stryker

Cayman®

United Plate System

Surgical technique guide

Table of contents

Surgical technique steps

Product catalog

This publication sets for detailed recommended procedures for using the Cayman United Plate 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.

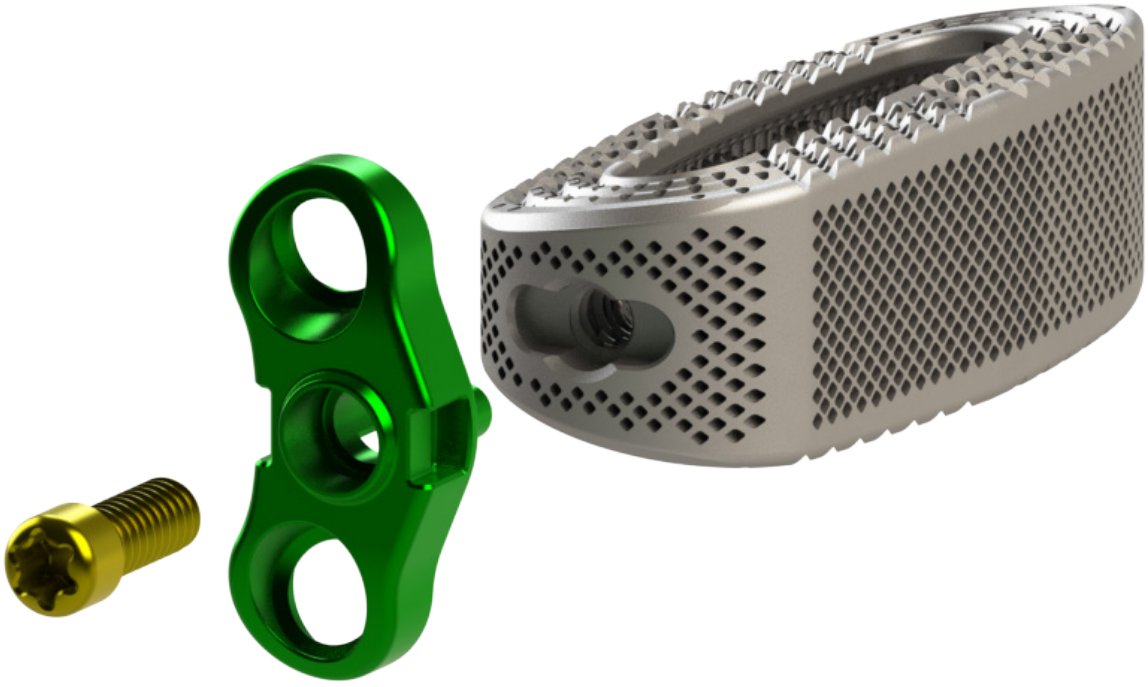
Features and benefits

Cayman United Plate System

- One- and Two-hole Screw Fixation Options
- Simplified Technique for Rigid Connection to Cascadia Lateral 3D Interbody
- Plates Sized to Match Cascadia Lateral 3D Implants
- Screw Holes Biased 15° Normal to Plate
- Tifix® Locking Technology
- Streamlined Instrumentation Allows for Back Table or In-situ Cage/Plate Assembly

Cascadia Lateral 3D Interbody System

- Available in Lengths from 45–60mm
- Available in Heights from 8–20mm
- Available in Widths of 18 and 22mm
- Available in 0°, 8°, 12°, 15°, 22°, and 28° Lordotic Sagittal Profiles
- Reverse hourglass design allows for a large graft volume
- 3-5 um surface roughness to allow for direct bony ongrowth
- Implants are Manufactured From Medical Grade Titanium Alloy

