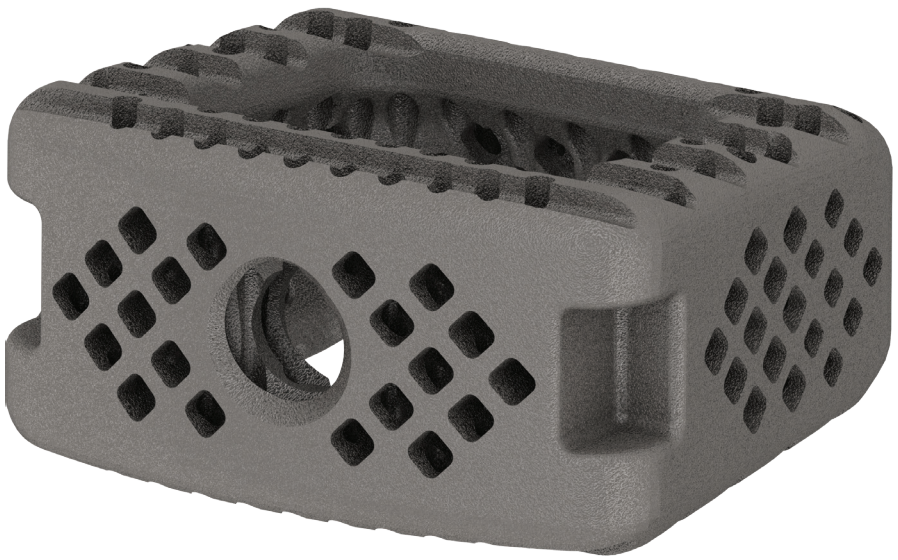
stryker

Cascadia®

Cervical 3D Interbody System



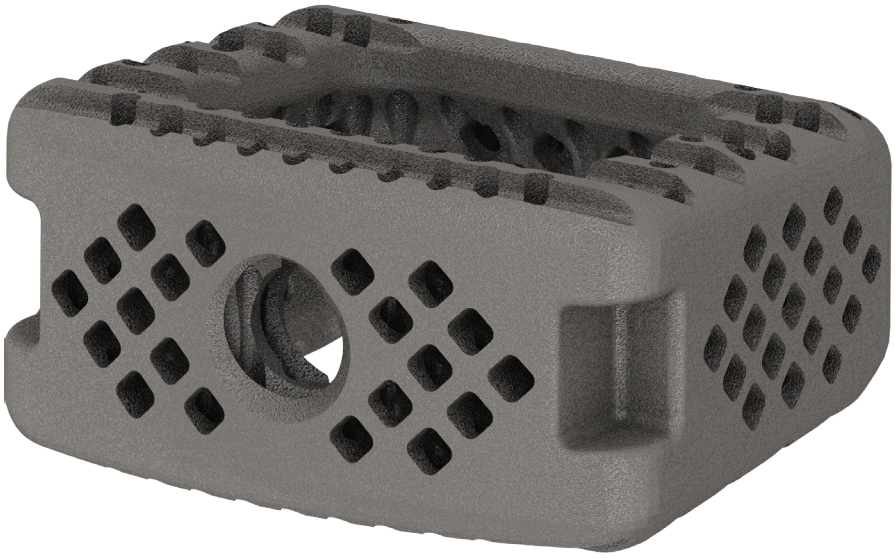
Surgical technique guide

Table of contents

Surgical technique steps

Product catalog

This publication sets for detailed recommended procedures for using the Cascadia Cervical 3D Interbody System. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient, and make appropriate adjustments when and as required.

