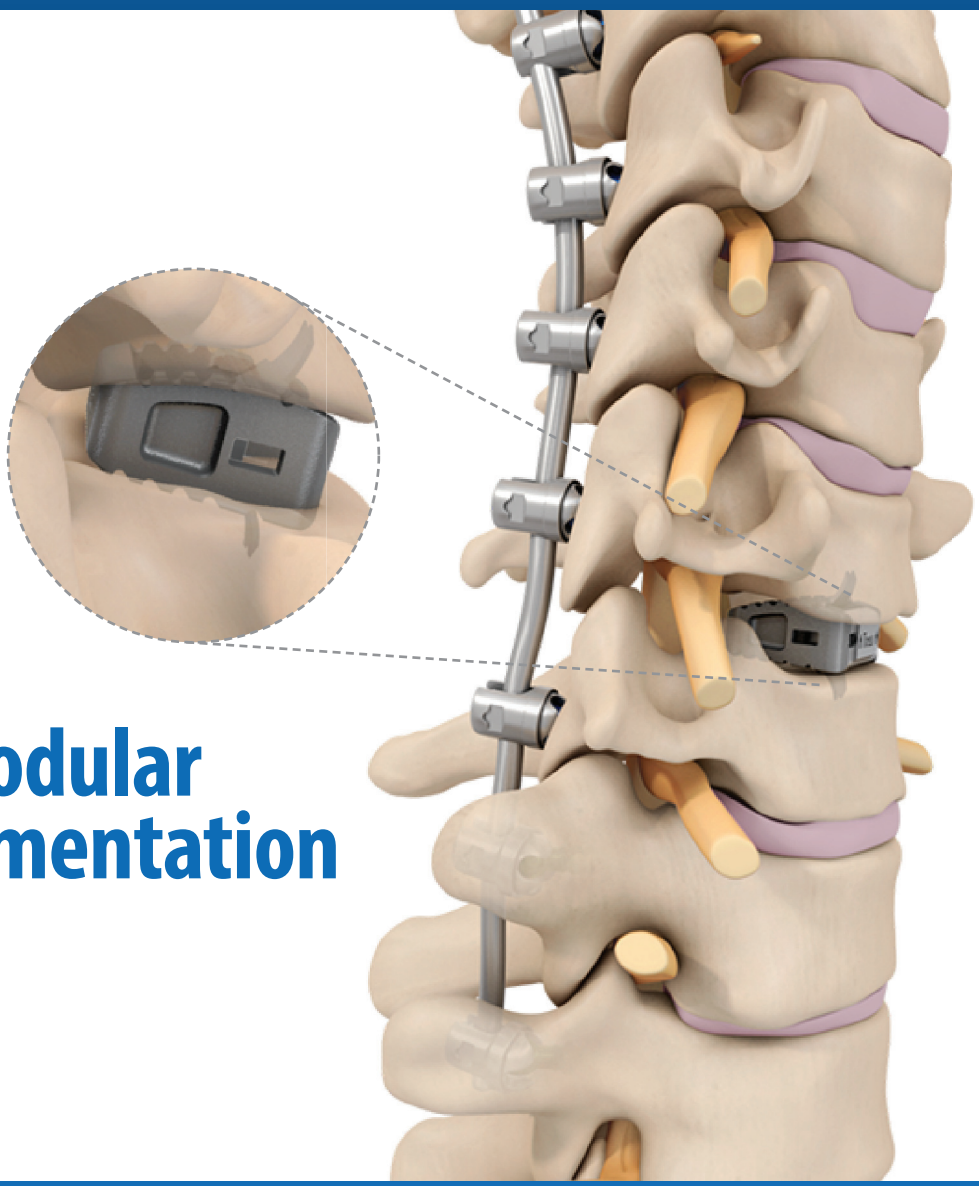
Paramount®

Anterior Cervical Cage

SURGICAL TECHNIQUE



Modular Instrumentation

SpineWave

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SYSTEM OVERVIEW

Controlled Anchor Plate Deployment

- Threaded deployment avoids aggressive impaction of anchor plates in the cervical spine
- Both anchor plates deploy simultaneously, simplifying the procedure

Maximized Grafting

- Post-packing is designed to optimize graft material to endplate contact
- Roughened titanium implant design increases surface area for bone-implant interface

Less Invasive

- Self-contained anchor plates are deployed in the same plane as the disc space, minimizing the exposure