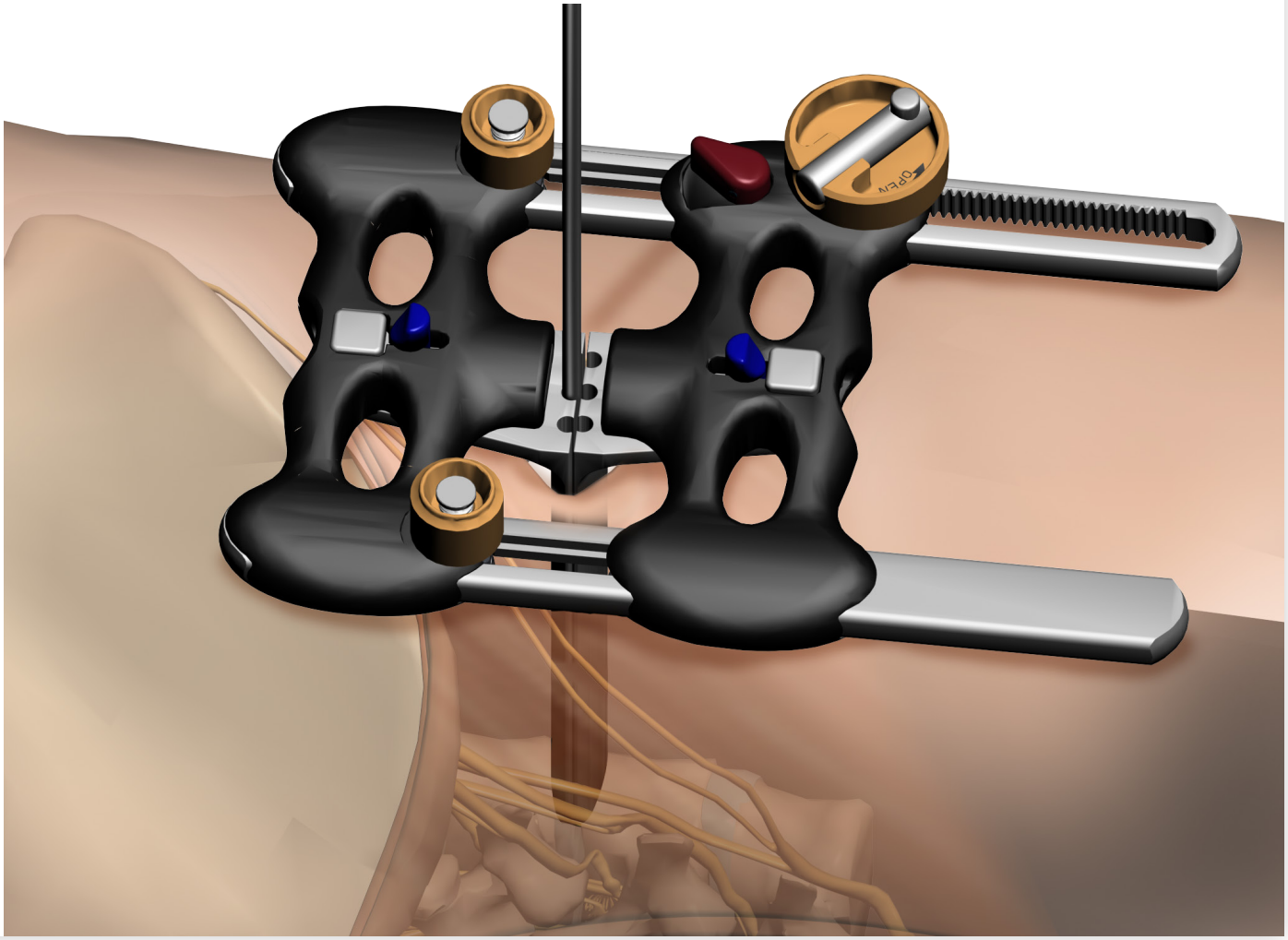


Surgical technique

Step 1

Ravine Retractor insertion

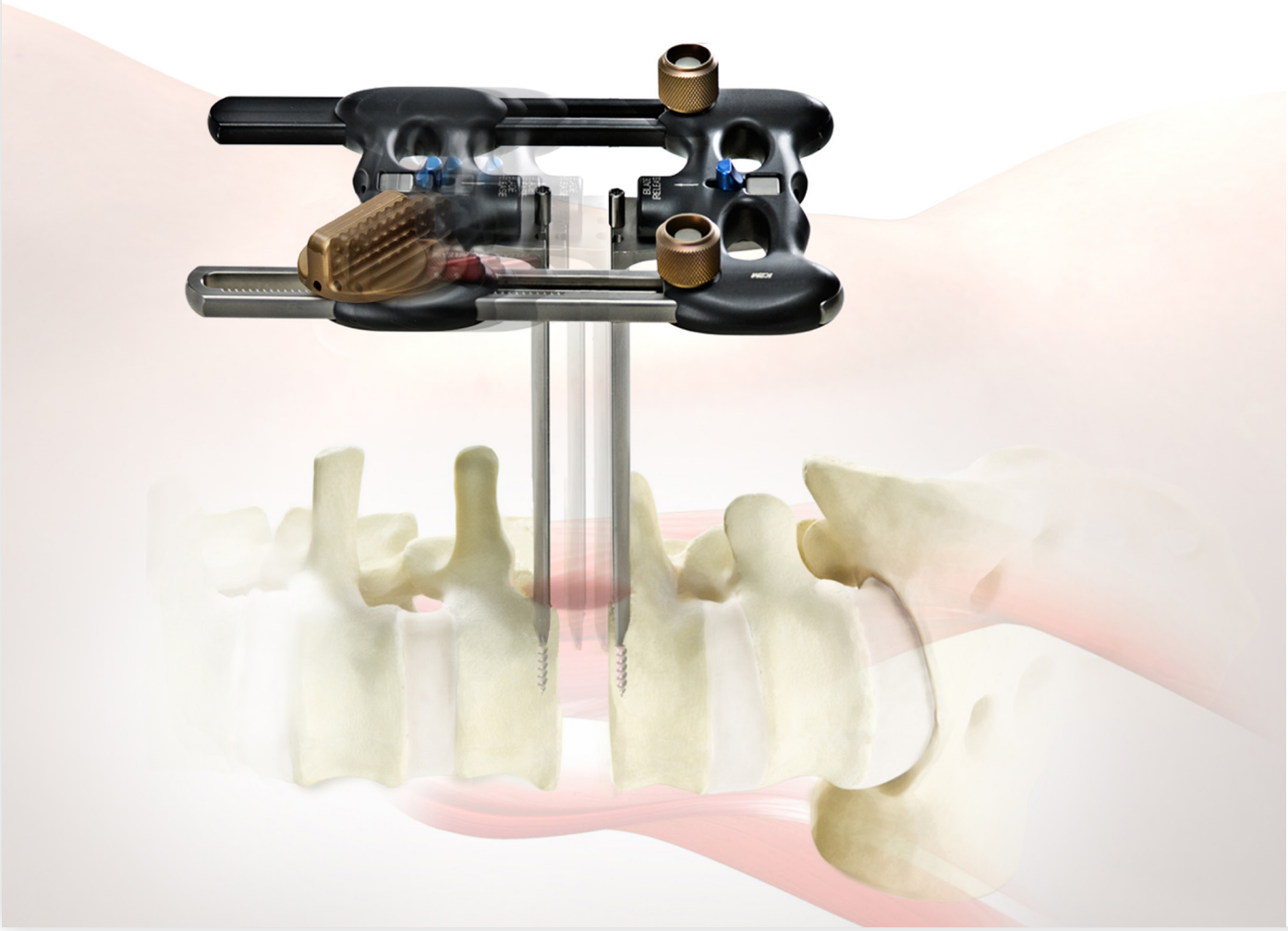
For step-by-step instructions on how to place the Retractor, please reference the Ravine Lateral Access System Surgical Technique (K2-27-7000-01).



Step 2

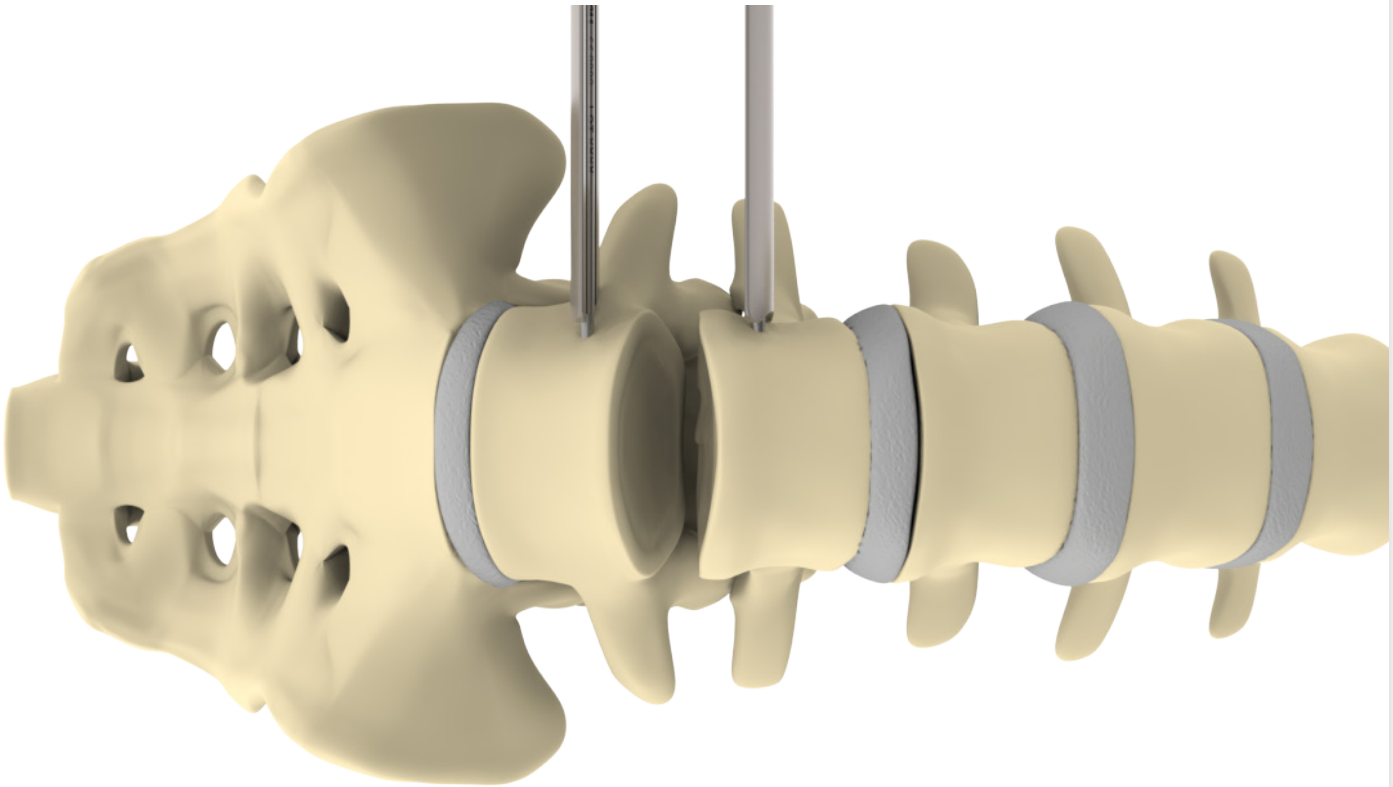
Retractor Blade placement

Prior to final positioning of the Ravine Retractor and Fixation Pin placement, make sure the Retractor is 8mm past the endplate to leave adequate space for the Cayman United Plate. This will eliminate the need to reposition the Retractor after the Cascadia Lateral 3D interbody placement.



