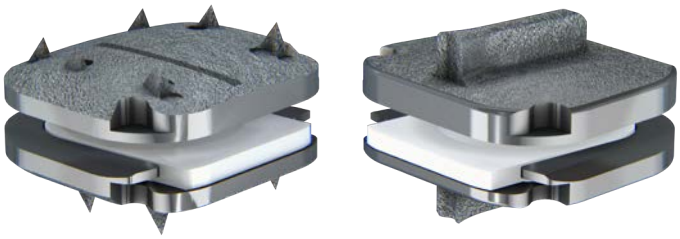
CENTINEL SPINE®

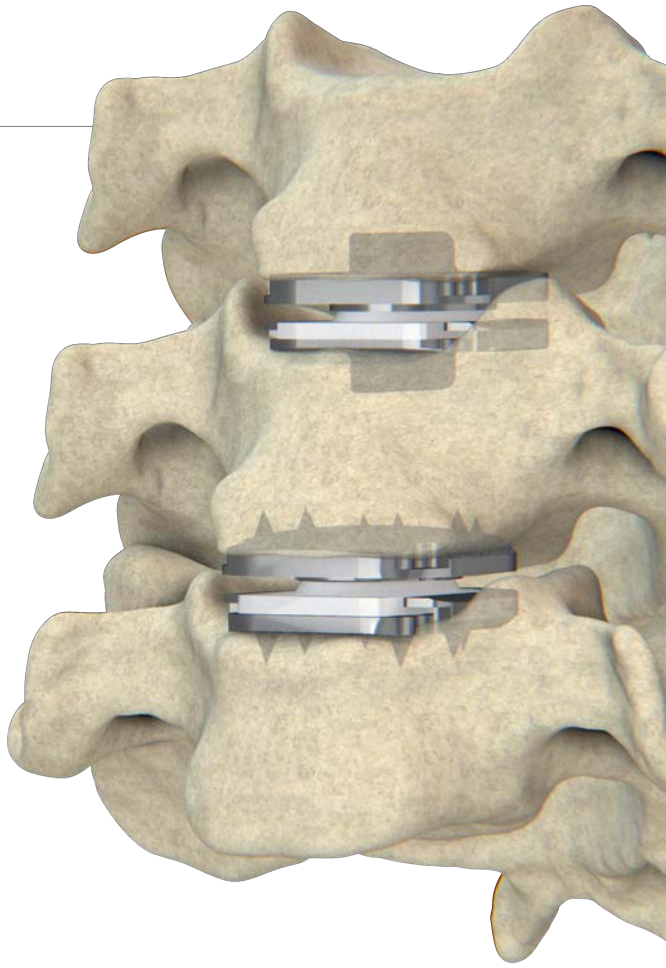
prodisc® C Vivo | prodisc® C SK

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

TABLE OF CONTENTS

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

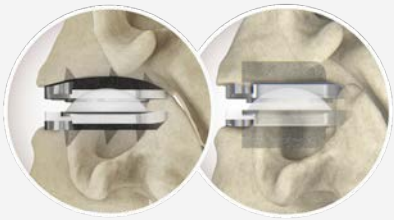
SINCE 1990 · 35+ YEARS OF CLINICAL SUCCESS

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

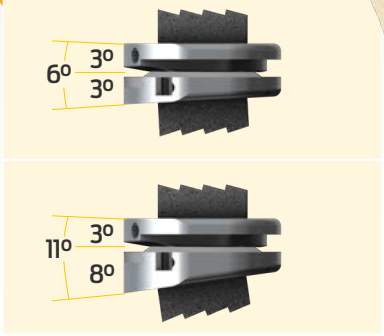
* prodisc C Vivo & prodisc C SK are approved for both 1- and 2-level usage. prodisc C Nova & prodisc C are approved for 1-level usage only.

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

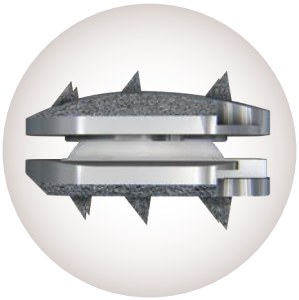
NOW AVAILABLE: ANATOMIC ENDPLATES™



MATCH THE DISC™

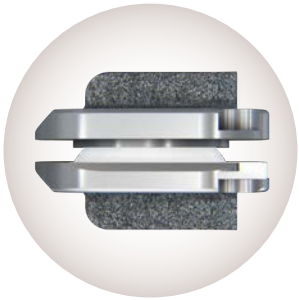
LEARN MORE:
match.centinelspine.com

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]

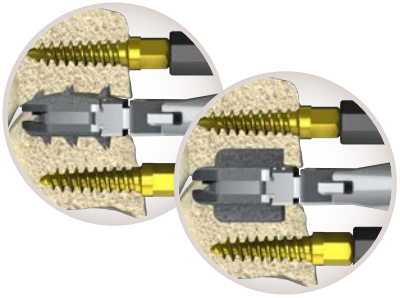


prodisc® C SK

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

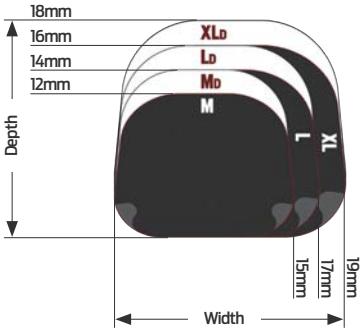
Powered by prodisc CORE

- 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)

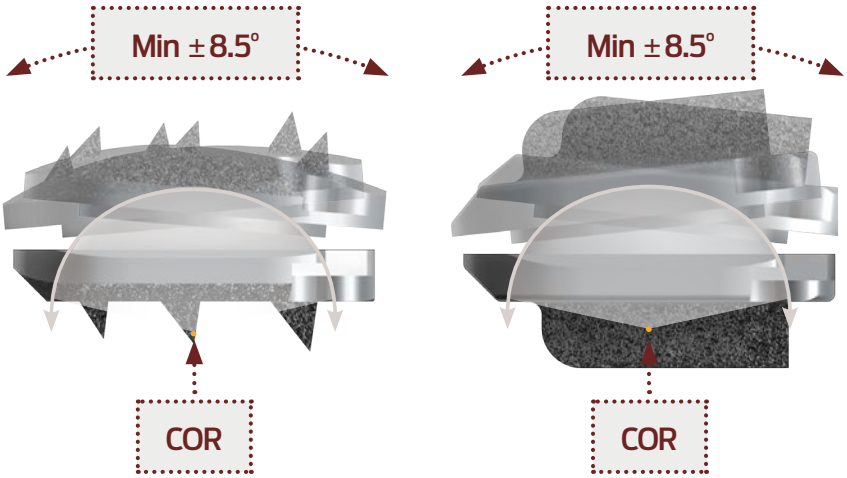
Proven Materials

- 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.

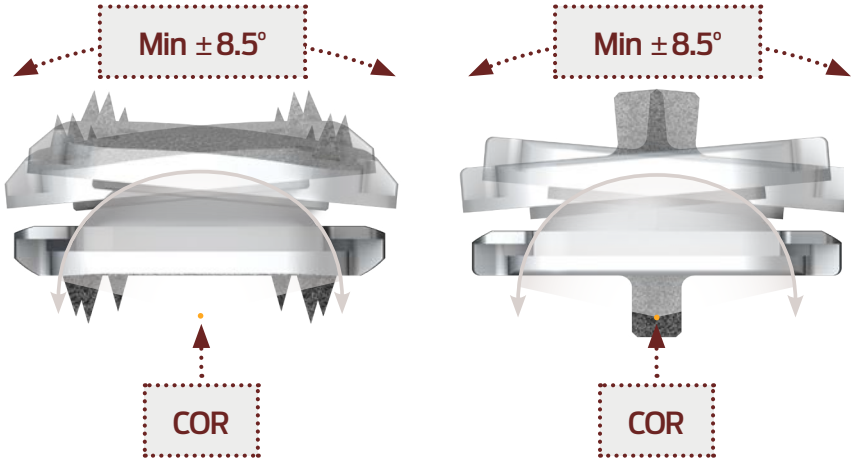
Flexion/Extension

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



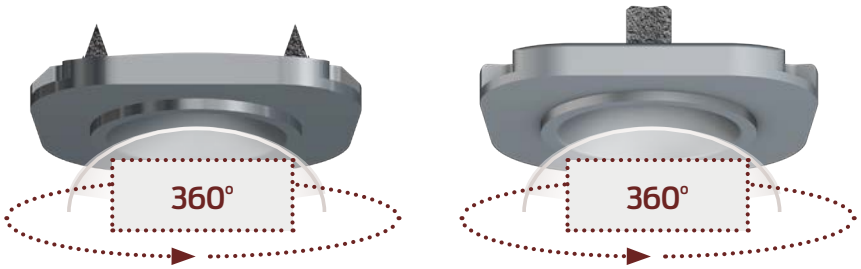
Lateral Bending

- 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.

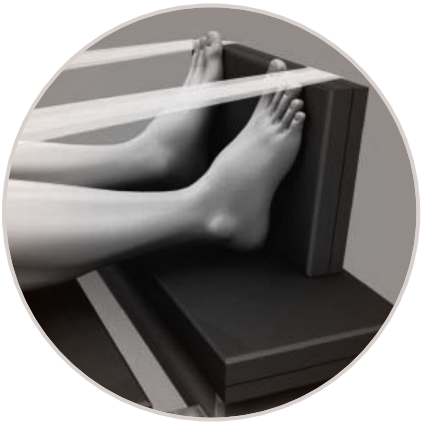


Figure 3.

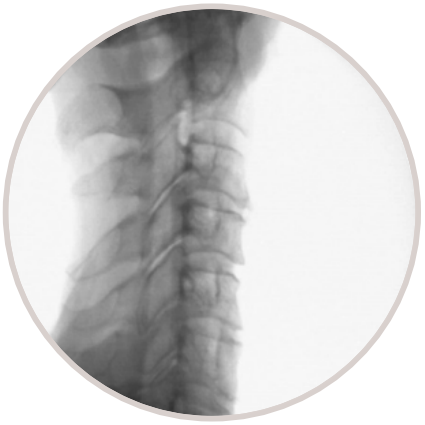


Figure 4.

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)**.

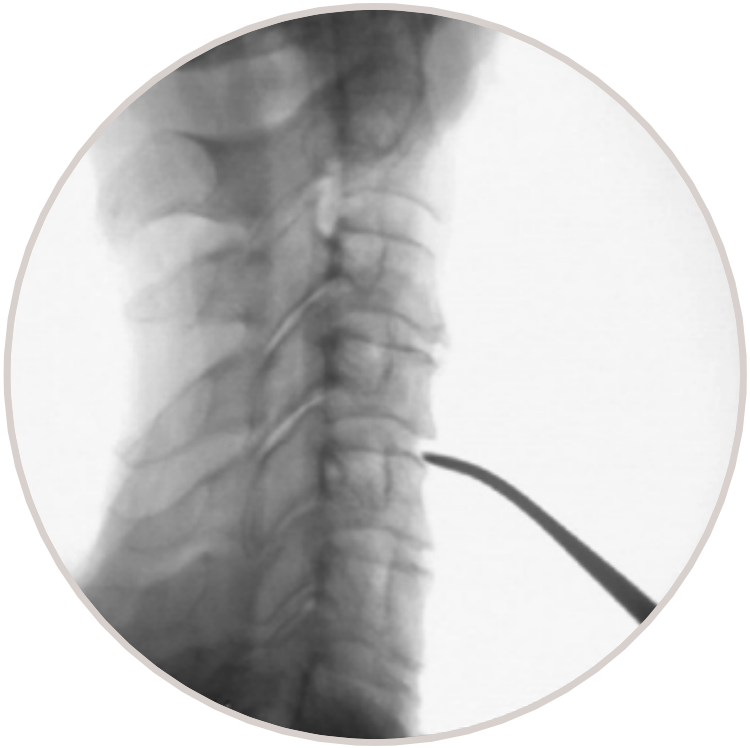


Figure 5.

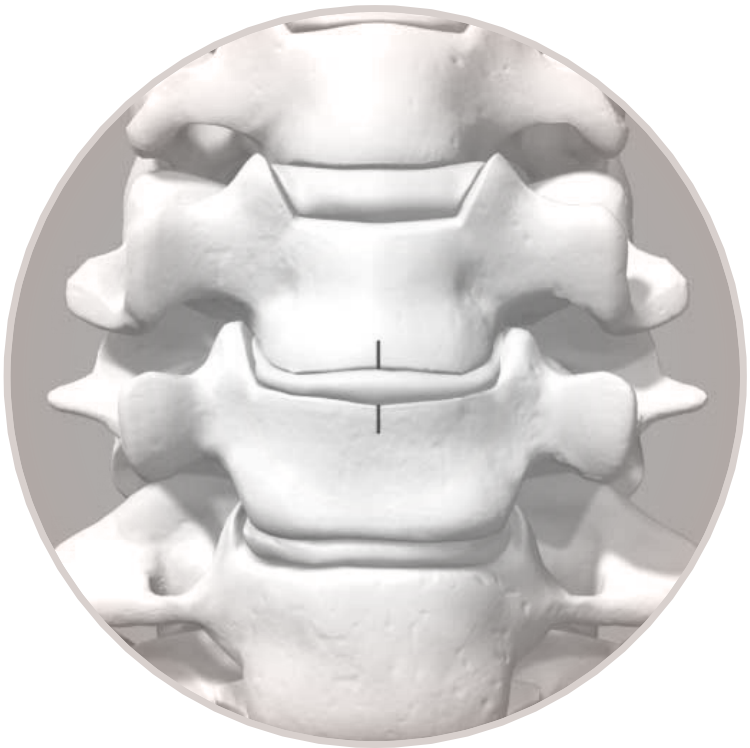
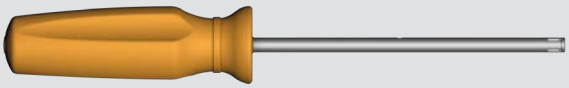
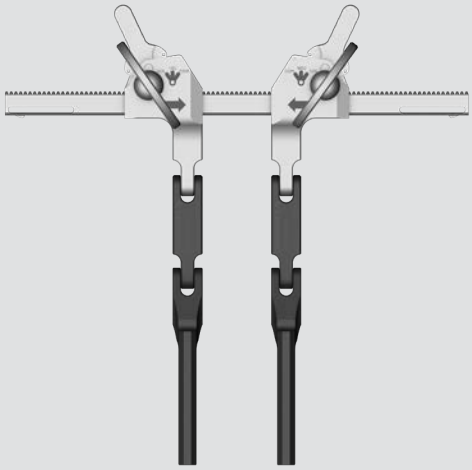
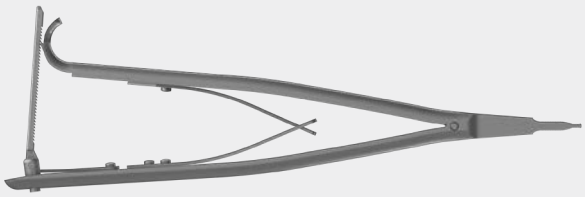
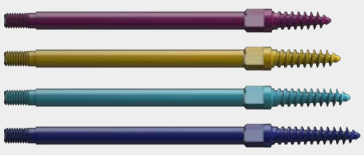


Figure 6.

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		
03.820.100	Awl, 12mm	
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.***

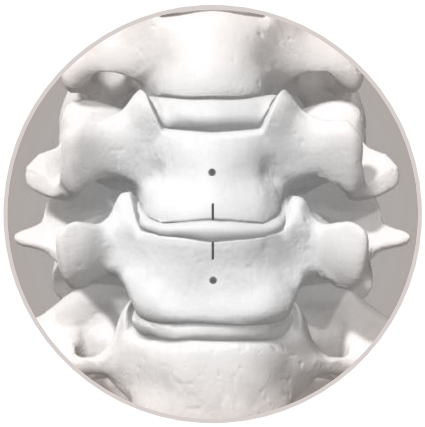


Figure 7.

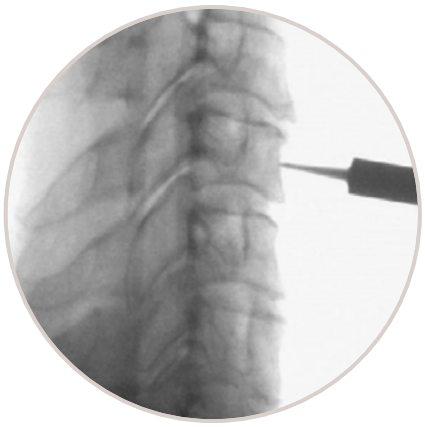


Figure 8.

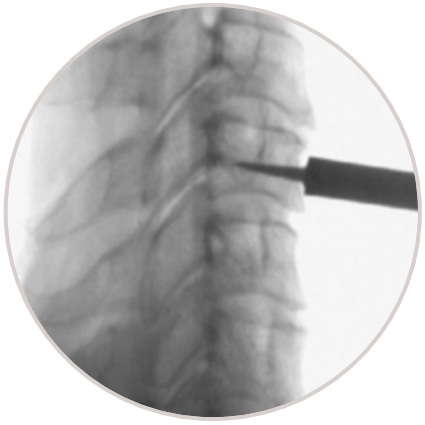


Figure 9.

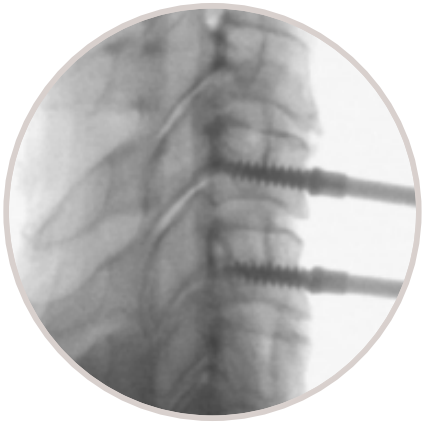


Figure 10.

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.

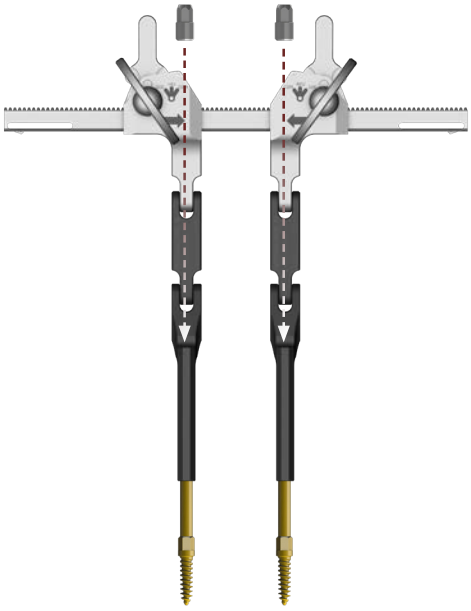


Figure 12.

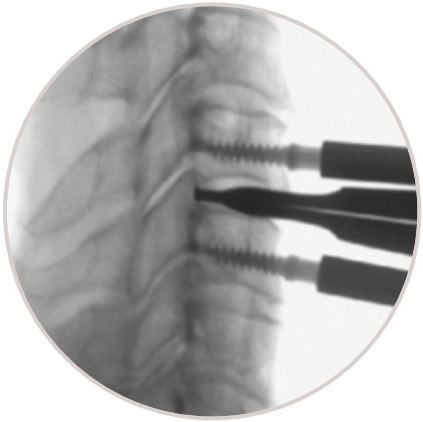


Figure 13.

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.

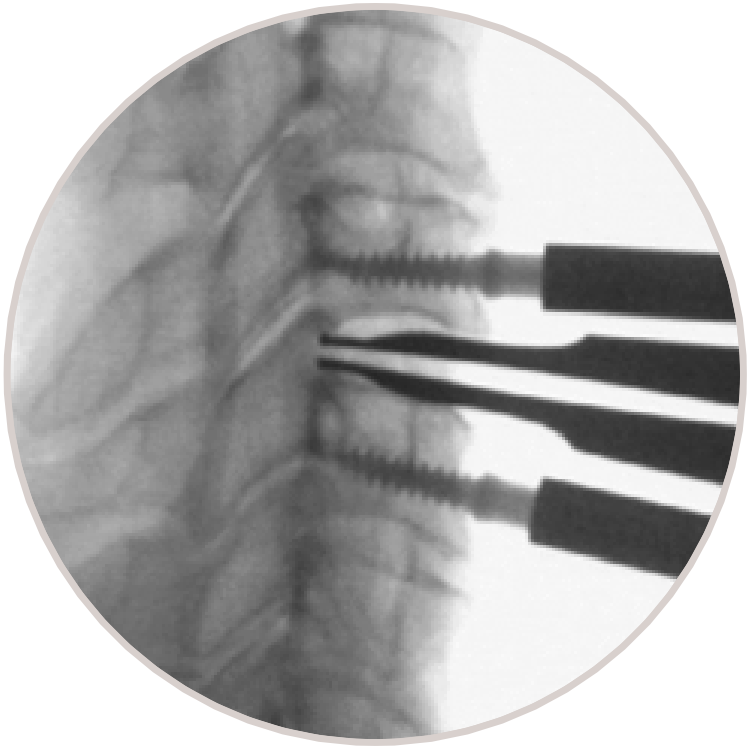


Figure 14.

Implant Selection

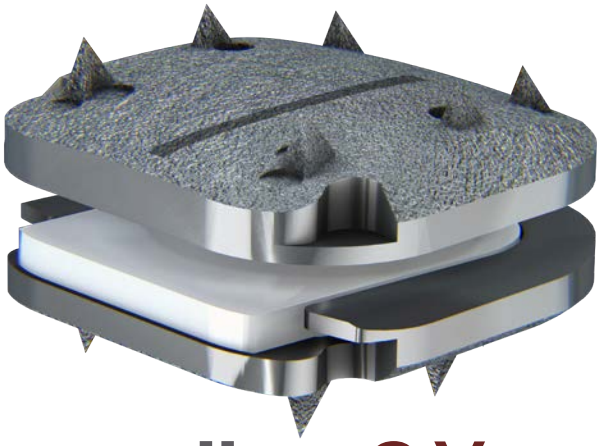
Trial with **prodisc C Vivo** and/or **prodisc C SK** to determine best implant fit and position. Select the largest footprint to maximize coverage of the vertebral body endplates and the smallest appropriate height to match healthy adjacent discs.

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

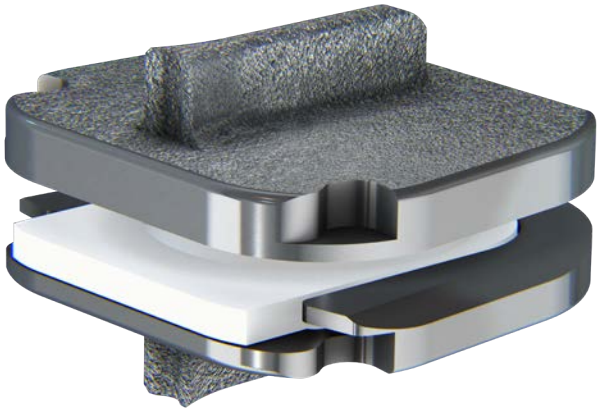
1. **Trial**
2. **Insert Implant**

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:

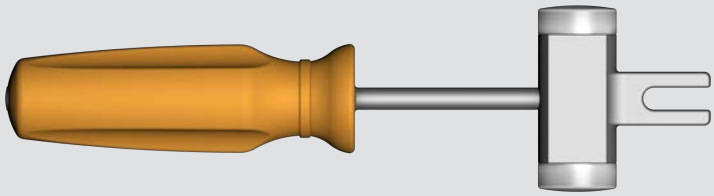
1. **Trial**
2. **Insert Implant**

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)**.

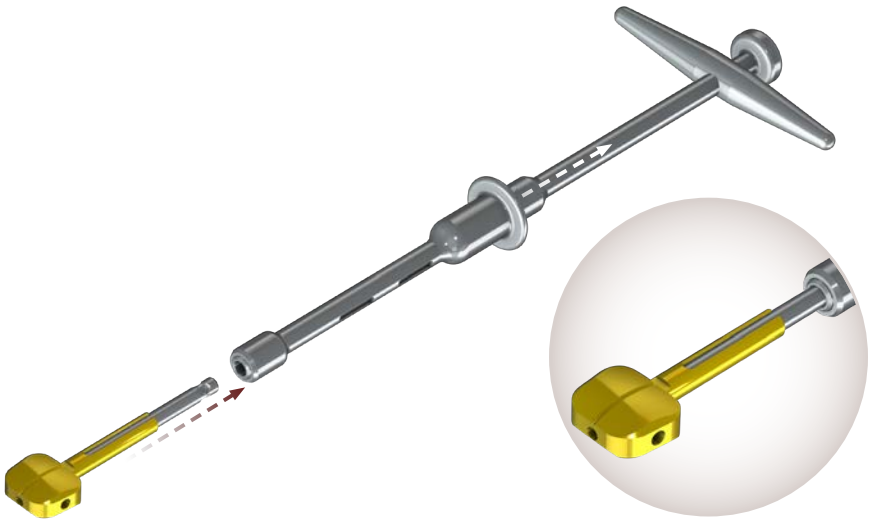


Figure 15.

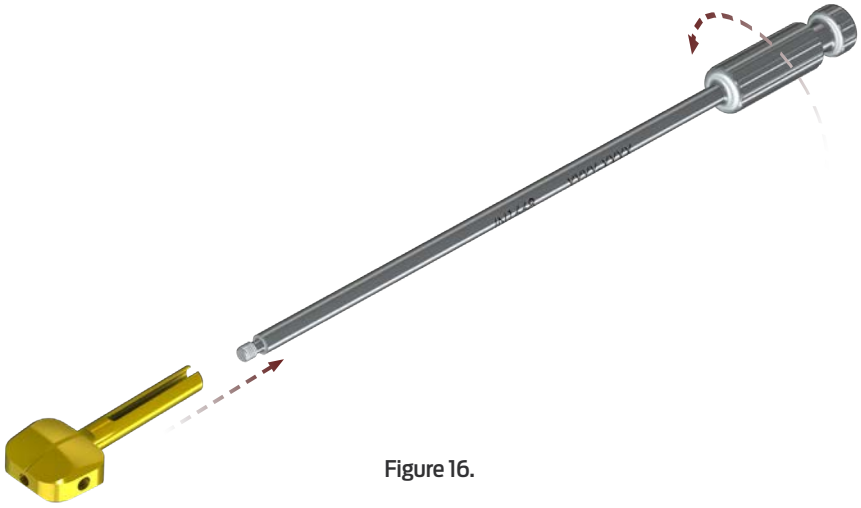


Figure 16.

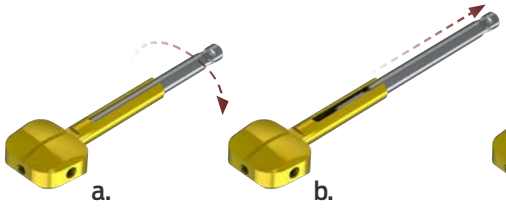


Figure 17.

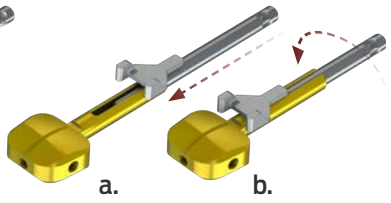


Figure 18.

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.

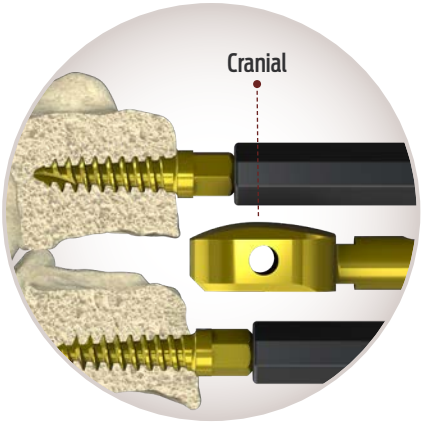


Figure 20.

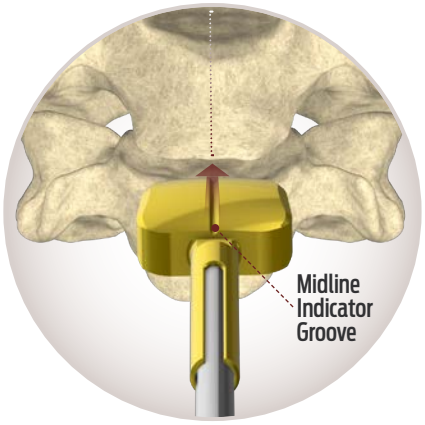


Figure 21.

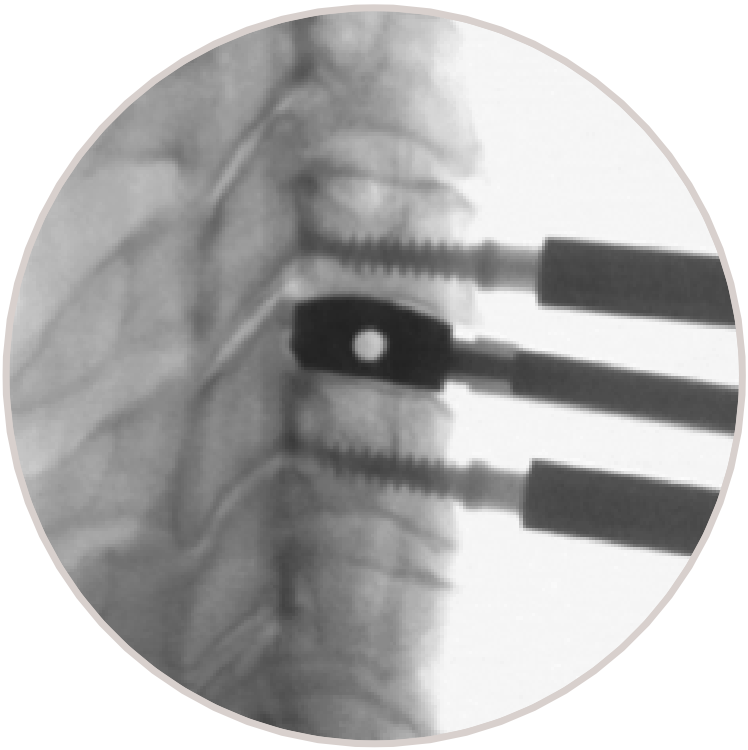


Figure 22.

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)**.