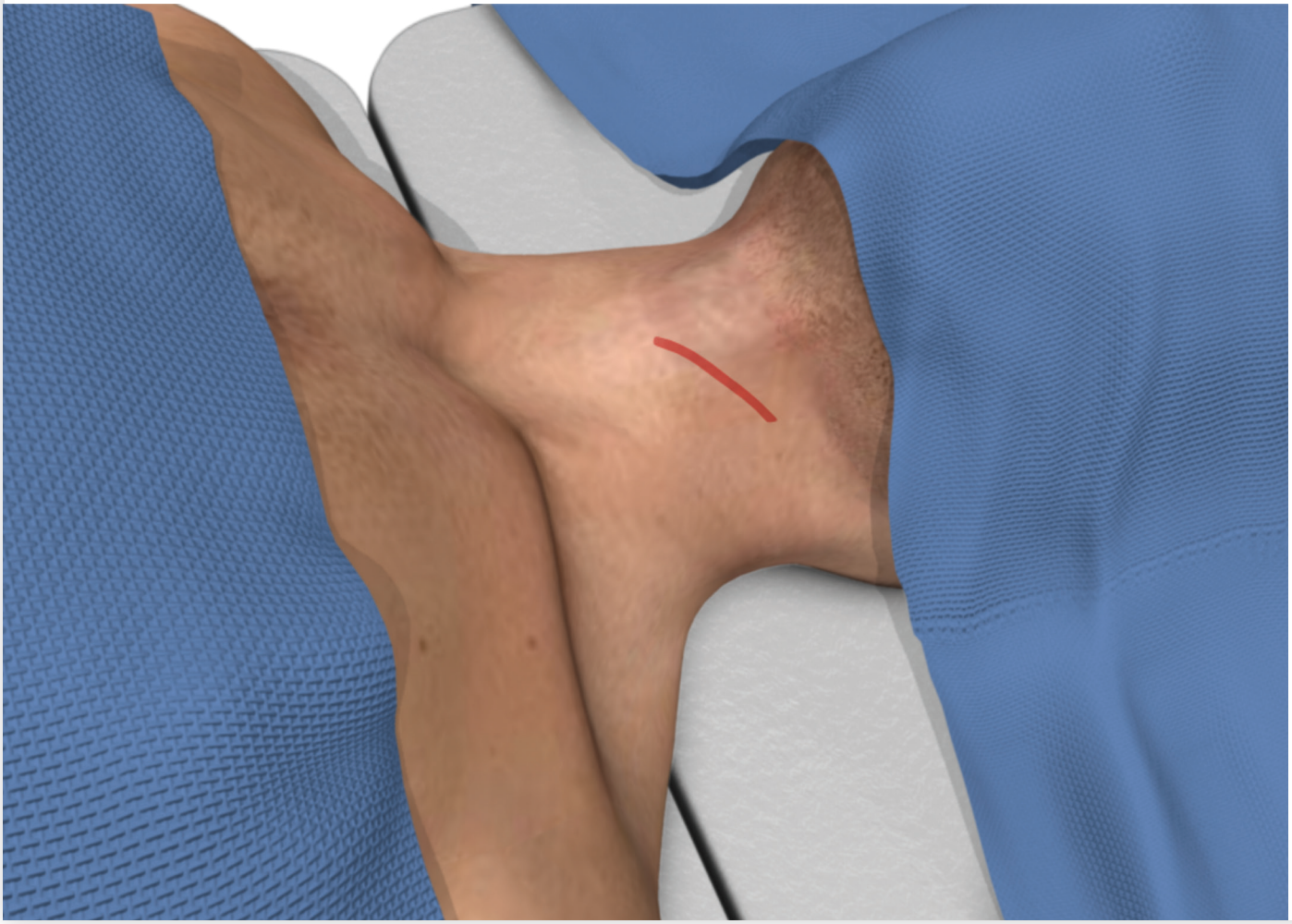


Surgical technique

Step 1

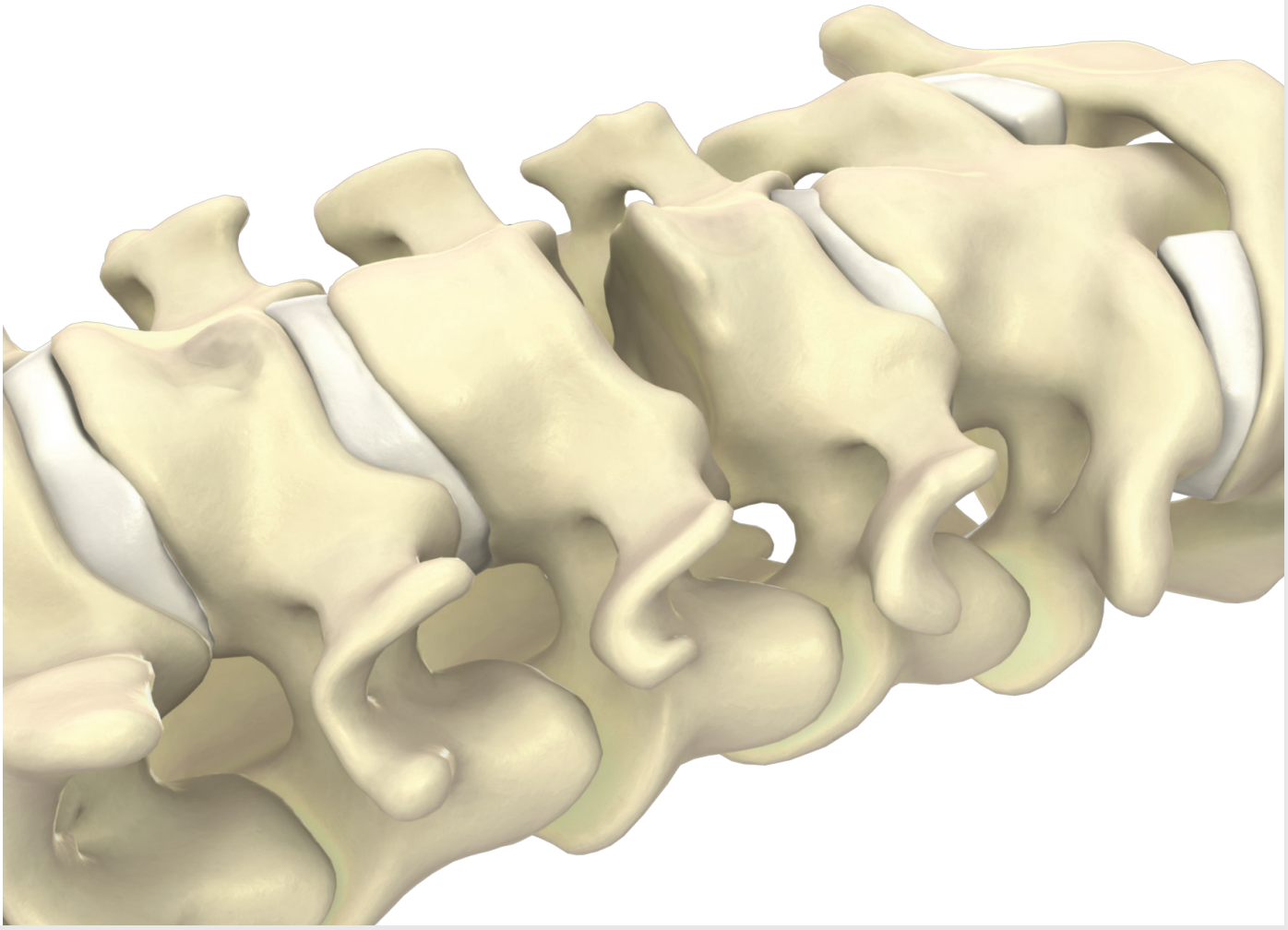
Planning, approach, and patient positioning

Pre-surgical planning helps define the type of construct, the most appropriate implants, and the optimal implant location. The Cascadia Cervical 3D Interbody System set is designed to facilitate the anterior surgical approach.



Discectomy and endplate preparation

Perform a standard incision and exposure of the ventral cervical spine and then complete a standard discectomy. A 5mm, 7° Rasp in both footprints is available to help prepare the vertebral endplates. Removal of the superficial layers of cartilaginous endplates results in exposure of bleeding bone.