Disc space preparation

Before inserting the Cascadia Lateral 3D interbody, the disc material is appropriately removed and the endplates at the treated level are prepared. The lateral surface of the vertebral body is properly addressed and freed of any large osteophytes to achieve a smooth surface.



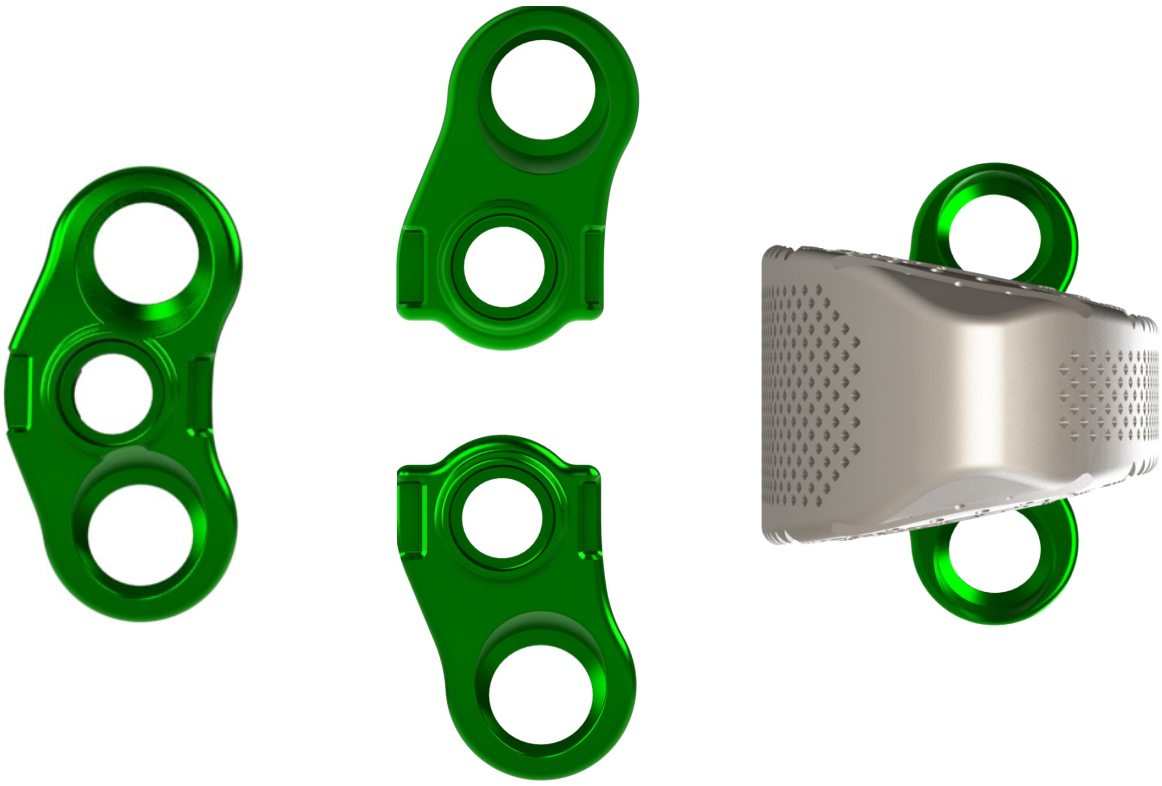
Step 4

Plate selection and Retractor Blade placement

Cayman United plates are designed to provide minimal extension past the endplates of adjacent vertebral bodies. Depending on the height and lordosis of the Cascadia Lateral 3D interbody chosen, select the appropriate corresponding plate size. See Plate Selection Chart (Appendix A) for details on selecting a plate size. The Cayman United plate is available in two-hole as well as one-hole left- and right-handed configurations for a customized construct.

Note: A Cascadia Lateral 3D interbody with a Cayman United plate is intended to be used with supplemental fixation.

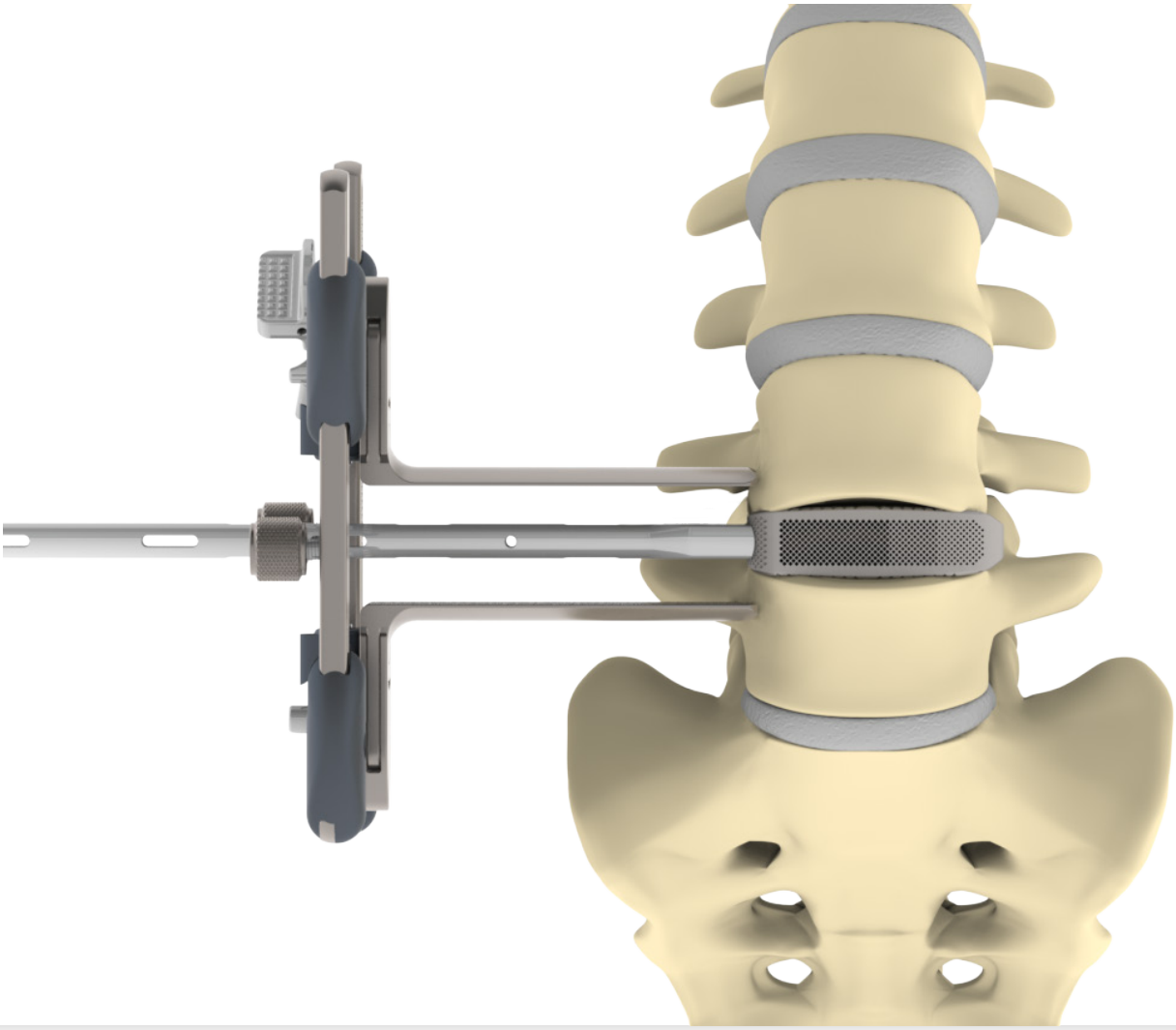
If a larger plate size was chosen than the Ravine Retractor will allow, remove the Ravine Blade Fixation Pins and reinsert once each Retractor Blade has been adjusted to the necessary position.