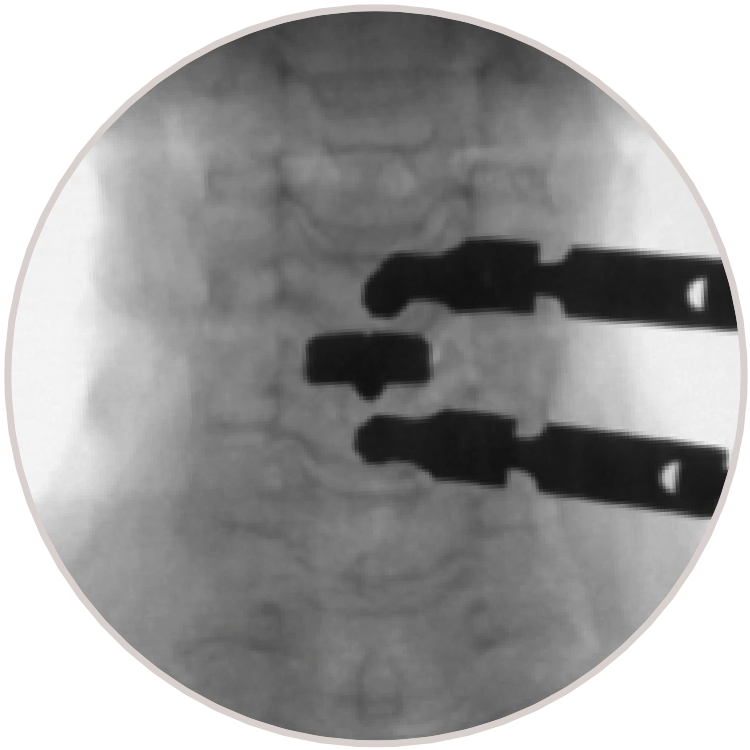


Figure 23.

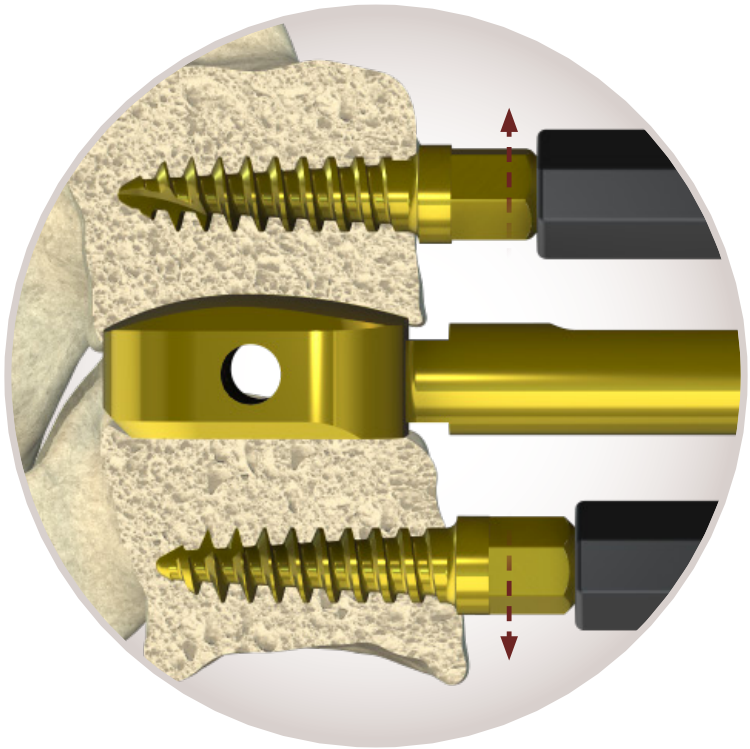
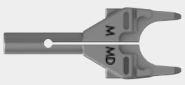
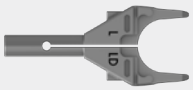
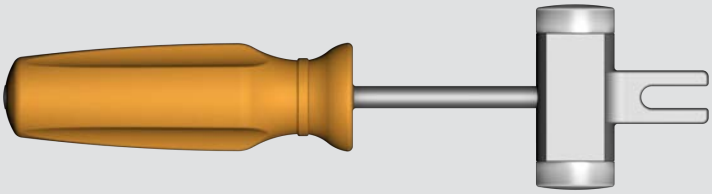


Figure 24.

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.

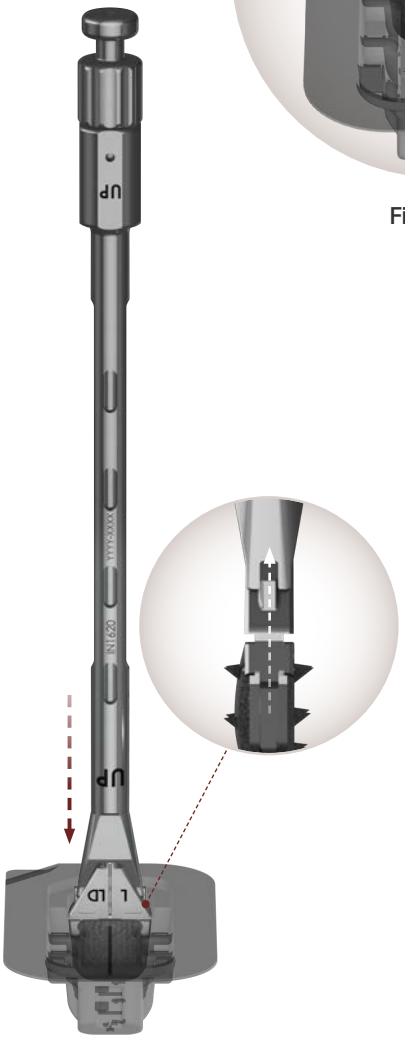


Figure 26.

Figure 27.

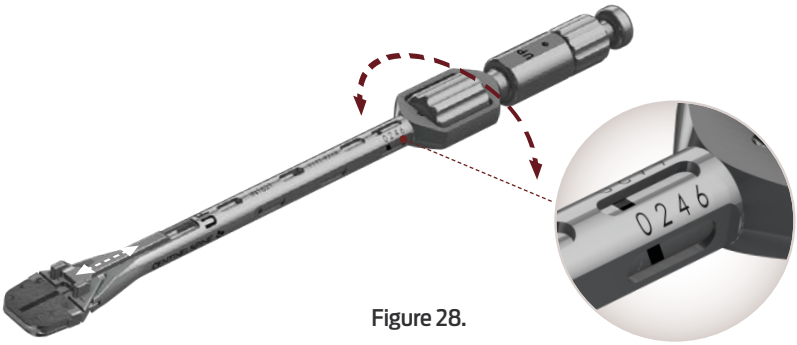


Figure 28.

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.

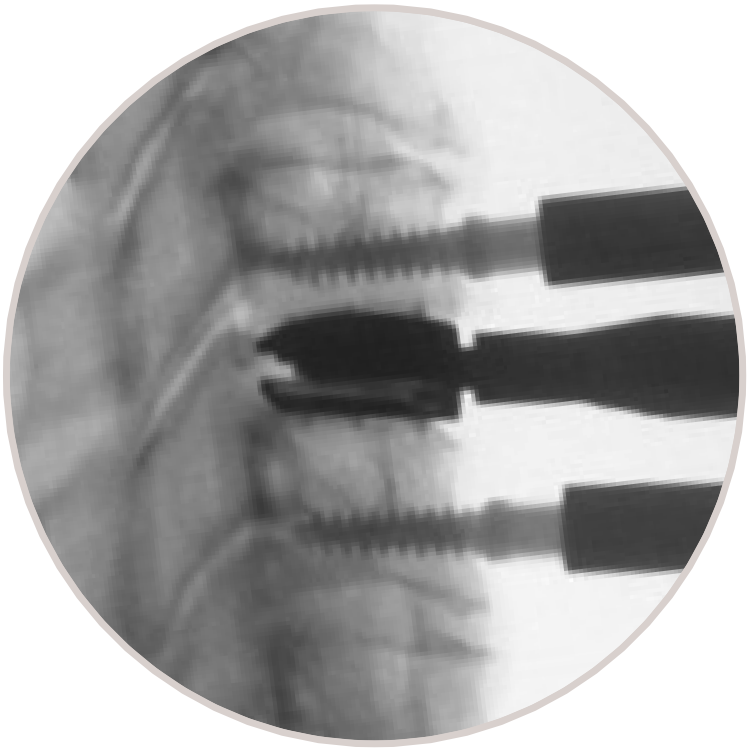


Figure 29.

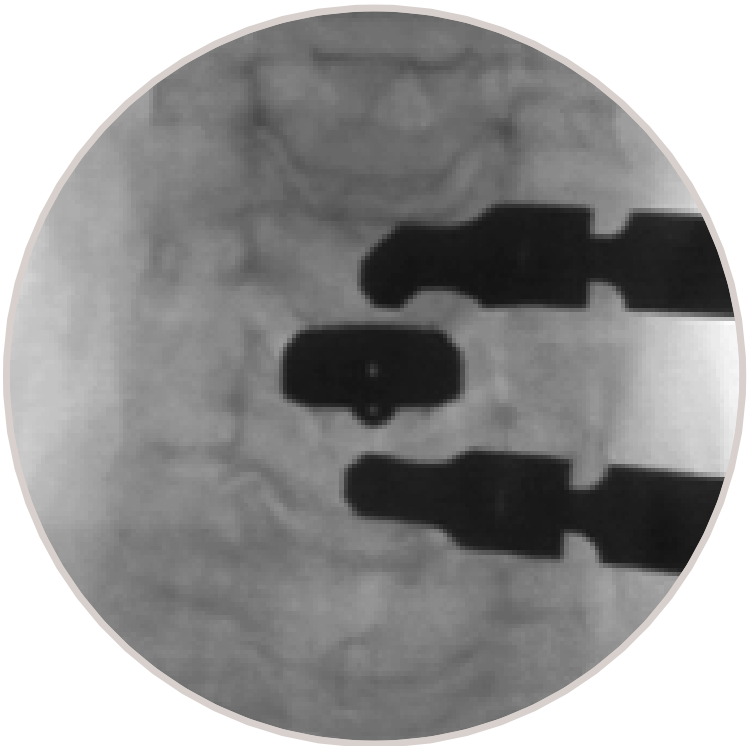


Figure 30.

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.

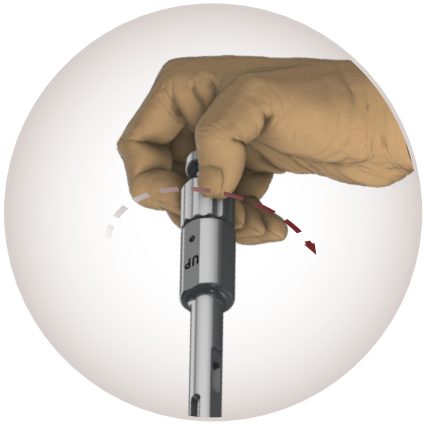


Figure 31.

Figure 32.

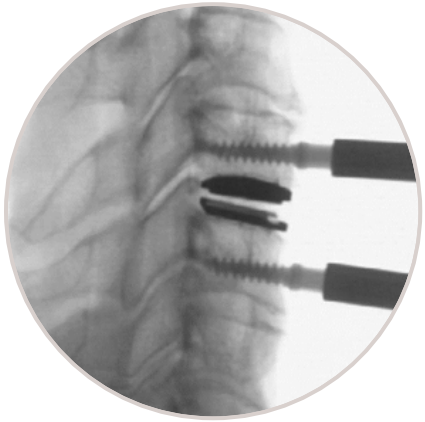


Figure 33.

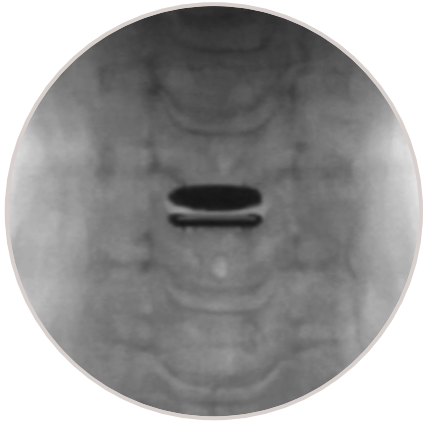


Figure 34.

Implantation of prodisc® C SK

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

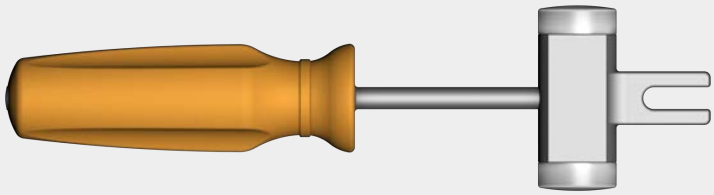
1. **Trial**
2. **Chisel**
3. **Insert Implant**

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.***

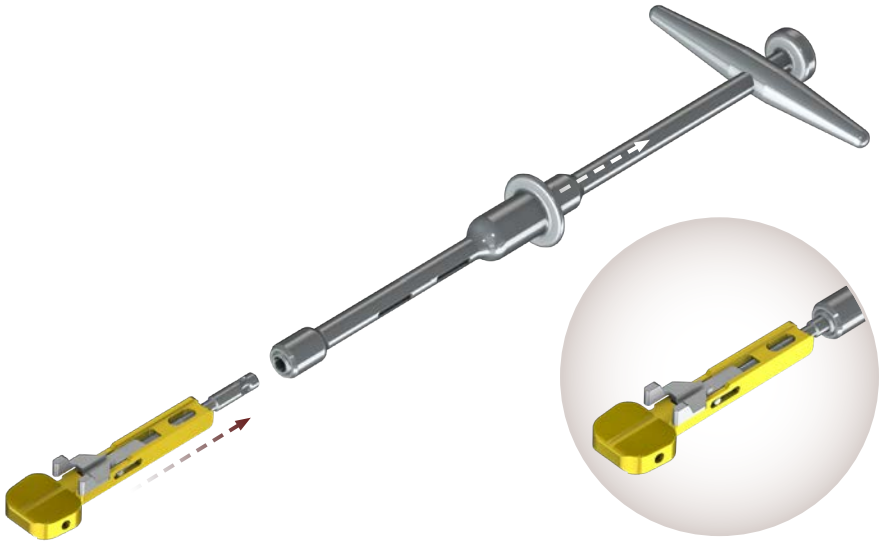


Figure 35.

Figure 36.

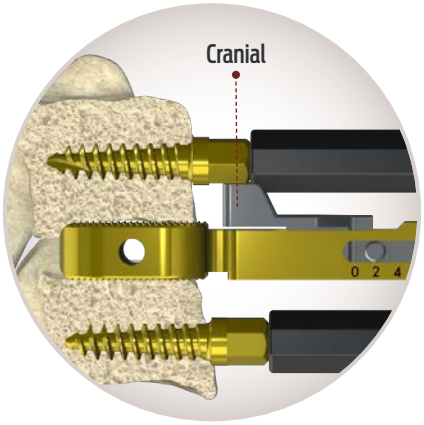


Figure 37.

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)**.

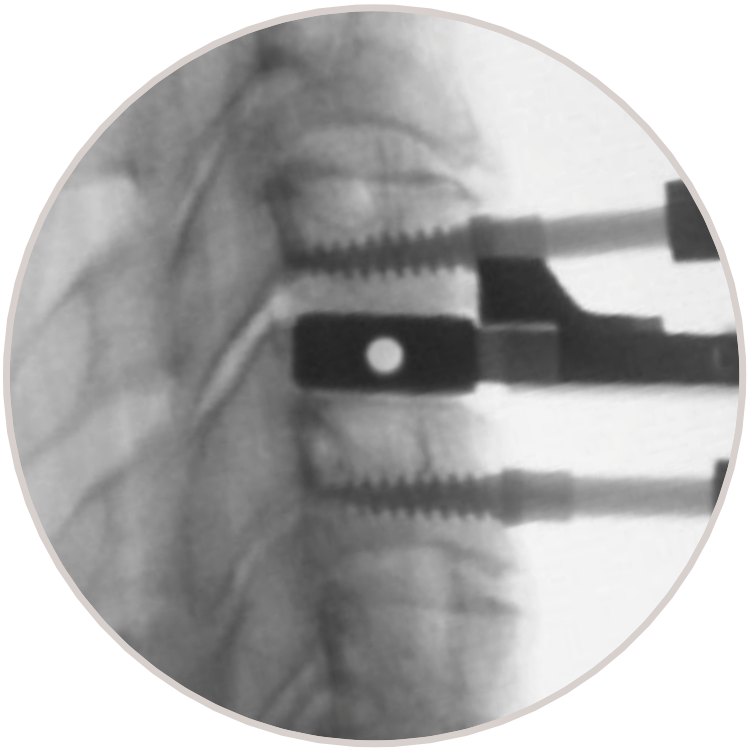


Figure 38.

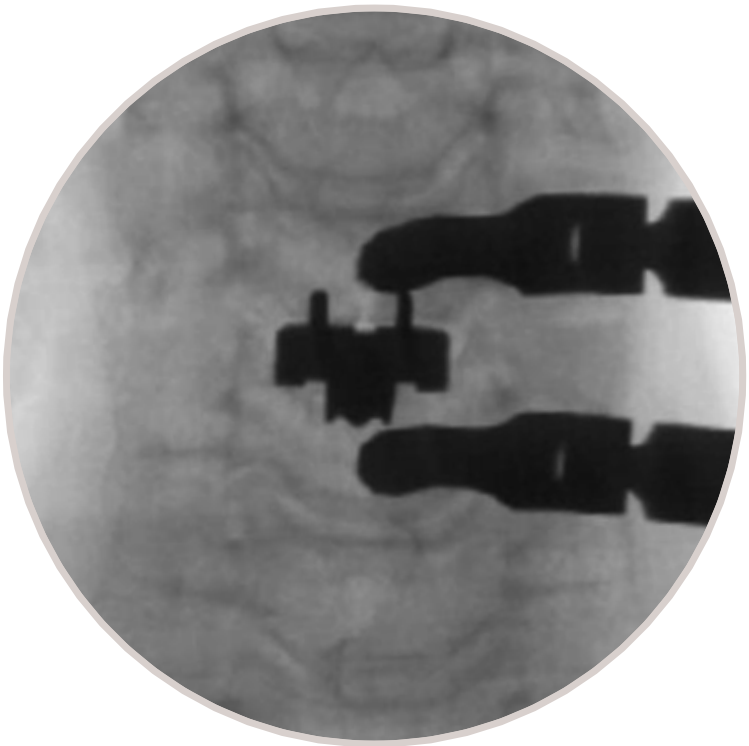
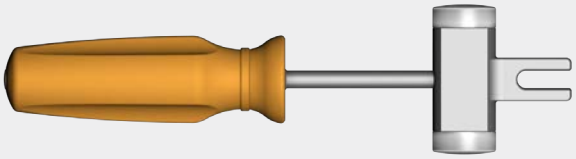
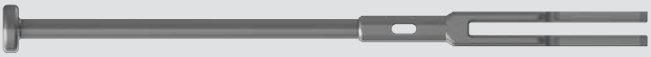


Figure 39.

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.

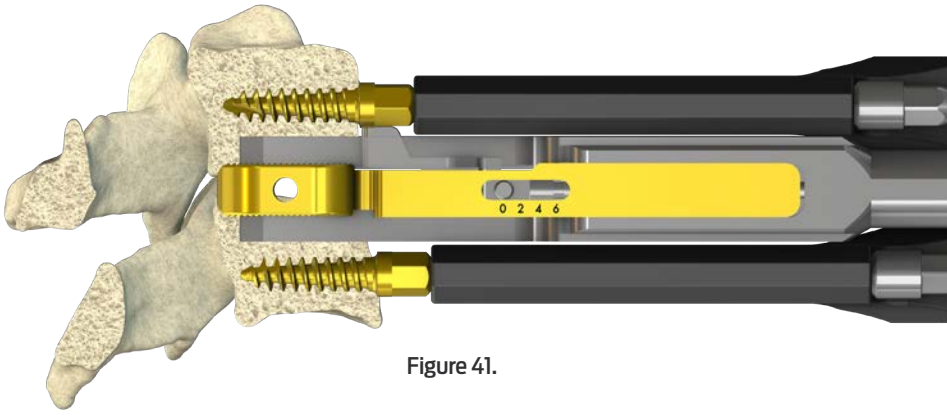
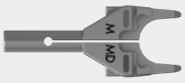
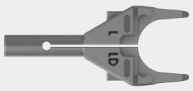
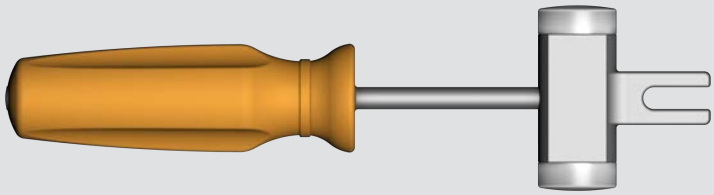


Figure 41.

*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.

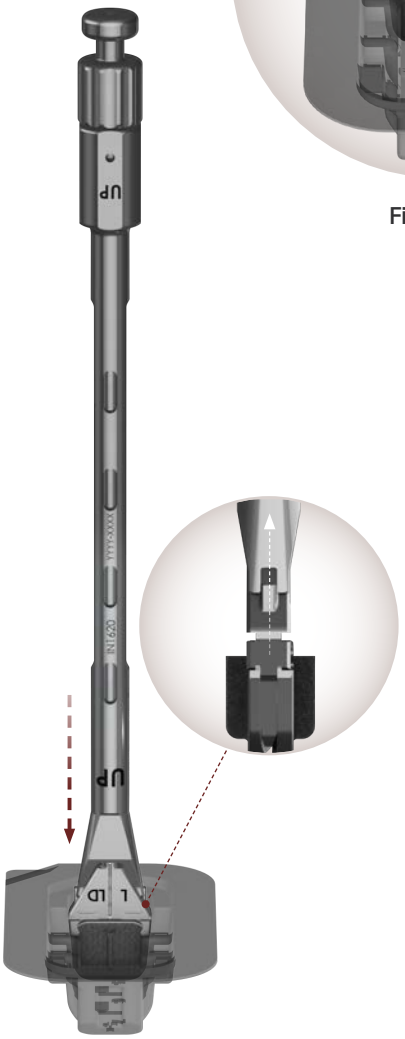


Figure 43.

Figure 44.

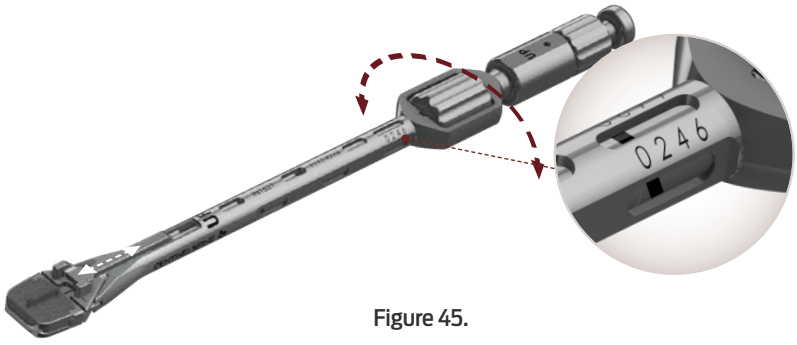


Figure 45.

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.

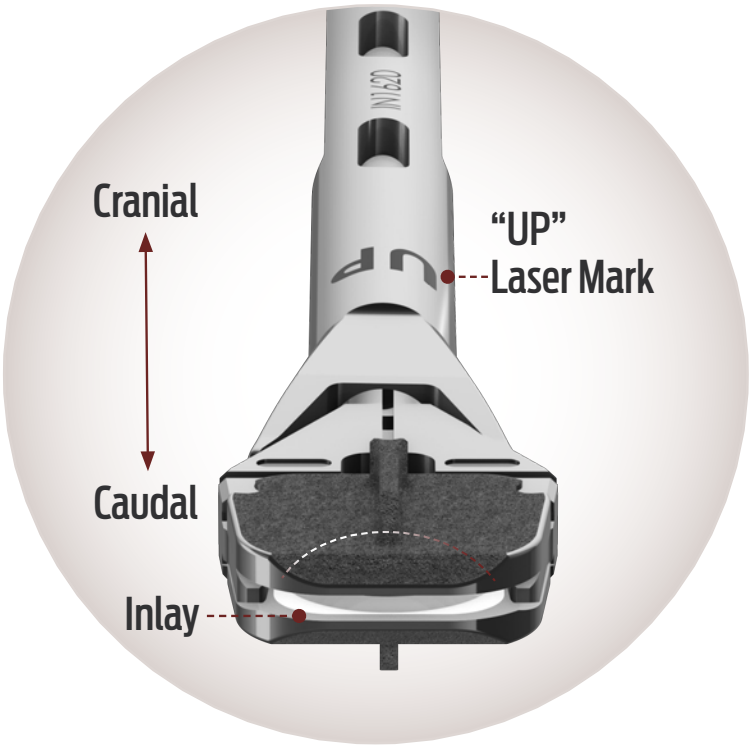


Figure 46.

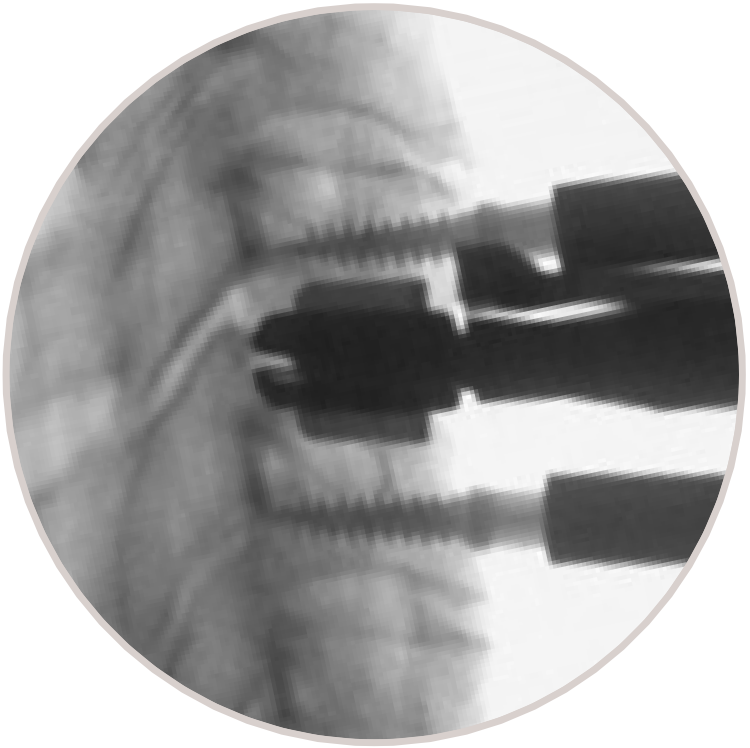


Figure 47.

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.

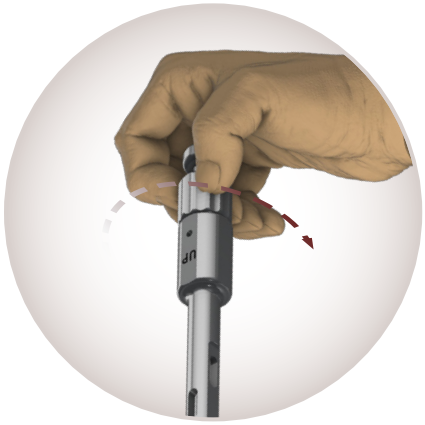


Figure 48.

Figure 49.

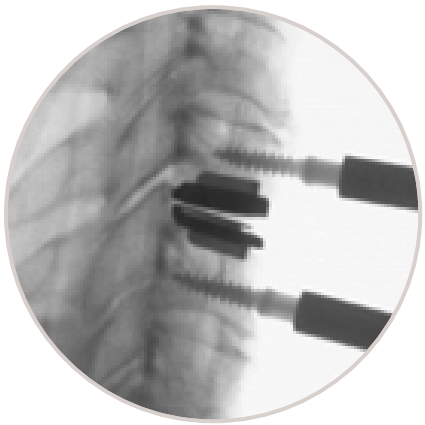


Figure 50.

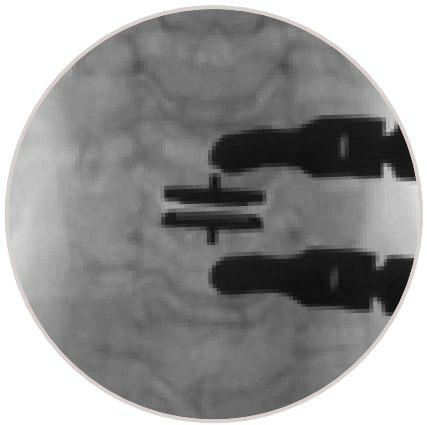
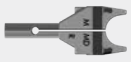
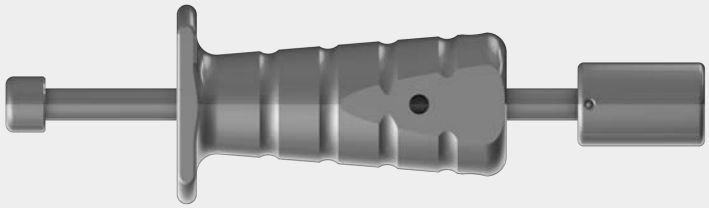


Figure 51.

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.***

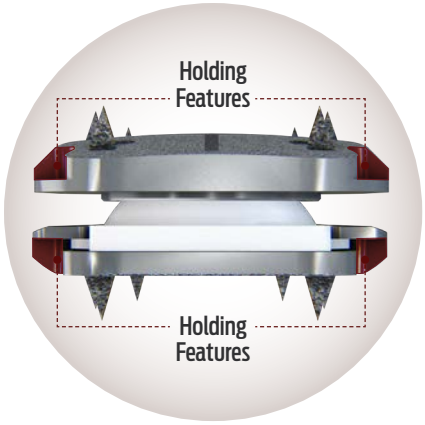


Figure 52.

Figure 53.

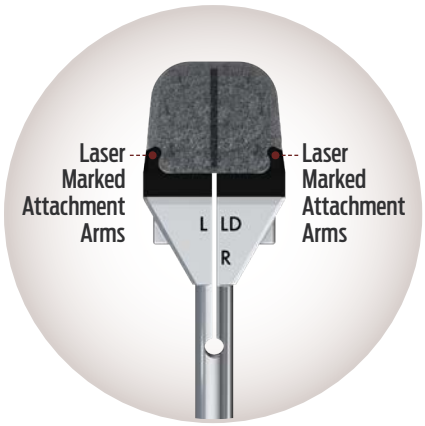


Figure 54.

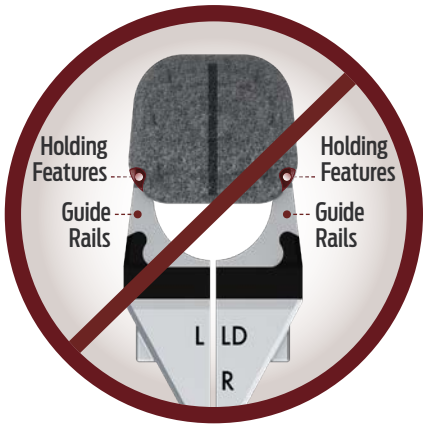


Figure 55.