IMPLANT DESIGN

Cage

- Roughened, titanium alloy
- Anatomic & lordotic profile options
    - Anatomic implants have 3° of lordosis and Lordotic implants have 7° of lordosis
- Size offering
    - 14 (W) mm x 12 (D) mm x 5-10 (H) mm, Lordotic
    - 15.5 (W) mm x 14 (D) mm x 5-10 (H) mm, Lordotic
    - 14 (W) mm x 12 (D) mm x 5-8 (H) mm, Anatomic
    - 15.5 (W) mm x 14 (D) mm x 5-8 (H) mm, Anatomic

Anchor Plate

- CP titanium

Graft Containment Plate

- PEEK-Optima with 6% barium sulfate
- Size specific to each width and height

Paramount® Anterior Cervical Cage and Paramount® Graft Containment Plates are sterile packed individually.

STEP 1 SURGICAL APPROACH

After properly positioning the patient in the supine position, expose the vertebral bodies to be fused. Prepare the fusion site using an appropriate technique (see Figure 1).

Note: *Careful preparation and cage sizing helps to achieve optimal results.*

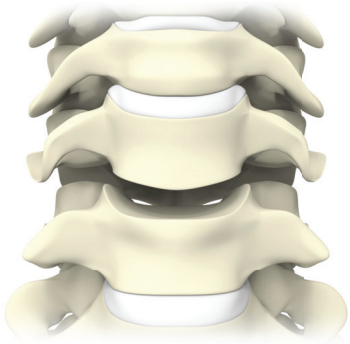
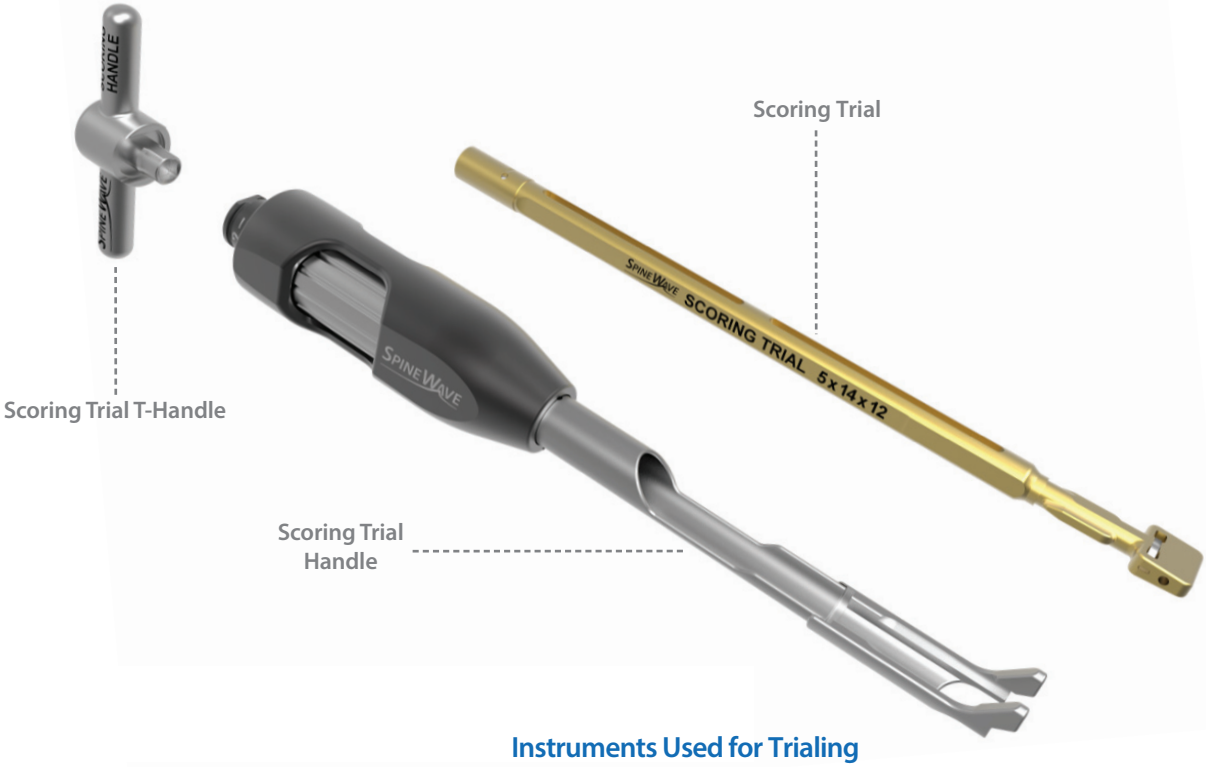


Figure 1

STEP 2 TRIALING



Instruments Used for Trialing

After choosing the appropriate footprint, begin with the smallest height trial and sequentially trial until the desired fit is achieved. Trials are offered in both lordotic and anatomic shapes in footprints of 14 mm x 12 mm and 15.5 mm x 14 mm.