Interbody insertion without Plate

The Cayman United plate can be inserted together with the Cascadia Lateral 3D interbody, or attached separately in-situ depending on technique preference. To insert the Cascadia Lateral 3D interbody first without attaching to the Cayman United plate, utilize the standard Lateral Interbody Inserter.

Note: To allow room for attachment of Cayman United plate, it is recommended that the cage be left slightly proud during initial insertion. Once the plate is attached, the construct can be further impacted into its final position.



Step 5

Interbody insertion without Plate (cont.)

To attach the Cayman United plate, load the appropriate plate onto the Plate Inserter. To attach the plate to the Plate Inserter, position the prongs of the Inserter into the corresponding pockets on the plate and thread the outer sleeve clockwise until the plate is fully captured.

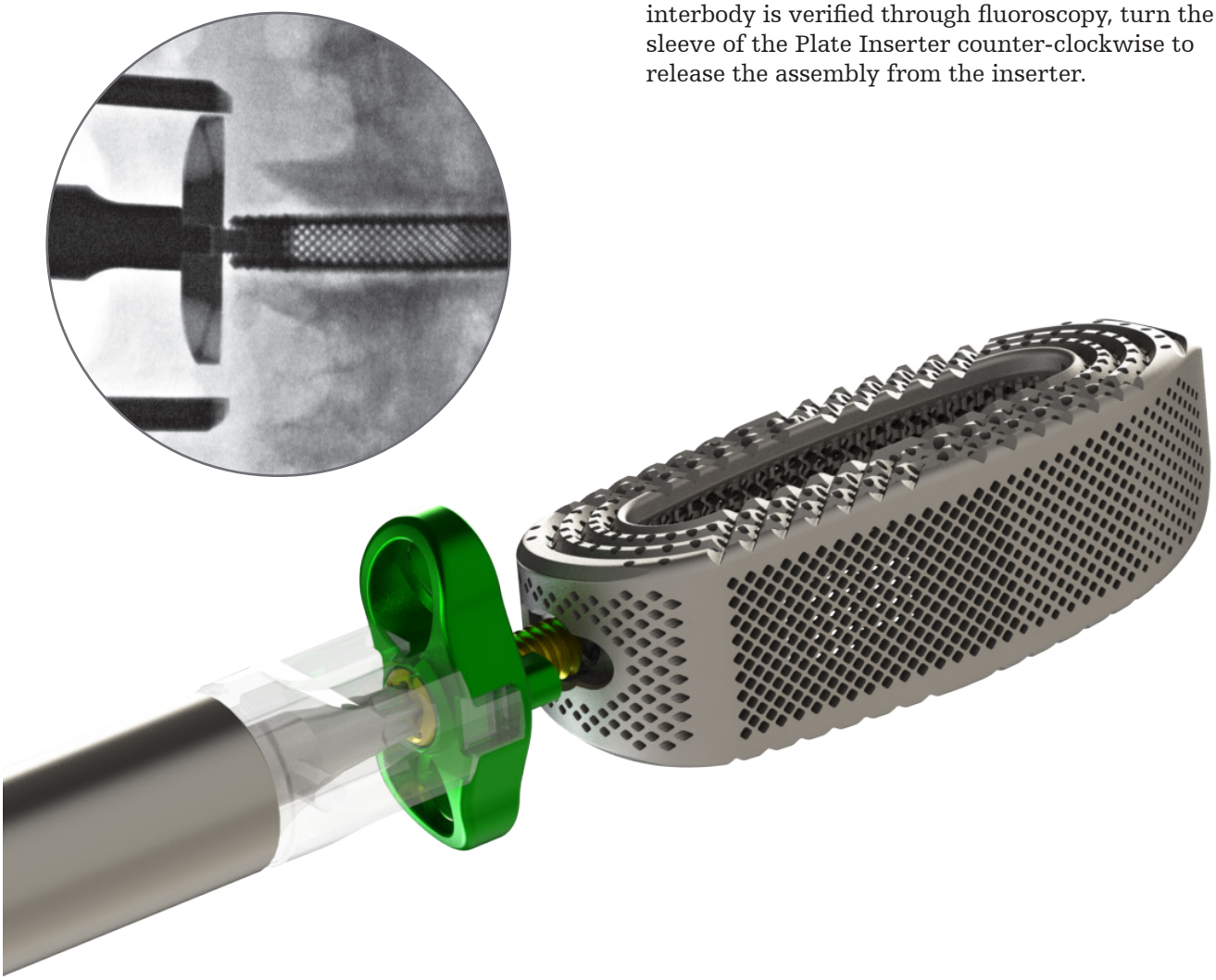
Cayman United
Plate Inserter

Once the plate is properly positioned onto the interbody, use the Tapered Plate Assembly Driver to grab a Plate Assembly Screw and insert through the Inner Shaft of the Plate Inserter. Turn the Plate Assembly Screw clockwise until it has been fully inserted.

Note: A 0.5mm gap is designed between the Cayman United plate and Cascadia Lateral 3D cage when fully seated to allow for minor protrusions on the lateral surface of the vertebral body.

Note: Before final locking the Cayman United plate, ensure the outer rim of the Cascadia Lateral 3D interbody is positioned flush to the rim of the lateral endplate. Removal of osteophytes may be required to ensure plate is fully seated to cage. If proper alignment between the interbody and plate cannot be achieved, alternative forms of supplemental fixation should be considered.

To final lock the assembly, attach the Plate Assembly Final Tightener to the 20 in-lb Torque Handle and re-engage the Plate Assembly Screw until an audible click is heard. Once position of the plate and interbody is verified through fluoroscopy, turn the sleeve of the Plate Inserter counter-clockwise to release the assembly from the inserter.