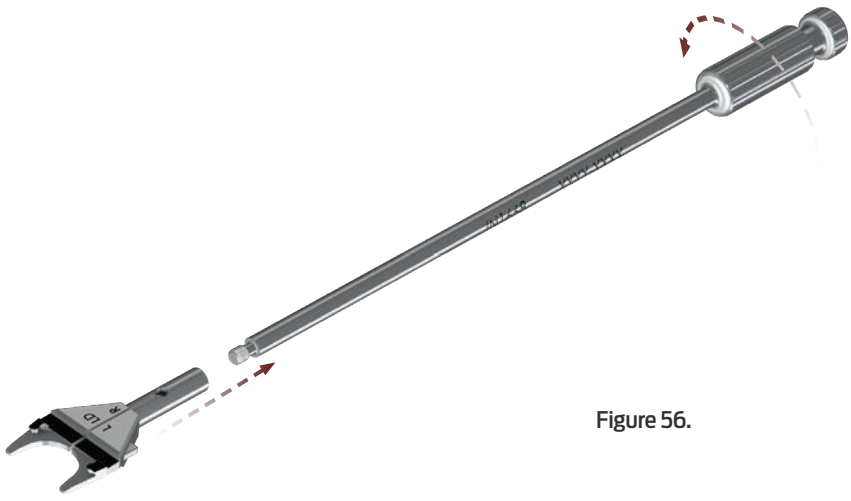


Figure 56.

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)**.

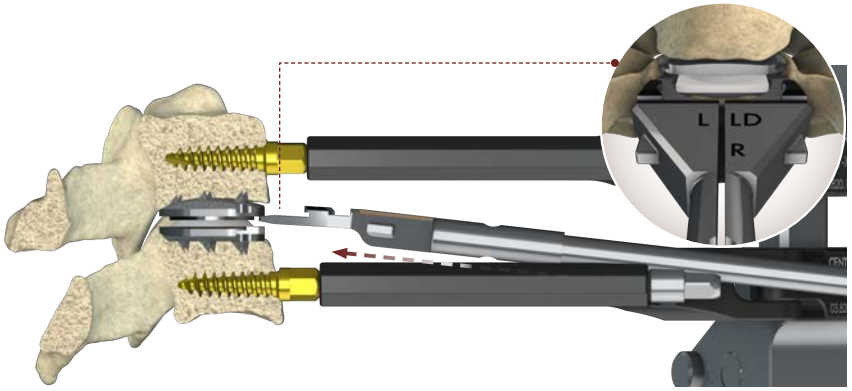


Figure 57.

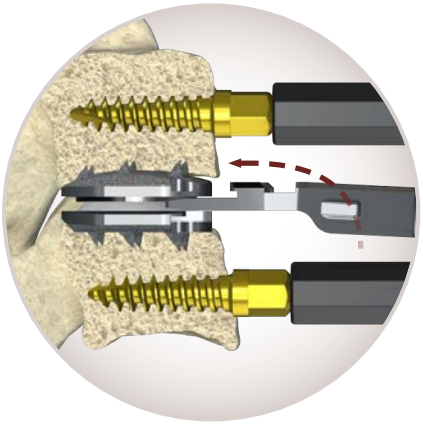


Figure 58.

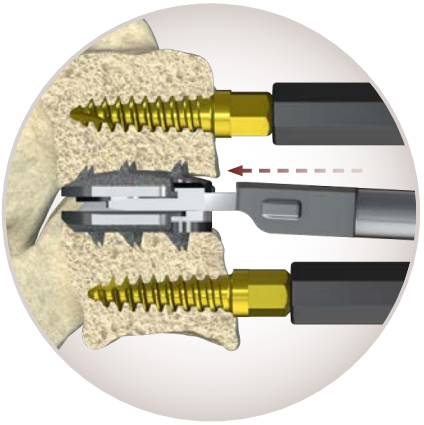


Figure 59.

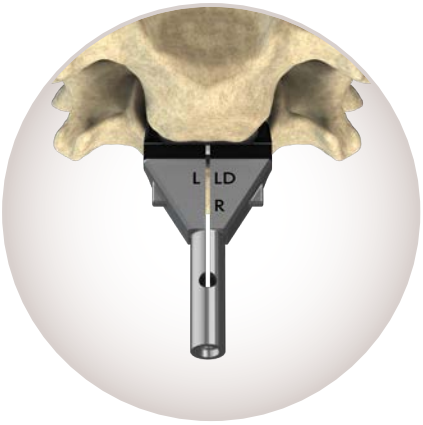


Figure 60.

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.

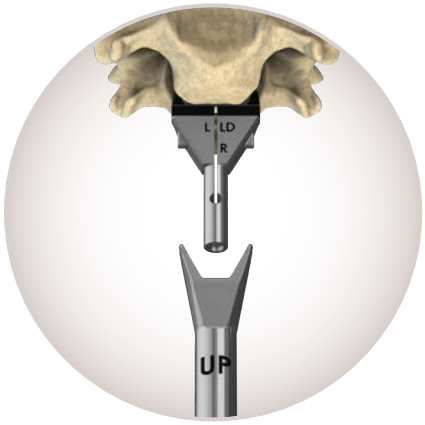


Figure 61.

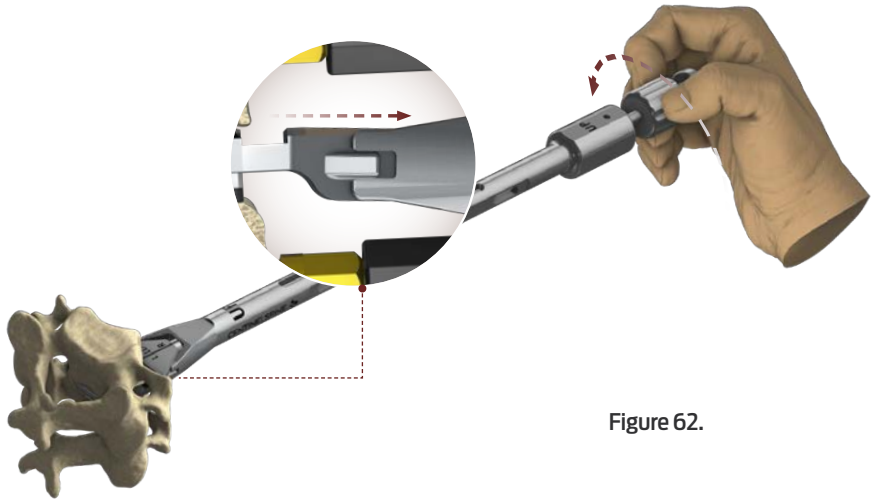


Figure 62.

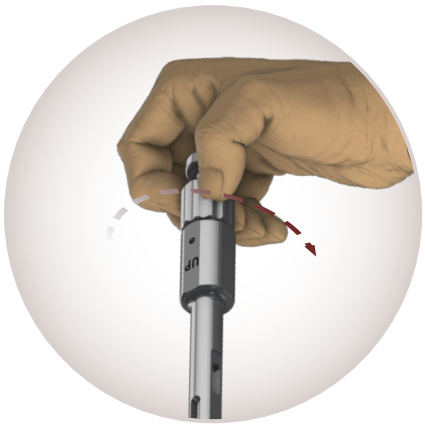


Figure 63.

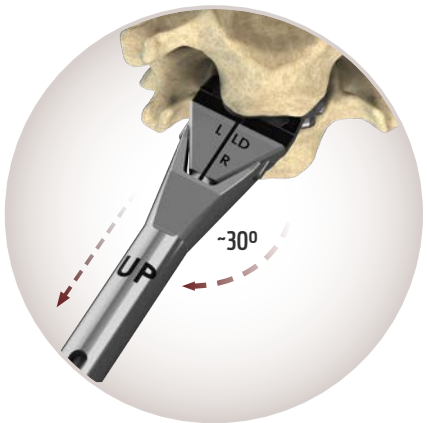


Figure 64.

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.

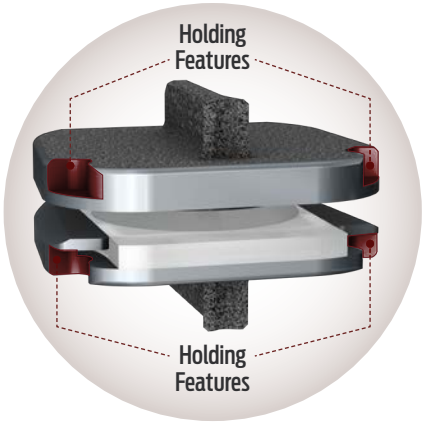


Figure 65.

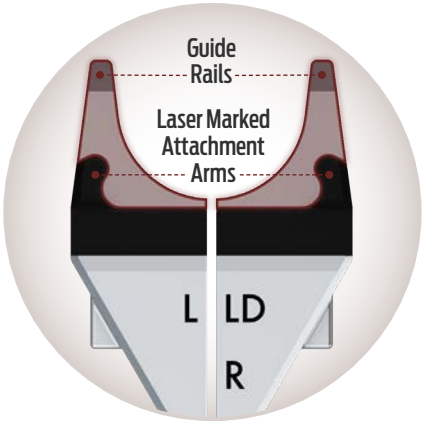


Figure 66.

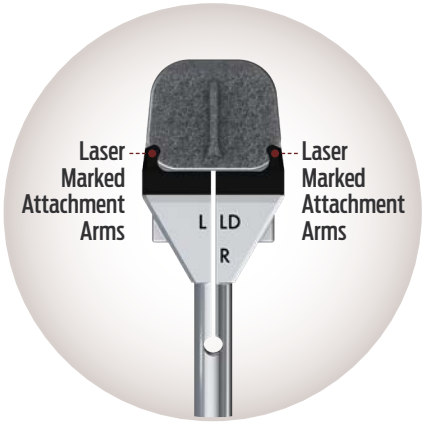


Figure 67.

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.

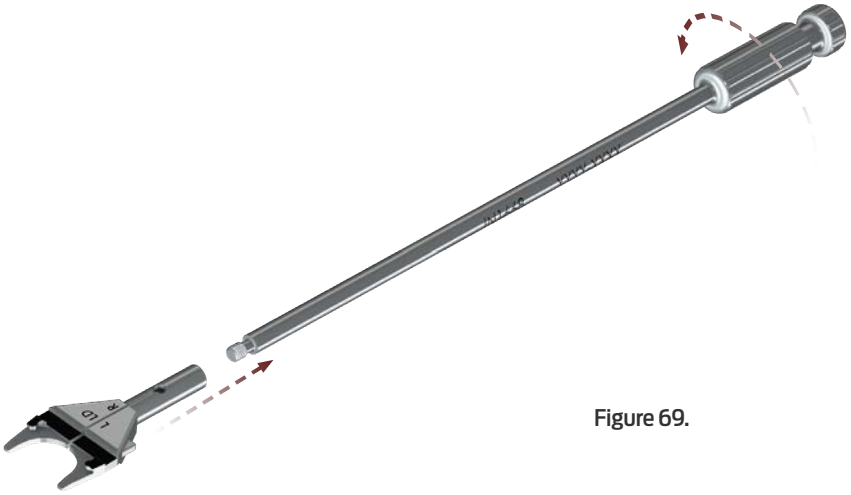


Figure 69.

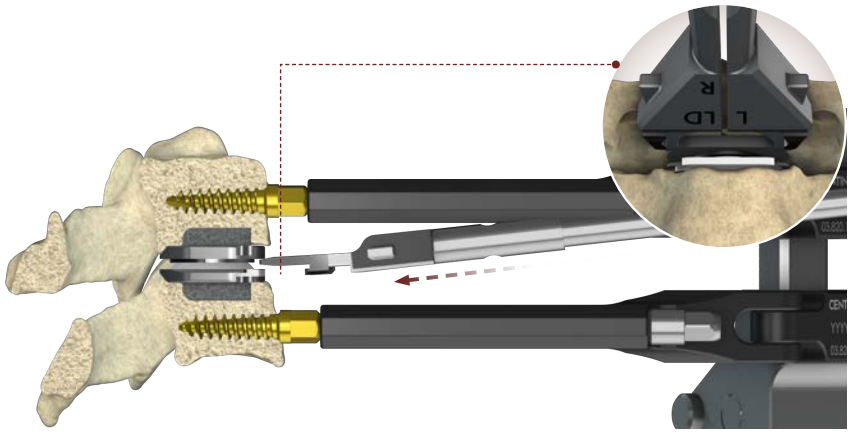


Figure 70.

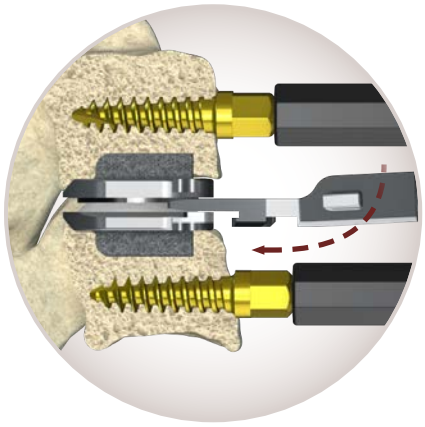


Figure 71.

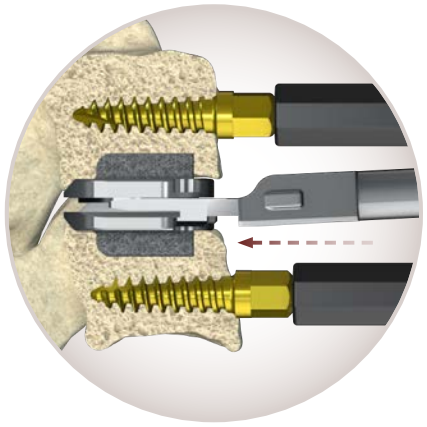


Figure 72.

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)**.

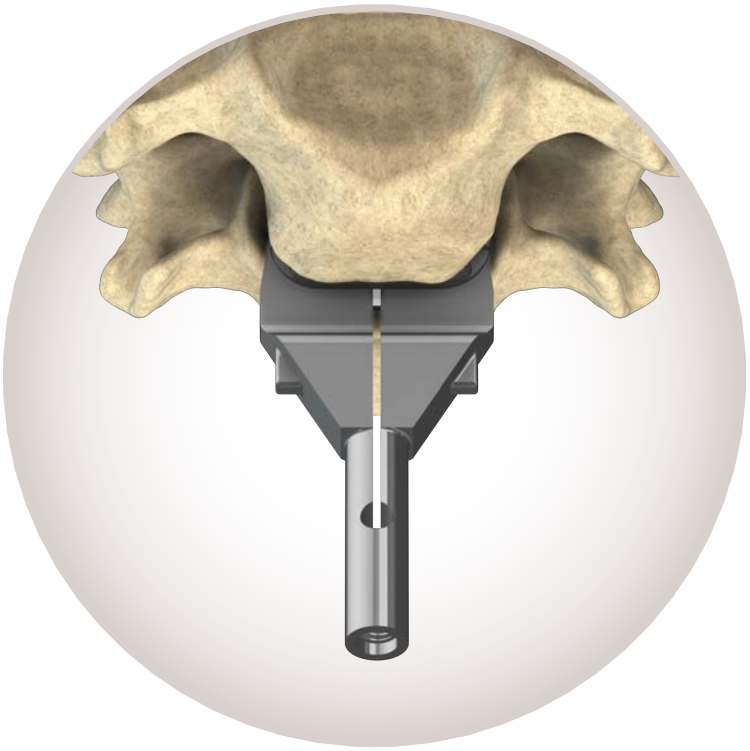


Figure 73.

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.

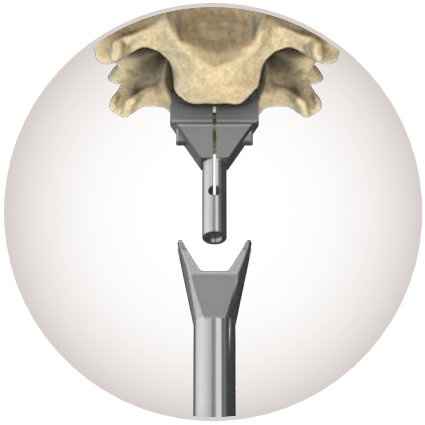


Figure 74.

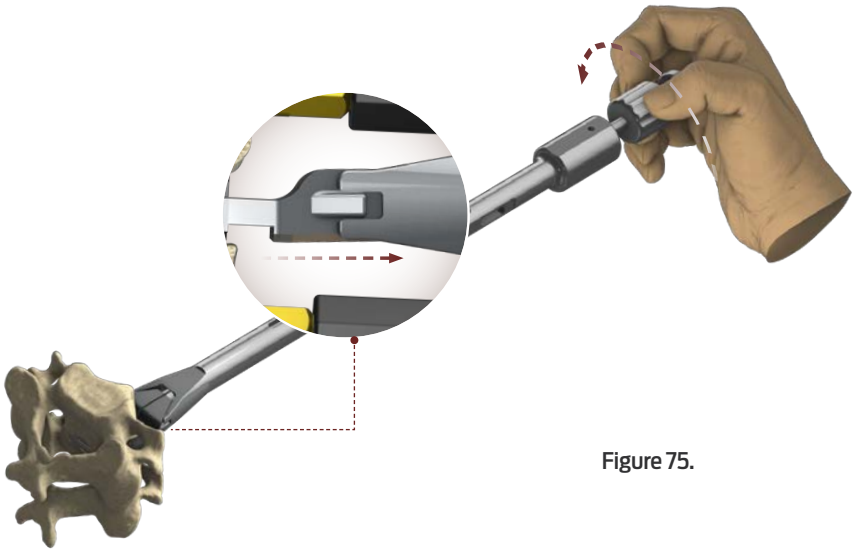


Figure 75.

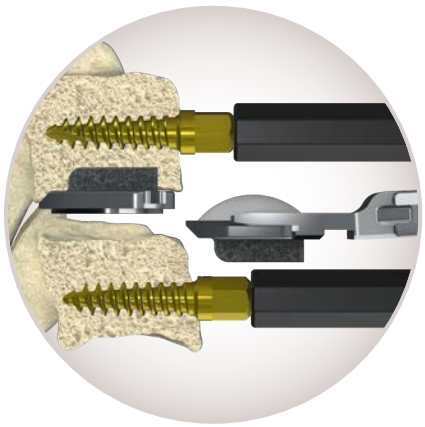


Figure 76.

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).

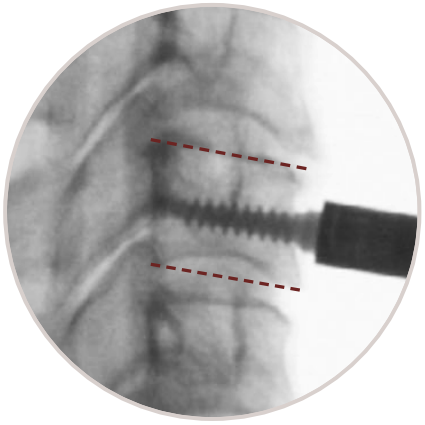


Figure 77.

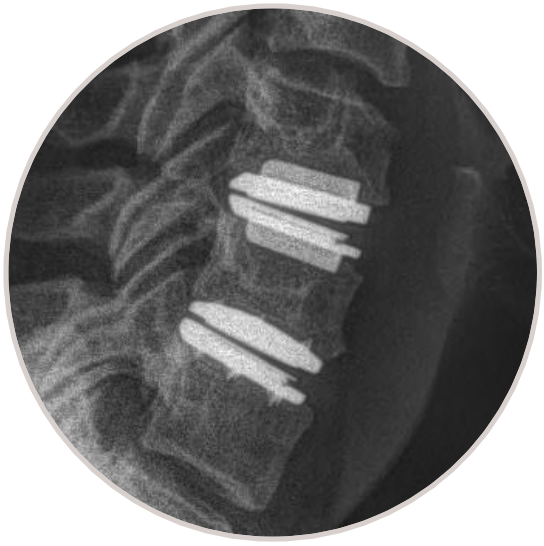


Figure 78.

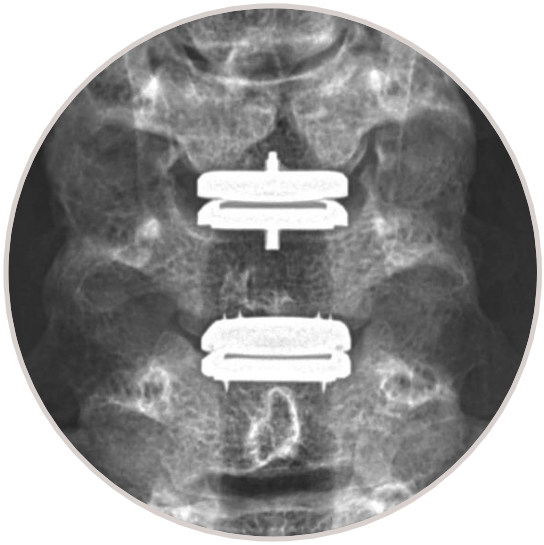


Figure 79.

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.

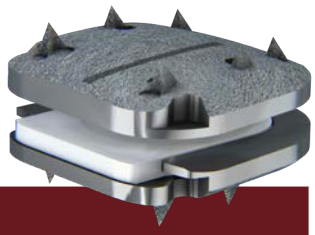
Use an interbody distractor or retainer device to distract the disc space. Using a fine osteotome, pry the superior implant endplate from the vertebral body and extract the superior implant endplate from the space with a Kocher clamp or other grasping instrument. Repeat this technique on the inferior 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.**

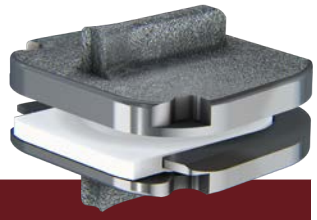
prodisc C Vivo *Implants*



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*

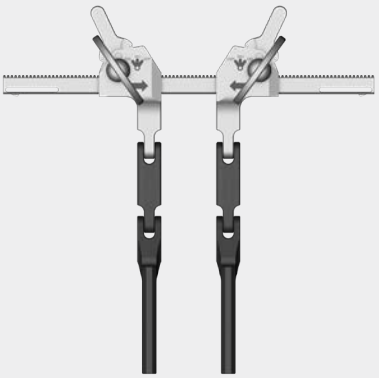
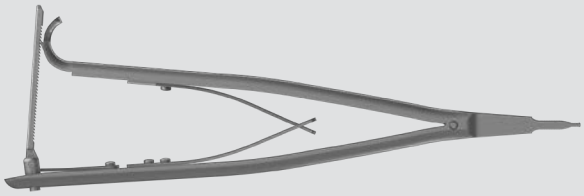
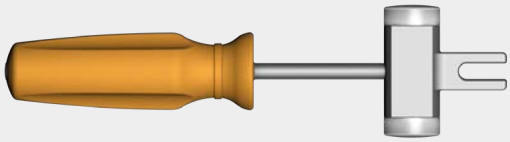
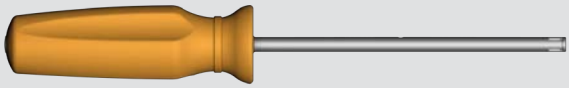
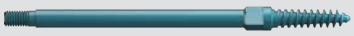
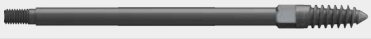


prodisc C SK Total Disc Replacement Implants, Sterile

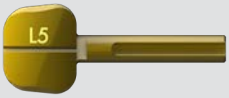
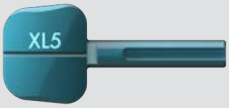
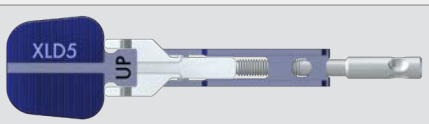
Implant Footprints			Part Numbers		
	Depth (mm)	Width (mm)	5 mm Height	6 mm Height	7 mm Height (available by special request only)
M	12	15	PDSM5	PDSM6	PDSM7
MD	14	15	PDSMD5	PDSMD6	PDSMD7
L	14	17	PDSL5	PDSL6	PDSL7
LD	16	17	PDSLD5	PDSLD6	PDSLD7
XL	16	19	PDSXL5	PDSXL6	PDSXL7
XLD	18	19	PDSXLD5	PDSXLD6	PDSXLD7

prodisc *Cervical Gen2 Instrument Set*

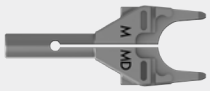
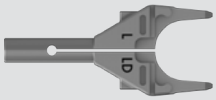
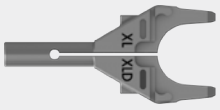
TOP TRAY | Instruments

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	

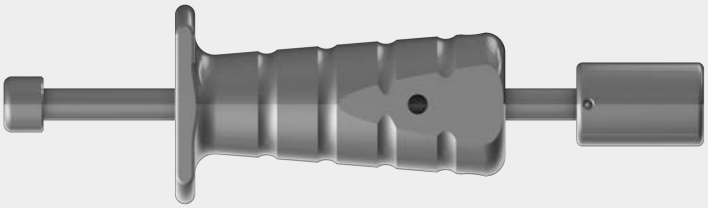
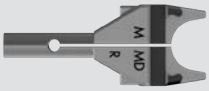
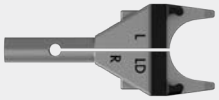
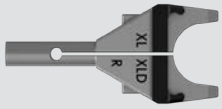
MIDDLE TRAY | Instruments

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	

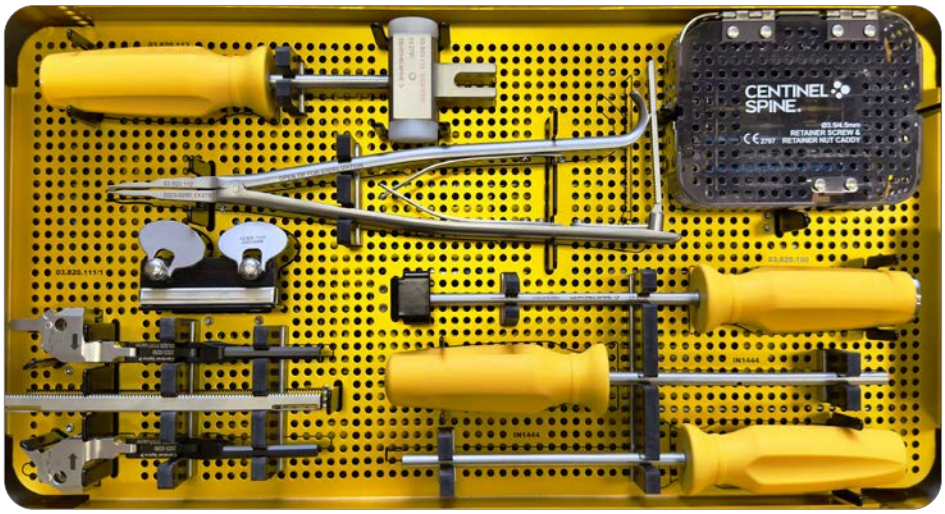
BOTTOM TRAY | Instruments

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	

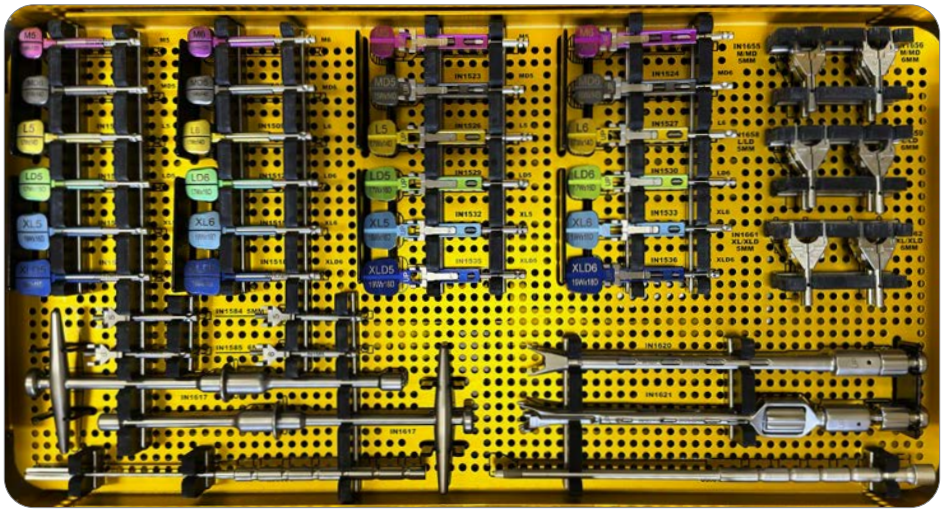
* Available by special request only.

Instrument Set Configuration

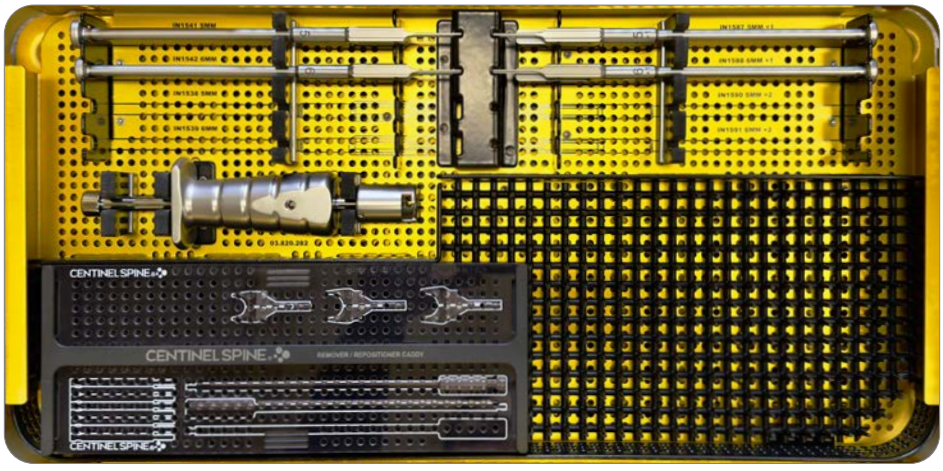
TOP TRAY | Instrument Set Configuration



MIDDLE TRAY | Instrument Set Configuration



BOTTOM TRAY | Instrument Set Configuration

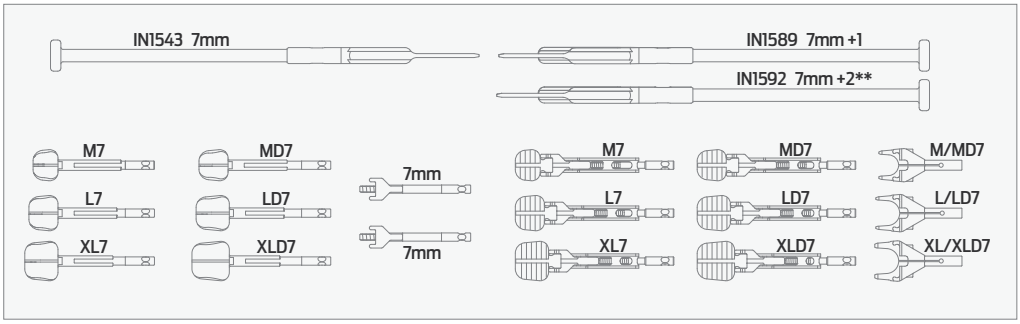


prodisc *Cervical Auxiliary Instrument Set**

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
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Email (US): info@centinelspine.com
Web: www.centinelspine.com

Instructions for use

prodisc ® C SK – Cervical Total Disc Replacement Implant
prodisc® C Vivo – Cervical Total Disc Replacement Implant

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

IMPORTANT: prodisc ® C SK and prodisc ® C Vivo Cervical Total Disc Replacement Implants are provided sterile by irradiation. The instruments are provided non-sterile and must be sterilized using the validated instructions.