Note: *Anatomic trials range in height from 5-8 mm (1 mm increments) and lordotic trials range in height from 5-10 mm (1 mm increments).*

Note: *Trials are color coordinated based on footprint (15.5 mm x 14 mm trials are silver and 14 mm x 12 mm trials are gold).*

STEP 3 ENDPLATE SCORING

Adjust the depth setting on the scoring trial handle by turning the knob counterclockwise to the load/unload position (see Figure 2). The load/unload position is when the depth setting is flush with the handle. Slide the trial into the scoring trial handle.

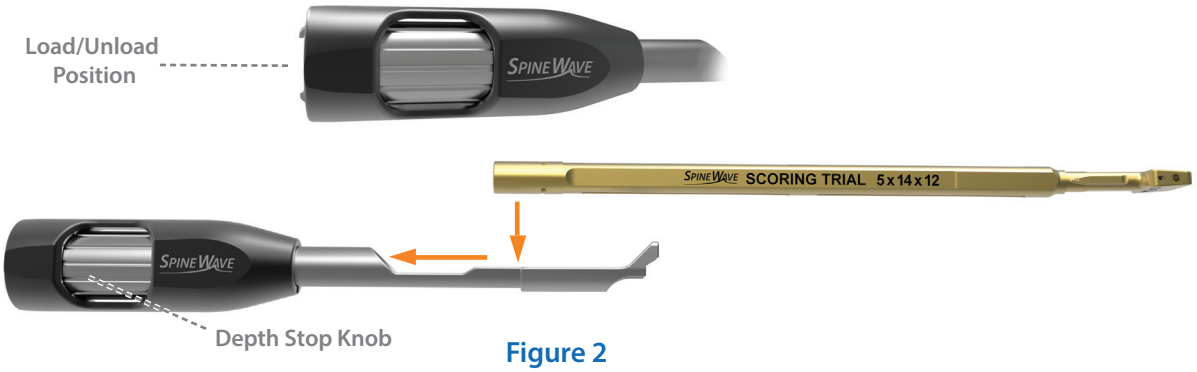


Figure 2

Lock the trial in the handle by turning the knob clockwise until the depth setting reads "0" (see Figure 3).

Note: *The depth setting is read on the scoring trial handle and implant inserter where the indicators reference 0, 1, or 2.*

Figure 3

Insert the trial into the disc space until the depth stop contacts the anterior aspect of the vertebral body (see Figure 4).

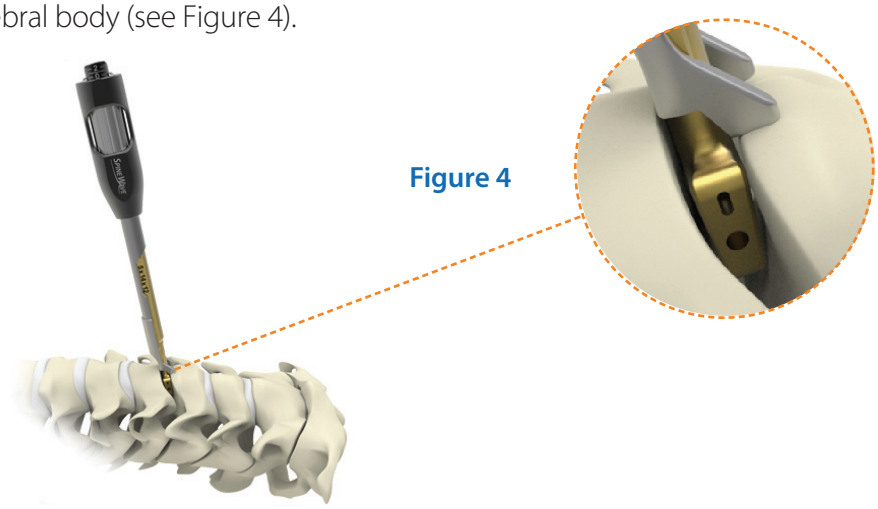


Figure 4

Note: *Ensure the trial cutter is recessed in the trial prior to insertion to prevent damage to the instrument or vertebral body.*

STEP 3 ENDPLATE SCORING (CONTINUED)

The depth setting can be adjusted in 1 mm increments by turning the knob.