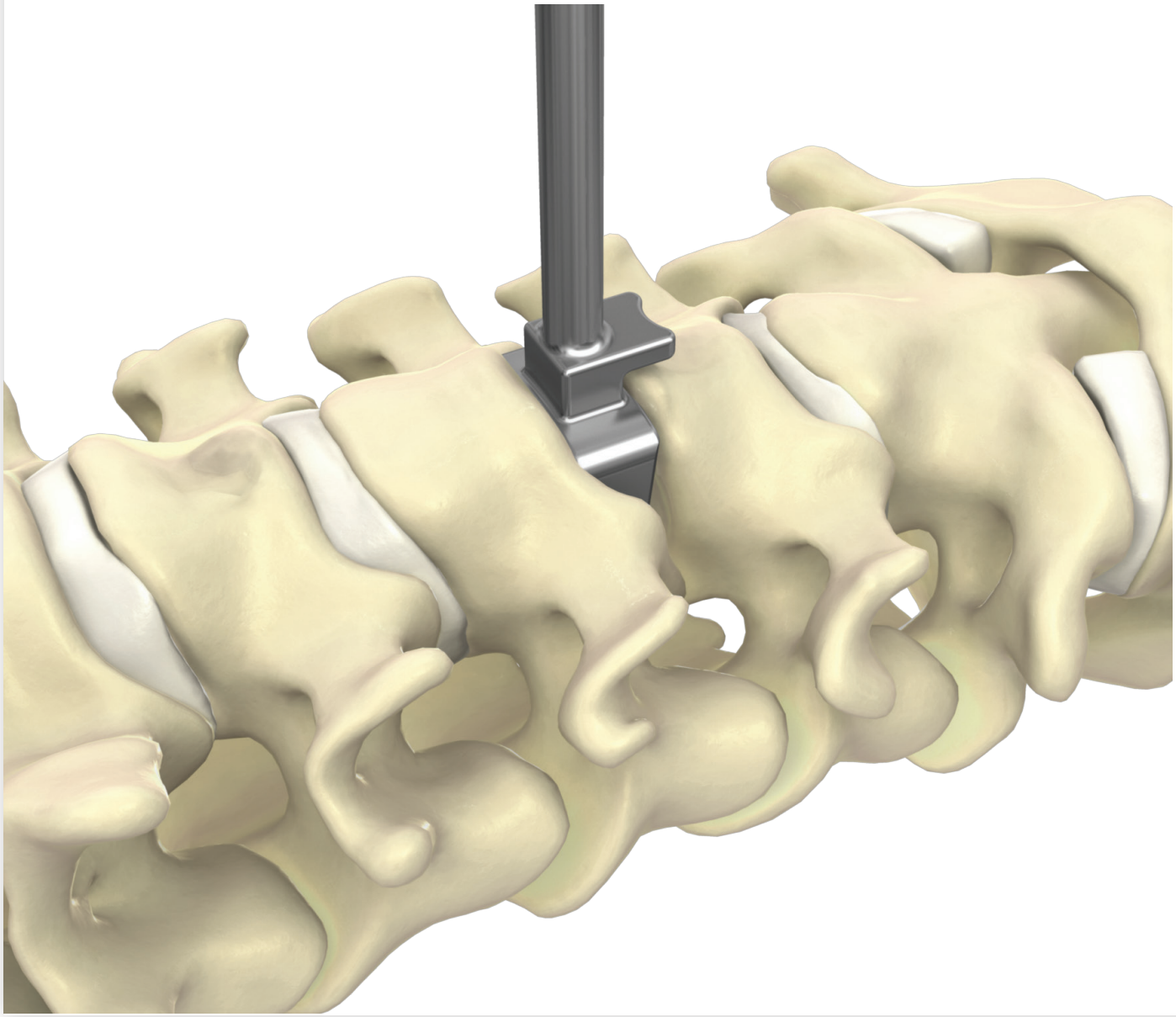


Rasp

Step 3

Determining interbody size

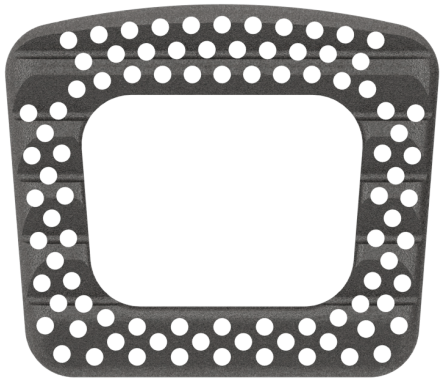
Trials are available to aid in the initial test fitting and size confirmation of the interbody. Trials are 0.5mm undersized to allow for a slight press fit of the interbody. If the Trial appears to be too small, gradually increase the size until a secure fit is achieved.



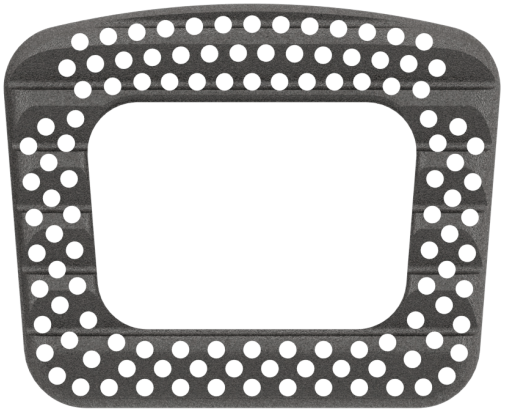
Interbody selection

An appropriately sized interbody is chosen at the discretion of the surgeon. The interbody should be securely seated with a tight fit between the endplates when the segment is fully distracted. Interbodies are sized at 12 x 14 and 13 x 16mm and are available in 0°, 7°, and 12° of lordosis. Heights range from 5 - 13mm in 1mm increments.

The height of the interbody is measured from the tip-of-tooth to tip-of-tooth. The implant should be tightly packed with autogenous or allograft bone graft prior to implantation. Packing bone graft may be achieved by using standard surgical tools, such as a Bone Tamp, or may be packed by hand depending on surgeon preference.



12 x 14mm
0°, 7°, and 12° lordosis



13 x 16mm
0°, 7°, and 12° lordosis

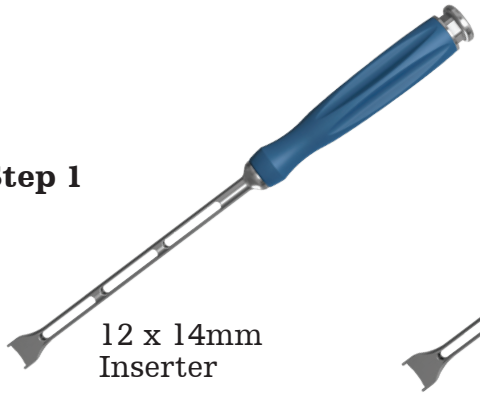
Step 5

Interbody insertion

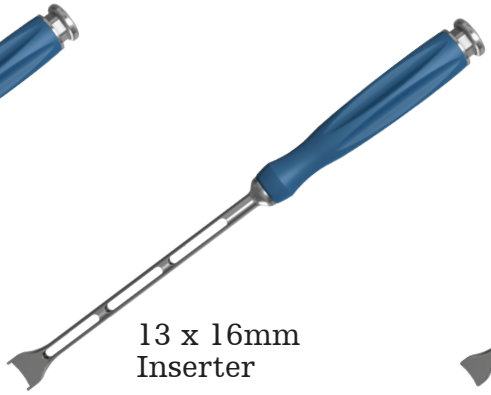
To ensure proper use of the Inserter, complete the following steps:

1. Choose the Inserter for the corresponding interbody footprint or the Universal Inserter.
2. Insert the Inner Shaft through the proximal end of the Inserter and rotate clockwise 1 - 2 turns to engage the threads.
3. Load the interbody onto the distal end of the Inserter, making sure the interbody is loaded onto the tongs.
4. Turn the Inner Shaft thumbwheel on the proximal end in a clockwise direction to secure the implant.