Instructions for use

prodisc ® C SK and prodisc ® C Vivo – Cervical Total Disc Replacement

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 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

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

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

Indications for Use

The prodisc ® C SK and prodisc ® C Vivo 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 SK and prodisc ® C Vivo are implanted using an

anterior approach. Patients 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 SK and prodisc ® C Vivo.

Device Description

The prodisc ® C SK and prodisc ® C Vivo 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 spikes 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.

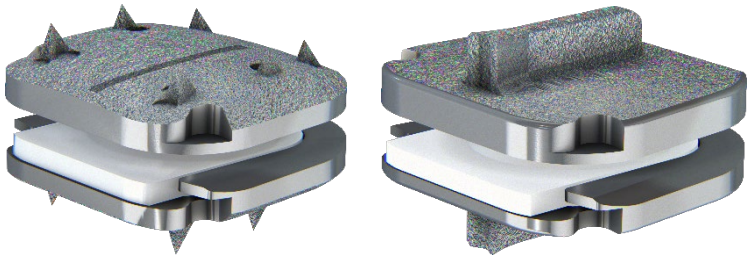

Figure 1: prodisc ® C Vivo (Left) and prodisc ® C SK (Right)

The prodisc ® C SK and prodisc ® C Vivo 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.

Table 1: Components of prodisc ® C Vivo and prodisc ® C SK

	prodisc ® C Vivo	**prodisc ® C SK**
Inferior Endplate	An inferior cobalt chromium molybdenum alloy (Co-28Cr-6Mo (CoCrMo)) plate with six spikes 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 spikes 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	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

	prodisc ® C Vivo	prodisc ® C SK
	surface that articulates with the convex UHMWPE spherical dome.	spherical dome.

Table 2: prodisc ® C Vivo and prodisc ® C SK Part Listing and Size Overview

Implant Type	Catalog Number	Width (mm)	Depth (mm)	Height (mm)
prodisc ® C Vivo				
prodisc ® C Vivo, Size M	PDVM5	15	12	5
prodisc ® C Vivo, Size M	PDVM6	15	12	6
prodisc ® C Vivo, Size M	PDVM7	15	12	7
prodisc ® C Vivo, Size MD	PDVMD5	15	14	5
prodisc ® C Vivo, Size MD	PDVMD6	15	14	6
prodisc ® C Vivo, Size MD	PDVMD7	15	14	7
prodisc ® C Vivo, Size L	PDVL5	17	14	5
prodisc ® C Vivo, Size L	PDVL6	17	14	6
prodisc ® C Vivo, Size L	PDVL7	17	14	7
prodisc ® C Vivo, Size LD	PDVLD5	17	16	5
prodisc ® C Vivo, Size LD	PDVLD6	17	16	6
prodisc ® C Vivo, Size LD	PDVLD7	17	16	7
prodisc ® C Vivo, Size XL	PDVXL5	19	16	5
prodisc ® C Vivo, Size XL	PDVXL6	19	16	6
prodisc ® C Vivo, Size XL	PDVXL7	19	16	7
prodisc ® C Vivo, Size XLD	PDVXLD5	19	18	5
prodisc ® C Vivo, Size XLD	PDVXLD6	19	18	6
prodisc ® C Vivo, Size XLD	PDVXLD7	19	18	7
prodisc ® C SK				
prodisc ® C SK, Size M	PDSM5	15	12	5
prodisc ® C SK, Size M	PDSM6	15	12	6
prodisc ® C SK, Size M	PDSM7	15	12	7
prodisc ® C SK, Size MD	PDSMD5	15	14	5
prodisc ® C SK, Size MD	PDSMD6	15	14	6
prodisc ® C SK, Size MD	PDSMD7	15	14	7
prodisc ® C SK, Size L	PDSL5	17	14	5
prodisc ® C SK, Size L	PDSL6	17	14	6
prodisc ® C SK, Size L	PDSL7	17	14	7
prodisc ® C SK, Size LD	PDSLD5	17	16	5
prodisc ® C SK, Size LD	PDSLD6	17	16	6
prodisc ® C SK, Size LD	PDSLD7	17	16	7
prodisc ® C SK, Size XL	PDSXL5	19	16	5
prodisc ® C SK, Size XL	PDSXL6	19	16	6
prodisc ® C SK, Size XL	PDSXL7	19	16	7
prodisc ® C SK, Size XLD	PDSXLD5	19	18	5
prodisc ® C SK, Size XLD	PDSXLD6	19	18	6
prodisc ® C SK, Size XLD	PDSXLD7	19	18	7

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 11° of angular difference from either adjacent level
- Ossification of posterior longitudinal ligament (OPLL)
- Cervical anatomical deformity or malalignment (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

- Correct placement of the device is essential for optimal performance of the prodisc® C SK and prodisc® C Vivo 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 SK and prodisc® C Vivo 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 postoperative, 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 Risks of Surgery

General surgical risks are, 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 are, 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 Total Disc Replacement Risks

Risks specific to cervical total disc replacement, including the prodisc ® C Vivo and prodisc ® C SK, are, 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 SK and prodisc ® C Vivo 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 SK and prodisc ® C Vivo system are MR conditional. These articles can be scanned safely under the following conditions:

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

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

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 SK or prodisc ® C Vivo implant and it may be necessary to optimize MR imaging parameters in order to compensate for the presence of the implant.

A representative implant has been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by prodisc ® C SK or prodisc ® C Vivo implants may present issues if the MR imaging area of interest is in or near the area where the implant is located.

- For FFE sequence: Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15°, 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 70°, worst-case artifact will extend approximately 2.5 cm from the implant

Processing, Reprocessing, Care, & Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to: https://guides.centinelspine.com

For general information about reprocessing, care, and maintenance of Centinel Spine reusable devices, instrument trays, and cases, please refer to:
https://guides.centinelspine.com

For further information
If further information on this product is needed, please contact your local Centinel Spine representative or dealer.

SUMMARY OF PRIMARY CLINICAL STUDY

Study Design

Subjects in the pivotal clinical trial were treated between July 2019 and December 2024. The prospective, multi-center, randomized, controlled clinical study was conducted under IDE G190041 to compare the prodisc® C SK and prodisc® C Vivo investigational devices to the Mobi-C control device, a PMA approved artificial cervical disc. The database for this PMA reflects data collected on a total of 480 subjects that were randomized and enrolled in the study; of the 480 subjects, 47 of these subjects, remained blinded, and ultimately were not treated, 433 of these subjects (N=293 prodisc® C SK and prodisc® C Vivo; and N=140 Mobi-C) had an incision time recorded. Subjects were treated at 31 US sites. Subjects in the investigational device arm could receive: treatment at two-levels with prodisc® C SK; treatment at two-levels with prodisc® C Vivo; or, treatment with a prodisc® C SK at one-level and prodisc® C Vivo at a contiguous level. It was determined that the subject device designs were similar enough to allow for different combinations in the investigational group.

Subjects were randomized in a 2:1 ratio to the two-level prodisc® C SK and/or prodisc® C Vivo device (investigational group) or to the two-level Mobi-C device (control group), respectively. A statistical plan was designed to test for non-inferiority between the two groups.

Clinical Inclusion and Exclusion Criteria

To be eligible for the IDE study, subjects had to meet all of the inclusion criteria and none of the exclusion criteria in **Table 3**:

Table 3: Study Inclusion and Exclusion Criteria

Study Inclusion Criteria	Study Exclusion Criteria
In order to be eligible to participate in this study, subjects must meet all of the following criteria: 1. Male or female, age ≥18 and ≤69 years. 2. Diagnosis of radiculopathy or myeloradiculopathy of the cervical spine, with pain, paresthesia or paralysis in a specific nerve root distribution C3 through C7, including at least one of the following:	Subjects who meet any of the following criteria will be excluded from participating in this study: 1. Have an active systemic infection or infection at the operative site. 2. Have a history of or anticipated treatment for active systemic infection, including HIV or Hepatitis C.

Study Inclusion Criteria	Study Exclusion Criteria
a. Neck and/or arm pain (at least 30 mm on the 100 mm visual analogue scale [VAS] scale). b. Decreased muscle strength of at least one level on the clinical evaluation 0 to 5 scale. c. Abnormal sensation including hyperesthesia or hypoesthesia; and/or d. Abnormal reflexes. 3. Symptomatic cervical disc disease (SCDD) at two contiguous levels from C3 to C7. 4. Radiographically determined pathology at the level to be treated correlating to primary symptoms including at least one of the following: a. Decreased disc height on radiography, computed tomography (CT), or magnetic resonance imaging (MRI) in comparison to a normal adjacent disc. b. Degenerative spondylosis on CT or MRI. c. Disc herniation on CT or MRI 5. NDI Score ≥30% 6. Unresponsive to non-operative, conservative treatment (rest, heat, electrotherapy, physical therapy, chiropractic care and/or analgesics) with the following conditions: a. Approximately six weeks or more of radicular symptoms; or b. Have the presence of progressive symptoms or signs of nerve root/spinal cord compression despite continued non-operative, conservative treatment; or c. Sooner than 6 weeks for worsening symptoms of neurologic compromise. 7. Appropriate for treatment using an anterior surgical approach. 8. Reported to be medically cleared for surgery. 9. Physically and mentally able and willing to comply with the Protocol, including the ability to read and complete required forms and willing and able to adhere to the scheduled follow-up visits and requirements of the Protocol. 10. Written informed consent provided by subject	3. Have more than one immobile vertebral level between C1 to C7 from any cause including but not limited to congenital abnormalities and osteoarthritic "spontaneous" fusions. 4. Have previous trauma to the C3 to C7 levels resulting in significant bony or disco-ligamentous cervical spine injury. 5. Have had any prior cervical spine surgery at the operative level(s), i.e., laminotomy. 6. Have had a prior cervical TDR or fusion procedure at any level. 7. Have axial neck pain in the absence of other symptoms of radiculopathy or myeloradiculopathy justifying the need for surgical intervention. 8. Have disc height less than 3 mm as measured from the center of the disc in a neutral position. 9. Have radiographic confirmation of severe cervical facet joint disease or degeneration at any level. 10. Have osteoporosis or is at increased risk of osteoporosis, defined as a DEXA bone density measured T-score of ≤ -1.5 or worse (i.e., -1.6, -1.7, etc.). Note: A qualifying T-score from either the hip or spine may be used to confirm eligibility. For subjects without a DEXA within 24 months of screening, a score of ≥ 6 on either the SCORE (females) or MORES (males) requires a DEXA to determine eligibility. 11. Have Paget's disease of bone, osteomalacia or any other metabolic bone disease other than osteoporosis, which is addressed above. 12. Have active malignancy that included a history of any invasive malignancy (except non-melanoma skin cancer), unless the subject had been treated with curative intent and there had been no clinical signs or symptoms of the malignancy for at least five years. 13. Have Symptomatic Cervical Disc Disease or significant cervical spondylosis at three (3) or more levels. 14. Have marked cervical instability on resting (neutral) lateral or flexion-extension radiographs demonstrated by: a. Translation ≥ 3.5 mm, and/or b. Greater than 11° angular difference to that of either adjacent level 15. Have known allergies to cobalt, chromium, molybdenum, titanium, nickel, or polyethylene.

Study Inclusion Criteria	Study Exclusion Criteria
	16. Are currently pregnant or breastfeeding at time of enrollment or have plans to become pregnant within the next three years. 17. Have rheumatoid arthritis, lupus, or other autoimmune disease that affect the musculoskeletal system. 18. Have congenital bony and/or spinal cord abnormalities that affect spinal stability. 19. Have diseases or conditions that would preclude accurate clinical evaluation (e.g. neuromuscular disorders, uncontrolled fibromyalgia). 20. Have concomitant conditions requiring daily, high-dose oral and/or inhaled steroids. High dose steroid use is defined as: a. Daily, chronic use of oral steroids equivalent to 5 mg/day of prednisone or greater. b. Daily, chronic use of inhaled corticosteroids (at least twice per day). c. Use of short-term (less than 10 days) oral steroids at a daily dose greater than 40mg prednisone equivalent within one month of the study procedure. 21. Have current or recent history (defined ≤ 1 year prior to screening) of substance abuse (alcoholism and/or narcotic addiction) requiring intervention. 22. Have a Body Mass Index (BMI) > 40 kg/m2. 23. Using any other investigational drug or medical device within the last 30 days prior to surgery. 24. Have evidence of symptomatic moderate to severe facet joint degeneration or disease where the investigator felt this was a major contributor to the subject's pain as diagnosed by injection and imaging. 25. Taking medications known to potentially interfere with bone/soft tissue healing (e.g., high-dose oral and/or inhaled steroids, immunosuppressant medication, chemotherapeutic agents). High dose steroid use is defined as part of Exclusion Criterion #21. 26. Have pending personal litigation relating to spinal injury (worker's compensation is not an exclusion). 27. Have a current history of heavy smoking (more than one pack of cigarettes per day). 28. Currently reside in a location, or anticipating a potential relocation, that may interfere with completion of follow-up examinations.

Study Inclusion Criteria	Study Exclusion Criteria
	29. Have mental illness or belonged to a vulnerable population, as determined by the investigator (e.g., prisoner or developmentally disabled), that would compromise ability to provide informed consent or compliance with follow-up requirements. 30. Have an uncontrolled seizure disorder. 31. Have had a cervical epidural steroid injection within 14 days prior to surgery

Control

Control subjects were prospectively enrolled and randomized to treatment with the Mobi-C (N=140), a PMA-approved artificial cervical disc. The Mobi-C Cervical Disc was implanted according to its surgical technique guide.

Follow-Up Schedule

All subjects were evaluated pre-operatively, at treatment/discharge (prior to the subject being discharged from the hospital) and post-operatively at Week 6 (±2 weeks), Month 3 (±2 weeks), Month 6 (±1 month), Month 12 (±2 months), Month 24 (±2 months), Month 36 (±2 months) and annually thereafter (±3 months). The following parameters were measured throughout the study (**Figure 2**):

Procedures	Screening[1]	Surgery (Day 0)	Day 14 (+/- 7 days)	6 Wk (+/- 2 wks)	3 Mo (+/- 2 wks)	6 Mo (+/- 4 wks)	12 Mo (+/- 8 wks)	18 Mo[6] (+/- 8 wks)	24 Mo (+/- 8 wks)	36-84 Mos (+/- 8 wks)	Unscheduled
Informed Consent	X	-	-	-	-	-	-	-	-	-	-
Inclusion/Exclusion Criteria	X	X	-	-	-	-	-	-	-	-	-
Demographics	X	-	-	-	-	-	-	-	-	-	-
Medical History	X	-	-	-	-	-	-	-	-	-	-
Pregnancy Test	-	X	-	-	-	-	-	-	-	-	-
MRI or CAT Scan	X	-	-	-	-	-	-	-	-	-	-
DEXA Scan	X[2]	-	-	-	-	-	-	-	-	-	-
X-Ray	X	X[5]	X	X	X	X	X	-	X	X	X[7]
Assessments	X[3,4]	-	-	X[3,4]	X[3,4]	X[3,4]	X[3,4]	-	X[3,4]	X[3,4]	X[3]
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X[7]
Adverse Events	-	X	X	X	X	X	X	X	X	X	X[7]
Device Deficiencies	-	X	X	X	X	X	X	X	X	X	X[7]
Review Rehabilitation	-	X	X	X	X	X	X	-	X	-	X[7]

1. Screening may begin up to 60 days before surgery. Refer to Section 8.2 for the screening visit procedures that should be conducted before randomization occurs.
2. DEXA required if the subject has a SCORE/MORES value ≥ 6. A new DEXA is not required if the subject had a DEXA within the 24 months prior to the screening visit.
3. Subject will complete Patient Reported Outcome questionnaires: VAS neck pain, VAS arm/shoulder pain, VAS hoarseness, Treatment Satisfaction (not at Screening), NDI Questionnaire, SF-12 Health Survey, and Dysphagia Handicap Index. These surveys should be administered prior to any other study visit assessments or procedures being performed.
4. The Investigator/designee will complete the following assessments: a physical examination, the Nurick scale, Odom's Criteria (starting at the 6 Wk. visit), and a neurological assessment.
5. Intraoperative AP and lateral radiographs/fluoroscopy should be taken prior to closure to verify proper implant positioning.
6. The 18-month visit will be completed by telephone.
7. The following procedures may be performed, if deemed necessary by the Investigator: Physical Examination, X-rays, Nurick Scale, Odom's Criteria Assessment ,Neurological Assessment

Figure 2: Clinical Study Schedule of Procedures

Clinical Endpoints

The safety of the prodisc® C SK and prodisc® C Vivo at two levels was assessed by comparison to the Mobi-C control group with respect to the nature and frequency of adverse events (overall and in terms of severity and relationship to the implant), subsequent index level surgical procedures, and maintenance or improvement in neurological status.

The effectiveness of the prodisc® C SK and prodisc® C Vivo at two levels was assessed by comparison to the Mobi-C control group with respect to a primary composite endpoint, as described below. Effectiveness was further evaluated by assessing improvement in the Neck Disability Index (NDI), neck and arm pain questionnaires, and quality of life using the short-form questionnaire (SF-12), as well as subject satisfaction of the prodisc® C SK and prodisc® C Vivo treatment as compared to the Mobi-C Cervical treatment. Similar criteria were used to measure success in both groups.

Primary Endpoint

The primary composite endpoint was defined as:

- 15-point improvement in NDI Score (out of 100) in subjects at the Month 24 timepoint compared with baseline;
- Maintenance or improvement in neurological status (motor and sensory only) at Month 24 compared to baseline;
- No secondary surgical interventions (revision, removal, re-operation, supplemental fixation) at the index level(s); and,
- Absence of major device-related adverse events (DRAEs) defined as radiographic failure, neurological failure, or failure by AE as adjudicated by the Clinical Events Committee (CEC).

For the purpose of determining individual subject success, the subject may not experience a major AE. A major AE was defined as any of the following which are definitely related to the device system or to a device component as determined by the CEC:

- No new or worsening permanent neurologic deficit;
- Implant or component breakage or migration that does not require revision, reoperation or removal, but causes persistent or moderate to severe dysphagia and/or,
- Subject death.

Subject success was evaluated using the primary composite endpoint above at Month 24. Study success was evaluated for the Month 24 Composite Clinical Success (CCS) using the following pre-specified hypotheses pertaining to clinical non-inferiority:

H_0: $\pi_T - \pi_C <= -0.10$ (the CCS rate of investigational device was clinical inferior to control)
H_a: $\pi_T - \pi_C > -0.10$ (the CCS rate of investigational device was not clinical inferior to control)

where π_T and π_C are the probabilities of achieving Month 24 CCS of the investigational and control devices, respectively. In all circumstances, non-inferiority hypotheses were based on the *a priori*

selected non-inferiority margin, $\delta = -0.10$.

The claim of non-inferiority was pre-specified to be accepted if the posterior probability of non-inferiority, is greater than or equal to 0.967. That is, if, $Pr(\pi_T - \pi_C > - \delta \mid \text{Trial Results}) \geq 0.967$.

This posterior probability is calculated using Beta(1, 1) non-informative priors for both the investigational arm. A Bayesian posterior probability threshold of 0.967 controls type 1 error to 0.044 with statistical power of 84.6%.

Per FDA Guidance for the Preparation of IDEs for Spinal Systems (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-document-preparation-ides-spinal-systems-guidance-industry-andor-fda-staff, the following definitions applied:

- Reoperation - any surgical procedure at the index level(s) that does not involve modification, addition, or removal of any components of the device in the post-operative or follow-up period.
- Revision – any procedure in the post-operative or follow-up period that adjusts, modifies, or removes part of the original implant configuration with or without replacement of a component – may include adjusting the position of the original configuration in the post-operative or follow-up period.
- Removal – a procedure where the entire device is removed with or without replacement of the device in the post-operative or follow-up period.
- Supplemental fixation – a procedure in which additional instrumentation not under study is implanted (e.g., supplemental placement of a plate/ screw fusion system).

Secondary Endpoints

The Secondary endpoints measured in both groups included:

- Neck pain related disability as measured on a 100-point scale using the NDI questionnaire;
- Neck pain as measured on a 100mm Visual Analog Scale (VAS) at baseline and at each follow-up time-point;
- Worse arm/shoulder pain as measured separately on a 100mm VAS at baseline and at each follow-up time-point;
- VAS Hoarseness on a 100mm scale at baseline and at each follow-up time-point;
- Health Survey (SF-12v2) Physical Component Summary (PCS) at baseline and at each follow-up time-point (Results for MCS will be summarized);
- Treatment Satisfaction;
- Dysphagia Handicap Index (DHI) at Month 24 compared to baseline;
- Results at Month 24 for both treatment groups as categorized by the physician according to Odom's Criteria;
- Myelopathy based on the Nurick scale. A change of at least one grade at Month 24 compared to baseline will be regarded as clinically significant.

In addition to the above secondary endpoints, various neurologic and radiographic (quantitative and qualitative) assessments were measured and evaluated in both groups.

Clinical Events Committee

A CEC was utilized for the prodisc® C SK and prodisc® C Vivo IDE study, including the Mobi-C Cervical Disc control group, to mitigate reporting bias of safety-related events. The CEC consisted of two spine surgeons and one neurosurgeon who are not affiliated with the sponsor and did not participate in the study. The CEC charter was used to define the role of the CEC. The recommendations of the CEC override the investigator's classification and become part of the clinical trial data set. The CEC adjudicated all AEs, secondary surgical interventions (SSIs), protocol deviations, and Month 24 neurological status.

AEs were reviewed to confirm or re-classify the AE term, severity, seriousness, anticipated versus unanticipated, and relationship to the investigational or control devices and/or the associated procedures. For events determined to be Serious, the CEC reviewed for the potential to re-classify the event as an Unanticipated Adverse Device Effect (UADE) or not a UADE. For the events determined to be definitely related to device, the CEC determined if they qualified as a 'Major' AE, per the primary endpoint. AEs which led to SSI were reviewed to determine if the SSI met the primary endpoint criteria for SSI failure and re-classify the event as reoperation, revision, removal or supplemental fixation. Protocol deviations were classified as 'major' or 'minor'. Lastly, the CEC adjudicated neurologic status at Month 24 for all subjects to determine if neurologic status was maintained, improved, or deteriorated relative to baseline.

Accountability of PMA Cohort

At the time of the December 31, 2024 database lock, a total of 480 subjects signed the informed consent form and were randomized (Intent-to-Treat Analysis Set):

- A total of **47** subjects were randomized, remained blinded, and ultimately not treated.
    - A total of **46** of the 47 subjects did not meet the eligibility criteria defined in Section 7.1 and Section 7.2 of the Protocol prior to treatment.
    - A total of **1** of the 47 subjects was not treated because they did not meet insurance requirements.

The resulting 433 available randomized subjects, with an operation date at the time of the database lock (293 prodisc® C SK and prodisc® C Vivo subjects and 140 Mobi-C control subjects) were assessed as part of the modified Intent-to-Treat (mITT) Analysis Set. Two subjects in the prodisc® C SK and prodisc® C Vivo group received fusion; therefore, the As-Treated (AT) Analysis Set includes 291 prodisc® C SK and prodisc® C Vivo subjects, and 140 Mobi-C subjects. There were a total of 25 major protocol deviations, leaving the Per Protocol (PP) Analysis Set to include 406 subjects (274 prodisc® C SK and prodisc® C Vivo subjects, and 132 Mobi-C subjects). This information is presented in tabular form in **Table 4** below; similarly, this information is presented graphically via a patient accounting tree in **Figure 3** below.

Table 4: Accounting Information

	prodisc® C SK and prodisc® C Vivo	**Mobi-C**
Randomized (ITT Analysis Set)	321	159
Subjects randomized but not treated*	28	19
mITT Analysis Set	293	140
As Treated (AT Analysis Set)	291	140

Number yet to reach 24 months (Day 730) as of database lock (mITT Analysis Set)	16**	2
Theoretical due (Day 730) as of database lock (mITT Analysis Set)	277	138
Subjects with known primary outcome (CCS) at the time of database lock (mITT Analysis Set)	253	127
Subjects with missing CCS outcome (mITT Set)	**Subjects without CCS N=40** • Not yet overdue (between 730 and 790) **(N=5)** • Below Day 730 **(N=14)**** • Missing for other reasons (**N=21**): o Lost to Follow-up **(N=4)** o Death **(N=2)** o Missed 24 Month Visit **(N=10)** o Missing CCS Component **(N=5)**	**Subjects without CCS N=13** • Not yet overdue (**N=2)** • Below Day 730 **(N=2)** • Missing for Other Reasons **(N=9)** o Withdrawn by investigator due to AE (**N=1**) o Missed 24 Month Visit (**N=3**) o Missing CCS Component (**N=5**)

*This includes subjects who were randomized, but not treated because they did not meet eligibility criteria per Section 7.1 and 7.2 of the Protocol. One of these subjects was withdrawn because of an issue with insurance.
**The difference between Number Yet to Reach Day 730 (N=16) and subjects Below Day 730 (N=14) is two subjects (06-039, 06-040) who had an SSI before Day 730, therefore they had a known CCS outcome, and are not a subject with a missing CCS.

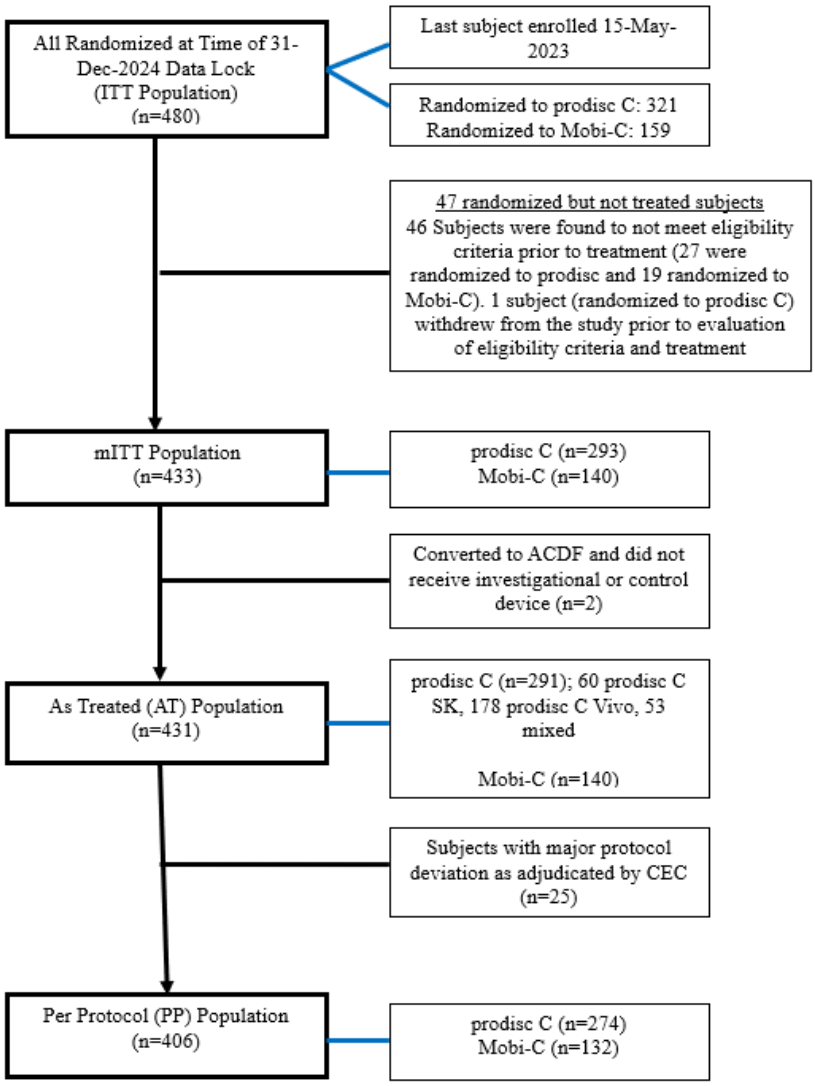

Figure 3: Subject Analysis Populations

This submission includes data up to the database lock that occurred on December 31, 2024. The Month 24 CCS endpoint within the PP Analysis Set is based on 93% (342/367) of all subjects expected due. The Month 24 CCS endpoint for the mITT Analysis Set is based on 89% (348/392) of all subjects expected due. Within the mITT Analysis Set, 94.5% (277/293) of prodisc® C SK and prodisc® C Vivo subjects, and 98.6% (138/140) of Mobi-C subjects are theoretically due (Day 730); within this same analysis set, 91.3% (253/277) of prodisc® C SK and prodisc® C Vivo subjects, and 92.0% (127/138) of Mobi-C subjects have a known primary outcome.

The subject accountability summary through the Month 24 timepoint is presented in **Table 5** for the mITT Analysis Set. The accounting table is stratified by treatment arm with the overall prodisc® C SK and prodisc® C Vivo group subjects referred to hereafter as the investigational group ("I"), and Control group ("C") for subjects that have completed follow up through Month 24.

Table 5: Subject Accounting Summary (mITT Population, N=433) Through Month 24

	Pre-Op		Treatment		Week 06		Month 03		Month 06		Month 12		Month 24	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Accounting														
(1) Theoretical follow-up	293	140	293	140	293	140	293	140	293	140	293	140	277	138
(2) Cumulative Death			0	0	0	0	0	0	0	0	1	0	2	0
(3) Cumulative SSI Failures			0	0	1	0	1	1	2	3	4	4	9	6
(4) Not Yet Overdue			0	0	0	0	0	0	0	0	0	0	6	2
(5) Deaths+SSI failures among theoretically due			0	0	1	0	1	1	2	3	5	4	9	6
(6) Expected Due [(6)=(1)-(4)-(5)]					292	140	292	139	291	137	288	136	262	130
(7) SSI failures among theoretically due			0	0	1	0	1	1	2	3	4	4	7	6
(8) Expected due+SSI failures among theoretically Due [(8)=(6)+(7)]					293	140	293	140	293	140	292	140	269	136
All Evaluated Accounting (Actual[B]) Among Expected Due Procedures														
(9) Procedures with any clinical data in interval†	293	140			272	134	279	135	280	136	277	130	243	121
(10) Visit Compliance (%)					93%	96%	96%	97%	96%	99%	96%	96%	93%	93%
(11) Change in NDI					272	134	279	135	280	136	277	130	243	121
(12) Composite Clinical Success (CCS)													243	121
(13) Actual[B] % Follow-up for CCS													93%	93%
Within Window Accounting (Actual[A]) Among Expected Due Procedures														
(14) Procedures with any clinical data in interval†	293	140			263	132	224	111	243	121	269	125	233	116
(15) Visit Compliance (%)					90%	94%	77%	80%	84%	88%	93%	92%	89%	89%
(16) Change in NDI					263	132	224	111	243	121	269	125	233	116
(17) Composite Clinical Success (CCS)													232	116
(18) Actual[A] % Follow-up for CCS													89%	89%

[A] Patients with complete data for each endpoint, within window.