Note: *The depth stop position (also referred to as "countersink") is the distance from the distal face of the depth stop to the anterior surface of the trial head. The countersink settings are 0, 1, and 2 which are equivalent to countersink depths 2 mm, 3 mm, and 4 mm, respectively.*

Once the trial is in its final position, insert the T-handle into the proximal end of the scoring trial handle to engage the cutter. Depress the T-handle and rotate to score the endplates (see Figure 5).

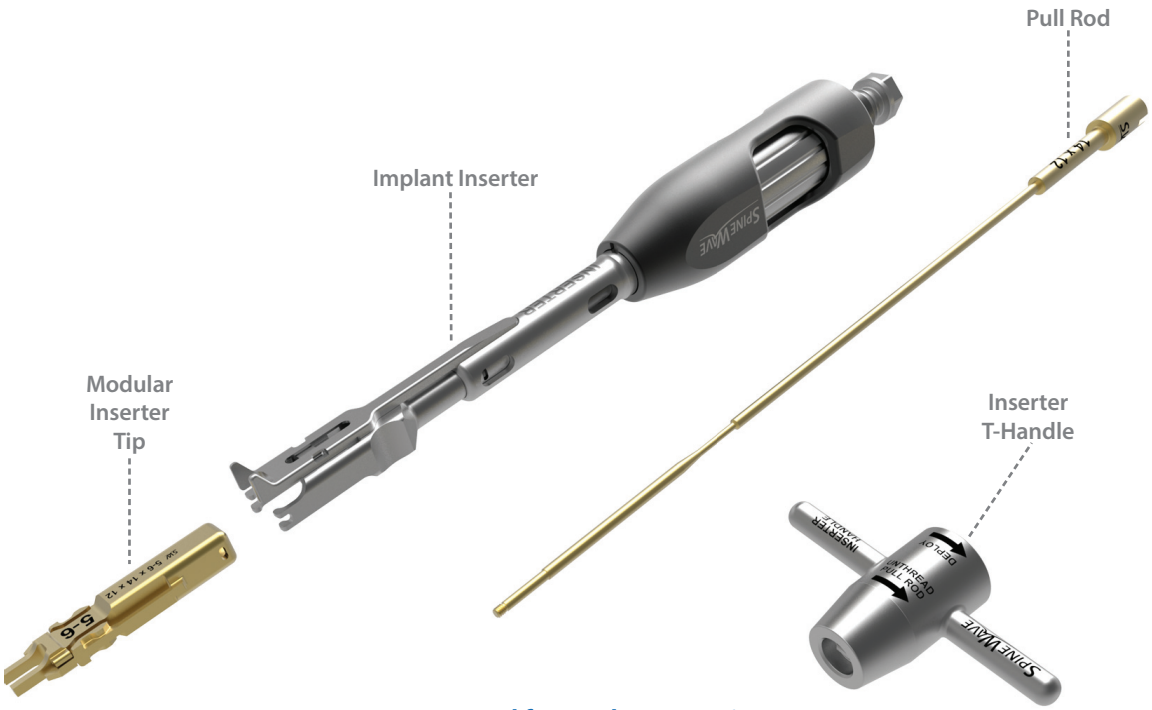
Note: *The trial cutter is designed to penetrate ~1.5 mm into each endplate.*

Return the cutter to the recessed position and remove T-handle prior to removing the scoring trial from disc space.

TIP: To prevent damage to the instrument or vertebral body, the scoring trial T-handle cannot be removed if the cutter is exposed.

Figure 5

STEP 4 INSERTER ASSEMBLY



Instruments used for Implant Insertion

Adjust the inserter depth setting to match the scoring trial depth setting.

Insert the corresponding modular tip until an audible click is heard. Confirm the modular tip is secure by visualizing the locking sleeve resting in the notches (see Figure 6).

Note: *Modular tips are color coordinated based on footprint (15.5 mm x 14 mm tips are silver and 14 mm x 12 mm tips are gold). Modular tips also correspond to implant height (e.g. 5-6, 7-8, 9-10).*

TIP: An audible click indicates that the modular tip is fully seated.