Tapered Plate Assembly Driver

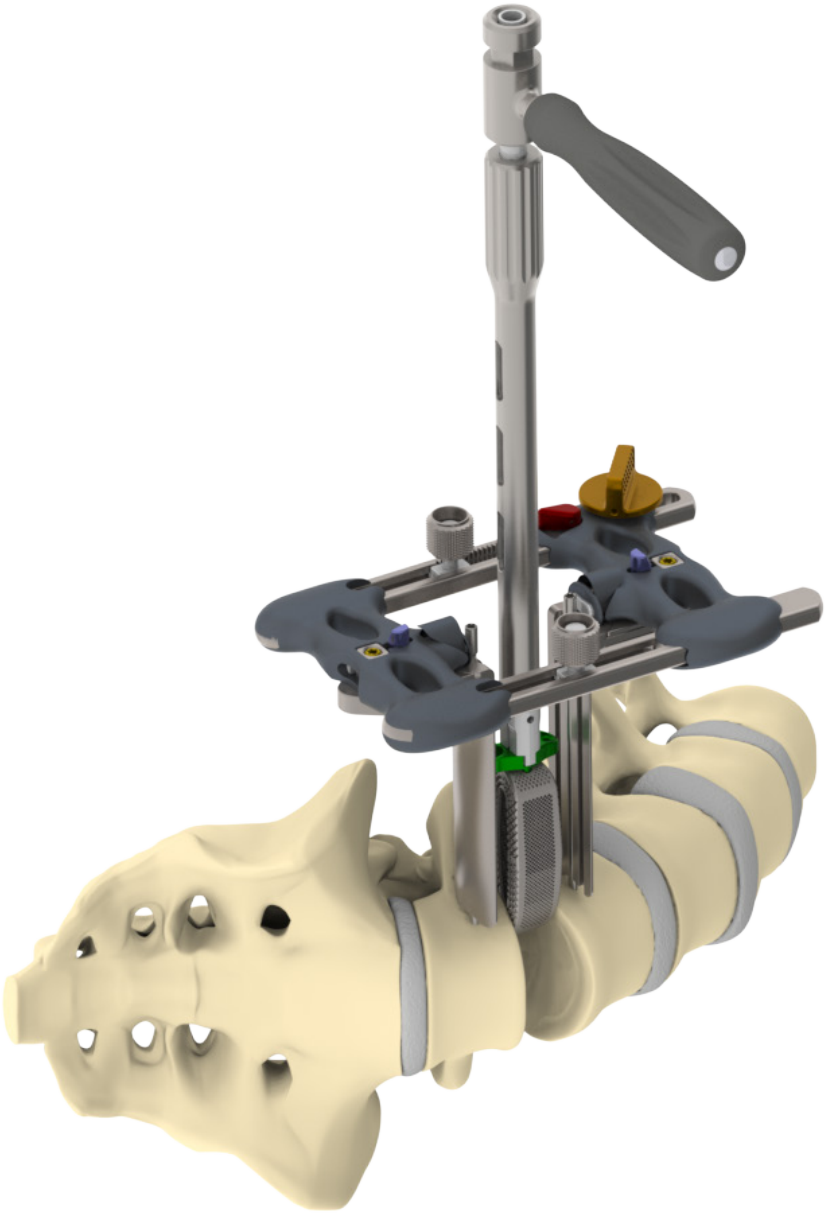
Plate Assembly Final Tightener

Torque Limiting Handle, 20 in-lbs

Step 6

Interbody insertion with Plate attached

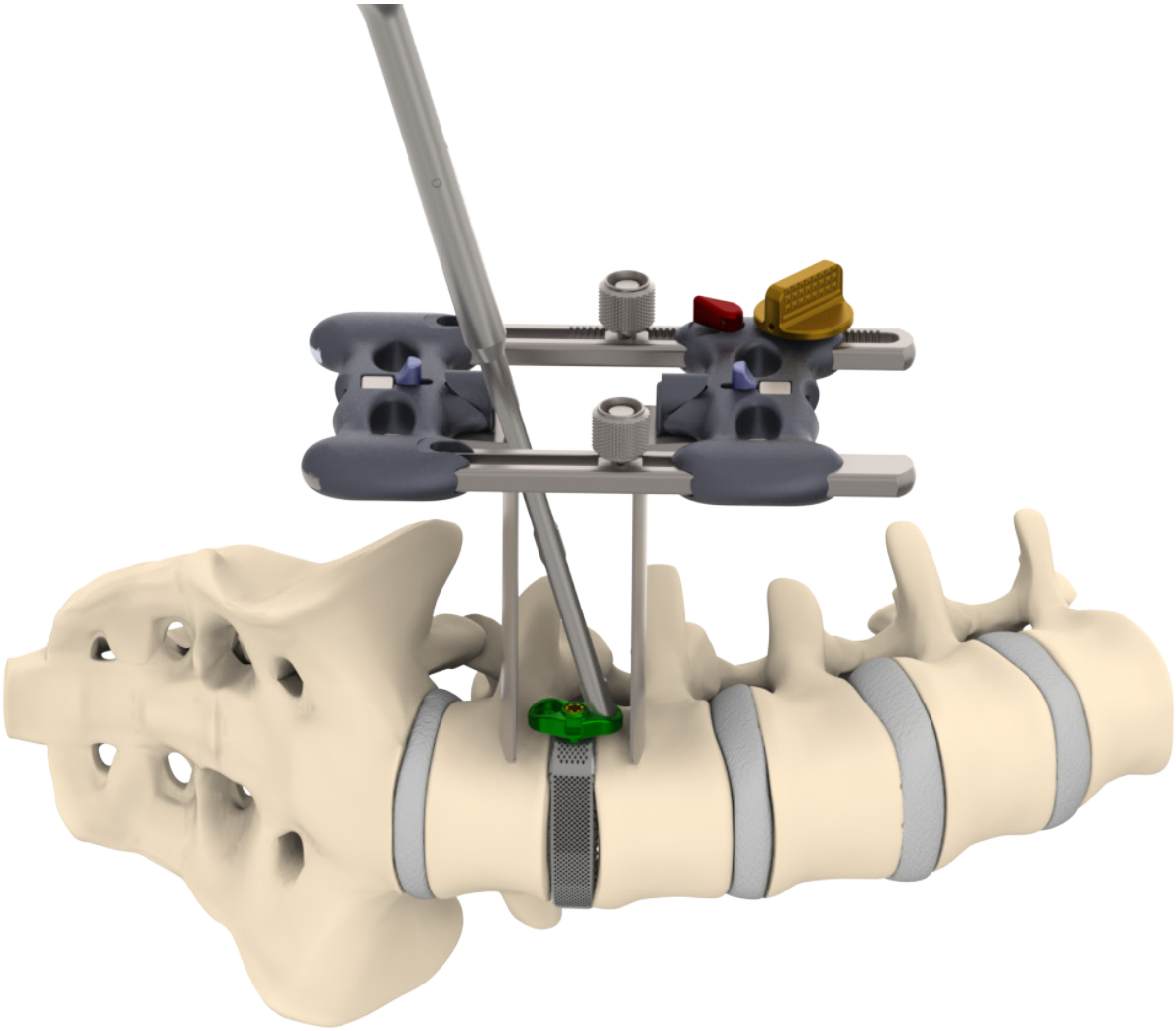
If inserting the Cayman United plate and Cascadia Lateral 3D interbody together is desired, pre-assemble the components using the technique for attaching the plate in-situ. The assembly can then be inserted into the disc space together.