Step 1



12 x 14mm Inserter

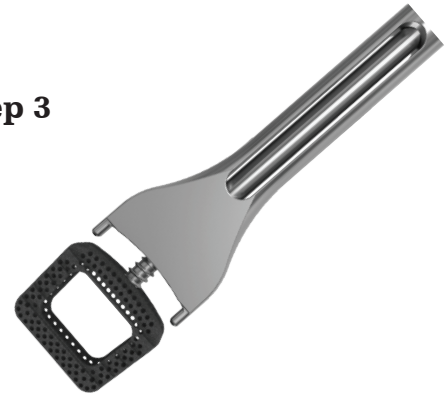


13 x 16mm Inserter

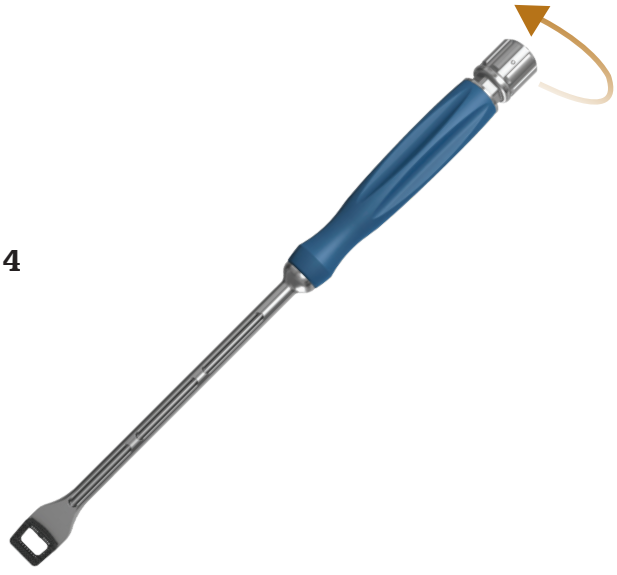
Universal Inserter

Step 2

Step 3

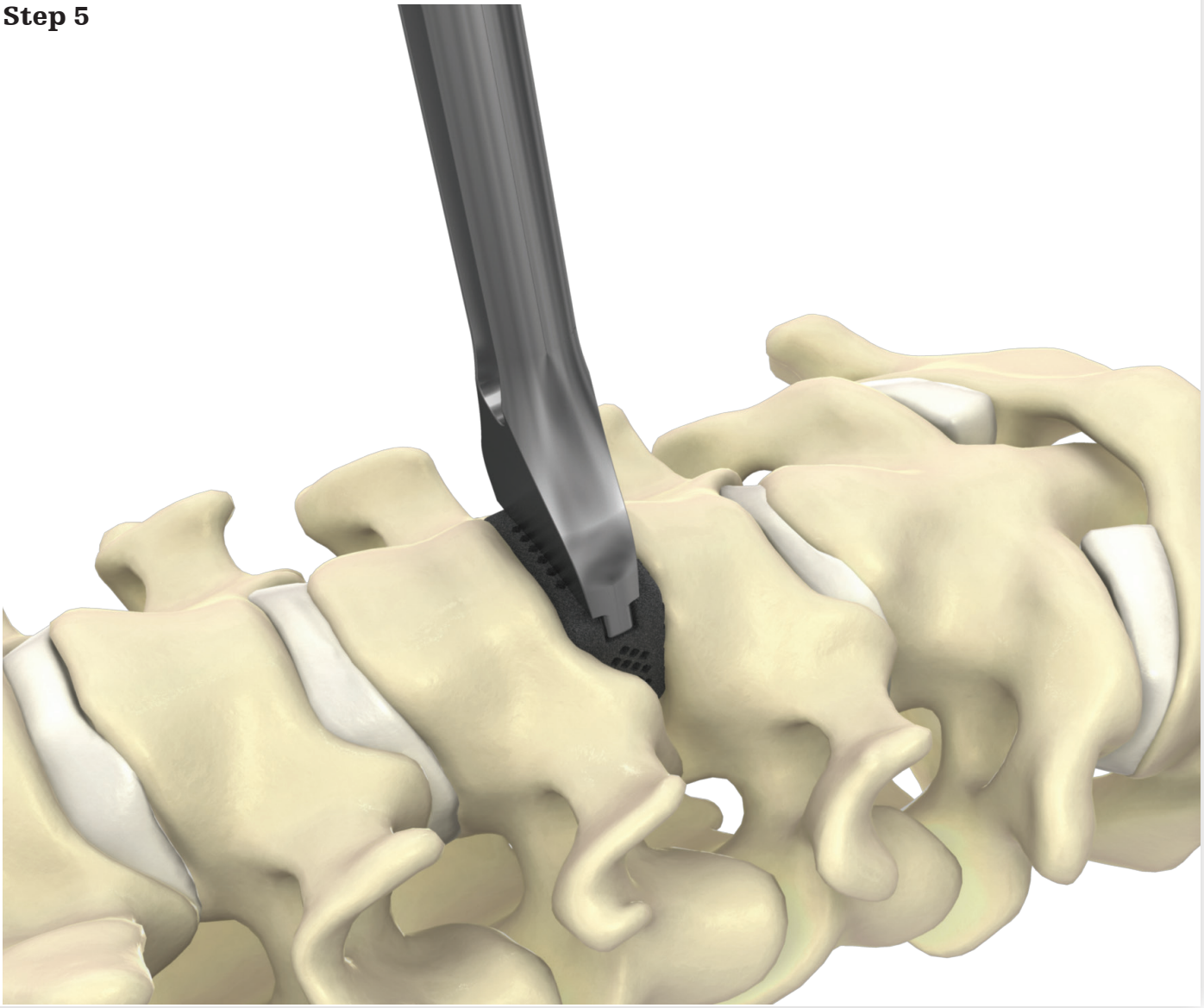


Step 4



5. After the interbody is properly seated in the disc space, turn the Inner Shaft thumbwheel in a counter-clockwise direction to disengage the interbody.

Step 5

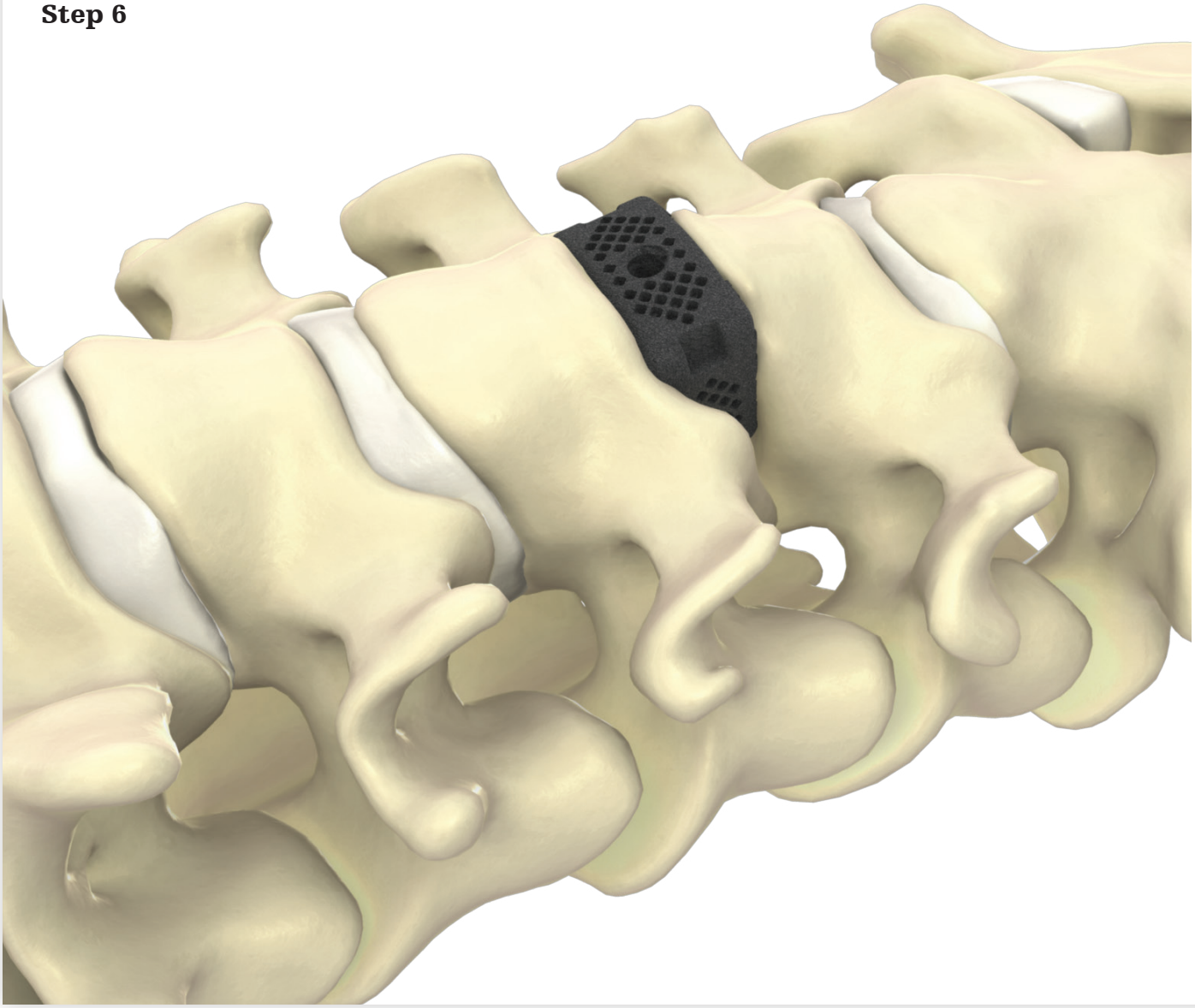


Step 5

Interbody insertion (cont.)

6. The Small Mallet and Straight Impactor may be used to aid in implant placement. X-ray or fluoroscopy may be used live or periodically to verify placement.

