | Instruments

03.820.282	Slide Hammer		
	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	

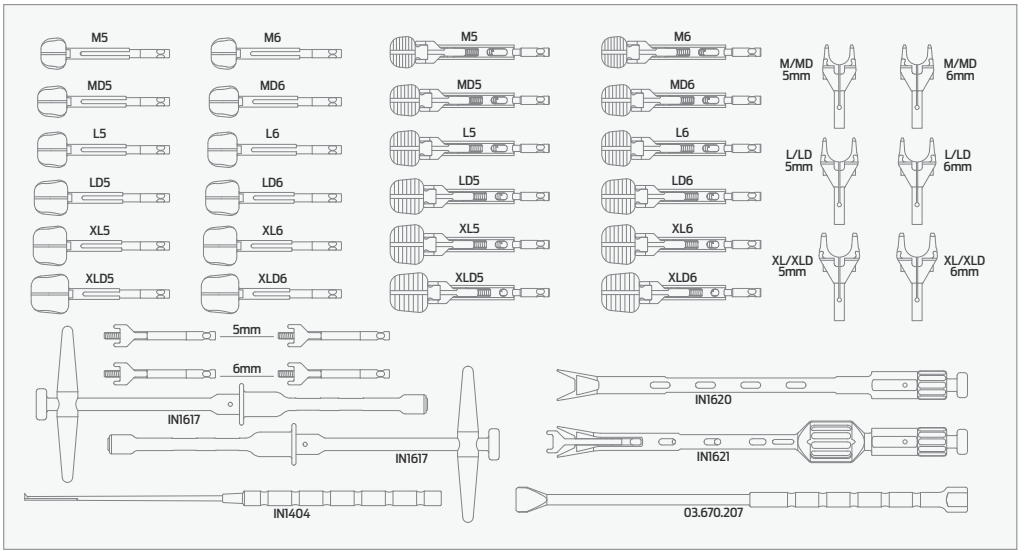
* Available by special request only.

Instrument Set Configuration

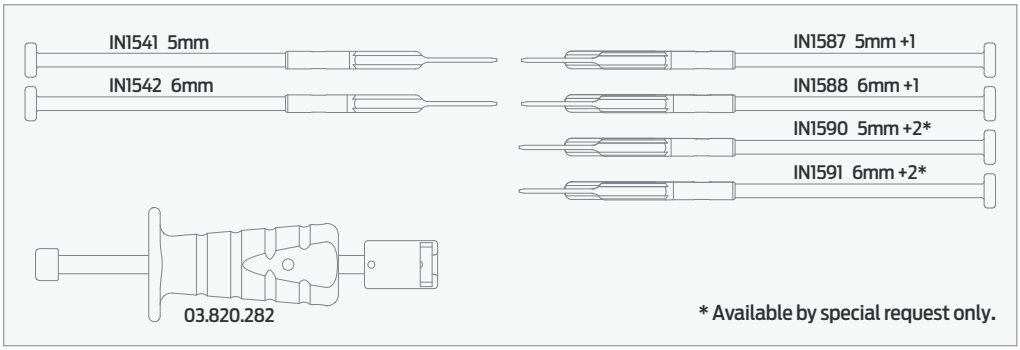
TOP TRAY | Instrument Set Configuration



MIDDLE TRAY | Instrument Set Configuration



BOTTOM TRAY | Instrument Set Configuration

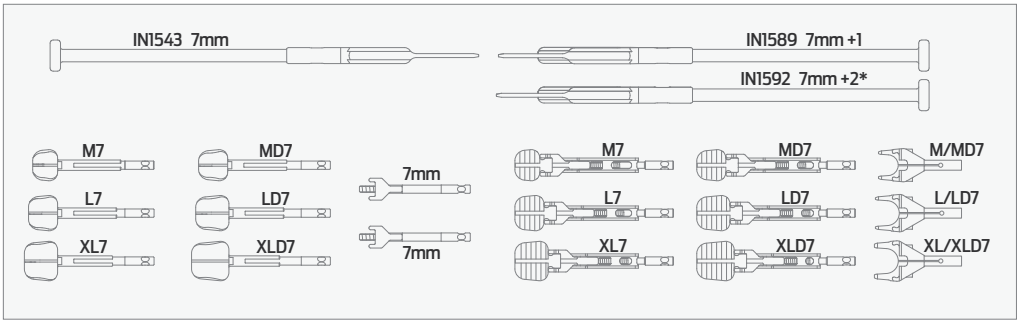


prodisc *Cervical Auxiliary Instrument Set (Optional)*

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



* Available by special request only.

References

[1] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2021.

[2] Data on file at Centinel Spine.

[3] Since 1991, Hartshill Horseshoe, STALIF®, STALIF TT®, STALIF C®, STALIF MIDLINE®, STALIF L™

[4] Stein MI, et al. The Spine Journal, 14(1): 128-136, 2014.

[5] A.N. Nayak, et al. The Spine Journal, 2014.

[6] Interim Report of Prospective STALIF C Study – Protocol SC-001.

[7] Represents single-level fusion data presented as part of IDE Clinical Study for Mobi-C cervical disc, including the Mobi-C experimental arm and the ACDF control arm. ACDF's were treated using an anterior cervical plate with screws [SLIM-LOC™ Anterior Cervical Plate System (DePuy Spine) and ATLANTIS™ or ATLANTIS™ VISION Anterior Cervical Plate Systems (Medtronic)] and corticocancellous allograft bone. Reference: Hisey, MS, et al. Multi-center, Prospective, Randomized, Controlled Investigational Device Exemption Clinical Trial Comparing Mobi-C Cervical Artificial Disc to Anterior Discectomy and Fusion in the Treatment of Symptomatic Degenerative Disc Disease in the Cervical Spine. International Journal of Spine Surgery. 8(7), doi: 10.14444/1007, 2014.

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

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

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