Pilot hole preparation

Create the pilot hole using the 20mm Spring Loaded Awl. Align the end of the Awl with the desired plate screw hole and apply downward force or slight impaction in order to perforate the vertebral cortex.

Note: The United plate screw holes are biased 15° and allow for an additional 15° of angle variation allowing placement of the screws anywhere from normal (parallel to the endplates) up to 30° angled (cephalad/caudal).

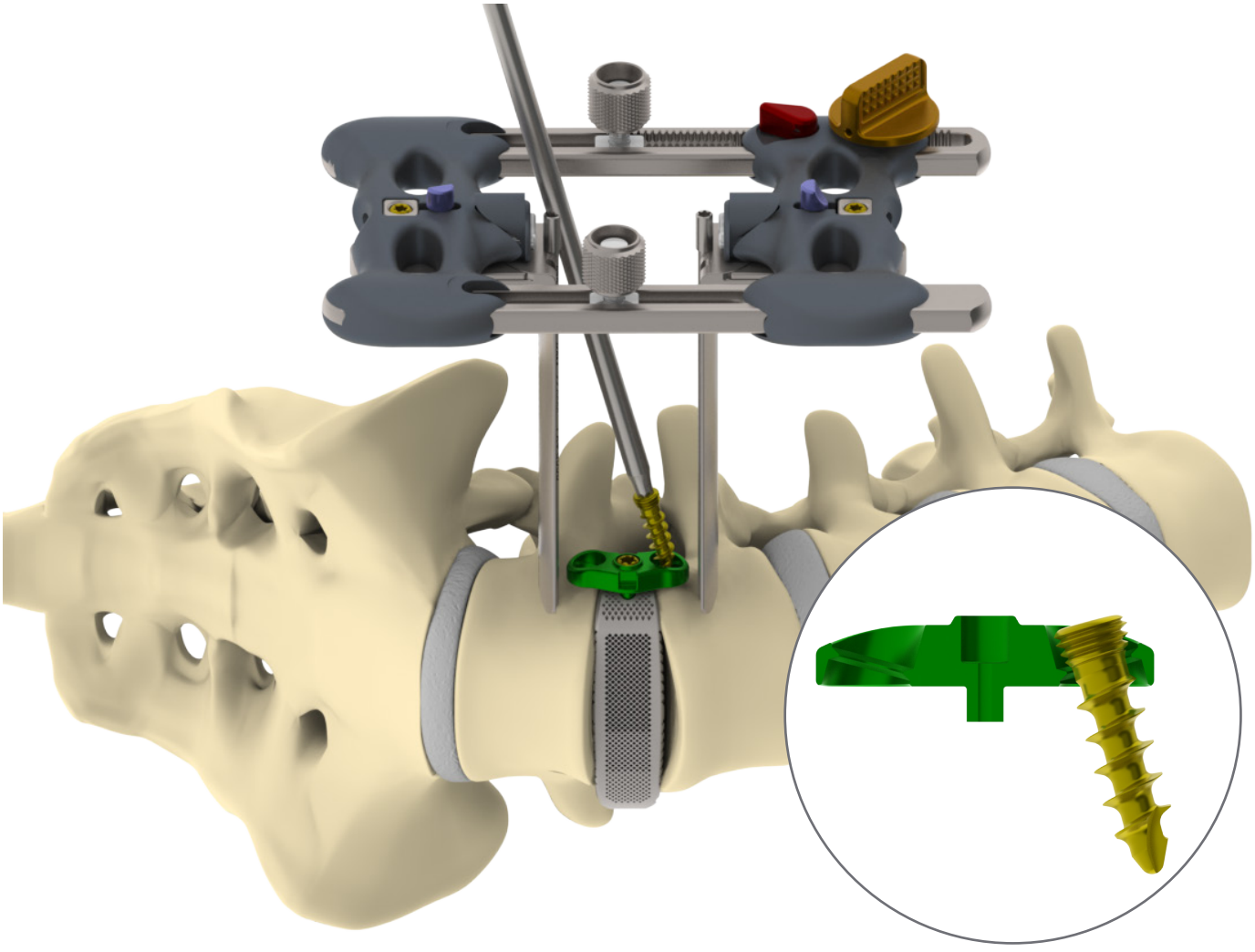


Spring Loaded Awl, 20mm

Step 8

Screw insertion

Insert the appropriately sized screw through the plate using the Tapered Plate Assembly Driver. Follow the same procedure to insert the remaining screws.



Tapered Plate Assembly Driver

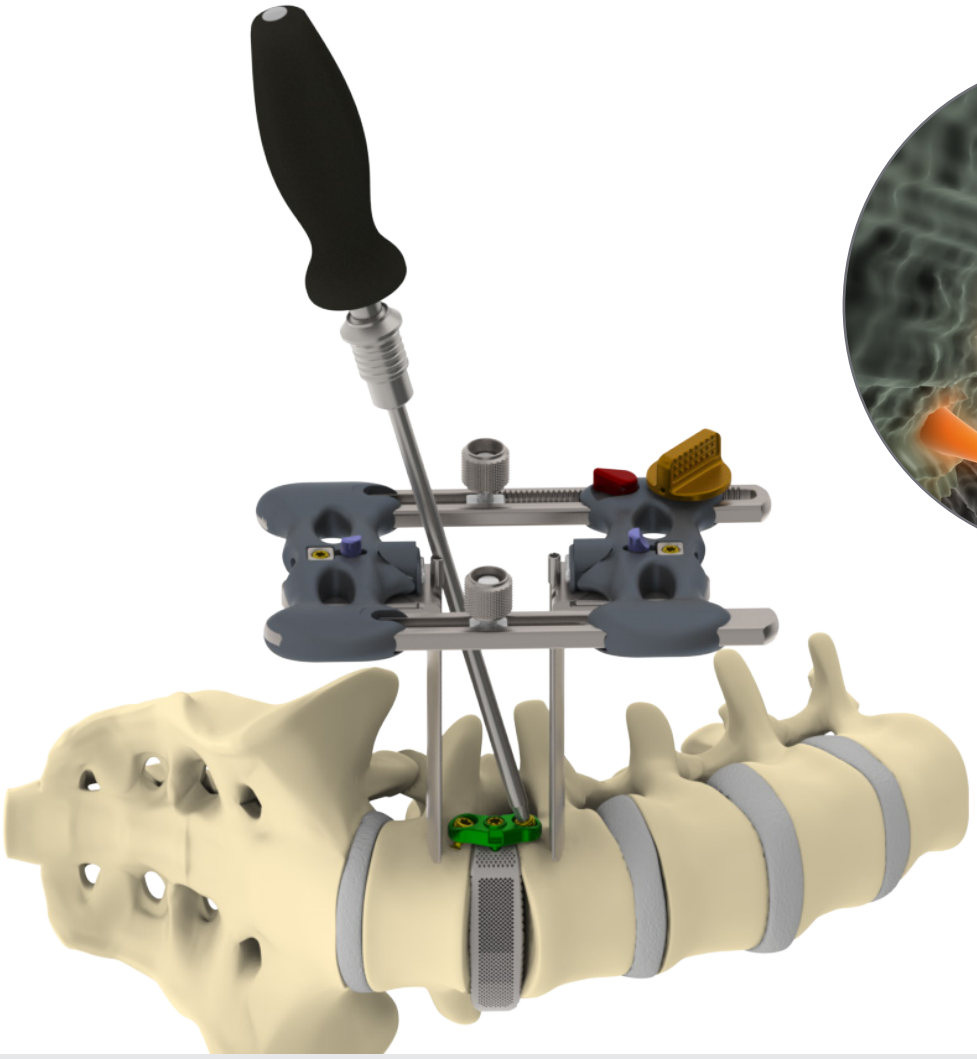
Locking the screw

Final locking of the screw should only be performed once the plate and screw positions have been verified via intraoperative radiographs. Once the screws are tightened, they are designed to become locked to the plate. Use the Plate Assembly Final Tightener attached to the gray Torque Limiting Handle to final tighten the screws to 20 in-lbs.