Step 6

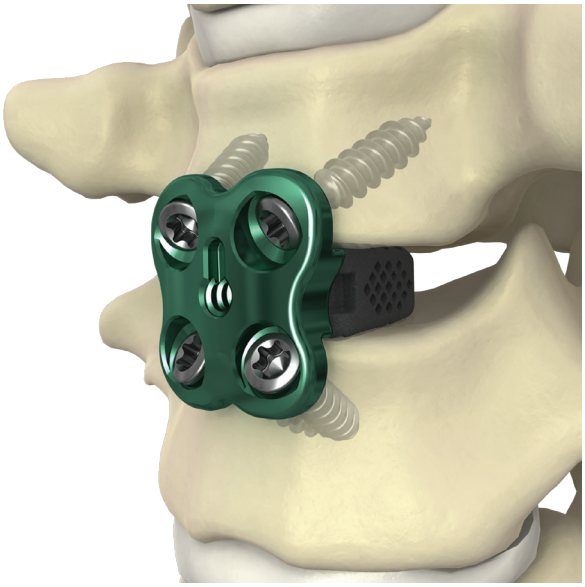


Wound closure

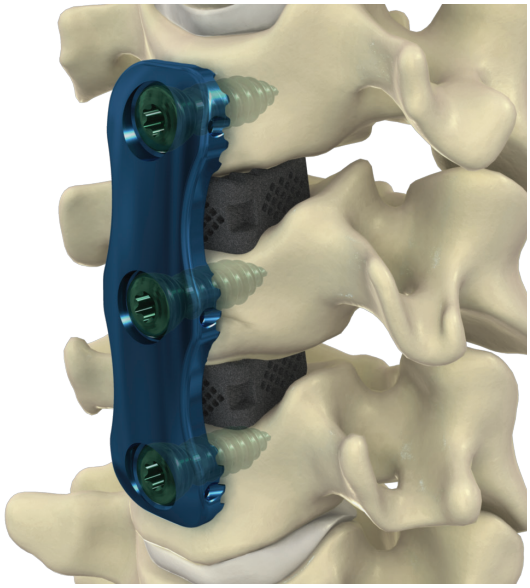
When the construct, including supplemental fixation, is complete, perform a standard multi-layer wound closure.

Should implant removal be necessary, the appropriate implant Inserter and Inner Shaft can be re-attached to the implant and used for removal.

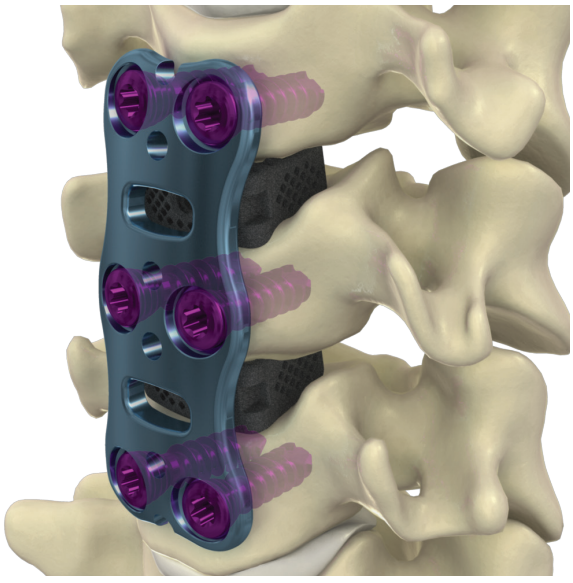
Note: To help prevent graft expulsion or for additional anterior support, the Pyrenees, Aviator or Ozark Cervical Plate Systems may be used. See the Pyrenees or Blue Ridge Surgical Techniques for additional instructions.



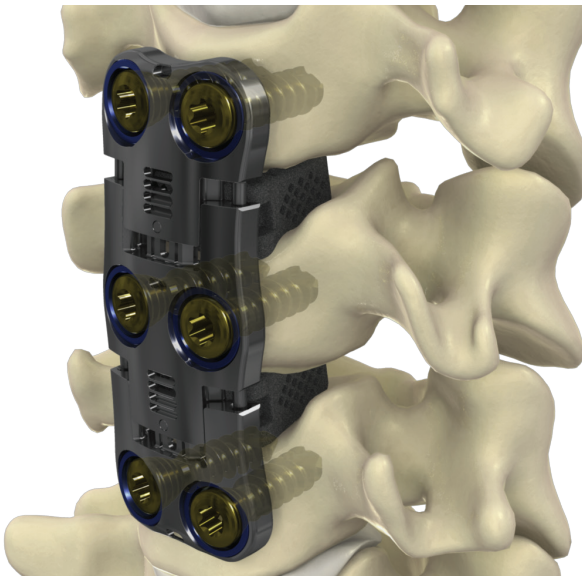
Pictured with Pyrenees Segmental Cervical Plate System



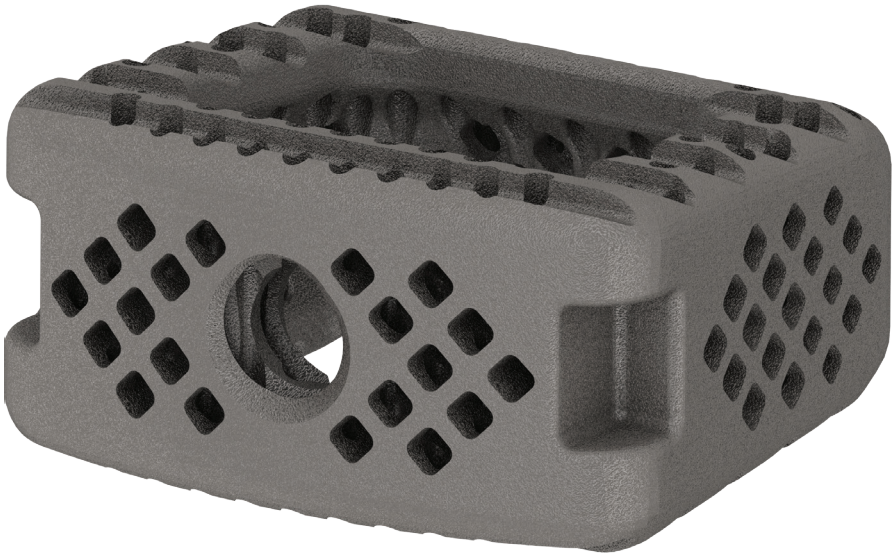
Pictured with Pyrenees Mono Cervical Plate System



Pictured with Pyrenees Constrained Cervical Plate System

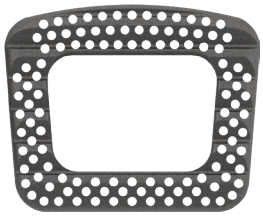


Pictured with Pyrenees Translational Cervical Plate System



Product catalog

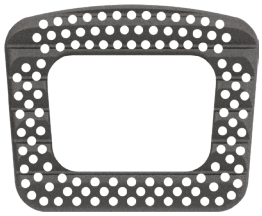
12 x 14mm



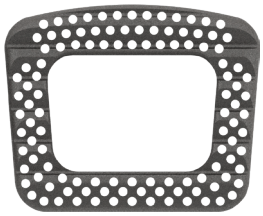
13 x 16mm

Reference number	Description Height x Depth x Width x Lordotic angle
6101-2121405CP-G2	12 x 14 x 5mm, 0° Cervical Interbody
6101-2121406CP-G2	12 x 14 x 6mm, 0° Cervical Interbody
6101-2121407CP-G2	12 x 14 x 7mm, 0° Cervical Interbody
6101-2121408CP-G2	12 x 14 x 8mm, 0° Cervical Interbody
6101-2121409CP-G2	12 x 14 x 9mm, 0° Cervical Interbody
6101-2121410CP-G2	12 x 14 x 10mm, 0° Cervical Interbody
6101-2121411CP-G2	12 x 14 x 11mm, 0° Cervical Interbody
6101-2121412CP-G2	12 x 14 x 12mm, 0° Cervical Interbody
6101-2131605CP-G2	13 x 16 x 5mm, 0° Cervical Interbody
6101-2131606CP-G2	13 x 16 x 6mm, 0° Cervical Interbody
6101-2131607CP-G2	13 x 16 x 7mm, 0° Cervical Interbody
6101-2131608CP-G2	13 x 16 x 8mm, 0° Cervical Interbody
6101-2131609CP-G2	13 x 16 x 9mm, 0° Cervical Interbody
6101-2131610CP-G2	13 x 16 x 10mm, 0° Cervical Interbody
6101-2131611CP-G2	13 x 16 x 11mm, 0° Cervical Interbody
6101-2131612CP-G2	13 x 16 x 12mm, 0° Cervical Interbody