[B] Patients with any follow-up data reviewed or evaluated by investigator ("all evaluated" accounting).

†Change in NDI;

Source: Tables Follow-up Compliance mITT.sas; Analyzed: 31MAR2025

Study Population Demographics and Baseline Parameters

The tables below provide a summary of pre-operative and demographic variables for subjects treated in the study for both the investigational and control groups in the mITT Analysis Set. Variables summarized include age, BMI, height, and weight stratified by gender as well as race and ethnicity. Further, the demographics of the study population are typical for a cervical total disc replacement study performed in the United States. The proportions enrolled are consistent with the sex, age, racial and ethnicity of other cervical total disc replacement studies conducted to support a PMA with two-level indications in the US.

Table 6: Pre-operative and Demographic Continuous Variables (mITT Analysis, N=433)

	prodisc® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
All																
Age (years)	293	49.4	8.8	50.0	22.6	69.5	140	48.7	9.1	47.9	29.1	69.0	0.7	-1.0	2.5	0.448
BMI (kg/m^2)	292	29.2	4.8	29.2	17.7	40.6	140	28.4	4.5	28.2	18.5	39.8	0.9	0.0	1.8	0.069
Height (inches)	292	67.7	3.9	68.0	58.0	76.0	140	67.9	4.0	68.0	55.0	78.0	-0.2	-1.0	0.6	0.647
Weight (lbs)	292	191.5	37.9	190.0	103.0	275.0	140	186.8	36.8	182.3	118.0	284.0	4.7	-2.5	12.1	0.225
Female																
Age (years)	146	48.9	8.4	48.8	22.6	66.9	66	47.9	9.2	46.6	29.1	68.4	1.0	-1.3	3.6	0.422
BMI (kg/m^2)	145	28.6	5.5	28.1	17.7	40.6	66	27.5	5.1	26.9	18.5	39.8	1.1	-0.4	2.6	0.194
Height (inches)	145	64.7	2.7	65.0	58.0	71.0	66	64.9	2.7	65.0	55.0	70.0	-0.1	-0.9	0.6	0.716
Weight (lbs)	145	170.0	33.3	167.6	103.0	270.0	66	164.4	30.6	159.5	118.0	239.0	5.6	-3.3	15.1	0.254
Male																
Age (years)	147	49.8	9.1	52.0	26.6	69.5	74	49.3	8.9	49.6	31.4	69.0	0.4	-2.0	2.9	0.740
BMI (kg/m^2)	147	29.9	3.9	29.5	23.0	39.5	74	29.1	3.7	29.1	20.8	39.0	0.8	-0.2	1.9	0.143
Height (inches)	147	70.7	2.4	70.5	63.0	76.0	74	70.6	2.8	70.5	63.0	78.0	0.1	-0.6	0.8	0.861
Weight (lbs)	147	212.7	29.3	210.0	135.0	275.0	74	206.7	29.9	203.0	155.0	284.0	6.0	-1.8	14.2	0.156
Clinical Scores																
Neck Disability Index (NDI)	293	58.9	15.8	58.0	30.0	100.0	140	57.2	15.9	56.0	28.0	96.0	1.7	-1.3	4.8	0.305
VAS Back	293	73.8	18.7	77.0	2.0	100.0	140	74.3	17.4	77.0	0.0	100.0	-0.5	-4.0	3.1	0.786
VAS Hoarseness	293	19.0	25.9	5.0	0.0	100.0	140	19.5	27.2	4.0	0.0	100.0	-0.6	-5.6	4.7	0.827
VAS Left Arm/Shoulder	293	53.2	34.0	60.0	0.0	100.0	140	52.5	35.4	63.0	0.0	100.0	0.8	-5.8	7.6	0.828
VAS Right Arm/Shoulder	293	52.0	33.4	59.0	0.0	100.0	140	54.1	33.2	66.5	0.0	100.0	-2.0	-8.4	4.6	0.546

*Device group mean differences and 95% Credible Intervals.
Nominal Two-sided t-test p-value (equal variance).
Source: Tables Baseline Demo mITT.sas; Analyzed: 12MAR2025

Table 7: Pre-operative and Demographic Categorical Variables (mITT Analysis, N=433)

	prodisc® C			Mobi-c			
	N	n	%	N	n	%	p*
Race							
Black or African American		17	5.8%		3	2.1%	
Native Hawaiian or Other Pacific Islander	293	2	0.7%	140	0	0.0%	0.242
Asian		1	0.3%		2	1.4%	
White		265	90.4%		131	93.6%	
Other		8	2.7%		4	2.9%	
Ethnicity							
Hispanic or Latino	293	14	4.8%	140	9	6.4%	0.496
Not Hispanic or Latino		279	95.2%		131	93.6%	

* Exact test p-value.
Source: Tables Baseline Demo Categorical.sas; Analyzed: 2025-03-31

The tables below provide a summary of intraoperative surgical variables for subjects treated in the study for both the investigational and control groups in the AT Analysis Set, and mITT Analysis Set. Variables summarized include operative time, blood loss, and length of stay. There was a difference in blood loss, in favor of Mobi-C. It is important to note that this difference is expected as Mobi-C does not require a keel cut during implantation. Furthermore, the keel cut into the

cancellous bone, which is required during implantation of prodisc® C SK, will create more bone bleeding than should be seen on average with prodisc® C Vivo or Mobi-C.

Table 8: Summary of Continuous Intra-Operative Variables (mITT Analysis, N=433)

	prodisc® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
All																
Operative Time (minutes)	293	104.1	38.0	97.0	35.0	241.0	140	102.5	38.1	97.0	42.0	214.0	1.6	-5.7	9.1	0.697
Length of Stay (days)	293	0.5	0.8	0.0	0.0	9.0	140	0.5	0.6	0.5	0.0	4.0	0.0	-0.2	0.1	0.642
Blood Loss (cc)	293	33.6	30.5	25.0	5.0	200.0	140	26.7	17.9	25.0	5.0	100.0	7.0	1.8	12.3	0.013

*Device group mean differences and 95% Credible Intervals.
Nominal Two-sided t-test p-value (equal variance).
Source: Tables Intra-Op mITT.sas; Analyzed: 17MAR2025

As demonstrated above, the investigational subjects and control subjects that make up the mITT analysis population are not significantly different with respect to baseline variables. Intra-operative data differed only for blood loss, with the control group reporting a lower mean amount ($p = 0.013$) than the investigational group.

Safety Results

Adverse Event Summary

The CEC reviewed all safety events for both treatment groups, including AEs and SSIs, to allow for uniform adjudication of study-related events and evaluations and to eliminate any site-by-site variations in reporting. Specifically, the CEC reviewed and adjudicated AE category, severity, procedure and implant-relatedness, seriousness, and if serious, whether or not the event was anticipated.

Table 9 shows a summary of AE categories and rates between the investigational and control groups in the ITT Analysis Set. Overall, similar rates of AEs occurred in the investigational group (78.5% - 252/321) and control group (78.6% - 125/159). SAEs that were considered "definitely" device-related were also comparable between the two groups, where 1.6% (5/321) of investigational subjects had "definitely" device-related SAEs, while 1.9% (3/159) control of subjects had "definitely" device-related SAEs. Lastly, the rate of SAEs that were considered "definitely" procedure-related was 3.1% (10/321) in investigational subjects and 1.9% (3/159) in control subjects.

Table 9: Adverse Event Summary (ITT Analysis Set, N=480)

	prodisc® C (N= 321)			Mobi-C (N= 159)			prodisc® C - Mobi-C			
	Events	n	%	Events	n	%	Δ	LB[3]	UB[3]	p-value[4]
Adverse Events (AE)										
All	832	252	78.5%	354	125	78.6%	-0.1%	-7.9%	7.7%	0.999
Device Related[1]	153	123	38.3%	82	65	40.9%	-2.6%	-11.9%	6.7%	0.620
Device Related - Definitely	9	8	2.5%	4	4	2.5%	0.0%	-3.0%	2.9%	0.999
Procedure Related[2]	252	158	49.2%	124	78	49.1%	0.2%	-9.3%	9.7%	0.999
Procedure Related - Definitely	41	35	10.9%	21	17	10.7%	0.2%	-5.7%	6.1%	0.999
Serious Adverse Events (SAE)										
All	72	60	18.7%	31	28	17.6%	1.1%	-6.2%	8.4%	0.803
Device Related[1]	10	9	2.8%	7	7	4.4%	-1.6%	-5.3%	2.1%	0.419
Device Related - Definitely	6	5	1.6%	3	3	1.9%	-0.3%	-2.8%	2.2%	0.724
Procedure Related[2]	19	17	5.3%	9	9	5.7%	-0.4%	-4.7%	4.0%	0.834
Procedure Related - Definitely	10	10	3.1%	3	3	1.9%	1.2%	-1.6%	4.1%	0.559
AE by Severity										
Mild	485	202	62.9%	204	90	56.6%	6.3%	-3.0%	15.7%	0.197
Moderate	261	137	42.7%	107	73	45.9%	-3.2%	-12.7%	6.2%	0.558
Severe	86	70	21.8%	43	36	22.6%	-0.8%	-8.8%	7.1%	0.907
SAE by Severity										
Mild	1	1	0.3%	1	1	0.6%	-0.3%	-1.7%	1.1%	0.553
Moderate	7	7	2.2%	6	6	3.8%	-1.6%	-5.0%	1.8%	0.372
Severe	64	54	16.8%	24	23	14.5%	2.4%	-4.5%	9.2%	0.597
Death										
All	2	2	0.6%	0	0	0.0%	0.6%	-0.2%	1.5%	0.999

NA=Not applicable.
[1]Device related is anything that was possibly, probably or definitely related to the device.
[2]Procedure related is anything that was possibly, probably or definitely related to the procedure.
[3]95% Exact unconditional confidence intervals.
[4]Fisher's exact test.
Source: Tables AE Summary ITT.sas; Analyzed: 01APR2025

All Adverse Events

Table 10 lists all AEs reported as of the database lock by AE term, with the number of subjects experiencing the events. Percentages are calculated as the number of subjects experiencing an event divided by the number of subjects treated in the ITT Analysis Set. The investigational group presented with 832 events occurring in 78.5% (252/321) of the 321 prodisc® subjects, compared to 354 events occurring in 78.6% (125/159) of the 125 Mobi-C control subjects.

The most common AEs (rate of 5% or more) included: dysphagia (investigational – 7.8%, 25/321; control – 8.8%, 14/159); general disorders and administrative site conditions – Covid-19 (investigational –*:* 9.3%, 30/321; control – 8.2%, 13/159); joint pain (investigational – 11.5%, 37/321; control – 13.2%, 21/159); spasms (investigational – 7.5%, 24/321; control – 4.4%, 7/159); other musculoskeletal pain (investigational – 6.2%, 20/321; control – 6.9%, 11/159); numbness/tingling (investigational – 7.2%, 23/321; control – 5.7%, 9/159); radiculopathy (investigational – 21.5%, 69/321; control – 23.9%, 38/159); and trauma (investigational – 10.0%, 32/321; control – 11.9%, 19/159).

Table 10: All Adverse Events (ITT Analysis Set N=480)

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
All	**832**	**252**	**78.5%**	**354**	**125**	**78.6%**	**-0.1%**	**-7.9%**	**7.7%**
Blood and Lymphatic System Disorders	**9**	**9**	**2.8%**	**2**	**2**	**1.3%**	**1.5%**	**-1.3%**	**4.4%**
Anemia	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Blood Clots (non-pulmonary)	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Blood and Lymphatic System Disorders	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
Cardiac Disorders	**8**	**8**	**2.5%**	**4**	**4**	**2.5%**	**0.0%**	**-3.0%**	**2.9%**
Acute Coronary Syndrome	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Atrial Fibrillation	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Chest Pain	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Myocardial Infarction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Syncope/Fainting	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Ventricular Arrhythmia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Cardiac Disorders	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Ear and Labyrinth Disorders	**6**	**6**	**1.9%**	**3**	**2**	**1.3%**	**0.6%**	**-1.8%**	**3.0%**
Ear Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Impaired Hearing	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Vertigo	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Ear and Labyrinth Disorders	2	2	0.6%	3	2	1.3%	-0.6%	-2.4%	1.1%
Endocrine Disorders	**11**	**9**	**2.8%**	**4**	**3**	**1.9%**	**0.9%**	**-2.1%**	**3.9%**
Diabetes Mellitus	6	6	1.9%	1	1	0.6%	1.2%	-1.0%	3.5%
Hypothyroidism	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Hyperlipidemia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Endocrine Disorder	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Eye Disorders	**8**	**6**	**1.9%**	**2**	**2**	**1.3%**	**0.6%**	**-1.8%**	**3.0%**
Blurred Vision	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Cataract	3	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Dry Eye	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Glaucoma	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Retinal Detachment	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Eye Disorders	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Gastrointestinal Disorders	**60**	**47**	**14.6%**	**32**	**26**	**16.4%**	**-1.7%**	**-8.5%**	**5.1%**
Constipation	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Diarrhea	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Dyspepsia	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Dysphagia	26	25	7.8%	14	14	8.8%	-1.0%	-6.2%	4.2%
Gastroesophageal Reflux Disease	8	8	2.5%	1	1	0.6%	1.9%	-0.7%	4.4%
Hemorrhage	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Hemorrhoids	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Nausea	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Vomiting	2	2	0.6%	3	3	1.9%	-1.3%	-3.2%	0.7%
Gastrointestinal Pain, Specify Location	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Pancreatits	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Ulcer, Specify Location	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Appendicitis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Gastrointestinal Disorder	10	10	3.1%	5	5	3.1%	0.0%	-3.3%	3.3%
General Disorders and Administration	**48**	**40**	**12.5%**	**15**	**13**	**8.2%**	**4.3%**	**-1.7%**	**10.2%**
Fatigue	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Fever	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Flu-like symptoms	7	6	1.9%	1	1	0.6%	1.2%	-1.0%	3.5%
Gait Disturbance	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
General Pain, Not Specified Elsewhere	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
General Disorders and Administrative Site Conditions - COVID-19	33	30	9.3%	14	13	8.2%	1.2%	-4.3%	6.6%
Other General Disorders and Administrative Site Conditions	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
Hepatobiliary Disorders	**7**	**7**	**2.2%**	**0**	**0**	**0.0%**	**2.2%**	**-0.1%**	**4.5%**
Gallbladder Obstruction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Gallbladder Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Hepatobiliary Disorders	4	4	1.2%	0	0	0.0%	1.2%	-0.5%	3.0%
Immune System Disorders	**10**	**9**	**2.8%**	**2**	**2**	**1.3%**	**1.5%**	**-1.3%**	**4.4%**
Allergic Reaction	7	6	1.9%	0	0	0.0%	1.9%	-0.2%	4.0%
Autoimmune Disorder	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Infections and Infestations	**35**	**31**	**9.7%**	**11**	**10**	**6.3%**	**3.4%**	**-1.9%**	**8.7%**
Infection, Surgical Site	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Infection, Not at Surgical Site	13	13	4.0%	6	5	3.1%	0.9%	-2.7%	4.5%
Sinusitis	7	6	1.9%	0	0	0.0%	1.9%	-0.2%	4.0%
Rash	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Sepsis	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Other Infections and Infestations	4	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Musculoskeletal and Connective Tissue Disorders	**272**	**163**	**50.8%**	**122**	**76**	**47.8%**	**3.0%**	**-6.5%**	**12.5%**
Fracture, Any Bone	4	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Joint Pain	40	37	11.5%	24	21	13.2%	-1.7%	-7.9%	4.5%
Joint Stiffness	4	4	1.2%	3	3	1.9%	-0.6%	-2.9%	1.6%
Ligament Injury	3	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Muscle Weakness	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Osteoarthritis	12	12	3.7%	4	4	2.5%	1.2%	-2.2%	4.6%
Spasms	26	24	7.5%	7	7	4.4%	3.1%	-1.6%	7.7%
Sprain	4	4	1.2%	2	2	1.3%	0.0%	-2.1%	2.1%
Other Musculoskeletal Pain, Specify Location	27	20	6.2%	11	11	6.9%	-0.7%	-5.4%	4.0%
Adjacent Segment Degeneration	7	7	2.2%	6	6	3.8%	-1.6%	-4.7%	1.5%
Lumbar Degenerative Disc Disease	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Pseudarthrosis	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Cervical Pain	48	47	14.6%	21	19	11.9%	2.7%	-3.9%	9.2%
Lumbar Pain	27	25	7.8%	12	12	7.5%	0.2%	-4.8%	5.3%
Facet Joint Deterioration	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spinal Stenosis	5	5	1.6%	0	0	0.0%	1.6%	-0.4%	3.5%
Spondylosis	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Soft Tissue Injury/Inflammation	33	29	9.0%	17	14	8.8%	0.2%	-5.2%	5.7%
Thoracic Pain	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Other Musculoskeletal and Connective Tissue Disorder	18	17	5.3%	8	8	5.0%	0.3%	-4.0%	4.5%
Nervous System Disorders	**178**	**121**	**37.7%**	**83**	**57**	**35.8%**	**1.8%**	**-7.3%**	**11.0%**
Amnesia	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Central Nervous System Necrosis	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Cognitive Disturbance	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Dizziness	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Dysesthesia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Dysphasia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Headache	15	13	4.0%	9	9	5.7%	-1.6%	-5.6%	2.4%
Neuralgia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Neurological Deterioration (Motor, Sensory or Reflex)	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Numbness/Tingling	25	23	7.2%	12	9	5.7%	1.5%	-3.2%	6.2%
Paresthesia	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Peripheral Sensory Neuropathy	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Syncope	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Tremors	4	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Compressive Neuropathy	28	24	7.5%	9	8	5.0%	2.4%	-2.3%	7.2%
Radiculopathy	79	69	21.5%	47	38	23.9%	-2.4%	-10.3%	5.5%
Weakness	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Other Nervous System Disorder	7	7	2.2%	0	0	0.0%	2.2%	-0.1%	4.5%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
Psychiatric Disorders	**17**	**17**	**5.3%**	**11**	**10**	**6.3%**	**-1.0%**	**-5.4%**	**3.4%**
Anxiety Disorders	5	5	1.6%	6	6	3.8%	-2.2%	-5.1%	0.6%
Depression	6	6	1.9%	0	0	0.0%	1.9%	-0.2%	4.0%
Insomnia	4	4	1.2%	2	2	1.3%	0.0%	-2.1%	2.1%
Opioid Dependency	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Psychiatric Disorder	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Renal and Urinary Disorders	**13**	**12**	**3.7%**	**5**	**5**	**3.1%**	**0.6%**	**-2.9%**	**4.1%**
Chronic Kidney Disease	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Renal Calculi	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Urinary incontinence	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Urinary Tract Infection	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Other Renal and Urinary Disorder	5	5	1.6%	3	3	1.9%	-0.3%	-2.8%	2.1%
Respiratory, Thoracic and Mediastinal Disorders	**35**	**31**	**9.7%**	**6**	**6**	**3.8%**	**5.9%**	**0.8%**	**11.0%**
Allergic Rhinitis	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Asthma	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Dyspnea	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Hoarseness	8	7	2.2%	1	1	0.6%	1.6%	-0.9%	4.0%
Nasal Congestion	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Pneumonia	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Sleep Apnea	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Sore Throat	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Pulmonary Embolism	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Airway Obstruction	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Sinusitis	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Respiratory, Thoracic and Medistinal Disorders Disorder	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Skin and Subcutaneous Tissue Disorders	**21**	**20**	**6.2%**	**8**	**7**	**4.4%**	**1.8%**	**-2.6%**	**6.2%**
Hematoma	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Itching/Pruritus	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Seroma	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Urticaria	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Wound complications (eg., dehiscence, bruising) and soft tissue damage	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Wound secretions / drainage	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Skin and Subcutaneous Tissue Disorder	9	9	2.8%	3	3	1.9%	0.9%	-2.1%	3.9%
Vascular Disorders	**22**	**18**	**5.6%**	**6**	**6**	**3.8%**	**1.8%**	**-2.3%**	**6.0%**
Hemorrhage, Not Requiring Transfusion	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Hypertension	10	10	3.1%	5	5	3.1%	0.0%	-3.3%	3.3%
Neurovascular Injury	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Thromboembolic Event	2	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Vasculitis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Vascular Disorder	7	7	2.2%	1	1	0.6%	1.6%	-0.9%	4.0%
Device (non system specific)	**11**	**10**	**3.1%**	**4**	**4**	**2.5%**	**0.6%**	**-2.6%**	**3.8%**
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Implant Migration	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Implant/Joint Noise	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Other Complications/Events	**61**	**49**	**15.3%**	**34**	**28**	**17.6%**	**-2.3%**	**-9.3%**	**4.6%**
Surgery at a location other than the spine	7	7	2.2%	1	1	0.6%	1.6%	-0.9%	4.0%
Trauma	37	32	10.0%	24	19	11.9%	-2.0%	-7.8%	3.9%
Cancer	6	6	1.9%	3	3	1.9%	0.0%	-2.6%	2.6%
Adverse Reaction to Medication	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Other Event, Describe	4	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Dental Disorder	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Other Gynecological Event	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%

*Percentage of subjects experiencing specific event.
†Normal approximation 95% Confidence Interval.
Source: Tables Safety ITT.sas; Analyzed: 13MAR2025

All Adverse Events Time course

Table 11 presents all AEs through Month 24 for both treatment groups. The time course interval where the highest number of AEs took place was between Month 12 and Month 24 for the investigational group, and between Month 6 and Month 12 for the control group.

Table 1: All Adverse Events (Time Course) (ITT Analysis Set N=480)

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
All	**17**	**12**	**0**	**0**	**44**	**16**	**80**	**30**	**79**	**48**	**107**	**43**	**140**	**84**	**240**	**80**	**125**	**41**	**832**	**354**
Blood and Lymphatic System Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**0**	**0**	**0**	**0**	**0**	**2**	**1**	**3**	**1**	**1**	**0**	**9**	**2**
Anemia	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	3	1
Blood Clots (non-pulmonary)	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Other Blood and Lymphatic System Disorders	0	0	0	0	0	0	2	0	0	0	0	0	1	0	1	1	1	0	5	1
Cardiac Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**3**	**2**	**3**	**2**	**1**	**0**	**8**	**4**
Acute Coronary Syndrome	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Atrial Fibrillation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Chest Pain	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	0	2	1
Myocardial Infarction	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	0
Syncope/Fainting	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	0	0	2	1
Ventricular Arrhythmia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Cardiac Disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Ear and Labyrinth Disorders	**1**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**2**	**0**	**0**	**0**	**2**	**2**	**6**	**3**
Ear Pain	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Impaired Hearing	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	0
Vertigo	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Other Ear and Labyrinth Disorders	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	2	2	3
Endocrine Disorders	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**2**	**0**	**4**	**0**	**4**	**2**	**11**	**4**
Diabetes Mellitus	0	1	0	0	0	0	0	0	0	0	0	0	1	0	2	0	3	0	6	1
Hypothyroidism	0	0	0	0	0	0	0	0	0	1	0	0	1	0	1	0	0	1	2	2
Hyperlipidemia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Endocrine Disorder	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	1	2	1
Eye Disorders	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**5**	**1**	**2**	**0**	**8**	**2**
Blurred Vision	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Cataract	0	0	0	0	0	0	0	0	0	1	0	0	0	0	3	0	0	0	3	1
Dry Eye	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Glaucoma	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Retinal Detachment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Other Eye Disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Gastrointestinal Disorders	**2**	**0**	**0**	**0**	**9**	**7**	**13**	**6**	**0**	**2**	**3**	**2**	**7**	**4**	**18**	**4**	**8**	**7**	**60**	**32**
Constipation	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	1	1
Diarrhea	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Dyspepsia	0	0	0	0	0	1	0	0	0	0	0	0	2	0	1	0	0	0	3	1
Dysphagia	0	0	0	0	7	5	8	2	0	0	1	0	1	2	6	3	3	2	26	14
Gastroesophageal Reflux Disease	1	0	0	0	0	0	1	0	0	0	1	1	1	0	4	0	0	0	8	1
Hemorrhage	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Hemorrhoids	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	1	2	1
Nausea	1	0	0	0	1	0	0	0	0	0	0	0	0	1	1	0	1	0	4	1
Vomiting	0	0	0	0	0	1	1	0	0	0	1	0	0	1	0	0	0	1	2	3
Gastrointestinal Pain, Specify Location	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0	0	1	0	2	2
Pancreatits	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Ulcer, Specify Location	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Appendicitis	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Other Gastrointestinal Disorder	0	0	0	0	1	0	1	0	0	1	0	0	2	0	3	1	3	3	10	5
General Disorders and Administration	**0**	**0**	**0**	**0**	**2**	**0**	**5**	**0**	**6**	**3**	**7**	**2**	**7**	**6**	**17**	**3**	**4**	**1**	**48**	**15**
Fatigue	0	0	0	0	1	0	1	0	1	0	0	0	0	0	0	0	0	0	3	0
Fever	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Flu-like symptoms	0	0	0	0	0	0	1	0	1	0	0	0	2	0	3	0	0	1	7	1
Gait Disturbance	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2	0
General Pain, Not Specified Elsewhere	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
General Disorders and Administrative Site Conditions - COVID-19	0	0	0	0	0	0	1	0	4	3	7	2	5	6	13	3	3	0	33	14
Other General Disorders and Administrative Site Conditions	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Hepatobiliary Disorders	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**7**	**0**
Gallbladder Obstruction	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2	0
Gallbladder Pain	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Other Hepatobiliary Disorders	0	0	0	0	0	0	0	0	0	0	1	0	1	0	1	0	1	0	4	0
Immune System Disorders	**1**	**0**	**0**	**0**	**1**	**0**	**2**	**0**	**0**	**0**	**1**	**0**	**2**	**0**	**1**	**2**	**2**	**0**	**10**	**2**
Allergic Reaction	0	0	0	0	1	0	2	0	0	0	1	0	1	0	0	0	2	0	7	0
Autoimmune Disorder	1	0	0	0	0	0	0	0	0	0	0	0	1	0	1	2	0	0	3	2
Infections and Infestations	**1**	**0**	**0**	**0**	**1**	**0**	**3**	**3**	**5**	**1**	**4**	**1**	**6**	**3**	**6**	**2**	**9**	**1**	**35**	**11**
Infection, Surgical Site	0	0	0	0	0	0	3	1	1	1	1	0	0	0	1	0	0	0	6	2
Infection, Not at Surgical Site	1	0	0	0	1	0	0	1	3	0	2	1	3	3	2	1	1	0	13	6
Sinusitis	0	0	0	0	0	0	0	0	1	0	1	0	2	0	0	0	3	0	7	0
Rash	0	0	0	0	0	0	0	1	0	0	0	0	1	0	1	0	3	0	5	1
Sepsis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2
Other Infections and Infestations	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0	4	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Musculoskeletal and Connective Tissue Disorders	**5**	**5**	**0**	**0**	**10**	**4**	**20**	**13**	**26**	**13**	**34**	**11**	**45**	**29**	**83**	**30**	**49**	**17**	**272**	**122**
Fracture, Any Bone	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	1	1	0	4	1
Joint Pain	1	0	0	0	3	0	5	4	4	6	5	1	2	4	13	7	7	2	40	24
Joint Stiffness	0	0	0	0	0	0	2	0	0	0	0	1	1	0	1	2	0	0	4	3
Ligament Injury	0	0	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	3	0
Muscle Weakness	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Osteoarthritis	2	1	0	0	0	0	0	0	0	0	2	0	4	1	4	2	0	0	12	4
Spasms	0	0	0	0	3	1	2	0	4	0	6	2	2	3	6	0	3	1	26	7
Sprain	0	0	0	0	1	0	0	0	0	1	0	0	1	1	2	0	0	0	4	2
Other Musculoskeletal Pain, Specify Location	0	0	0	0	0	0	5	3	2	1	2	0	1	2	6	1	11	4	27	11
Adjacent Segment Degeneration	0	0	0	0	0	0	0	0	1	1	0	0	3	3	3	2	0	0	7	6
Lumbar Degenerative Disc Disease	1	0	0	0	0	0	0	0	1	0	1	0	1	2	1	0	0	0	5	2
Pseudarthrosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	1	1
Cervical Pain	0	0	0	0	0	2	5	2	3	3	5	3	15	3	12	3	8	5	48	21
Lumbar Pain	0	0	0	0	1	1	0	1	3	0	6	3	6	3	8	4	3	0	27	12
Facet Joint Deterioration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Spinal Stenosis	0	0	0	0	0	0	0	0	0	0	1	0	1	0	1	0	2	0	5	0
Spondylosis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	2	0
Soft Tissue Injury/Inflammation	0	4	0	0	1	0	0	3	3	1	5	0	5	3	16	5	3	1	33	17
Thoracic Pain	0	0	0	0	0	0	0	0	2	0	0	0	1	2	2	0	0	0	5	2
Other Musculoskeletal and Connective Tissue Disorder	0	0	0	0	0	0	1	0	0	0	0	1	2	2	4	2	11	3	18	8
Nervous System Disorders	**3**	**2**	**0**	**0**	**6**	**2**	**14**	**7**	**23**	**12**	**33**	**16**	**39**	**21**	**41**	**19**	**19**	**4**	**178**	**83**
Amnesia	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0
Central Nervous System Necrosis	0	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0	0	0	3	0
Cognitive Disturbance	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Dizziness	0	0	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	0	4	1
Dysesthesia	0	0	0	0	2	0	0	1	0	0	0	0	0	0	0	0	0	0	2	1
Dysphasia	0	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	2	1
Headache	0	1	0	0	0	1	1	1	3	1	4	1	2	1	2	3	3	0	15	9
Neuralgia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Neurological Deterioration (Motor, Sensory or Reflex)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Numbness/Tingling	1	0	0	0	0	0	3	0	3	4	2	1	9	3	5	3	2	1	25	12
Paresthesia	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	2
Peripheral Sensory Neuropathy	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Syncope	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Tremors	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0	0	0	4	0
Compressive Neuropathy	0	1	0	0	0	0	0	0	5	0	7	5	4	1	9	2	3	0	28	9
Radiculopathy	2	0	0	0	3	1	9	5	7	7	17	7	19	13	13	11	9	3	79	47
Weakness	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	0	0	0	3	0
Other Nervous System Disorder	0	0	0	0	0	0	0	0	0	0	0	0	2	0	4	0	1	0	7	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Psychiatric Disorders	**1**	**1**	**0**	**0**	**1**	**0**	**1**	**0**	**2**	**3**	**2**	**3**	**3**	**2**	**6**	**1**	**1**	**1**	**17**	**11**
Anxiety Disorders	1	0	0	0	0	0	1	0	0	2	0	2	1	2	2	0	0	0	5	6
Depression	0	0	0	0	0	0	0	0	1	0	1	0	2	0	2	0	0	0	6	0
Insomnia	0	1	0	0	1	0	0	0	1	0	1	0	0	0	1	1	0	0	4	2
Opioid Dependency	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Other Psychiatric Disorder	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	1	1	2	2
Renal and Urinary Disorders	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**0**	**3**	**0**	**1**	**0**	**0**	**2**	**7**	**2**	**1**	**0**	**13**	**5**
Chronic Kidney Disease	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Renal Calculi	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Urinary incontinence	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	1
Urinary Tract Infection	0	0	0	0	0	0	1	0	3	0	0	0	0	0	1	1	0	0	5	1
Other Renal and Urinary Disorder	0	1	0	0	0	0	0	0	0	0	1	0	0	2	4	0	0	0	5	3
Respiratory, Thoracic and Mediastinal Disorders	**0**	**0**	**0**	**0**	**6**	**0**	**6**	**1**	**3**	**1**	**5**	**0**	**4**	**3**	**6**	**1**	**5**	**0**	**35**	**6**
Allergic Rhinitis	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0
Asthma	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Dyspnea	0	0	0	0	2	0	1	0	0	0	0	0	0	0	0	0	0	0	3	0
Hoarseness	0	0	0	0	3	0	1	0	1	1	1	0	0	0	2	0	0	0	8	1
Nasal Congestion	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0	0	3	1
Pneumonia	0	0	0	0	1	0	1	0	0	0	1	0	0	2	2	0	0	0	5	2
Sleep Apnea	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0
Sore Throat	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	3	0
Pulmonary Embolism	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2	0
Airway Obstruction	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Sinusitis	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	2	0
Other Respiratory, Thoracic and Medistinal Disorders Disorder	0	0	0	0	0	0	0	1	1	0	1	0	1	1	0	0	0	0	3	2
Skin and Subcutaneous Tissue Disorders	**1**	**0**	**0**	**0**	**3**	**3**	**4**	**0**	**1**	**2**	**2**	**0**	**1**	**3**	**6**	**0**	**3**	**0**	**21**	**8**
Hematoma	0	0	0	0	3	1	2	0	0	0	0	0	0	1	0	0	0	0	5	2
Itching/Pruritus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Seroma	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Urticaria	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2	0
Wound complications (eg., dehiscence, bruising) ar	0	0	0	0	0	1	2	0	0	1	0	0	0	0	0	0	1	0	3	2
Wound secretions / drainage	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Other Skin and Subcutaneous Tissue Disorder	1	0	0	0	0	1	0	0	0	0	0	0	1	2	5	0	2	0	9	3

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Vascular Disorders	**0**	**1**	**0**	**0**	**1**	**0**	**1**	**0**	**2**	**1**	**4**	**0**	**0**	**1**	**9**	**2**	**5**	**1**	**22**	**6**
Hemorrhage, Not Requiring Transfusion	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Hypertension	0	0	0	0	1	0	0	0	2	1	2	0	0	1	3	2	2	1	10	5
Neurovascular Injury	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Thromboembolic Event	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0
Vasculitis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Other Vascular Disorder	0	1	0	0	0	0	0	0	0	0	1	0	0	0	4	0	2	0	7	1
Device (non system specific)	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**3**	**2**	**3**	**0**	**3**	**1**	**1**	**0**	**11**	**4**
Implant Loosening	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	0
Implant Malalignment	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1
Implant Migration	0	0	0	0	0	0	0	0	0	1	2	1	2	0	2	0	0	0	6	2
Implant/Joint Noise	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	1	0	0	2	1
Other Complications/Events	**1**	**1**	**0**	**0**	**0**	**0**	**5**	**0**	**7**	**7**	**7**	**5**	**13**	**7**	**21**	**9**	**7**	**5**	**61**	**34**
Surgery at a location other than the spine	0	0	0	0	0	0	0	0	0	0	1	0	2	0	2	1	2	0	7	1
Trauma	0	0	0	0	0	0	3	0	6	3	6	5	9	7	11	6	2	3	37	24
Cancer	1	1	0	0	0	0	1	0	0	0	0	0	1	0	3	1	0	1	6	3
Adverse Reaction to Medication	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	1	0	0	3	1
Other Event, Describe	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	3	1	4	2
Dental Disorder	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	1	1
Other Gynecological Event	0	0	0	0	0	0	0	0	0	2	0	0	1	0	2	0	0	0	3	2

All Adverse Events Severity

Table 12 presents the AEs observed in the investigational group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 485 mild AEs, 261 moderate AEs, and 86 Severe AEs reported in the prodisc® C group in the ITT Analysis Set.