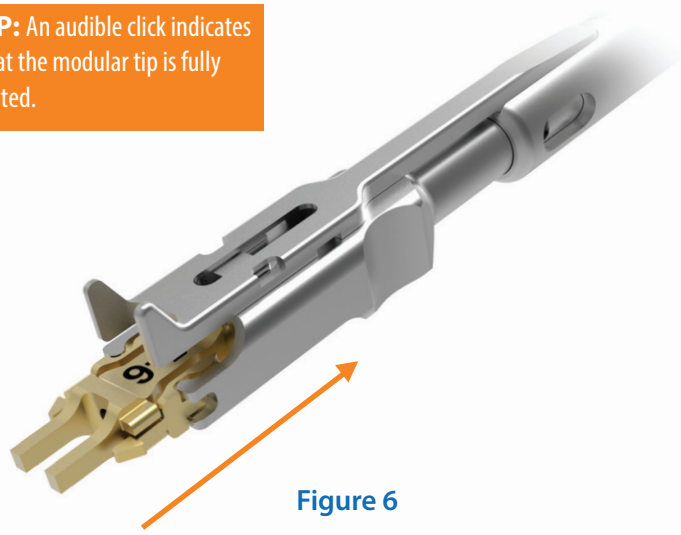


Figure 6

STEP 5 IMPLANT INSERTION

Fully seat the implant onto the inserter tip. An audible click and direct visualization will indicate the implant is loaded properly (see Figure 7).

Note: *Visually inspect the connection between the implant and inserter to ensure the retractable clips are fully engaged with the cage.*

Note: *When using an anatomic implant, visually inspect the connection to ensure the implant is loaded in the correct orientation.*

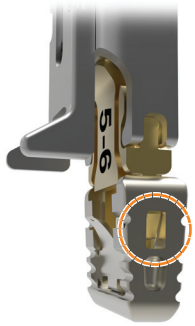


Figure 7

Turn the hex feature at the proximal end of the inserter handle counterclockwise to ensure it is all the way forward. Select the pull rod that matches the implant footprint. Insert the pull rod through the center cannulation of the inserter (see Figure 8). Thread the pull rod into the anchor blades until it is finger tight.

Note: *The pull rods are color coordinated based on footprint (15.5 mm x 14 mm pull rods are silver and 14 mm x 12 mm pull rods are gold).*

Figure 8

Insert the implant into the disc space by gently impacting the top of the pull rod until the inserter depth stop contacts the anterior aspect of the vertebral body (see Figure 9).

TIP: Fluoroscopy can be used to confirm the implant position.

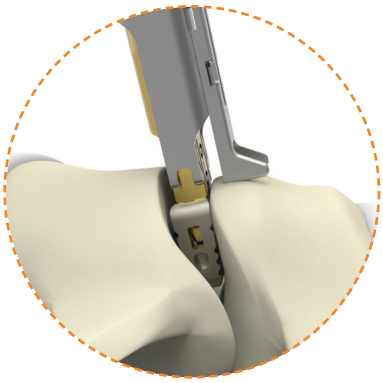


Figure 9

STEP 5 IMPLANT INSERTION (CONTINUED)

Slide the inserter T-handle over the pull rod (see Figure 10). Rotate the inserter T-handle clockwise to advance the anchor plates into the vertebral bodies (see Figure 11). The anchor plates are fully deployed when the inserter T-handle can no longer rotate.

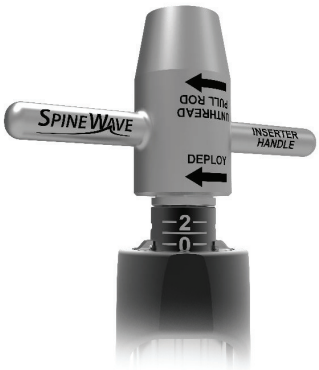


Figure 10

Figure 11

STEP 6 INSERTER REMOVAL

There are two sequential steps to release the insterter from the implant. First, adjust the inserter depth stop to the "release position"(see Figure 12). The release position is when the depth setting is flush with the handle.

Note: *If the anchor plate is not fully deployed the depth stop cannot be adjusted to the release position.*

Release Position

Figure 12

Second, unthread the pull rod by turning counter clockwise (see Figure 13). Remove the inserter from the disc space.

Note: *The opposite side of the inserter T-handle can be used to loosen the pull rod.*

Note: *Removing the pull rod prior to releasing the implant may allow the modular tip to disengage from the inserter*

Figure 13

STEP 7 GRAFT CONTAINMENT PLATE INSERTION

Pack bone graft into the cage through windows on either side of anchor plate (see Figure 14).

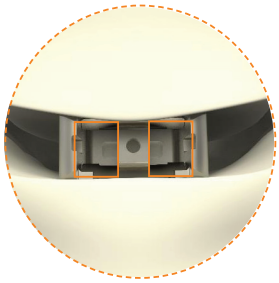


Figure 14

Select the mating graft containment plate. Use the forceps to insert the graft containment plate by snapping the hooks into side windows of the cage (see Figure 15).