Implants



	Reference number	Description Height x Depth x Width x Lordotic angle
12 x 14mm	6101-2121405CL7-G2	12 x 14 x 5mm, 7° Cervical Interbody
	6101-2121406CL7-G2	12 x 14 x 6mm, 7° Cervical Interbody
	6101-2121407CL7-G2	12 x 14 x 7mm, 7° Cervical Interbody
	6101-2121408CL7-G2	12 x 14 x 8mm, 7° Cervical Interbody
	6101-2121409CL7-G2	12 x 14 x 9mm, 7° Cervical Interbody
	6101-2121410CL7-G2	12 x 14 x 10mm, 7° Cervical Interbody
	6101-2121411CL7-G2	12 x 14 x 11mm, 7° Cervical Interbody
	6101-2121412CL7-G2	12 x 14 x 12mm, 7° Cervical Interbody
13 x 16mm	6101-2131605CL7-G2	13 x 16 x 5mm, 7° Cervical Interbody
	6101-2131606CL7-G2	13 x 16 x 6mm, 7° Cervical Interbody
	6101-2131607CL7-G2	13 x 16 x 7mm, 7° Cervical Interbody
	6101-2131608CL7-G2	13 x 16 x 8mm, 7° Cervical Interbody
	6101-2131609CL7-G2	13 x 16 x 9mm, 7° Cervical Interbody
	6101-2131610CL7-G2	13 x 16 x 10mm, 7° Cervical Interbody
	6101-2131611CL7-G2	13 x 16 x 11mm, 7° Cervical Interbody
	6101-2131612CL7-G2	13 x 16 x 12mm, 7° Cervical Interbody



	Reference number	Description Height x Depth x Width x Lordotic angle
12 x 14mm	6101-2121406CL12-G2	12 x 14 x 6mm, 12° Cervical Interbody
	6101-2121407CL12-G2	12 x 14 x 7mm, 12° Cervical Interbody
	6101-2121408CL12-G2	12 x 14 x 8mm, 12° Cervical Interbody
	6101-2121409CL12-G2	12 x 14 x 9mm, 12° Cervical Interbody
	6101-2121410CL12-G2	12 x 14 x 10mm, 12° Cervical Interbody
	6101-2121411CL12-G2	12 x 14 x 11mm, 12° Cervical Interbody
	6101-2121412CL12-G2	12 x 14 x 12mm, 12° Cervical Interbody
	6101-2121413CL12-G2	12 x 14 x 13mm, 12° Cervical Interbody
13 x 16mm	6101-2131606CL12-G2	13 x 16 x 6mm, 12° Cervical Interbody
	6101-2131607CL12-G2	13 x 16 x 7mm, 12° Cervical Interbody
	6101-2131608CL12-G2	13 x 16 x 8mm, 12° Cervical Interbody
	6101-2131609CL12-G2	13 x 16 x 9mm, 12° Cervical Interbody
	6101-2131610CL12-G2	13 x 16 x 10mm, 12° Cervical Interbody
	6101-2131611CL12-G2	13 x 16 x 11mm, 12° Cervical Interbody
	6101-2131612CL12-G2	13 x 16 x 12mm, 12° Cervical Interbody
	6101-2131613CL12-G2	13 x 16 x 13mm, 12° Cervical Interbody

Instruments

Catalog #	Description
6101-90019	5mm, 12 x 14mm, 7° Lordotic Rasp
402-90314	5mm, 13 x 16mm, 7° Lordotic Rasp
402-90236	Inserter, 14mm
402-90232	Inserter, 16mm
6101-90138	Implant Inserter
402-90237	Cervical Inserter, Inner Shaft

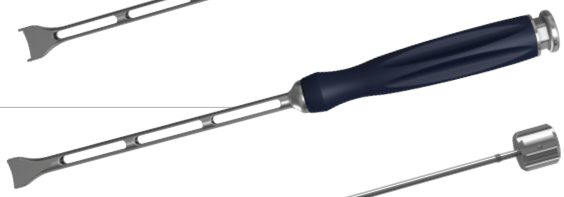
5mm, 12 x 14mm, 7° Lordotic Rasp

5mm, 13 x 16mm, 7° Lordotic Rasp

Inserter, 14mm

Inserter, 16mm

Implant Inserter



Cervical Inserter, Inner Shaft

Catalog #	Description (Height, Depth x Width)
402-90338	5mm, 12 x 14mm, 0° Parallel Trial
402-90339	6mm, 12 x 14mm, 0° Parallel Trial
402-90340	7mm, 12 x 14mm, 0° Parallel Trial
402-90341	8mm, 12 x 14mm, 0° Parallel Trial
402-90342	9mm, 12 x 14mm, 0° Parallel Trial
402-90343	10mm, 12 x 14mm, 0° Parallel Trial
402-90344	11mm, 12 x 14mm, 0° Parallel Trial
402-90345	12mm, 12 x 14mm, 0° Parallel Trial

5mm, 12 x 14mm, 0° Parallel Trial

6mm, 12 x 14mm, 0° Parallel Trial

7mm, 12 x 14mm, 0° Parallel Trial

8mm, 12 x 14mm, 0° Parallel Trial

9mm, 12 x 14mm, 0° Parallel Trial

10mm, 12 x 14mm, 0° Parallel Trial

11mm, 12 x 14mm, 0° Parallel Trial

12mm, 12 x 14mm, 0° Parallel Trial

Trials

Catalog #	Description (Height, Depth x Width)
402-90393	5mm, 13 x 16mm, 0° Parallel Trial
402-90394	6mm, 13 x 16mm, 0° Parallel Trial
402-90395	7mm, 13 x 16mm, 0° Parallel Trial
402-90396	8mm, 13 x 16mm, 0° Parallel Trial
402-90397	9mm, 13 x 16mm, 0° Parallel Trial
402-90398	10mm, 13 x 16mm, 0° Parallel Trial
402-90399	11mm, 13 x 16mm, 0° Parallel Trial
402-90400	12mm, 13 x 16mm, 0° Parallel Trial