Table 2: All Adverse Events (Severity)- prodisc® C Investigational (ITT Analysis Set N=321)

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All	**485**	**58.3%**	**261**	**31.4%**	**86**	**10.3%**	**832**
Blood and Lymphatic System Disorders	**8**	**88.9%**	**1**	**11.1%**	**0**	**0.0%**	**9**
Anemia	2	66.7%	1	33.3%	0	0.0%	3
Blood Clots (non-pulmonary)	1	100.0%	0	0.0%	0	0.0%	1
Other Blood and Lymphatic System Disorders	5	100.0%	0	0.0%	0	0.0%	5
Cardiac Disorders	**5**	**62.5%**	**0**	**0.0%**	**3**	**37.5%**	**8**
Acute Coronary Syndrome	0	0.0%	0	0.0%	1	100.0%	1
Chest Pain	2	100.0%	0	0.0%	0	0.0%	2
Myocardial Infarction	0	0.0%	0	0.0%	2	100.0%	2
Syncope/Fainting	2	100.0%	0	0.0%	0	0.0%	2
Ventricular Arrhythmia	1	100.0%	0	0.0%	0	0.0%	1
Ear and Labyrinth Disorders	**3**	**50.0%**	**2**	**33.3%**	**1**	**16.7%**	**6**
Ear Pain	1	100.0%	0	0.0%	0	0.0%	1
Impaired Hearing	1	50.0%	1	50.0%	0	0.0%	2
Vertigo	0	0.0%	1	100.0%	0	0.0%	1
Other Ear and Labyrinth Disorders	1	50.0%	0	0.0%	1	50.0%	2
Endocrine Disorders	**9**	**81.8%**	**0**	**0.0%**	**2**	**18.2%**	**11**
Diabetes Mellitus	5	83.3%	0	0.0%	1	16.7%	6
Hypothyroidism	2	100.0%	0	0.0%	0	0.0%	2
Hyperlipidemia	1	100.0%	0	0.0%	0	0.0%	1
Other Endocrine Disorder	1	50.0%	0	0.0%	1	50.0%	2
Eye Disorders	**4**	**50.0%**	**4**	**50.0%**	**0**	**0.0%**	**8**
Blurred Vision	1	100.0%	0	0.0%	0	0.0%	1
Cataract	0	0.0%	3	100.0%	0	0.0%	3
Dry Eye	1	100.0%	0	0.0%	0	0.0%	1
Glaucoma	1	100.0%	0	0.0%	0	0.0%	1
Other Eye Disorders	1	50.0%	1	50.0%	0	0.0%	2
Gastrointestinal Disorders	**43**	**71.7%**	**13**	**21.7%**	**4**	**6.7%**	**60**
Constipation	0	0.0%	1	100.0%	0	0.0%	1
Diarrhea	1	100.0%	0	0.0%	0	0.0%	1
Dyspepsia	3	100.0%	0	0.0%	0	0.0%	3
Dysphagia	20	76.9%	6	23.1%	0	0.0%	26
Gastroesophageal Reflux Disease	6	75.0%	1	12.5%	1	12.5%	8
Hemorrhoids	2	100.0%	0	0.0%	0	0.0%	2
Nausea	4	100.0%	0	0.0%	0	0.0%	4
Vomiting	2	100.0%	0	0.0%	0	0.0%	2
Gastrointestinal Pain, Specify Location	0	0.0%	1	50.0%	1	50.0%	2
Ulcer, Specify Location	0	0.0%	1	100.0%	0	0.0%	1
Other Gastrointestinal Disorder	5	50.0%	3	30.0%	2	20.0%	10

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
General Disorders and Administration	**45**	**93.8%**	**2**	**4.2%**	**1**	**2.1%**	**48**
Fatigue	3	100.0%	0	0.0%	0	0.0%	3
Fever	1	100.0%	0	0.0%	0	0.0%	1
Flu-like symptoms	6	85.7%	1	14.3%	0	0.0%	7
Gait Disturbance	2	100.0%	0	0.0%	0	0.0%	2
General Pain, Not Specified Elsewhere	1	100.0%	0	0.0%	0	0.0%	1
General Disorders and Administrative Site Conditions - COVID-19	31	93.9%	1	3.0%	1	3.0%	33
Other General Disorders and Administrative Site Conditions	1	100.0%	0	0.0%	0	0.0%	1
Hepatobiliary Disorders	**3**	**42.9%**	**1**	**14.3%**	**3**	**42.9%**	**7**
Gallbladder Obstruction	0	0.0%	1	50.0%	1	50.0%	2
Gallbladder Pain	0	0.0%	0	0.0%	1	100.0%	1
Other Hepatobiliary Disorders	3	75.0%	0	0.0%	1	25.0%	4
Immune System Disorders	**6**	**60.0%**	**4**	**40.0%**	**0**	**0.0%**	**10**
Allergic Reaction	5	71.4%	2	28.6%	0	0.0%	7
Autoimmune Disorder	1	33.3%	2	66.7%	0	0.0%	3
Infections and Infestations	**20**	**57.1%**	**10**	**28.6%**	**5**	**14.3%**	**35**
Infection, Surgical Site	3	50.0%	0	0.0%	3	50.0%	6
Infection, Not at Surgical Site	8	61.5%	4	30.8%	1	7.7%	13
Sinusitis	3	42.9%	4	57.1%	0	0.0%	7
Rash	5	100.0%	0	0.0%	0	0.0%	5
Other Infections and Infestations	1	25.0%	2	50.0%	1	25.0%	4
Musculoskeletal and Connective Tissue Disorders	**131**	**48.2%**	**117**	**43.0%**	**24**	**8.8%**	**272**
Fracture, Any Bone	2	50.0%	2	50.0%	0	0.0%	4
Joint Pain	24	60.0%	14	35.0%	2	5.0%	40
Joint Stiffness	1	25.0%	3	75.0%	0	0.0%	4
Ligament Injury	1	33.3%	2	66.7%	0	0.0%	3
Osteoarthritis	1	8.3%	7	58.3%	4	33.3%	12
Spasms	18	69.2%	8	30.8%	0	0.0%	26
Sprain	2	50.0%	2	50.0%	0	0.0%	4
Other Musculoskeletal Pain, Specify Location	18	66.7%	9	33.3%	0	0.0%	27
Adjacent Segment Degeneration	2	28.6%	4	57.1%	1	14.3%	7
Lumbar Degenerative Disc Disease	0	0.0%	1	20.0%	4	80.0%	5
Pseudarthrosis	0	0.0%	0	0.0%	1	100.0%	1
Cervical Pain	33	68.8%	14	29.2%	1	2.1%	48
Lumbar Pain	9	33.3%	15	55.6%	3	11.1%	27
Facet Joint Deterioration	1	100.0%	0	0.0%	0	0.0%	1
Spinal Stenosis	0	0.0%	3	60.0%	2	40.0%	5
Spondylosis	0	0.0%	1	50.0%	1	50.0%	2
Soft Tissue Injury/Inflammation	7	21.2%	22	66.7%	4	12.1%	33
Thoracic Pain	3	60.0%	2	40.0%	0	0.0%	5
Other Musculoskeletal and Connective Tissue Disorder	9	50.0%	8	44.4%	1	5.6%	18
Nervous System Disorders	**99**	**55.6%**	**71**	**39.9%**	**8**	**4.5%**	**178**
Amnesia	2	100.0%	0	0.0%	0	0.0%	2
Central Nervous System Necrosis	1	33.3%	2	66.7%	0	0.0%	3
Dizziness	4	100.0%	0	0.0%	0	0.0%	4
Dysesthesia	1	50.0%	1	50.0%	0	0.0%	2
Dysphasia	2	100.0%	0	0.0%	0	0.0%	2
Headache	11	73.3%	4	26.7%	0	0.0%	15
Neuralgia	1	100.0%	0	0.0%	0	0.0%	1
Neurological Deterioration (Motor, Sensory or Reflex)	0	0.0%	1	100.0%	0	0.0%	1
Numbness/Tingling	20	80.0%	5	20.0%	0	0.0%	25
Peripheral Sensory Neuropathy	0	0.0%	1	100.0%	0	0.0%	1
Syncope	1	100.0%	0	0.0%	0	0.0%	1
Tremors	4	100.0%	0	0.0%	0	0.0%	4
Compressive Neuropathy	20	71.4%	8	28.6%	0	0.0%	28
Radiculopathy	28	35.4%	44	55.7%	7	8.9%	79
Weakness	1	33.3%	2	66.7%	0	0.0%	3
Other Nervous System Disorder	3	42.9%	3	42.9%	1	14.3%	7

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Psychiatric Disorders	**12**	**70.6%**	**3**	**17.6%**	**2**	**11.8%**	**17**
Anxiety Disorders	3	60.0%	2	40.0%	0	0.0%	5
Depression	4	66.7%	1	16.7%	1	16.7%	6
Insomnia	4	100.0%	0	0.0%	0	0.0%	4
Other Psychiatric Disorder	1	50.0%	0	0.0%	1	50.0%	2
Renal and Urinary Disorders	**6**	**46.2%**	**5**	**38.5%**	**2**	**15.4%**	**13**
Chronic Kidney Disease	0	0.0%	1	100.0%	0	0.0%	1
Renal Calculi	0	0.0%	1	100.0%	0	0.0%	1
Urinary incontinence	0	0.0%	1	100.0%	0	0.0%	1
Urinary Tract Infection	3	60.0%	1	20.0%	1	20.0%	5
Other Renal and Urinary Disorder	3	60.0%	1	20.0%	1	20.0%	5
Respiratory, Thoracic and Mediastinal Disorders	**24**	**68.6%**	**7**	**20.0%**	**4**	**11.4%**	**35**
Allergic Rhinitis	1	50.0%	1	50.0%	0	0.0%	2
Asthma	1	100.0%	0	0.0%	0	0.0%	1
Dyspnea	2	66.7%	1	33.3%	0	0.0%	3
Hoarseness	8	100.0%	0	0.0%	0	0.0%	8
Nasal Congestion	3	100.0%	0	0.0%	0	0.0%	3
Pneumonia	1	20.0%	2	40.0%	2	40.0%	5
Sleep Apnea	2	100.0%	0	0.0%	0	0.0%	2
Sore Throat	3	100.0%	0	0.0%	0	0.0%	3
Pulmonary Embolism	0	0.0%	0	0.0%	2	100.0%	2
Airway Obstruction	0	0.0%	1	100.0%	0	0.0%	1
Sinusitis	2	100.0%	0	0.0%	0	0.0%	2
Other Respiratory, Thoracic and Medistinal Disorders	1	33.3%	2	66.7%	0	0.0%	3
Skin and Subcutaneous Tissue Disorders	**16**	**76.2%**	**2**	**9.5%**	**3**	**14.3%**	**21**
Hematoma	3	60.0%	0	0.0%	2	40.0%	5
Itching/Pruritus	1	100.0%	0	0.0%	0	0.0%	1
Urticaria	1	50.0%	1	50.0%	0	0.0%	2
Wound complications (eg., dehiscence, bruising) and soft tissue damage	2	66.7%	0	0.0%	1	33.3%	3
Wound secretions / drainage	1	100.0%	0	0.0%	0	0.0%	1
Other Skin and Subcutaneous Tissue Disorder	8	88.9%	1	11.1%	0	0.0%	9
Vascular Disorders	**17**	**77.3%**	**2**	**9.1%**	**3**	**13.6%**	**22**
Hemorrhage, Not Requiring Transfusion	1	100.0%	0	0.0%	0	0.0%	1
Hypertension	9	90.0%	0	0.0%	1	10.0%	10
Neurovascular Injury	0	0.0%	0	0.0%	1	100.0%	1
Thromboembolic Event	0	0.0%	1	50.0%	1	50.0%	2
Vasculitis	0	0.0%	1	100.0%	0	0.0%	1
Other Vascular Disorder	7	100.0%	0	0.0%	0	0.0%	7
Device (non system specific)	**3**	**27.3%**	**2**	**18.2%**	**6**	**54.5%**	**11**
Implant Loosening	0	0.0%	0	0.0%	2	100.0%	2
Implant Malalignment	1	100.0%	0	0.0%	0	0.0%	1
Implant Migration	0	0.0%	2	33.3%	4	66.7%	6
Implant/Joint Noise	2	100.0%	0	0.0%	0	0.0%	2
Other Complications/Events	**31**	**50.8%**	**15**	**24.6%**	**15**	**24.6%**	**61**
Surgery at a location other than the spine	0	0.0%	2	28.6%	5	71.4%	7
Trauma	23	62.2%	11	29.7%	3	8.1%	37
Cancer	0	0.0%	0	0.0%	6	100.0%	6
Adverse Reaction to Medication	2	66.7%	1	33.3%	0	0.0%	3
Other Event, Describe	3	75.0%	0	0.0%	1	25.0%	4
Dental Disorder	0	0.0%	1	100.0%	0	0.0%	1
Other Gynecological Event	3	100.0%	0	0.0%	0	0.0%	3

Table 13 presents the AEs observed in the control group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 204 mild AEs, 107 moderate

AEs, and 43 Severe AEs reported in the control group. The most frequently occurring Severe AEs in the control group were joint pain (4 events) and adjacent segment degeneration (4 events).

Table 3: All Adverse Events (Severity)- Mobi-C Control (ITT Analysis Set N=159)

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All	**204**	**57.6%**	**107**	**30.2%**	**43**	**12.1%**	**354**
Blood and Lymphatic System Disorders	**1**	**50.0%**	**1**	**50.0%**	**0**	**0.0%**	**2**
Anemia	1	100.0%	0	0.0%	0	0.0%	1
Other Blood and Lymphatic System Disorders	0	0.0%	1	100.0%	0	0.0%	1
Cardiac Disorders	**1**	**25.0%**	**3**	**75.0%**	**0**	**0.0%**	**4**
Atrial Fibrillation	0	0.0%	1	100.0%	0	0.0%	1
Chest Pain	1	100.0%	0	0.0%	0	0.0%	1
Syncope/Fainting	0	0.0%	1	100.0%	0	0.0%	1
Other Cardiac Disorders	0	0.0%	1	100.0%	0	0.0%	1
Ear and Labyrinth Disorders	**1**	**33.3%**	**2**	**66.7%**	**0**	**0.0%**	**3**
Other Ear and Labyrinth Disorders	1	33.3%	2	66.7%	0	0.0%	3
Endocrine Disorders	**4**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**4**
Diabetes Mellitus	1	100.0%	0	0.0%	0	0.0%	1
Hypothyroidism	2	100.0%	0	0.0%	0	0.0%	2
Other Endocrine Disorder	1	100.0%	0	0.0%	0	0.0%	1
Eye Disorders	**0**	**0.0%**	**1**	**50.0%**	**1**	**50.0%**	**2**
Cataract	0	0.0%	1	100.0%	0	0.0%	1
Retinal Detachment	0	0.0%	0	0.0%	1	100.0%	1
Gastrointestinal Disorders	**24**	**75.0%**	**7**	**21.9%**	**1**	**3.1%**	**32**
Constipation	1	100.0%	0	0.0%	0	0.0%	1
Dyspepsia	1	100.0%	0	0.0%	0	0.0%	1
Dysphagia	11	78.6%	3	21.4%	0	0.0%	14
Gastroesophageal Reflux Disease	1	100.0%	0	0.0%	0	0.0%	1
Hemorrhage	1	100.0%	0	0.0%	0	0.0%	1
Hemorrhoids	1	100.0%	0	0.0%	0	0.0%	1
Nausea	1	100.0%	0	0.0%	0	0.0%	1
Vomiting	2	66.7%	1	33.3%	0	0.0%	3
Gastrointestinal Pain, Specify Location	2	100.0%	0	0.0%	0	0.0%	2
Pancreatits	0	0.0%	1	100.0%	0	0.0%	1
Appendicitis	0	0.0%	0	0.0%	1	100.0%	1
Other Gastrointestinal Disorder	3	60.0%	2	40.0%	0	0.0%	5
General Disorders and Administration	**15**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**15**
Flu-like symptoms	1	100.0%	0	0.0%	0	0.0%	1
General Disorders and Administrative Site Conditions - COVID-19	14	100.0%	0	0.0%	0	0.0%	14
Immune System Disorders	**0**	**0.0%**	**2**	**100.0%**	**0**	**0.0%**	**2**
Autoimmune Disorder	0	0.0%	2	100.0%	0	0.0%	2
Infections and Infestations	**6**	**54.5%**	**2**	**18.2%**	**3**	**27.3%**	**11**
Infection, Surgical Site	2	100.0%	0	0.0%	0	0.0%	2
Infection, Not at Surgical Site	3	50.0%	2	33.3%	1	16.7%	6
Rash	1	100.0%	0	0.0%	0	0.0%	1
Sepsis	0	0.0%	0	0.0%	2	100.0%	2

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Musculoskeletal and Connective Tissue Disorders	**69**	**56.6%**	**34**	**27.9%**	**19**	**15.6%**	**122**
Fracture, Any Bone	0	0.0%	1	100.0%	0	0.0%	1
Joint Pain	14	58.3%	6	25.0%	4	16.7%	24
Joint Stiffness	2	66.7%	1	33.3%	0	0.0%	3
Muscle Weakness	0	0.0%	1	100.0%	0	0.0%	1
Osteoarthritis	0	0.0%	1	25.0%	3	75.0%	4
Spasms	5	71.4%	2	28.6%	0	0.0%	7
Sprain	2	100.0%	0	0.0%	0	0.0%	2
Other Musculoskeletal Pain, Specify Location	7	63.6%	4	36.4%	0	0.0%	11
Adjacent Segment Degeneration	1	16.7%	1	16.7%	4	66.7%	6
Lumbar Degenerative Disc Disease	0	0.0%	1	50.0%	1	50.0%	2
Pseudarthrosis	0	0.0%	1	100.0%	0	0.0%	1
Cervical Pain	15	71.4%	5	23.8%	1	4.8%	21
Lumbar Pain	9	75.0%	1	8.3%	2	16.7%	12
Soft Tissue Injury/Inflammation	6	35.3%	8	47.1%	3	17.6%	17
Thoracic Pain	2	100.0%	0	0.0%	0	0.0%	2
Other Musculoskeletal and Connective Tissue Disorder	6	75.0%	1	12.5%	1	12.5%	8
Nervous System Disorders	**44**	**53.0%**	**30**	**36.1%**	**9**	**10.8%**	**83**
Cognitive Disturbance	0	0.0%	1	100.0%	0	0.0%	1
Dizziness	1	100.0%	0	0.0%	0	0.0%	1
Dysesthesia	0	0.0%	1	100.0%	0	0.0%	1
Dysphasia	1	100.0%	0	0.0%	0	0.0%	1
Headache	7	77.8%	2	22.2%	0	0.0%	9
Numbness/Tingling	11	91.7%	1	8.3%	0	0.0%	12
Paresthesia	1	50.0%	1	50.0%	0	0.0%	2
Compressive Neuropathy	4	44.4%	3	33.3%	2	22.2%	9
Radiculopathy	19	40.4%	21	44.7%	7	14.9%	47
Psychiatric Disorders	**7**	**63.6%**	**4**	**36.4%**	**0**	**0.0%**	**11**
Anxiety Disorders	5	83.3%	1	16.7%	0	0.0%	6
Insomnia	1	50.0%	1	50.0%	0	0.0%	2
Opioid Dependency	0	0.0%	1	100.0%	0	0.0%	1
Other Psychiatric Disorder	1	50.0%	1	50.0%	0	0.0%	2
Renal and Urinary Disorders	**4**	**80.0%**	**1**	**20.0%**	**0**	**0.0%**	**5**
Urinary incontinence	1	100.0%	0	0.0%	0	0.0%	1
Urinary Tract Infection	1	100.0%	0	0.0%	0	0.0%	1
Other Renal and Urinary Disorder	2	66.7%	1	33.3%	0	0.0%	3
Respiratory, Thoracic and Mediastinal Disorders	**1**	**16.7%**	**5**	**83.3%**	**0**	**0.0%**	**6**
Hoarseness	0	0.0%	1	100.0%	0	0.0%	1
Nasal Congestion	0	0.0%	1	100.0%	0	0.0%	1
Pneumonia	0	0.0%	2	100.0%	0	0.0%	2
Other Respiratory, Thoracic and Medistinal Disorders	1	50.0%	1	50.0%	0	0.0%	2
Skin and Subcutaneous Tissue Disorders	**3**	**37.5%**	**4**	**50.0%**	**1**	**12.5%**	**8**
Hematoma	1	50.0%	1	50.0%	0	0.0%	2
Seroma	0	0.0%	1	100.0%	0	0.0%	1
Wound complications (eg., dehiscence, bruising) and soft tissue damage	2	100.0%	0	0.0%	0	0.0%	2
Other Skin and Subcutaneous Tissue Disorder	0	0.0%	2	66.7%	1	33.3%	3

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Vascular Disorders	**5**	**83.3%**	**1**	**16.7%**	**0**	**0.0%**	**6**
Hypertension	4	80.0%	1	20.0%	0	0.0%	5
Other Vascular Disorder	1	100.0%	0	0.0%	0	0.0%	1
Device (non system specific)	**1**	**25.0%**	**0**	**0.0%**	**3**	**75.0%**	**4**
Implant Malalignment	0	0.0%	0	0.0%	1	100.0%	1
Implant Migration	0	0.0%	0	0.0%	2	100.0%	2
Implant/Joint Noise	1	100.0%	0	0.0%	0	0.0%	1
Other Complications/Events	**18**	**52.9%**	**10**	**29.4%**	**6**	**17.6%**	**34**
Surgery at a location other than the spine	0	0.0%	0	0.0%	1	100.0%	1
Trauma	12	50.0%	9	37.5%	3	12.5%	24
Cancer	1	33.3%	0	0.0%	2	66.7%	3
Adverse Reaction to Medication	1	100.0%	0	0.0%	0	0.0%	1
Other Event, Describe	2	100.0%	0	0.0%	0	0.0%	2
Dental Disorder	1	100.0%	0	0.0%	0	0.0%	1
Other Gynecological Event	1	50.0%	1	50.0%	0	0.0%	2

Device-Related Adverse Events

Table 14 presents all device-related AEs recorded in the ITT Analysis Set. Overall, the investigational group presented with 153 device-related AEs in 38.3% (123/321) of the 321 prodisc® subjects, compared to 82 device-related AEs in 40.9% (65/159) of the 159 Mobi-C subjects.

The most common device-related AEs included cervical pain (investigational – 12.1%, 39/321; control – 9.4%, 15/159), spasms (investigational – 5.3%, 17/321; control – 2.5%, 4/159), and radiculopathy (investigational – 14.3%, 46/321; control – 17.6%, 28/159).

The majority of device-related AE occurred between Month 6 and Month 12 for both groups. In the investigational group, the most frequently occurring device-related AEs classified as Severe were implant migration (n=4 events), implant loosening (n=2 events), and radiculopathy (n=2 events). In the control group, the most frequently occurring device-related AEs classified as Severe were adjacent segment degeneration (n=4 events), radiculopathy (n=3 events), and implant migration (n=2 events).

Table 14: All Device- Related Adverse Events (ITT Analysis Set N=480)

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
All	**153**	**123**	**38.3%**	**82**	**65**	**40.9%**	**-2.6%**	**-11.8%**	**6.7%**
Ear and Labyrinth Disorders	**0**	**0**	**0.0%**	**1**	**1**	**0.6%**	**-0.6%**	**-1.5%**	**0.2%**
Other Ear and Labyrinth Disorders	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Gastrointestinal Disorders	**2**	**2**	**0.6%**	**1**	**1**	**0.6%**	**0.0%**	**-1.5%**	**1.5%**
Dysphagia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Infections and Infestations	**1**	**1**	**0.3%**	**0**	**0**	**0.0%**	**0.3%**	**-0.6%**	**1.2%**
Infection, Surgical Site	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Musculoskeletal and Connective Tissue Disorders	**72**	**66**	**20.6%**	**35**	**32**	**20.1%**	**0.4%**	**-7.2%**	**8.1%**
Joint Pain	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Joint Stiffness	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Muscle Weakness	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Osteoarthritis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spasms	18	17	5.3%	4	4	2.5%	2.8%	-1.1%	6.7%
Sprain	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Other Musculoskeletal Pain, Specify Location	4	4	1.2%	3	3	1.9%	-0.6%	-2.9%	1.6%
Adjacent Segment Degeneration	7	7	2.2%	6	6	3.8%	-1.6%	-4.7%	1.5%
Cervical Pain	39	39	12.1%	16	15	9.4%	2.7%	-3.3%	8.7%
Facet Joint Deterioration	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Musculoskeletal and Connective Tissue Disorder	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Nervous System Disorders	**67**	**59**	**18.4%**	**39**	**36**	**22.6%**	**-4.3%**	**-11.8%**	**3.3%**
Dysesthesia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Headache	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Numbness/Tingling	13	12	3.7%	4	4	2.5%	1.2%	-2.2%	4.6%
Paresthesia	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Radiculopathy	49	46	14.3%	31	28	17.6%	-3.3%	-10.1%	3.6%
Weakness	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Nervous System Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Device (non system specific)	**11**	**10**	**3.1%**	**4**	**4**	**2.5%**	**0.6%**	**-2.6%**	**3.8%**
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Implant Migration	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Implant/Joint Noise	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Other Complications/Events	**0**	**0**	**0.0%**	**2**	**2**	**1.3%**	**-1.3%**	**-2.5%**	**0.0%**
Trauma	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%

Procedure-Related Adverse Events

Table 15 presents all procedure-related AEs recorded in the ITT Analysis Set. Overall, there were 252 procedure-related AEs in 49.2% (158/321) of the 321 prodisc® subjects, compared to 124 procedure-related AEs in 49.1% (78/159) of the 159 Mobi-C subjects.

The most common procedure-related AEs included: dysphagia (investigational – 7.2%, 23/321; control – 6.3%, 10/159); spasms (investigational – 5.9%, 19/321; control – 3.8%, 6/159); and radiculopathy (investigational – 15%, 48/321; control – 18.9%, 30/159).

The majority of procedure-related AEs occurred between 0 and 30 days post-operatively for both groups. In the investigational group, the most frequently occurring procedure-related AEs classified as Severe were implant migration (n=4 events), implant loosening (n=2 events), and radiculopathy (n=2 events), hematoma (n=2 events), and surgical site infection (n=2 events). In the control group, the most frequently occurring device-related AEs classified as Severe were adjacent segment degeneration (n=4 events), radiculopathy (n=3 events), and implant migration (n=2 events).