Note: *Graft containment plates are width and height specific.*

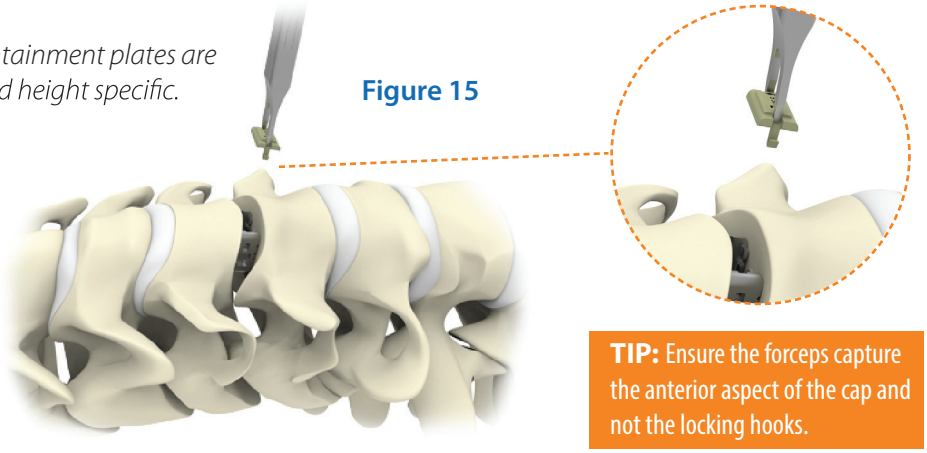


Figure 15

TIP: Ensure the forceps capture the anterior aspect of the cap and not the locking hooks.

STEP 8 POSTERIOR SUPPLEMENTAL FIXATION

Paramount® Anterior Cervical Cage is indicated with posterior supplemental fixation. Complete posterior fixation procedure by following the steps indicated in the respective surgical technique.

STEP 9 IMPLANT REMOVAL

To remove an implant, the anchor plates must not be impeded by graft. Remove the graft containment plate by using the forceps to grasp the graft containment plate and pull out. This step can be accomplished with a standard surgical grasper, such as a rongeur. Dock the removal instrument outer sleeve onto the implant by aligning the hooks of the instrument with the lateral slots of the cage. Fully advance the plunger to engage the implant by applying downward pressure and threading the plunger into the outer sleeve. Distract the corresponding disc space to eliminate compression. While distracting, pull back on the removal instrument to remove the entire implant from the disc space.

Note: *Use fluoroscopy to confirm the anchor plates are retracted to starting position.*

Note: *Do not remove the plunger prior to removal of the implant construct from the disc space.*

PRODUCT CATALOG

Paramount® Anterior Cervical Cage

Catalog #	Description
21-8920	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 5 (H) mm, 7° Lordotic
21-8921	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 6 (H) mm, 7° Lordotic
21-8922	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 7 (H) mm, 7° Lordotic
21-8923	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 8 (H) mm, 7° Lordotic
21-8924	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 9 (H) mm, 7° Lordotic
21-8925	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 10 (H) mm, 7° Lordotic
21-8936	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 5 (H) mm, 7° Lordotic
21-8937	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 6 (H) mm, 7° Lordotic
21-8938	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 7 (H) mm, 7° Lordotic
21-8939	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 8 (H) mm, 7° Lordotic
21-8940	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 9 (H) mm, 7° Lordotic
21-8941	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 10 (H) mm, 7° Lordotic
21-8952	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 5 (H) mm, Anatomic
21-8953	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 6 (H) mm, Anatomic
21-8954	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 7 (H) mm, Anatomic
21-8955	Paramount® Anterior Cervical Cage with Plate, 14 (W) x 12 (L) x 8 (H) mm, Anatomic
21-8968	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 5 (H) mm, Anatomic
21-8969	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 6 (H) mm, Anatomic
21-8970	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 7 (H) mm, Anatomic
21-8971	Paramount® Anterior Cervical Cage with Plate, 15.5 (W) x 14 (L) x 8 (H) mm, Anatomic