Note: When the screw head engages on the locking lip of the plate, the plate is designed to lag down to the bone commencing the tifix Locking Technology (Figure 1).

Due to a difference in material hardness and design, the screw head begins to reshape the lip of the plate, the metals bind, and an autogenic lock is formed.

Note: If realignment of the screw is necessary after final locking, the screw may be unlocked using the Ratcheting Hudson Handle and Plate Assembly Final Tightener and locked again up to three times without compromising the locking mechanism.



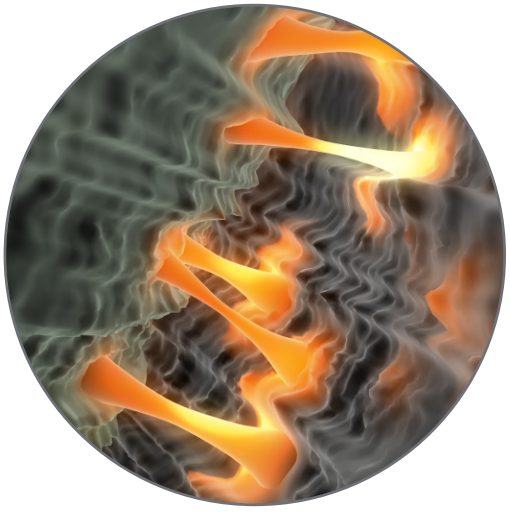


Figure 1

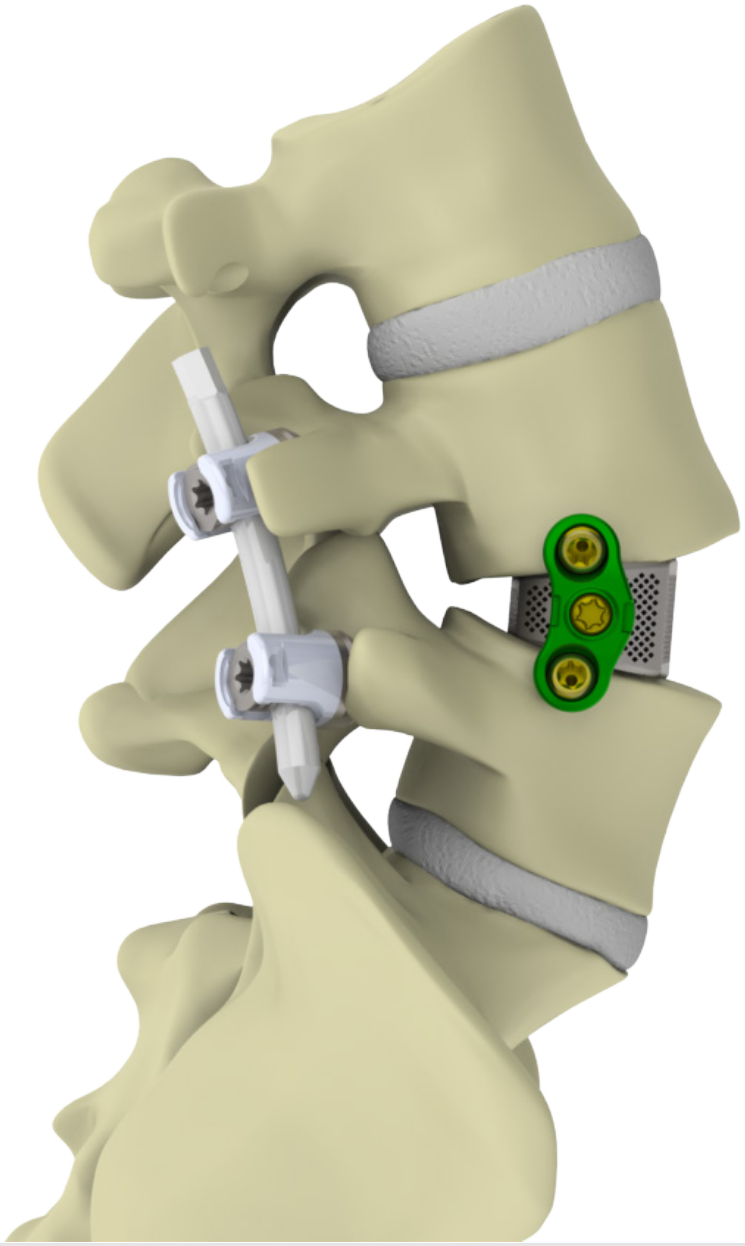
Plate Assembly Final Tightener

Torque Limiting Handle, 20 in-lbs

Step 10

Final construct

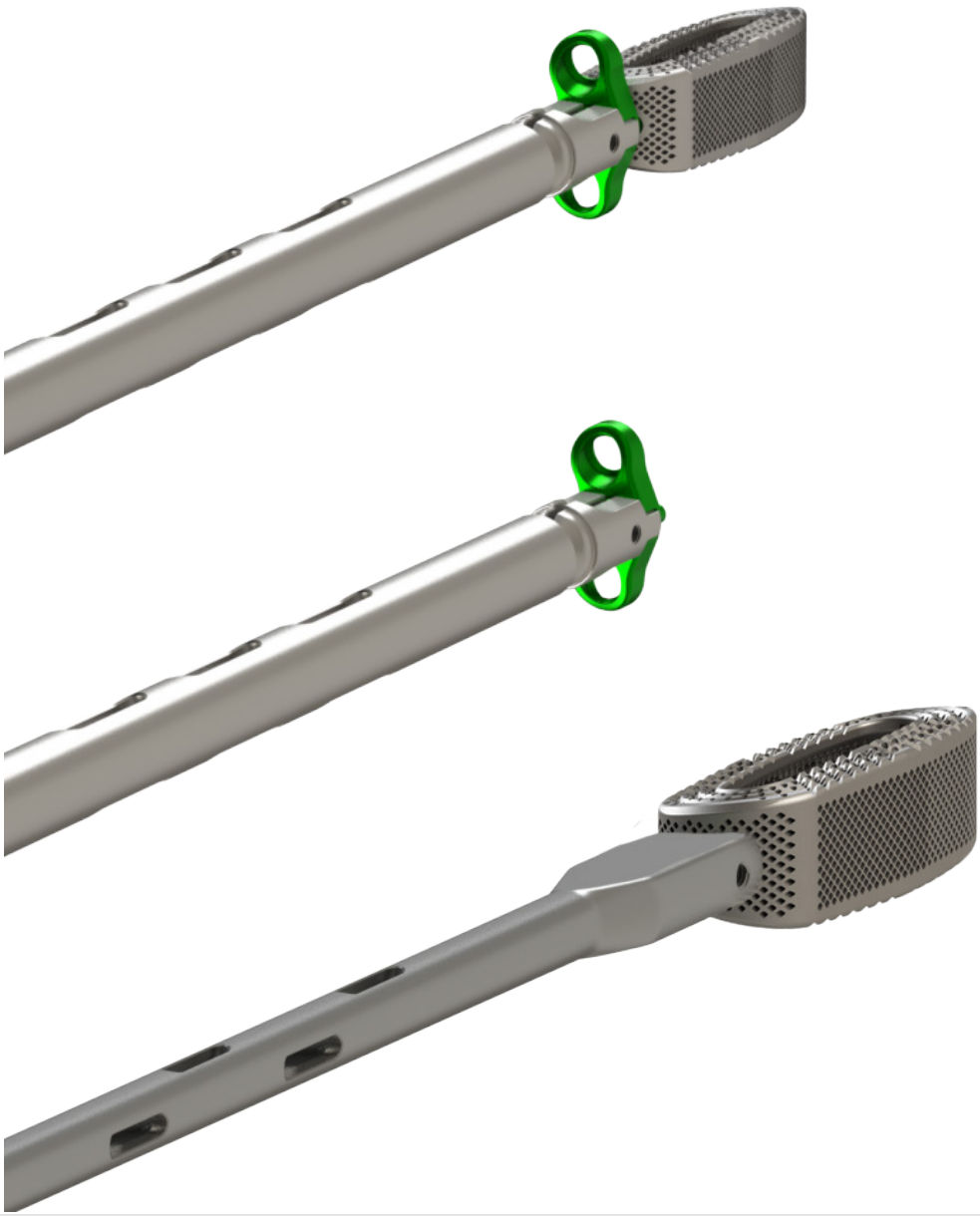
Following placement of the Cayman United Plate, apply supplemental internal fixation device appropriate for the implanted level, such as a Stryker Spine pedicle screw system to finalize the construct.

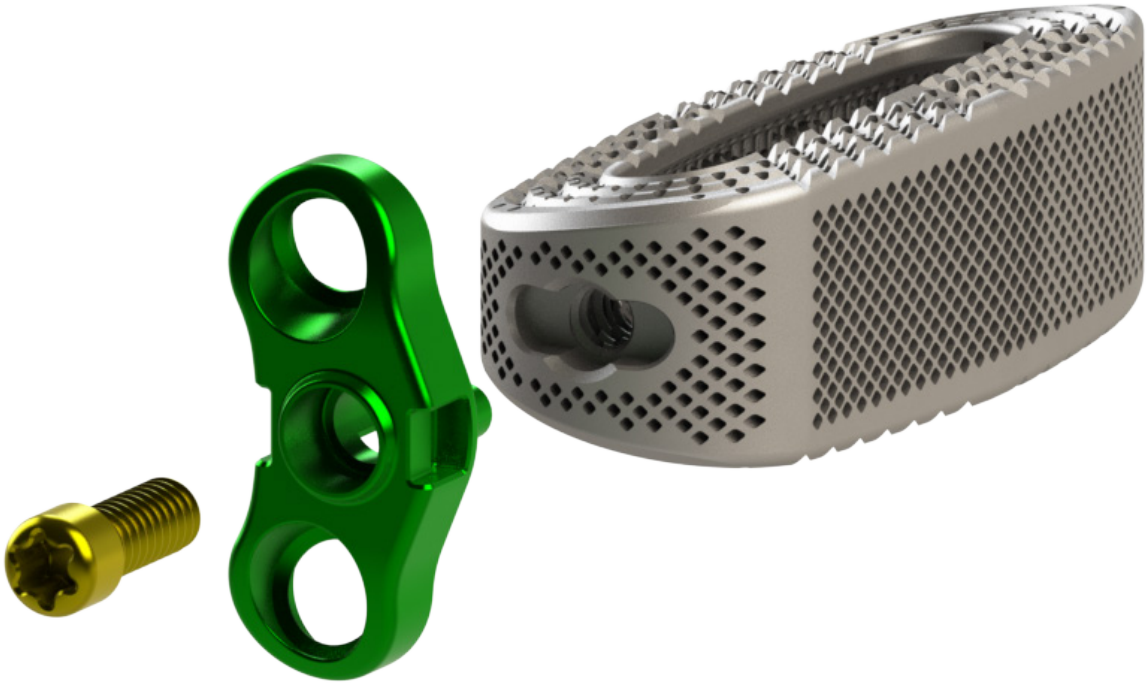


Removal instructions