Table 15: All Procedure- Related Adverse Events (ITT Analysis Set N= 480)

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
All	**252**	**158**	**49.2%**	**124**	**78**	**49.1%**	**0.2%**	**-9.3%**	**9.7%**
Blood and Lymphatic System Disorders	**2**	**2**	**0.6%**	**0**	**0**	**0.0%**	**0.6%**	**-0.6%**	**1.8%**
Blood Clots (non-pulmonary)	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Blood and Lymphatic System Disorders	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Ear and Labyrinth Disorders	**1**	**1**	**0.3%**	**1**	**1**	**0.6%**	**-0.3%**	**-1.5%**	**0.9%**
Ear Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Ear and Labyrinth Disorders	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
Gastrointestinal Disorders	**30**	**28**	**8.7%**	**15**	**12**	**7.5%**	**1.2%**	**-4.1%**	**6.4%**
Diarrhea	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Dyspepsia	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Dysphagia	24	23	7.2%	10	10	6.3%	0.9%	-3.9%	5.7%
Gastroesophageal Reflux Disease	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Hemorrhage	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Nausea	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Vomiting	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Gastrointestinal Pain, Specify Location	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Pancreatits	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Gastrointestinal Disorder	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
General Disorders and Administration	**3**	**3**	**0.9%**	**0**	**0**	**0.0%**	**0.9%**	**-0.6%**	**2.4%**
Fatigue	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Fever	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Hepatobiliary Disorders	**1**	**1**	**0.3%**	**0**	**0**	**0.0%**	**0.3%**	**-0.6%**	**1.2%**
Gallbladder Obstruction	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Immune System Disorders	**2**	**2**	**0.6%**	**0**	**0**	**0.0%**	**0.6%**	**-0.6%**	**1.8%**
Allergic Reaction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Infections and Infestations	**5**	**5**	**1.6%**	**4**	**4**	**2.5%**	**-1.0%**	**-3.5%**	**1.6%**
Infection, Surgical Site	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Infection, Not at Surgical Site	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Rash	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Musculoskeletal and Connective Tissue Disorders	**92**	**80**	**24.9%**	**46**	**36**	**22.6%**	**2.3%**	**-5.9%**	**10.4%**
Fracture, Any Bone	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Joint Pain	7	7	2.2%	3	3	1.9%	0.3%	-2.4%	3.0%
Joint Stiffness	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Muscle Weakness	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Osteoarthritis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spasms	20	19	5.9%	6	6	3.8%	2.1%	-2.1%	6.4%
Sprain	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Other Musculoskeletal Pain, Specify Location	6	6	1.9%	5	5	3.1%	-1.3%	-4.1%	1.6%
Adjacent Segment Degeneration	7	7	2.2%	6	6	3.8%	-1.6%	-4.7%	1.5%
Cervical Pain	41	41	12.8%	18	17	10.7%	2.1%	-4.1%	8.3%
Lumbar Pain	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Facet Joint Deterioration	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Soft Tissue Injury/Inflammation	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Other Musculoskeletal and Connective Tissue Disorder	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Nervous System Disorders	**78**	**65**	**20.2%**	**44**	**39**	**24.5%**	**-4.3%**	**-12.1%**	**3.6%**
Dizziness	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Dysesthesia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Dysphasia	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Headache	5	5	1.6%	3	3	1.9%	-0.3%	-2.8%	2.1%
Numbness/Tingling	15	14	4.4%	4	4	2.5%	1.8%	-1.8%	5.5%
Paresthesia	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Radiculopathy	51	48	15.0%	33	30	18.9%	-3.9%	-10.9%	3.1%
Weakness	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Nervous System Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Psychiatric Disorders	**2**	**2**	**0.6%**	**1**	**1**	**0.6%**	**0.0%**	**-1.5%**	**1.5%**
Anxiety Disorders	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Insomnia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Opioid Dependency	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference[†]		
	Events	**Subjs**	**%***	**Events**	**Subjs**	**%***	**Δ**	**LB**	**UB**
Renal and Urinary Disorders	**2**	**2**	**0.6%**	**0**	**0**	**0.0%**	**0.6%**	**-0.6%**	**1.8%**
Urinary Tract Infection	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Respiratory, Thoracic and Mediastinal Disorders	**11**	**11**	**3.4%**	**2**	**2**	**1.3%**	**2.2%**	**-0.9%**	**5.3%**
Dyspnea	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Hoarseness	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Pneumonia	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Pulmonary Embolism	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Airway Obstruction	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Respiratory, Thoracic and Medistinal Disorders Disorder	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Skin and Subcutaneous Tissue Disorders	**8**	**8**	**2.5%**	**5**	**4**	**2.5%**	**0.0%**	**-3.0%**	**2.9%**
Hematoma	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Seroma	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Wound complications (eg., dehiscence, bruising) and soft tissue damage	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Wound secretions / drainage	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Skin and Subcutaneous Tissue Disorder	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Vascular Disorders	**1**	**1**	**0.3%**	**0**	**0**	**0.0%**	**0.3%**	**-0.6%**	**1.2%**
Neurovascular Injury	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Device (non system specific)	**11**	**10**	**3.1%**	**4**	**4**	**2.5%**	**0.6%**	**-2.6%**	**3.8%**
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Implant Migration	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Implant/Joint Noise	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Other Complications/Events	**3**	**3**	**0.9%**	**2**	**2**	**1.3%**	**-0.3%**	**-2.3%**	**1.6%**
Trauma	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Adverse Reaction to Medication	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%

Serious Adverse Events

Table 16 below presents a summary of all SAEs for all investigational prodisc® C SK and prodisc® C Vivo subjects and Mobi-C control subjects in the ITT analysis population (N=480). No SAEs had a rate of 5% or more.

Table 4: Serious Adverse Events by AE Code - (ITT Analysis Set N= 480)

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
All	**72**	**60**	**18.7%**	**31**	**28**	**17.6%**	**1.1%**	**-6.3%**	**8.4%**
Cardiac Disorders	**3**	**3**	**0.9%**	**1**	**1**	**0.6%**	**0.3%**	**-1.4%**	**2.0%**
Acute Coronary Syndrome	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Chest Pain	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Myocardial Infarction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Endocrine Disorders	**2**	**1**	**0.3%**	**0**	**0**	**0.0%**	**0.3%**	**-0.6%**	**1.2%**
Diabetes Mellitus	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Endocrine Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Eye Disorders	**0**	**0**	**0.0%**	**1**	**1**	**0.6%**	**-0.6%**	**-1.5%**	**0.2%**
Retinal Detachment	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Gastrointestinal Disorders	**4**	**4**	**1.2%**	**2**	**2**	**1.3%**	**0.0%**	**-2.1%**	**2.1%**
Gastroesophageal Reflux Disease	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Gastrointestinal Pain, Specify Location	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Pancreatits	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Appendicitis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Gastrointestinal Disorder	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
General Disorders and Administration	**1**	**1**	**0.3%**	**0**	**0**	**0.0%**	**0.3%**	**-0.6%**	**1.2%**
General Disorders and Administrative Site Conditions - COVID-19	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Hepatobiliary Disorders	**3**	**3**	**0.9%**	**0**	**0**	**0.0%**	**0.9%**	**-0.6%**	**2.4%**
Gallbladder Obstruction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Hepatobiliary Disorders	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Infections and Infestations	**5**	**5**	**1.6%**	**3**	**3**	**1.9%**	**-0.3%**	**-2.8%**	**2.1%**
Infection, Surgical Site	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Infection, Not at Surgical Site	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Sinusitis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Sepsis	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Musculoskeletal and Connective Tissue Disorders	**17**	**15**	**4.7%**	**8**	**7**	**4.4%**	**0.3%**	**-3.7%**	**4.2%**
Fracture, Any Bone	2	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Joint Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Osteoarthritis	1	1	0.3%	2	2	1.3%	-0.9%	-2.4%	0.6%
Adjacent Segment Degeneration	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Lumbar Degenerative Disc Disease	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Pseudarthrosis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Cervical Pain	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Lumbar Pain	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Spinal Stenosis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spondylosis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Musculoskeletal and Connective Tissue Disorder	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Nervous System Disorders	**8**	**8**	**2.5%**	**6**	**6**	**3.8%**	**-1.3%**	**-4.5%**	**1.9%**
Compressive Neuropathy	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Radiculopathy	7	7	2.2%	4	4	2.5%	-0.3%	-3.2%	2.5%
Other Nervous System Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Psychiatric Disorders	**2**	**2**	**0.6%**	**0**	**0**	**0.0%**	**0.6%**	**-0.6%**	**1.8%**
Depression	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Psychiatric Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Renal and Urinary Disorders	**1**	**1**	**0.3%**	**0**	**0**	**0.0%**	**0.3%**	**-0.6%**	**1.2%**
Urinary Tract Infection	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Respiratory, Thoracic and Mediastinal Disorders	**4**	**4**	**1.2%**	**0**	**0**	**0.0%**	**1.2%**	**-0.5%**	**3.0%**
Pneumonia	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Pulmonary Embolism	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference†		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
Skin and Subcutaneous Tissue Disorders	**3**	**3**	**0.9%**	**1**	**1**	**0.6%**	**0.3%**	**-1.4%**	**2.0%**
Hematoma	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Seroma	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Wound complications (eg., dehiscence, bruising) and soft tissue damage	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Vascular Disorders	**3**	**3**	**0.9%**	**1**	**1**	**0.6%**	**0.3%**	**-1.4%**	**2.0%**
Hypertension	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Neurovascular Injury	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Thromboembolic Event	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Device (non system specific)	**6**	**5**	**1.6%**	**3**	**3**	**1.9%**	**-0.3%**	**-2.8%**	**2.1%**
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Implant Migration	4	4	1.2%	2	2	1.3%	0.0%	-2.1%	2.1%
Other Complications/Events	**10**	**10**	**3.1%**	**5**	**5**	**3.1%**	**0.0%**	**-3.3%**	**3.3%**
Surgery at a location other than the spine	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Trauma	1	1	0.3%	3	3	1.9%	-1.6%	-3.3%	0.2%
Cancer	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Other Event, Describe	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%

Serious Adverse Events Time course

Table 17 presents the SAEs through Month 24 for both treatment groups. The majority of SAEs occurred between Month 6 and Month 12 for the investigational group, and between Month 3 and Month 6 for the control group. While not shown, the majority of device- or procedure-related SAEs occurred between 0 and 30 days post-operatively for the investigational group, and between 30 and 90 days post-operatively for the control group.

Table 5: Serious Adverse Events (Time course) (ITT Analysis Set N= 480)

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
All	**2**	**1**	**0**	**0**	**3**	**0**	**7**	**3**	**8**	**3**	**11**	**8**	**15**	**6**	**15**	**7**	**11**	**3**	**72**	**31**
Cardiac Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**1**	**1**	**0**	**0**	**0**	**3**	**1**
Acute Coronary Syndrome	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Chest Pain	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Myocardial Infarction	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	0
Endocrine Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**2**	**0**
Diabetes Mellitus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Endocrine Disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Eye Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**
Retinal Detachment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Gastrointestinal Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**2**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**4**	**2**
Gastroesophageal Reflux Disease	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Gastrointestinal Pain, Specify Location	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Pancreatits	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Appendicitis	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Other Gastrointestinal Disorder	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	2	0
General Disorders and Administration	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**
General Disorders and Administrative Site Conditions - COVID-19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Hepatobiliary Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**3**	**0**
Gallbladder Obstruction	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2	0
Other Hepatobiliary Disorders	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Infections and Infestations	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**0**	**1**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**5**	**3**
Infection, Surgical Site	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	3	0
Infection, Not at Surgical Site	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	1	1
Sinusitis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Sepsis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Musculoskeletal and Connective Tissue Disorders	**1**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**0**	**5**	**1**	**4**	**3**	**2**	**3**	**3**	**0**	**17**	**8**
Fracture, Any Bone	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	2	0
Joint Pain	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Osteoarthritis	0	1	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	2
Adjacent Segment Degeneration	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	1	1
Lumbar Degenerative Disc Disease	0	0	0	0	0	0	0	0	1	0	1	0	1	1	1	0	0	0	4	1
Pseudarthrosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Cervical Pain	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Lumbar Pain	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0	1	0	0	3	2
Spinal Stenosis	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Spondylosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Musculoskeletal and Connective Tissue Disorder	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0	3	0
Nervous System Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**3**	**3**	**0**	**1**	**2**	**1**	**1**	**0**	**8**	**6**
Compressive Neuropathy	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2
Radiculopathy	0	0	0	0	0	0	1	0	1	1	3	1	0	1	1	1	1	0	7	4
Other Nervous System Disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Psychiatric Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**2**	**0**
Depression	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Other Psychiatric Disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Renal and Urinary Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
Urinary Tract Infection	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Respiratory, Thoracic and Mediastinal Disorders	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**4**	**0**
Pneumonia	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0
Pulmonary Embolism	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2	0
Skin and Subcutaneous Tissue Disorders	**0**	**0**	**0**	**0**	**2**	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**1**
Hematoma	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
Seroma	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Wound complications (eg., dehiscence, bruising) and soft tissue damage	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Vascular Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**3**	**1**
Hypertension	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	1	1
Neurovascular Injury	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Thromboembolic Event	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Device (non system specific)	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**2**	**3**	**0**	**1**	**0**	**1**	**0**	**6**	**3**
Implant Loosening	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	0
Implant Malalignment	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Implant Migration	0	0	0	0	0	0	0	0	0	1	1	1	2	0	1	0	0	0	4	2
Other Complications/Events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**3**	**1**	**3**	**1**	**3**	**1**	**10**	**5**
Surgery at a location other than the spine	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	2	0	3	1
Trauma	0	0	0	0	0	0	0	0	0	0	0	2	1	1	0	0	0	0	1	3
Cancer	1	0	0	0	0	0	0	0	0	0	0	0	1	0	3	0	0	1	5	1
Other Event, Describe	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0

Secondary Surgical Interventions

A total of 9 subjects (3.1% - 9/321) experienced an SSI through Month 24 in the investigational group, while a total of 6 subjects (4.3% - 6/159) experienced an SSI through Month 24 in the control group. In both cases, removals were the most frequent type of SSI. **Table 18** shows the SSI time course through Month 24 for both groups.

Table 18: SSI Time course by Treatment Type – AT Analysis Set N-431

Treatment Group		Event Time-Course (months)					Total Subjects
	SSI Type	<1.5	1.5-3	3-6	6-12	12-24	
Prodisc C	Removal	1	-	1	1	5*	7
	Revision	-	-	-	-	-	-
	Reoperation	-	-	-	1	1	2
	Supplemental Fixation	-	-	-	-	-	-
Total Events (Subjects)		**1**	-	**1**	**2**	**6**	**9 subjects**
Mobi-C (Control)	Removal	-	1	1	1	2	5
	Revision	-	-	-	-	-	-
	Reoperation	-	-	1	-	-	1
	Supplemental Fixation	-	-	-	-	-	-
Total Events (Subjects)			**1**	**2**	**1**	**2**	**6 subjects**

*One subject had two SSIs

Effectiveness Results

This clinical trial was designed to test the non-inferiority of the investigational device (prodisc® C SK and prodisc® C Vivo) as compared to the control device (Mobi-C) when used at two levels in the spine through the use of a primary composite endpoint.

Overall Success

A subject was considered a study success if the following criteria were met:

- 15-point improvement in NDI Score (out of 100) in subjects at the Month 24 timepoint compared with baseline;
- Maintenance or improvement in neurological status (motor and sensory only) at Month 24 compared to baseline;
- No secondary surgical interventions (revision, removal, re-operation, supplemental fixation) at the index level(s); and,
- Absence of major device-related AEs defined as radiographic failure, neurological failure, or failure by AE as adjudicated by the CEC.

Overall success was determined based on the mITT Analysis Set at Month 24. No data was imputed. The primary overall success outcomes are presented in **Table 19.**

Table 19: Overall Success (mITT Analysis Set, N=433)

Row		prodisc® C			mobi-c			Group Difference			
		N	n	%	N	n	%	Δ [2]	LB [1]	UB [1]	
1	Implanted	293	291	99.3%	140	140	100.0%	-0.7%	-2.5%	2.2%	
2	No secondary surgical intervention	293	284	96.9%	140	134	95.7%	1.2%	-2.4%	6.3%	
3	NDI 15-point Responder†	244	229	93.9%	121	109	90.1%	3.8%	-2.0%	11.0%	
4	No Neurological Deterioration (CEC)†	246	241	98.0%	125	121	96.8%	1.2%	-2.2%	6.2%	
5	No Major Adverse Event (CEC)	293	292	99.7%	140	140	100.0%	-0.3%	-2.0%	2.5%	
											PostProb NI [3]
6	CCS Completers vs. Current mobi-C	253	221	87.1%	127	107	83.7%	3.3%	-3.6%	10.8%	>0.999

[1] 95% Exact binomial CI.
[2] The top frame is the difference in observed proportions; the bottom frame is the difference between beta-distributions.
[3] Posterior probability of Non-inferiority (NI) (delta = -10%).
† Subjects censored at Index level secondary surgical interventions.
All Bayesian distributions based on uniform (1, 1) prior. 5000 imputations and 10000 beta draws used.
Source: CS2 Results PMA Lock 3.SAS; CS2 Primary v1 2025-04-14 mITT.R; Analyzed: 14APR2025

The success rate for the investigational group was 87.1% (221/253) as compared to a success rate of 83.7% (107/127) for the control group. Posterior probability is shown in row 6 to demonstrate that non-inferiority has been achieved. In this study, the posterior probability of greater than 99.99% indicates there is greater than 99.99% chance that the investigational group performs at least as well as the control group (i.e., is non-inferior). The study's pre-specified success criterion required this probability to exceed 96.7% to declare success, which was achieved in this analysis.

A secondary supporting sensitivity analysis of the primary endpoint was performed for the PP Analysis Set (which per the applicant's original protocol, was the primary analysis population). The results were similar, with a success rate of 88.7% (219/246) as compared to a success rate of 84.0% (104/123) for the control group. Non-inferiority was also demonstrated in the PP Analysis Set.

Tipping Point Analysis

A total of 40 investigational subjects did not have a Month 24 CCS; 14 had not yet reached Month 24, 5 were not yet overdue, and 21 were missing for other reasons. Likewise, there were a total of 13 control that did not have a Month 24 CCS; 2 had not yet reached Month 24, 2 were not yet overdue, and 9 were missing for other reasons.

A tipping point analysis was conducted to investigate the chance of the study conclusions changing as a result of this missing data. An assumption was made that the data is missing-at-random, thereby making no assumptions about their missingness. The results of the tipping point analysis indicated that the results were tipped only 19.5% of the time. In other words, non-inferiority was met 80.5% of the time with these imputations of the missing data, indicating robustness in the non-inferiority claim.

Composite Clinical Success Subcomponents

In looking at the individual subcomponents of the CCS in **Table 19**, the results are similar between both treatment groups. Row 2 identifies that 96.9% (284/293) of the investigational subjects and 95.7% (134/140) of the control subjects did not experience an SSI. Row 3 indicates that 93.9% (229/244) of the investigational subjects and 90.1% (109/121) of the control subjects demonstrated meaningful improvement in their NDI assessment at Month 24 compared to baseline. As for Row 4, the reported results indicate that 98.0% (241/246) of the investigational

subjects and 96.8% (121/125) of the control subjects did not experience neurological deterioration. Lastly, Row 5 identifies that 99.7% (292/293) of the investigational subjects and 100% (140/140) of the control subjects did not experience a major device-related AE.

Secondary Endpoint Analyses

In addition to the CCS subcomponents, a number of secondary endpoints were evaluated in the mITT Analysis Set, including: neck pain, arm pain, and subject quality of life.

Neck Pain – VAS

A 100mm VAS was administered to subjects in order to assess neck pain. In the investigational group, the pre-operative neck pain VAS mean score was 73.8mm, and significantly dropped post-operatively to a Month 24 neck pain VAS mean score of 16.6mm. Similarly, in the control group, the pre-operative neck pain VAS mean score was 74.3mm, and also significantly dropped post-operatively to a Month 24 neck pain VAS mean score of 16.6mm. An additional analysis looked at how many subjects responded to treatment with at least a 20mm reduction in VAS. **Table 20** illustrates that a large proportion of subjects in both groups experienced at least a 20mm reduction in their neck pain VAS score across all post-operative timepoints. At Month 24, 88.1% (214/243) of subjects in the investigational group reported at least a 20mm reduction in their neck pain VAS score, and 86.9% (106/122) of subjects in the control group reported at least a 20mm reduction in their neck pain VAS score.

Table 20: VAS (Neck) 20mm Responder (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C			Mobi C			Group Difference*		
	N	n	%	N	n	%	Δ	LB	UB
Week 06	275	244	88.7%	135	120	88.9%	-0.2%	-6.6%	6.3%
Month 03	280	258	92.1%	136	127	93.4%	-1.2%	-6.5%	4.0%
Month 06	282	260	92.2%	136	120	88.2%	4.0%	-2.3%	10.2%
Month 12	278	250	89.9%	130	112	86.2%	3.8%	-3.1%	10.7%
Month 24	243	214	88.1%	122	106	86.9%	1.2%	-6.1%	8.4%

Subjects censored at Index level secondary surgical interventions.
*Device group differences, Nominal 95% CI, and two-sided asymptomatic p-value.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

Left Arm Pain – VAS

A 100mm VAS was administered to subjects in order to assess left arm pain. In the investigational group, the pre-operative left arm pain VAS mean score was 53.2mm, and significantly dropped post-operatively to a Month 24 left arm pain VAS mean score of 11.9mm. Similarly, in the control group, the pre-operative left arm pain VAS mean score was 52.5mm, and also significantly dropped post-operatively to a Month 24 left pain VAS mean score of 13.9mm. An additional analysis looked at how many subjects responded to treatment with at least a 20mm reduction in VAS. While not as high as the reduction in neck pain VAS, **Table 21** illustrates that a large proportion of subjects in both groups experienced at least a 20mm reduction in their left arm pain VAS score across all post-operative timepoints. At Month 24, 66.3% (161/243) of subjects in the investigational group reported at least a 20mm reduction in their left arm pain VAS score, and

62.3% (76/122) of subjects in the control group reported at least a 20mm reduction in their left arm pain VAS score.

Table 21: VAS (left arm/shoulder) 20mm Responder (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C			Mobi C			Group Difference*		
	N	n	%	N	n	%	Δ	LB	UB
Week 06	276	189	68.5%	135	85	63.0%	5.5%	-4.3%	15.3%
Month 03	280	194	69.3%	136	89	65.4%	3.8%	-5.8%	13.5%
Month 06	282	201	71.3%	136	91	66.9%	4.4%	-5.1%	13.9%
Month 12	278	192	69.1%	130	81	62.3%	6.8%	-3.2%	16.7%
Month 24	243	161	66.3%	122	76	62.3%	4.0%	-6.5%	14.4%

Subjects censored at Index level secondary surgical interventions.
*Device group differences, Nominal 95% CI, and two-sided asymptomatic p-value.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

Right Arm Pain – VAS

A 100mm VAS was administered to subjects in order to also assess right arm pain. In the investigational group, the pre-operative right arm pain VAS mean score was 52.0mm, and significantly dropped post-operatively to a Month 24 right arm pain VAS mean score of 14.1mm. Similarly, in the control group, the pre-operative right arm pain VAS mean score was 54.1mm, and also significantly dropped post-operatively to a Month 24 right arm pain VAS mean score of 11.4mm. An additional analysis was also carried out that looked at how many subjects responded to treatment with at least a 20mm reduction in VAS. While not as high as the reduction in neck pain VAS, but similar to the change in left arm pain VAS, **Table 22** illustrates that a large proportion of subjects in both groups experienced at least a 20mm reduction in their right arm pain VAS score across all post-operative timepoints. At Month 24, 65.8% (160/243) of subjects in the investigational group reported at least a 20mm reduction in their right arm pain VAS score, and 68.0% (83/122) of subjects in the control group reported at least a 20mm reduction in their right arm pain VAS score.

Interestingly, the applicant looked at the "worst" arm pain VAS for each subject. At Month 24, 84.8% (206/243) of subjects in the investigational group reported at least a 20mm reduction in their "worst" arm pain VAS score, and 85.2% (104/122) of subjects in the control group reported at least a 20mm reduction in their "worst" arm pain VAS score.

Table 22: VAS (right arm/shoulder) 20mm Responder (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C			Mobi C			Group Difference*		
	N	n	%	N	n	%	Δ	LB	UB
Week 06	276	173	62.7%	135	95	70.4%	-7.7%	-17.3%	1.9%
Month 03	280	178	63.6%	136	90	66.2%	-2.6%	-12.4%	7.1%
Month 06	282	192	68.1%	136	93	68.4%	-0.3%	-9.8%	9.2%
Month 12	278	188	67.6%	130	85	65.4%	2.2%	-7.6%	12.1%
Month 24	243	160	65.8%	122	83	68.0%	-2.2%	-12.4%	8.0%

Subjects censored at Index level secondary surgical interventions.
*Device group differences, Nominal 95% CI, and two-sided asymptomatic p-value.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

Hoarseness – VAS

A 100mm VAS was administered to subjects in order to also assess hoarseness. As shown in **Table 23,** in the investigational group, the pre-operative hoarseness VAS mean score was 19.0mm, and dropped post-operatively to a Month 24 right arm pain VAS mean score of 6.6mm. Similarly, in the control group, the pre-operative hoarseness VAS mean score was 27.2mm, and also dropped post-operatively to a Month 24 hoarseness VAS mean score of 5.7mm.

Table 23: VAS Hoarseness Values Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	293	19.0	25.9	5.0	0.0	100.0	140	19.5	27.2	4.0	0.0	100.0	-0.6	-5.6	4.7
Week 06	275	10.2	18.1	2.0	0.0	100.0	135	9.6	18.3	2.0	0.0	100.0	0.6	-3.2	4.4
Month 03	280	6.1	12.8	1.0	0.0	85.0	136	6.1	13.6	1.0	0.0	68.0	0.0	-2.4	2.9
Month 06	282	5.4	13.3	0.0	0.0	97.0	136	5.7	13.0	1.0	0.0	72.0	-0.3	-3.0	2.4
Month 12	278	5.9	13.6	1.0	0.0	84.0	130	6.3	15.7	1.0	0.0	100.0	-0.4	-3.3	2.7
Month 24	243	6.6	15.2	1.0	0.0	98.0	122	5.7	13.3	0.0	0.0	79.0	0.8	-2.4	4.0

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

Dysphagia Handicap Index

DHI was administered to subjects in order to assess swallowing difficulties. As **Table 24** reports. in the investigational group, the pre-operative DHI mean score was 10.9, and dropped post-operatively to a Month 24 DHI mean score of 6.8. Similarly, in the control group, the pre-operative DHI mean score was 11.1, and also dropped post-operatively to a Month 24 DHI mean score of 7.7. This suggest that as a whole, both the investigational and control treatments do not significantly contribute to development of swallowing difficulties.

Table 24: DHI Scores Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	291	10.9	15.4	4.0	0.0	98.0	140	11.1	14.9	6.0	0.0	64.0	-0.2	-3.2	2.8
Week 06	271	10.2	12.5	4.0	0.0	74.0	133	10.9	12.9	6.0	0.0	68.0	-0.6	-3.2	2.1
Month 03	279	6.9	10.2	2.0	0.0	66.0	136	8.4	11.6	3.0	0.0	52.0	-1.5	-3.6	0.7
Month 06	277	6.2	11.0	2.0	0.0	92.0	136	8.0	12.2	3.0	0.0	58.0	-1.9	-4.2	0.4
Month 12	276	6.4	11.5	2.0	0.0	84.0	130	7.3	12.0	2.0	0.0	52.0	-0.9	-3.3	1.5
Month 24	244	6.8	11.3	2.0	0.0	60.0	121	7.7	11.6	2.0	0.0	56.0	-0.9	-3.3	1.7

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

SF-12 Physical Component Scores

The results of the PCS portion of the SF-12 are shown in **Table 25.** In the investigational group, the pre-operative SF-12 PCS mean score was 31.1, and increased post-operatively to a Month 24 SF-12 PCS mean score of 48.7. Similarly, in the control group, the pre-operative SF-12 PCS mean score was 32.0, and also increased post-operatively to a Month 24 SF-12 PCS mean score of 48.0.

Table 25: SF-12 (PCS) values over time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	293	31.1	8.1	30.6	11.4	54.5	140	32.0	8.6	32.3	9.2	53.9	-0.9	-2.5	0.8
Week 06	272	44.5	10.0	46.0	14.7	62.7	134	44.2	10.1	46.0	15.9	60.5	0.3	-1.7	2.5
Month 03	278	47.1	9.7	48.5	15.3	62.4	136	47.9	8.9	50.6	20.9	62.1	-0.8	-2.7	1.1
Month 06	279	48.0	9.9	50.2	11.2	66.8	136	47.8	10.4	50.7	17.4	62.1	0.2	-1.9	2.1
Month 12	277	48.5	10.8	52.4	13.2	68.9	130	47.3	10.7	51.3	15.0	62.1	1.3	-0.9	3.6
Month 24	243	48.7	10.9	53.2	7.8	65.5	121	48.0	10.1	50.6	17.3	62.1	0.7	-1.7	2.9

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

SF-12 Mental Component Scores

The results of the MCS portion of the SF-12 are shown in **Table 26.** In the investigational group, the pre-operative SF-12 MCS mean score was 44.0, and increased post-operatively to a Month 24 SF-12 MCS mean score of 52.0. Similarly, in the control group, the pre-operative SF-12 MCS mean score was 42.7, and also increased post-operatively to a Month 24 SF-12 MCS mean score of 51.2.

Table 26: SF-12 (MCS) Values Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	293	44.0	12.1	43.1	15.6	69.6	140	42.7	13.4	43.0	9.4	69.2	1.4	-1.0	3.9
Week 06	272	53.3	8.7	55.6	23.9	72.8	134	51.6	10.3	55.0	12.9	67.3	1.7	-0.1	3.7
Month 03	278	53.4	9.0	55.8	19.9	69.3	136	51.8	10.4	55.7	17.2	66.3	1.6	-0.3	3.5
Month 06	279	53.2	9.5	56.8	19.8	72.7	136	51.6	10.4	55.2	25.8	68.6	1.6	-0.4	3.5
Month 12	277	52.9	10.0	57.1	15.9	66.8	130	52.2	9.8	55.2	15.9	67.5	0.8	-1.2	3.0
Month 24	243	52.0	10.3	55.8	11.5	68.6	121	51.2	10.2	54.8	21.3	64.7	0.8	-1.5	2.9

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

Odom's Criteria

Odom's Criteria consist of a 4-point rating scale for surgeons to assess clinical outcomes following cervical spine surgery. **Table 27** provides the ratings for Odom's Criteria in the clinical study. In both groups, the predominant response is "Excellent" or "Good" at each post-operative timepoint. At Month 24, a response of "Excellent" was reported in 89.5% (221/247) of investigational cases, and similarly, a response of "Excellent" was reported in 86.5% (109/126) of control cases.