Paramount® Graft Containment Plates

Catalog #	Description
21-9009	Paramount® Graft Containment Plate, 14 (W) x 5 (H) mm
21-9010	Paramount® Graft Containment Plate, 14 (W) x 6 (H) mm
21-9011	Paramount® Graft Containment Plate, 14 (W) x 7 (H) mm
21-9012	Paramount® Graft Containment Plate, 14 (W) x 8 (H) mm
21-9013	Paramount® Graft Containment Plate, 14 (W) x 9 (H) mm
21-9014	Paramount® Graft Containment Plate, 14 (W) x 10 (H) mm
21-9017	Paramount® Graft Containment Plate, 15.5 (W) x 5 (H) mm
21-9018	Paramount® Graft Containment Plate, 15.5 (W) x 6 (H) mm
21-9019	Paramount® Graft Containment Plate, 15.5 (W) x 7 (H) mm
21-9020	Paramount® Graft Containment Plate, 15.5 (W) x 8 (H) mm
21-9021	Paramount® Graft Containment Plate, 15.5 (W) x 9 (H) mm
21-9022	Paramount® Graft Containment Plate, 15.5 (W) x 10 (H) mm

INSTRUMENT OVERVIEW

Scoring Trial Handle

Trial

Scoring Trial T-Handle

Implant Inserter

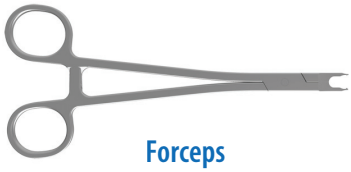
Pull Rod

Insterter T-Handle

Modular Inserter Tip

Removal Tool
(15.5 mm x 14 mm, 14 mm x 12 mm)

Removal Tool, Plunger



Forceps

Catalog #	Description
10-9020	Implant Inserter
10-9021	Modular Inserter Tip, 14 (W) x 12 (L) x 5/6 (H) mm
10-9022	Modular Inserter Tip, 14 (W) x 12 (L) x 7/8 (H) mm
10-9023	Modular Inserter Tip, 14 (W) x 12 (L) x 9/10 (H) mm
10-9024	Modular Inserter Tip, 15.5 (W) x 14 (L) x 5/6 (H) mm
10-9025	Modular Inserter Tip, 15.5 (W) x 14 (L) x 7/8 (H) mm
10-9026	Modular Inserter Tip, 15.5 (W) x 14 (L) x 9/10 (H) mm
10-9027	Inserter, Pull Rod, 14 x 12
10-9019	Inserter, Pull Rod, 15.5 x 14
10-9028	Inserter T-Handle
10-9029	Scoring Trial Handle
10-9058	Scoring Trial T-Handle
10-5490	Implant Removal Tool, 14 x 12
10-5492	Implant Removal Tool, 15.5 x 14
10-5489	Removal Tool, Plunger
10-5621	Forceps

Catalog #	Description
10-9030	Trial, 14 (W) x 12 (L) x 5 (H) mm, Lordotic
10-9031	Trial, 14 (W) x 12 (L) x 6 (H) mm, Lordotic
10-9032	Trial,14 (W) x 12 (L) x 7 (H) mm, Lordotic
10-9033	Trial, 14 (W) x 12 (L) x 8 (H) mm, Lordotic
10-9034	Trial, 14 (W) x 12 (L) x 9 (H) mm, Lordotic
10-9035	Trial, 14 (W) x 12 (L) x 10 (H) mm, Lordotic
10-9036	Trial, 15.5 (W) x 14 (L) x 5 (H) mm, Lordotic
10-9037	Trial, 15.5 (W) x 14 (L) x 6 (H) mm, Lordotic
10-9038	Trial, 15.5 (W) x 14 (L) x 7 (H) mm, Lordotic
10-9039	Trial, 15.5 (W) x 14 (L) x 8 (H) mm, Lordotic
10-9040	Trial, 15.5 (W) x 14 (L) x 9 (H) mm, Lordotic
10-9041	Trial, 15.5 (W) x 14 (L) x 10 (H) mm, Lordotic
10-9042	Trial, 14 (W) x 12 (L) x 5 (H) mm, Anatomic
10-9043	Trial, 14 (W) x 12 (L) x 6 (H) mm, Anatomic
10-9044	Trial, 14 (W) x 12 (L) x 7 (H) mm, Anatomic
10-9045	Trial, 14 (W) x 12 (L) x 8 (H) mm Anatomic
10-9046	Trial, 15.5 (W) x 14 (L) x 5 (H) mm, Anatomic
10-9047	Trial, 15.5 (W) x 14 (L) x 6 (H) mm, Anatomic
10-9048	Trial, 15.5 (W) x 14 (L) x 7 (H) mm, Anatomic
10-9049	Trial, 15.5 (W) x 14 (L) x 8 (H) mm, Anatomic

PRODUCT DESCRIPTION

The Paramount® Anterior Cervical Spine System consists of a family of cervical intervertebral body fusion devices that are available in multiple shapes and sizes to accommodate a range of anatomies. The Paramount® Anterior Cervical devices are multi-component devices that are comprised of cage body, anchor plate and graft containment plate that are assembled in-situ. The cage body of the implant is manufactured from Ti-6Al-4V (ASTM F136), the anchor plates are manufactured from unalloyed titanium (ASTM F67), and the graft containment plates are manufactured from PEEK-OPTIMA with 6% BaSO4.