5mm, 13 x 16mm, 0° Parallel Trial

6mm, 13 x 16mm, 0° Parallel Trial

7mm, 13 x 16mm, 0° Parallel Trial

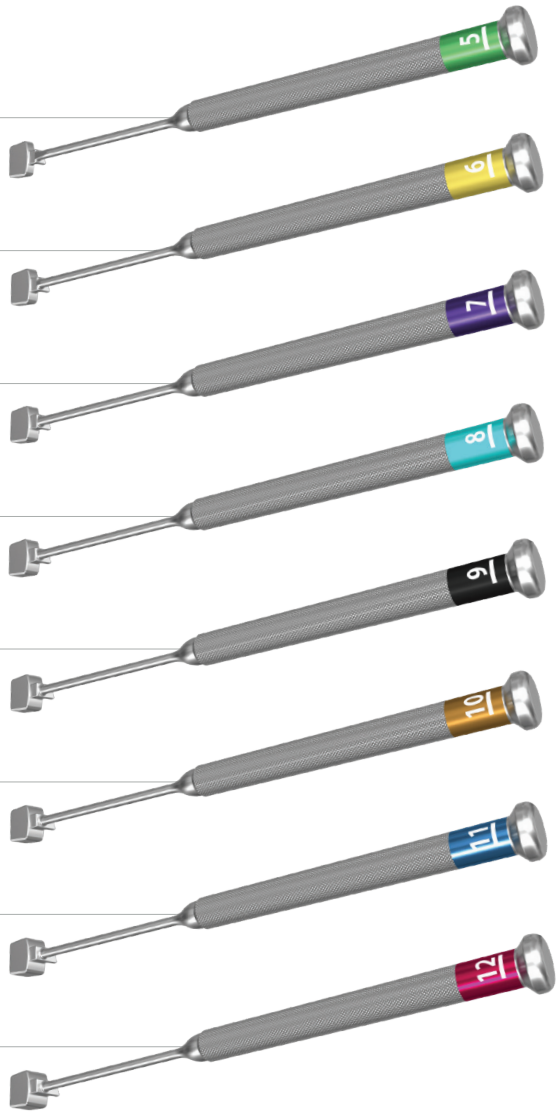
8mm, 13 x 16mm, 0° Parallel Trial

9mm, 13 x 16mm, 0° Parallel Trial

10mm, 13 x 16mm, 0° Parallel Trial

11mm, 13 x 16mm, 0° Parallel Trial

12mm, 13 x 16mm, 0° Parallel Trial



Catalog #	Description (Height, Depth x Width)
402-90177	5mm, 12 x 14mm, 7° Lordotic Trial
402-90178	6mm, 12 x 14mm, 7° Lordotic Trial
402-90179	7mm, 12 x 14mm, 7° Lordotic Trial
402-90180	8mm, 12 x 14mm, 7° Lordotic Trial
402-90181	9mm, 12 x 14mm, 7° Lordotic Trial
402-90182	10mm, 12 x 14mm, 7° Lordotic Trial
402-90183	11mm, 12 x 14mm, 7° Lordotic Trial
402-90184	12mm, 12 x 14mm, 7° Lordotic Trial

5mm, 12 x 14mm, 7° Lordotic Trial

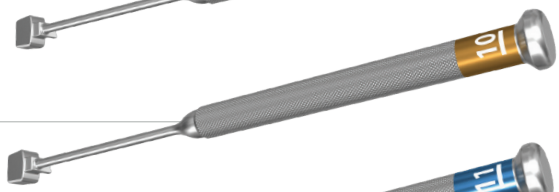
6mm, 12 x 14mm, 7° Lordotic Trial

7mm, 12 x 14mm, 7° Lordotic Trial

8mm, 12 x 14mm, 7° Lordotic Trial

9mm, 12 x 14mm, 7° Lordotic Trial

10mm, 12 x 14mm, 7° Lordotic Trial



11mm, 12 x 14mm, 7° Lordotic Trial

12mm, 12 x 14mm, 7° Lordotic Trial

Trials

Catalog #	Description (Height, Depth x Width)
402-90188	5mm, 13 x 16mm, 7° Lordotic Trial
402-90189	6mm, 13 x 16mm, 7° Lordotic Trial
402-90190	7mm, 13 x 16mm, 7° Lordotic Trial
402-90191	8mm, 13 x 16mm, 7° Lordotic Trial
402-90192	9mm, 13 x 16mm, 7° Lordotic Trial
402-90193	10mm, 13 x 16mm, 7° Lordotic Trial
402-90194	11mm, 13 x 16mm, 7° Lordotic Trial
402-90195	12mm, 13 x 16mm, 7° Lordotic Trial

5mm, 13 x 16mm, 7° Lordotic Trial

6mm, 13 x 16mm, 7° Lordotic Trial

7mm, 13 x 16mm, 7° Lordotic Trial

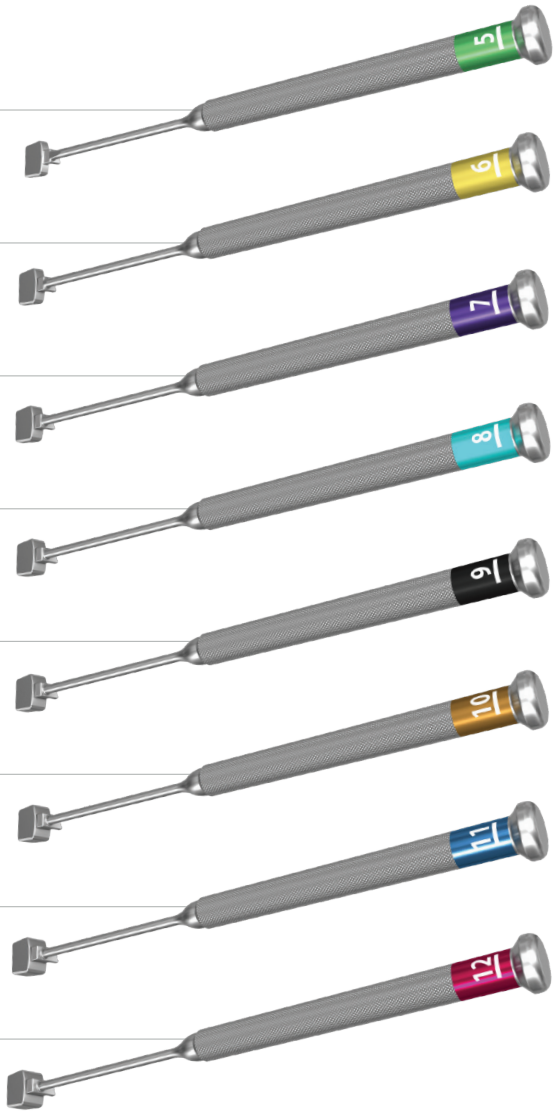
8mm, 13 x 16mm, 7° Lordotic Trial

9mm, 13 x 16mm, 7° Lordotic Trial

10mm, 13 x 16mm, 7° Lordotic Trial

11mm, 13 x 16mm, 7° Lordotic Trial

12mm, 13 x 16mm, 7° Lordotic Trial



Catalog #	Description (Height, Depth x Width)
402-90349	6mm, 12 x 14mm, 12° Lordotic Trial
402-90350	7mm, 12 x 14mm, 12° Lordotic Trial
402-90351	8mm, 12 x 14mm, 12° Lordotic Trial
402-90352	9mm, 12 x 14mm, 12° Lordotic Trial
402-90353	10mm, 12 x 14mm, 12° Lordotic Trial
402-90354	11mm, 12 x 14mm, 12° Lordotic Trial
402-90355	12mm, 12 x 14mm, 12° Lordotic Trial
402-90356	13mm, 12 x 14mm, 12° Lordotic Trial