Table 27: Odom's Criteria (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	Week 06						Month 3						Month 6					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Excellent	283	240	84.8%	138	111	80.4%	286	258	90.2%	137	119	86.9%	285	261	91.6%	137	115	83.9%
Good	283	36	12.7%	138	22	15.9%	286	25	8.7%	137	14	10.2%	285	20	7.0%	137	17	12.4%
Fair	283	7	2.5%	138	4	2.9%	286	2	0.7%	137	4	2.9%	285	3	1.1%	137	5	3.6%
Poor	283	0	0.0%	138	1	0.7%	286	1	0.3%	137	0	0.0%	285	1	0.4%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

	Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%
Excellent	282	257	91.1%	131	115	87.8%	247	221	89.5%	126	109	86.5%
Good	282	20	7.1%	131	9	6.9%	247	17	6.9%	126	10	7.9%
Fair	282	4	1.4%	131	6	4.6%	247	7	2.8%	126	6	4.8%
Poor	282	1	0.4%	131	1	0.8%	247	2	0.8%	126	1	0.8%

Subjects censored at Index level secondary surgical interventions.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

Nurick Scale

The Nurick Scale is a 6-grade classification system that is used for surgeons to assess the level of cervical spondylotic myelopathy while conducting a physical examination. The scale includes: Grade 0 (normal gait); Grade 1 (signs of spinal cord compression but with normal gait); Grade 2 (slight difficulty in walking that does not prevent full-time employment); Grade 3 (Difficulty in walking that prevents full-time employment or daily tasks, but does not require assistance with walking); Grade 4 (able to walk only with someone else's help or with the aid of a frame); and Grade 5 (chair-bound or bedridden). **Table 28** provides the gradings on the Nurick Scale pre-operatively and through the post-operative timepoints. The vast majority of subjects were Grade 0 pre-operatively and post-operatively, although there was a general increase in the proportion of subjects determined to be Grade 0 or Grade 1; by Month 24, only n=1 subject in the investigational group was classified as Grade 2, with all other subjects in both groups being classified as Grade 0 or 1.

Table 28: Myelopathy – Nurick Scale (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
0	291	224	77.0%	139	107	77.0%	283	279	98.6%	138	131	94.9%	286	283	99.0%	137	133	97.1%
1	291	50	17.2%	139	25	18.0%	283	2	0.7%	138	6	4.3%	286	2	0.7%	137	4	2.9%
2	291	7	2.4%	139	6	4.3%	283	0	0.0%	138	1	0.7%	286	1	0.3%	137	0	0.0%
3	291	8	2.7%	139	1	0.7%	283	1	0.4%	138	0	0.0%	286	0	0.0%	137	0	0.0%
4	291	1	0.3%	139	0	0.0%	283	1	0.4%	138	0	0.0%	286	0	0.0%	137	0	0.0%
5	291	1	0.3%	139	0	0.0%	283	0	0.0%	138	0	0.0%	286	0	0.0%	137	0	0.0%

Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
0	285	281	98.6%	137	129	94.2%	282	278	98.6%	131	128	97.7%	247	241	97.6%	126	124	98.4%
1	285	3	1.1%	137	8	5.8%	282	3	1.1%	131	3	2.3%	247	5	2.0%	126	2	1.6%
2	285	0	0.0%	137	0	0.0%	282	0	0.0%	131	0	0.0%	247	1	0.4%	126	0	0.0%
3	285	1	0.4%	137	0	0.0%	282	1	0.4%	131	0	0.0%	247	0	0.0%	126	0	0.0%
4	285	0	0.0%	137	0	0.0%	282	0	0.0%	131	0	0.0%	247	0	0.0%	126	0	0.0%
5	285	0	0.0%	137	0	0.0%	282	0	0.0%	131	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

Treatment Satisfaction

A Treatment Satisfaction questionnaire was administered to all subjects irrespective of intra-operative deviation or SSI.

In response to the question, "How satisfied are you with the results of your neck operation,"

approximately four-fifths of subjects in both groups indicated that they were "Extremely Satisfied" at all post-operative timepoints, with 81.1% (202/249) of investigational subjects and 78.9% (97/123) of control subjects expressing this perspective at Month 24.

In response to the question, "How satisfied are you with the relief of pain in your neck, shoulder, arms and hands following the operation," approximately three-fifths of subjects in both groups indicated that they were "Extremely Satisfied" at Week 6. Satisfaction appeared to improve with time, and 71.9% (179/249) of investigational subjects and 70.7% (87/123) of control subjects reported being "Extremely Satisfied" at Month 24.

In response to the question, "How satisfied are you with the ability to do housework, yard work or job following the operation," approximately half of subjects in both groups indicated that they were "Extremely Satisfied" at Week 6. Satisfaction appeared to improve with time, and 74.7% (186/249) of investigational subjects and 69.9% (86/123) of control subjects reported being "Extremely Satisfied" at Month 24.

In response to the question, "How satisfied are you with strength in your shoulders, arms and hands following the operation," approximately half of subjects in both groups indicated that they were "Extremely Satisfied" at Week 6. Satisfaction appeared to improve with time, and 66.7% (166/249) of investigational subjects and 61.0% (75/123) of control subjects reported being "Extremely Satisfied" at Month 24.

Lastly, in response to the question, "How satisfied are you with the feeling in your shoulders, arms and hands following the operation," slightly more than half of subjects in both groups indicated that they were "Extremely Satisfied" at Week 6. Satisfaction appeared to improve with time, and 65.1% (162/249) of investigational subjects and 62.6% (77/123) of control subjects reported being "Extremely Satisfied" at Month 24.

Device Condition

Based upon the radiographic data, device condition was assessed at each timepoint. All devices at the superior level in both groups were assessed to be intact (i.e., no evidence of device disassembly, fracture, or loosening), with the exception of one (1) device classified as loose (i.e., new or progressive radiolucency at the implant-bone interface indicating a loss of fixation, or clear presence of device migration or toggle) at Month 6 in the investigational group, two (2) devices classified as loose at Month 12 in the investigational group, and one (1) device classified as loose at Month 24 in the investigational group.

Table 29 identifies the device condition classification at the inferior level in both groups. The vast majority if devices were assessed to be intact, but a number of devices were classified as loose in both groups based upon the radiographic data. There was no evidence of device disassembly or fracture in either group. In some cases, an assessment was deemed indeterminate based upon the inability to make an assessment from the available images due to technical factors, sub-optimal image quality, obscured anatomy, obstructed view, or other imaging artifacts.

Table 29: Device Condition - Inferior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Intact	0	0	.	0	0	.	283	280	98.9%	139	137	98.6%	283	282	99.6%	137	137	100.0%
Disassembled	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Fractured	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Loose	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Indeterminate	0	0	.	0	0	.	283	3	1.1%	139	2	1.4%	283	1	0.4%	137	0	0.0%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Intact	284	281	98.9%	138	137	99.3%	283	280	98.9%	130	129	99.2%	247	244	98.8%	126	126	100.0%
Disassembled	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Fractured	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Loose	284	0	0.0%	138	0	0.0%	283	1	0.4%	130	0	0.0%	247	1	0.4%	126	0	0.0%
Indeterminate	284	3	1.1%	138	1	0.7%	283	2	0.7%	130	1	0.8%	247	2	0.8%	126	0	0.0%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

Device Migration

Based upon the radiographic data, device migration was assessed at each timepoint. All devices at the superior level in both groups were assessed to have no evidence of migration, with the exception of two (1) devices detected to have migrated (i.e., presence of AP or lateral change in implant position greater than or equal to 3mm) at Month 6 in the investigational group, three (3) devices detected to have migrated at Month 12 in the investigational group, and two (2) device detected to have migrated at Month 24 in the investigational group. There were a few devices in both groups at Week 6 where device migration could not be assessed due to missing images or inadequate field of view. All devices at the inferior level in both groups were assessed to have no evidence of migration, although there were a few cases at all post-operative timepoints in both groups that were indeterminate or could not be assessed.

Device Protrusion

Based upon the radiographic data, device protrusion was assessed at each timepoint. Most devices at the superior level in both groups were assessed to have no protrusion (i.e., no device migration beyond the margin of the disc space), with some devices having Grade I protrusion (i.e., less than or equal to 10% protrusion beyond the margin of the disc space), and a few devices with Grade II protrusion (i.e., 11-25% protrusion beyond the margin of the disc space), at the post-operative timepoints. At Month 24, 93.9% (232/247) of the investigational devices and 88.9% (112/126) of the control devices were assessed to have no protrusion, 4.9% (12/247) of the investigation devices and 10.3% (13/126) of the control devices were assessed to have Grade I protrusion, and 1.2% (3/247) of the investigational devices and 0.8% (1/126) of the control devices were assessed to have Grade II protrusion.

Similarly, most devices at the inferior level in both groups were assessed to have no protrusion, with some devices having Grade I protrusion, a few devices with Grade II protrusion, and a few devices determined to be indeterminate (i.e., an assessment could not be made from the available images due to technical factors, sub-optimal image quality, obscured anatomy, obstructed view or other imaging artifacts), at the post-operative timepoints. At Month 24, 94.7% (234/247) of the investigational devices and 91.3% (115/126) of the control devices were assessed to have no protrusion, 5.3% (13/247) of the investigation devices and 7.9% (10/126) of the control devices were assessed to have Grade I protrusion, and 0.8% (1/126) of the control devices were assessed to have Grade II protrusion.

Device Subsidence

Based upon the radiographic data, device subsidence was evaluated at each timepoint. Most devices at the superior level in both groups were assessed to have no subsidence (i.e., no evidence of cranial or caudal subsidence of the implant greater than or equal to 2mm), with 97.6% (241/247) of investigational devices and 100% (126/126) of control devices assessed to have no subsidence at Month 24.

Similarly, most devices at the inferior level in both groups were assessed to have no evidence of subsidence, with 96.0% (237/247) of investigational devices, 100% (126/126) of control devices assessed to have no subsidence, and 1.2% (3/247) of investigational devices rated as indeterminate, at Month 24.

Heterotopic Ossification

Based upon the radiographic data, HO was evaluated at each timepoint. The following definitions were used: none – no evidence of osteophyte formation or heterotopic ossification; Class I – HO is present in islands of bone within soft tissue but is not influencing the ROM of the vertebral motion segment. Bone is not between the planes formed by the two vertebral endplates; Class II – HO or post-operative osteophytes are present between the two planes formed by the vertebral endplates but are not significantly blocking or articulating between adjacent vertebral endplates or osteophytes; Class III – The ROM of the vertebral endplates is blocked by the formation of HO and/or post-operative osteophytes on flexion-extension or lateral bending radiographs; and, Class IV – An apparent continuous connection of bone exists across the adjacent vertebral endplates caused by bridging osteophytes or HO.

Table 30 identifies the findings related to HO at each timepoint at the superior level. There is increasing progression of HO over time, with Class II HO being the predominant type at later timepoints. A total of 42.9% (106/247) of investigational devices and 59.5% (75/126) of control devices were assessed to have Class II HO at Month 24.

Table 30: Heterotopic Ossification – Superior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	251	88.7%	139	115	82.7%	283	230	81.3%	137	97	70.8%
Class I	0	0	.	0	0	.	283	17	6.0%	139	16	11.5%	283	27	9.5%	137	21	15.3%
Class II	0	0	.	0	0	.	283	14	4.9%	139	8	5.8%	283	23	8.1%	137	17	12.4%
Class III	0	0	.	0	0	.	283	1	0.4%	139	0	0.0%	283	3	1.1%	137	2	1.5%
Class IV	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Indeterminate	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	185	65.1%	138	71	51.4%	283	120	42.4%	130	38	29.2%	247	59	23.9%	126	20	15.9%
Class I	284	39	13.7%	138	25	18.1%	283	41	14.5%	130	16	12.3%	247	28	11.3%	126	12	9.5%
Class II	284	53	18.7%	138	38	27.5%	283	92	32.5%	130	64	49.2%	247	106	42.9%	126	75	59.5%
Class III	284	6	2.1%	138	3	2.2%	283	25	8.8%	130	11	8.5%	247	47	19.0%	126	17	13.5%
Class IV	284	1	0.4%	138	1	0.7%	283	5	1.8%	130	1	0.8%	247	7	2.8%	126	2	1.6%
Indeterminate	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

Table 31 identifies the findings related to HO at each timepoint at the inferior level. Similarly, there is increasing progression of HO over time, with Class II HO being the predominant type at later timepoints. A total of 45.3% (112/247) of investigational devices and 54.0% (68/126) of control devices were assessed to have Class II HO at Month 24.

Table 31: Heterotopic Ossification – Inferior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	245	86.6%	139	111	79.9%	283	222	78.4%	137	95	69.3%
Class I	0	0	.	0	0	.	283	19	6.7%	139	13	9.4%	283	28	9.9%	137	22	16.1%
Class II	0	0	.	0	0	.	283	7	2.5%	139	12	8.6%	283	17	6.0%	137	18	13.1%
Class III	0	0	.	0	0	.	283	1	0.4%	139	0	0.0%	283	2	0.7%	137	0	0.0%
Class IV	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Indeterminate	0	0	.	0	0	.	283	11	3.9%	139	3	2.2%	283	14	4.9%	137	2	1.5%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	172	60.6%	138	69	50.0%	283	120	42.4%	130	37	28.5%	247	61	24.7%	126	23	18.3%
Class I	284	47	16.5%	138	19	13.8%	283	37	13.1%	130	10	7.7%	247	25	10.1%	126	6	4.8%
Class II	284	43	15.1%	138	43	31.2%	283	89	31.4%	130	66	50.8%	247	112	45.3%	126	68	54.0%
Class III	284	9	3.2%	138	5	3.6%	283	16	5.7%	130	14	10.8%	247	28	11.3%	126	24	19.0%
Class IV	284	0	0.0%	138	0	0.0%	283	8	2.8%	130	2	1.5%	247	14	5.7%	126	3	2.4%
Indeterminate	284	13	4.6%	138	2	1.4%	283	13	4.6%	130	1	0.8%	247	7	2.8%	126	2	1.6%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

Adjacent level Disc Degeneration (Kellgren-Lawrence)

Based upon the radiographic data, adjacent level disc degeneration (ALDD) was evaluated at each timepoint. The following scale was used: none – No degenerative changes; doubtful – Minimal osteophytosis only; minimal – Definite osteophytosis with some sclerosis of vertebral plates with slight narrowing of disk space; moderate – Marked osteophytosis with sclerosis of vertebral plates with slight narrowing of disc space; and, Severe –Large osteophytes, marked sclerosis of vertebral plates, and marked narrowing of disc space.

Table 32 reports the findings related to ALDD at each timepoint at the superior level. There is an increase in ALDD over time in both groups. However, only 1.2% (3/247) of investigational subjects and 1.6% (2/126) of control subjects are classified to have severe ALDD at Month 24.

Table 32: Adjacent Level DD – Superior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	91	32.2%	139	41	29.5%	283	81	28.6%	137	39	28.5%
Doubtful	0	0	.	0	0	.	283	81	28.6%	139	47	33.8%	283	87	30.7%	137	49	35.8%
Minimal	0	0	.	0	0	.	283	66	23.3%	139	33	23.7%	283	69	24.4%	137	31	22.6%
Moderate	0	0	.	0	0	.	283	42	14.8%	139	15	10.8%	283	42	14.8%	137	15	10.9%
Severe	0	0	.	0	0	.	283	3	1.1%	139	3	2.2%	283	4	1.4%	137	3	2.2%
Indeterminate	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	80	28.2%	138	37	26.8%	283	68	24.0%	130	31	23.8%	247	44	17.8%	126	27	21.4%
Doubtful	284	81	28.5%	138	48	34.8%	283	85	30.0%	130	46	35.4%	247	70	28.3%	126	39	31.0%
Minimal	284	76	26.8%	138	35	25.4%	283	78	27.6%	130	33	25.4%	247	83	33.6%	126	37	29.4%
Moderate	284	43	15.1%	138	15	10.9%	283	48	17.0%	130	17	13.1%	247	47	19.0%	126	19	15.1%
Severe	284	4	1.4%	138	3	2.2%	283	3	1.1%	130	3	2.3%	247	3	1.2%	126	2	1.6%
Indeterminate	284	0	0.0%	138	0	0.0%	283	1	0.4%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	2	1.6%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

Table 33 reports the findings related to ALDD at each timepoint at the inferior level. There is a similar increase in ALDD over time in both groups. However, only 3.2% (8/247) of investigational subjects and 2.4% (3/126) of control subjects are classified to have marked ALDD at Month 24, with the caveat that 29.6% (73/247) of investigational devices and 29.4% (37/126) of control devices at Month 24 were categorized as indeterminate.

Table 33: Adjacent Level DD – Inferior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	89	31.4%	139	52	37.4%	283	81	28.6%	137	44	32.1%
Doubtful	0	0	.	0	0	.	283	65	23.0%	139	26	18.7%	283	65	23.0%	137	33	24.1%
Minimal	0	0	.	0	0	.	283	15	5.3%	139	12	8.6%	283	16	5.7%	137	11	8.0%
Moderate	0	0	.	0	0	.	283	10	3.5%	139	5	3.6%	283	13	4.6%	137	5	3.6%
Severe	0	0	.	0	0	.	283	9	3.2%	139	3	2.2%	283	8	2.8%	137	3	2.2%
Indeterminate	0	0	.	0	0	.	283	95	33.6%	139	41	29.5%	283	100	35.3%	137	41	29.9%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	74	26.1%	138	44	31.9%	283	66	23.3%	130	34	26.2%	247	53	21.5%	126	28	22.2%
Doubtful	284	68	23.9%	138	32	23.2%	283	77	27.2%	130	30	23.1%	247	71	28.7%	126	33	26.2%
Minimal	284	25	8.8%	138	12	8.7%	283	28	9.9%	130	16	12.3%	247	29	11.7%	126	16	12.7%
Moderate	284	10	3.5%	138	6	4.3%	283	14	4.9%	130	5	3.8%	247	13	5.3%	126	9	7.1%
Severe	284	9	3.2%	138	4	2.9%	283	10	3.5%	130	4	3.1%	247	8	3.2%	126	3	2.4%
Indeterminate	284	98	34.5%	138	40	29.0%	283	88	31.1%	130	41	31.5%	247	73	29.6%	126	37	29.4%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

Angular Motion

Angular motion was defined as the change in angle between the adjacent endplates of the motion segment, and was calculated from lateral flexion-extension radiographs. **Table 34** reports the angular motion of the superior level for each timepoint in both groups. In addition, **Table 35** identifies the angular motion of the inferior level for each timepoint in both groups. The results for both groups, at the inferior and superior levels, suggest that no angular motion is lost over time relative to the pre-operative assessment.

Table 34: Angular Motion Superior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	286	8.43	4.45	8.40	0.00	23.90	138	9.31	4.63	9.00	0.00	24.00	-0.87	-1.74	0.06
Week 06	271	8.79	3.53	9.00	0.50	17.00	136	9.12	3.81	8.70	1.90	21.00	-0.33	-1.08	0.44
Month 03	280	9.89	3.88	9.70	1.00	19.40	137	10.99	4.45	10.80	3.20	24.80	-1.10	-1.94	-0.28
Month 06	282	10.23	4.26	10.65	0.10	22.10	138	12.11	5.08	12.40	1.20	25.10	-1.88	-2.78	-0.97
Month 12	281	9.93	4.67	10.30	0.10	23.70	129	12.04	5.41	12.20	0.90	24.30	-2.11	-3.14	-1.11
Month 24	247	9.36	4.96	9.40	0.10	21.90	124	11.54	5.45	11.70	0.10	25.10	-2.20	-3.33	-1.13

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Table 35: Angular Motion Inferior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	265	6.96	3.84	6.60	0.00	18.00	131	7.41	4.11	7.10	0.00	16.90	-0.44	-1.21	0.40
Week 06	248	8.18	4.08	8.00	0.20	19.00	129	7.06	4.27	6.50	0.00	18.40	1.13	0.27	2.04
Month 03	254	8.97	4.25	8.80	0.10	20.00	125	8.45	4.57	7.80	0.70	19.80	0.52	-0.40	1.44
Month 06	255	9.21	4.41	8.90	0.10	20.30	126	9.88	5.03	9.25	1.10	21.40	-0.68	-1.66	0.28
Month 12	248	8.90	4.72	8.80	0.00	20.10	122	9.32	5.06	8.90	0.70	21.40	-0.41	-1.45	0.63
Month 24	227	8.44	4.86	8.00	0.20	22.20	114	9.39	5.52	9.05	1.10	20.70	-0.97	-2.14	0.13

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Translational Motion

Translational Motion was defined as displacement of the posterior-inferior corner of the superior vertebra in a direction defined parallel to the superior endplate of the inferior vertebra. **Table 36** reports the translational motion of the superior level for each timepoint in both groups. Similarly, **Table 37** identifies the translational motion of the inferior level for each timepoint in both groups. Translational motion at the superior and inferior levels modestly increased at Week 6, and the increase was mostly maintained at later timepoints. The mean change from baseline in both groups was less than 1mm for all post-operative timepoints.

Table 36: Translational Motion Superior Index Level Over Time [mm] (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	285	1.07	0.66	1.00	0.00	3.40	138	1.25	0.76	1.15	0.00	3.50	-0.18	-0.32	-0.04
Week 06	270	1.17	0.56	1.10	0.00	4.40	136	1.51	0.72	1.40	0.20	4.00	-0.34	-0.48	-0.22
Month 03	279	1.29	0.57	1.20	0.00	3.00	137	1.81	0.82	1.80	0.30	4.20	-0.52	-0.66	-0.39
Month 06	281	1.32	0.60	1.30	0.00	3.10	138	2.01	0.97	1.95	0.00	5.20	-0.69	-0.84	-0.54
Month 12	280	1.27	0.66	1.30	0.00	3.10	129	1.97	0.99	2.00	0.00	5.00	-0.70	-0.86	-0.53
Month 24	247	1.16	0.67	1.10	0.00	2.90	124	1.83	0.93	1.80	0.00	4.90	-0.68	-0.85	-0.52

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Table 37: Translational Motion Inferior Index Level Over Time [mm] (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	264	0.58	0.44	0.50	0.00	2.40	131	0.69	0.56	0.60	0.00	2.90	-0.10	-0.20	0.00
Week 06	247	1.05	0.63	1.00	0.00	5.20	129	0.94	0.63	0.80	0.00	2.90	0.11	-0.02	0.26
Month 03	253	1.13	0.60	1.10	0.00	3.30	125	1.14	0.73	1.00	0.00	3.40	-0.01	-0.15	0.13
Month 06	254	1.14	0.61	1.10	0.00	3.40	126	1.33	0.78	1.20	0.10	3.70	-0.19	-0.33	-0.04
Month 12	247	1.11	0.64	1.10	0.00	3.40	122	1.23	0.78	1.10	0.00	3.70	-0.12	-0.27	0.03
Month 24	227	1.01	0.62	1.00	0.00	2.80	114	1.20	0.80	1.05	0.00	3.50	-0.19	-0.35	-0.04

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Global Range of Motion

Global ROM (GROM) was calculated by subtracting the C2-C7 angle in flexion from the C2-C7 angle in extension measured between the inferior endplate of C2 and the inferior endplate of C7.

Table 38 identifies the calculated GROM at the pre-operative and post-operative timepoints. After Week 6, the mean GROM was calculated as increasing relative to the pre-operative timepoint. The mean GROM was calculated as 46.96 degrees in the investigational group and 49.21 degrees in the control group at Month 24, relative to a mean GROM of 43.88 degrees in the investigational group and 45.57 degrees in the control group pre-operatively, suggesting a modestly higher GROM out to 24 months after surgery in both groups.

Table 38: Global Range of Motion (degrees) Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	258	43.88	13.69	43.15	6.50	84.80	129	45.57	15.51	45.60	7.30	95.30	-1.67	-4.55	1.28
Week 06	243	42.32	12.13	41.90	8.90	78.70	127	39.85	12.93	40.60	7.70	73.90	2.50	-0.21	5.14
Month 03	246	45.88	13.45	46.20	16.10	85.30	122	46.29	13.13	46.15	14.50	74.90	-0.38	-3.23	2.48
Month 06	249	47.76	13.58	48.00	10.20	85.40	124	51.32	15.66	50.05	16.50	94.30	-3.56	-6.53	-0.47
Month 12	241	47.74	14.60	48.00	16.70	92.40	119	50.33	14.66	48.20	15.60	98.60	-2.58	-5.80	0.59
Month 24	220	46.96	13.40	47.20	7.60	85.00	113	49.21	15.55	49.10	17.40	94.00	-2.30	-5.31	1.11

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Average Disc Height

Disc height was measured between the anterior-inferior (posterior-inferior) corner of the superior vertebra and the corresponding corner of the inferior vertebra. Average disc height was calculated as the simple mean of the anterior and posterior disc heights.

Table 39 reports the average disc height over time at the superior level. The mean average disc

height increased post-operatively in both groups and was maintained over time. The mean average disc height was calculated as 5.29mm in the investigational group and 5.50mm in the control group at Month 24. **Table 40** reports the average disc height over time at the inferior level. The mean average disc height increased post-operatively in both groups and was maintained over time. The mean average disc height was found to be 5.24mm in the investigational group and 5.51mm in the control group at Month 24.

Table 39: Average Disc Height Superior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	287	3.03	0.80	3.00	0.80	5.10	137	3.12	0.85	3.10	1.30	5.30	-0.09	-0.25	0.08
Post-Op	288	5.60	0.67	5.60	2.30	8.00	139	5.67	0.65	5.60	4.20	8.00	-0.07	-0.19	0.07
Week 06	282	5.56	0.68	5.60	2.30	8.00	139	5.57	0.65	5.60	3.90	8.00	-0.01	-0.15	0.13
Month 03	282	5.53	0.68	5.60	2.20	8.00	136	5.55	0.65	5.60	3.90	8.00	-0.02	-0.15	0.12
Month 06	283	5.49	0.71	5.50	2.30	8.00	138	5.53	0.65	5.50	3.70	7.90	-0.04	-0.17	0.11
Month 12	282	5.43	0.74	5.50	1.90	7.90	130	5.49	0.63	5.50	3.50	7.70	-0.06	-0.22	0.08
Month 24	247	5.29	0.84	5.40	1.90	7.90	125	5.50	0.65	5.50	3.70	7.70	-0.22	-0.40	-0.06

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Table 40: Average Disc Height Inferior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	274	3.17	0.77	3.10	1.30	5.40	132	3.19	0.86	3.10	1.60	6.00	-0.02	-0.19	0.15
Post-Op	275	5.48	0.60	5.60	3.80	7.00	136	5.63	0.72	5.70	3.00	7.60	-0.14	-0.27	-0.01
Week 06	272	5.46	0.60	5.50	3.70	7.00	137	5.54	0.72	5.60	3.00	7.60	-0.08	-0.22	0.05
Month 03	265	5.44	0.60	5.50	3.80	6.90	134	5.52	0.74	5.50	2.80	7.60	-0.09	-0.22	0.05
Month 06	268	5.42	0.60	5.50	3.60	6.80	137	5.53	0.71	5.60	3.00	7.50	-0.12	-0.24	0.02
Month 12	272	5.36	0.62	5.40	3.50	6.80	128	5.52	0.72	5.60	3.00	7.50	-0.17	-0.31	-0.03
Month 24	237	5.24	0.72	5.30	2.70	6.80	122	5.51	0.71	5.55	3.10	7.50	-0.28	-0.42	-0.11

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Disc Angle

Disc angle was measured as the angle formed between the endplates of adjacent vertebrae. A disc angle greater than 0 degrees corresponds to local lordosis, while a disc angle less than 0 degrees corresponds to local kyphosis.

Table 41 reports the disc angle over time at the superior level. The mean disc angle increased post-operatively in both groups and was maintained over time. The mean disc angle was calculated as 6.76 degrees in the investigational group and 8.53 degrees in the control group at Month 24. **Table 42** reports the disc angle over time at the inferior level. The mean disc angle increased post-operatively in both groups and was maintained over time. The mean disc angle was found to be 4.88 degrees in the investigational group and 6.10 degrees in the control group at Month 24.

Table 41: Disc Angle Superior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	288	2.03	4.17	1.95	-10.60	12.20	137	2.44	4.46	2.70	-9.40	11.60	-0.40	-1.26	0.43
Post-Op	289	6.97	4.71	7.30	-8.80	18.00	139	8.03	5.00	8.50	-4.20	19.80	-1.05	-1.97	-0.09
Week 06	283	7.07	4.75	7.00	-7.20	17.60	139	8.43	5.44	8.50	-5.00	20.40	-1.36	-2.41	-0.36
Month 03	283	7.04	4.76	7.30	-7.00	17.30	136	8.24	5.58	8.25	-5.40	25.10	-1.19	-2.21	-0.20
Month 06	284	6.79	4.76	7.15	-7.70	18.30	138	8.31	5.68	8.50	-4.60	22.30	-1.53	-2.54	-0.51
Month 12	283	6.68	4.89	7.20	-9.00	17.50	130	8.69	5.95	9.30	-3.80	25.50	-2.01	-3.07	-0.90
Month 24	247	6.76	5.02	6.90	-10.50	17.30	125	8.53	5.92	8.90	-3.30	25.50	-1.80	-2.98	-0.70

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Table 42: Disc Angle Inferior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	275	2.44	4.06	2.60	-10.00	15.90	132	3.61	3.78	3.55	-5.10	14.10	-1.17	-1.95	-0.33
Post-Op	276	4.77	4.69	4.65	-11.90	18.80	136	5.95	4.93	6.10	-7.50	16.10	-1.17	-2.09	-0.21
Week 06	273	5.05	4.80	5.00	-10.70	20.00	137	6.04	5.12	6.60	-8.60	17.30	-0.98	-1.98	0.06
Month 03	266	5.09	4.75	4.90	-10.10	18.90	134	5.84	5.09	6.60	-8.60	15.40	-0.74	-1.79	0.21
Month 06	269	5.09	4.67	4.90	-7.70	18.00	137	5.90	5.00	6.20	-6.70	16.30	-0.81	-1.77	0.16
Month 12	273	5.02	4.81	4.60	-7.80	18.80	128	6.11	5.31	7.10	-7.90	16.20	-1.08	-2.14	-0.06
Month 24	237	4.88	4.67	4.90	-8.50	18.90	122	6.10	5.28	6.70	-6.60	16.20	-1.24	-2.24	-0.15

Subjects censored at Index level secondary surgical interventions.
*Device group mean differences and 95% Credible Intervals.
Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

Device Retrieval

Should it be necessary to remove a prodisc ® C SK and/or prodisc ® C Vivo, please contact Centinel Spine to receive instructions regarding the data collection, including histopathological, mechanical, and adverse event information. Please refer to the prodisc ® C SK and prodisc ® C Vivo Surgical Technique Guide for information regarding the required surgical technique for device retrieval and instructions for returning the explanted device to Centinel Spine. All explanted devices must be returned to Centinel Spine for analysis.

Please note that the disc replacement device 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.

Symbols:

Catalog Number

Lot Number

See Instructions For Use

Do not reuse

Do not re-sterilize

Sterile using irradiation

Expiration Date (YYYY-MM)

CENTINEL SPINE®

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