NOTE: Please refer to the package label of this device for the implant dimensions and endplate configuration.

INDICATIONS FOR USE

The Paramount® Anterior Cervical Spine System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) weeks of nonoperative treatment. The Paramount® Anterior Cervical Spine System is to be used with autogenous bone graft and placed via an open, anterior approach; supplemental fixation (i.e., posterior cervical screw fixation) is required to properly utilize this system.

CONTRAINDICATIONS

The Paramount® Anterior Cervical Spine System is contraindicated for:

- Morbid obesity.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Any case where the implants or components selected would be either too large or too small to achieve a successful result.
- Uncorrectable coagulopathy or hemorrhagic diathesis.
- Allergy or sensitivity to any component of the treatment procedure.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Presence of fever, leukocytosis or acute, chronic, systemic, or localized infection.
- Inadequate tissue coverage over the operative site or inadequate bone stock, or bone quality.
- Anatomy or other factor that prohibits safe surgical access to the surgical body.
- Pediatric case or case where patient still has general skeletal growth.
- Any patient unwilling or unable to follow postoperative instructions.
- Mental illness.
- Pregnancy.
- Prior fusion at the level to be treated.
- Any condition not described in the indications for use.

WARNINGS AND PRECAUTIONS

- As this is a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of the device should be performed only by experienced spinal surgeons with specific training in the use of this device.
- Preoperative and operative procedures, including knowledge of surgical techniques and proper selection and placement of the implant are important considerations in the success of the surgery.
- Never reuse a surgical implant under any circumstances. Even when a removed implant appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Implants removed from a patient that has had contact with bodily tissues or fluids should never be reused at risk of contamination of the patient.
- Potential risks identified with the use of this system, which may require additional surgery, include device component fracture; loss of fixation; pseudoarthrosis (i.e., non-union); fracture of the vertebra; neurological injury; and vascular or visceral injury.
- Placement and adjustment of the Paramount® Anterior Cervical Spine System implant must only be done with the inserter instrument supplied with the system.
- Posterior supplemental fixation is required to properly utilize this system.
- The surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions that may impact the performance of the intervertebral body fusion device.
- Provide the patient with adequate instructions for postoperative care. The patient must be made aware of the limitations of the implants. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on them in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration and damage to nerves or blood vessels.
- A successful result is not always achieved in every surgical case. This is especially true in spinal surgery where other patient conditions may compromise the results.
- Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.
- Proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised and warned of this consequence. Patient who are obese, malnourished, and/or abuse alcohol abuse are also poor candidates for spine fusion.
- The Paramount® Anterior Cervical Spine System has not been evaluated for safety and compatibility in the MR environment. The Paramount™ Anterior Cervical Spine System has not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS

Possible adverse events with the use of this system include but are not limited to:

- Early or late loosening of the components.
- Implant migration.
- Disassembly, bending, and/or breakage of any or all of the components.
- Implant material sensitivity, or allergic reaction to a foreign body, including tumor formation and/or autoimmune disease.
- Infection, early or late.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
- Neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Bone loss or decrease in bone density due to stress shielding.
- Subsidence of the device into the vertebral body or bodies.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function resulting in inability to perform the activities of daily living.
- Pseudarthrosis, delayed union and/or mal-union.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the autograft or at the autograft harvest site.
- Autograft donor site complications including pain, fracture, infection, or wound healing problems.
- Herniated nucleus pulposis, disc disruption or degeneration above, or below the level of surgery.
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Wound necrosis or wound dehiscence.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

If such events occur, the intended clinical outcome may not be achieved.

HOW SUPPLIED

Please refer to corresponding instructions for use for information on sterility, cleaning, and sterilization.

PRODUCT COMPLAINTS

Any health care professional who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance of this device, should notify Spine Wave, Inc. If any Spine Wave, Inc. product "malfunctions" and may have caused or contributed to the death or serious injury of a patient, Spine Wave, Inc. should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, please provide the component(s) name(s), catalog number(s), lot number(s), your name and address, the nature of the complaint, and notification of whether a written report is requested.

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PATENT INFORMATION

Covered by one or more U.S. patents or patent applications.
See www.spinewave.com/contact_legal.html for details.

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