6mm, 12 x 14mm, 12° Lordotic Trial

7mm, 12 x 14mm, 12° Lordotic Trial

8mm, 12 x 14mm, 12° Lordotic Trial

9mm, 12 x 14mm, 12° Lordotic Trial

10mm, 12 x 14mm, 12° Lordotic Trial

11mm, 12 x 14mm, 12° Lordotic Trial

12mm, 12 x 14mm, 12° Lordotic Trial

13mm, 12 x 14mm, 12° Lordotic Trial

Trials

Catalog #	Description (Height, Depth x Width)
402-90404	6mm, 13 x 16mm, 12° Lordotic Trial
402-90405	7mm, 13 x 16mm, 12° Lordotic Trial
402-90406	8mm, 13 x 16mm, 12° Lordotic Trial
402-90407	9mm, 13 x 16mm, 12° Lordotic Trial
402-90408	10mm, 13 x 16mm, 12° Lordotic Trial
402-90409	11mm, 13 x 16mm, 12° Lordotic Trial
402-90410	12mm, 13 x 16mm, 12° Lordotic Trial
402-90411	13mm, 13 x 16mm, 12° Lordotic Trial

6mm, 13 x 16mm, 12° Lordotic Trial

7mm, 13 x 16mm, 12° Lordotic Trial

8mm, 13 x 16mm, 12° Lordotic Trial

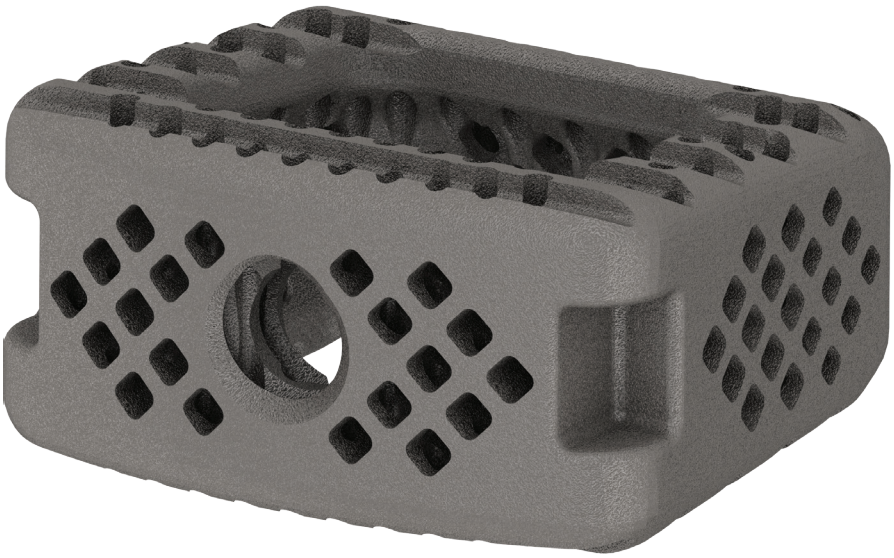
9mm, 13 x 16mm, 12° Lordotic Trial

10mm, 13 x 16mm, 12° Lordotic Trial

11mm, 13 x 16mm, 12° Lordotic Trial

12mm, 13 x 16mm, 12° Lordotic Trial

13mm, 13 x 16mm, 12° Lordotic Trial



Instructions for use

CASCADIA™
INTERBODY SYSTEM
STERILE / NON STERILE

EN
ENGLISH

PI051-2A11 REV 09 02/2024

K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175
USA
Toll Free: 1-866-526-4171
Direct: 1-703-777-3155
Fax: 1-703-777-4338

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT, Arnhem
The Netherlands

CE 2797

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the following: CASCADIA™ Interbody System. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

DESCRIPTION
The Cascadia Interbody System is comprised of hollow cages that are designed to allow for bony ingrowth. The implants are manufactured from medical grade titanium alloy and are available in a variety of lengths, widths and heights to accommodate anatomical variations. The bone contacting surfaces of the implants are designed to engage with the vertebral body end plates. Cayman United plates and screws (titanium) provide additional integrated fixation, once attached to the CASCADIA Interbodies.

INDICATIONS
The CASCADIA lumbar implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the CASCADIA lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. CASCADIA lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

The CASCADIA hyperlordotic lateral lumbar implants (≥22°), are intended for levels L2-L5 and are to be used with CAYMAN United plates in addition to posterior supplemental fixation. CAYMAN United plates are optional for use with non-hyperlordotic CASCADIA lumbar implants.

The CASCADIA cervical implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. These patients should be skeletally mature and have had six weeks of non-operative treatment. The CASCADIA cervical implants are also to be used with supplemental fixation; the hyperlordotic CASCADIA cervical implants (i.e., ≥ 10°) are required to be used with an anterior cervical plate as the form of supplemental fixation.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION

Non-Sterile Devices
Packaged components are packaged individually in sealed poly bags. **Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use.** Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles are recommended, however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility. The following steam autoclave cycles were validated to an SAL of 10-6 using the biological indicator (BI) overkill method however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	132°C (270°F)	4 minutes	30 minutes
Ouutside USA	Prevacuum	134°C (273°F)	3 minutes	30 minutes

Usage of a standard wrap or CSR wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions). NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

Sterile Devices
Implant components labeled as STERILE are gamma irradiated.

CAUTION: Do not use if package is damaged. If the tamper proof seals or sterile packaging appear to be compromised or damaged, return the package and its contents to K2M.

CAUTION: The implants are intended for single use only. Do not attempt to clean or resterilize the implants. Reprocessing of single use devices may introduce risks associated with guaranteeing sterility assurance.

STORAGE
Store sterile packages in a well-ventilated area that provides protection from dust, insects, moisture, and vermin. Store at ambient temperature.

INSTRUCTIONS FOR USE
(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

This system should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

CONTRAINDICATIONS
1. The CASCADIA Interbody System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. This device is not recommended for patients who have received prior fusion at the level(s) to be treated. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS
1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS
1. The CASCADIA Interbody System is intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers.
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use, the surgeon should be specifically trained in the use of this system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of breakage or migration of the device.
3. Patient selection and compliance is extremely important. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that an implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
4. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
5. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. The CASCADIA Interbody System implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
8. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating, migration or image artifacts in the MR environment.
9. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals (e.g. titanium and stainless steel) in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.

PREOPERATIVE
1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative planning should identify degree of correction possible without neurological damage using techniques similar to other spinal fusion procedures.
3. Check expiration date and integrity of sterile packaging.
4. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
5. An adequate inventory of implant sizes should be available at the time of the surgery.
6. All components should be clean and sterilize before use.
7. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE
1. The primary goal of spinal fusion surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. The placement of the implants should be checked radiographically.
3. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE
1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone, even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.

5. Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

SYMBOL KEY

This key contains all symbols used by K2M. Only symbols within the IFU text and on device label apply to the system listed in "IMPORTANT" section of the IFU.

	Manufacturer		Consult Instructions For Use
	Authorized EU Representative		Caution: Consult Accompanying Documentation
	Lot Number		Non-Sterile
	Catalog Number		Do Not Reuse
	Use-by Date		CE Mark and Identification Number
	Sterile		Sterilized Using Irradiation
	Sterilized Using Ethylene Oxide		Do Not Resterilize
	Do Not Use If Package is Damaged		Temperature Limit
	Keep Dry		Keep Away From Sunlight
	Federal (U.S.) law restricts this device to sale by or on the order of a physician		

stryker

Spine division

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of specific products before using them in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. The products depicted are CE marked according to the Medical Device Directive 93/42/EEC or Regulation (EU) 2017/745. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

CASC3D-ST-1_Rev-1_32058
SPINE-CAC-TECHG-1115626

Manufactured by:

K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175
t: 571 919 2000

www.stryker.com

CE
2797