If removal is required, the Cascadia Lateral 3D interbody and Cayman United plate may be retrieved by first extracting the Cayman MI screws with either the Size 20 Driver or Screw Extractor Tool. The plate/interbody assembly may be removed together by reattaching the Plate Inserter. Alternatively, the plate can be separated from the interbody using the Size 20 Driver through the Plate Inserter and removed separately.

If the Cascadia Lateral 3D interbody must be removed as well, the Lateral Inserter can be reattached. Both the Plate Inserter and Lateral Inserter contain a Slap Hammer compatible feature if required.





Appendix

Appendix A

Plate sizing chart

Cage lordosis	Cage height: 8mm	10mm	12mm	14mm	16mm	18mm	20mm
0°	Size 16	Size 18	Size 20	Size 22	Size 24		
8°	Size 16	Size 18	Size 20	Size 22	Size 24		
12°		Size 16	Size 18	Size 20	Size 22		
15°		Size 16	Size 18	Size 20	Size 22		
22°			Size 16	Size 18	Size 20	Size 22	
28°				Size 16	Size 18	Size 20	Size 22

Appendix B

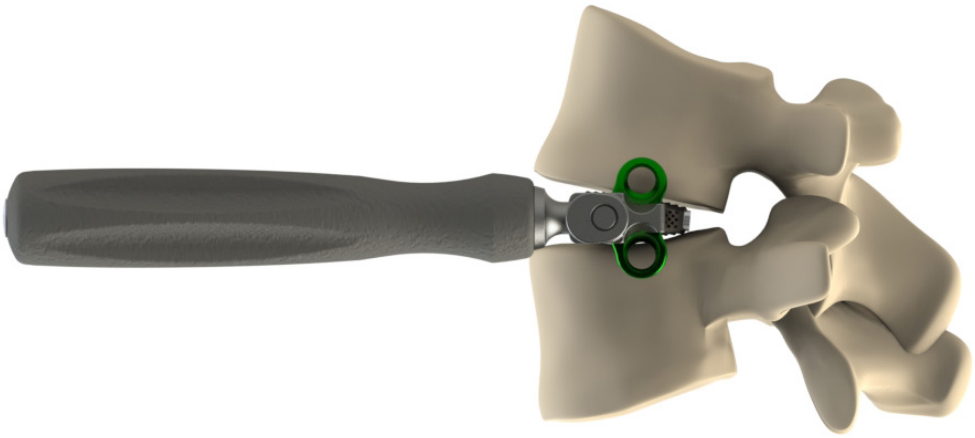
Offset Inserter

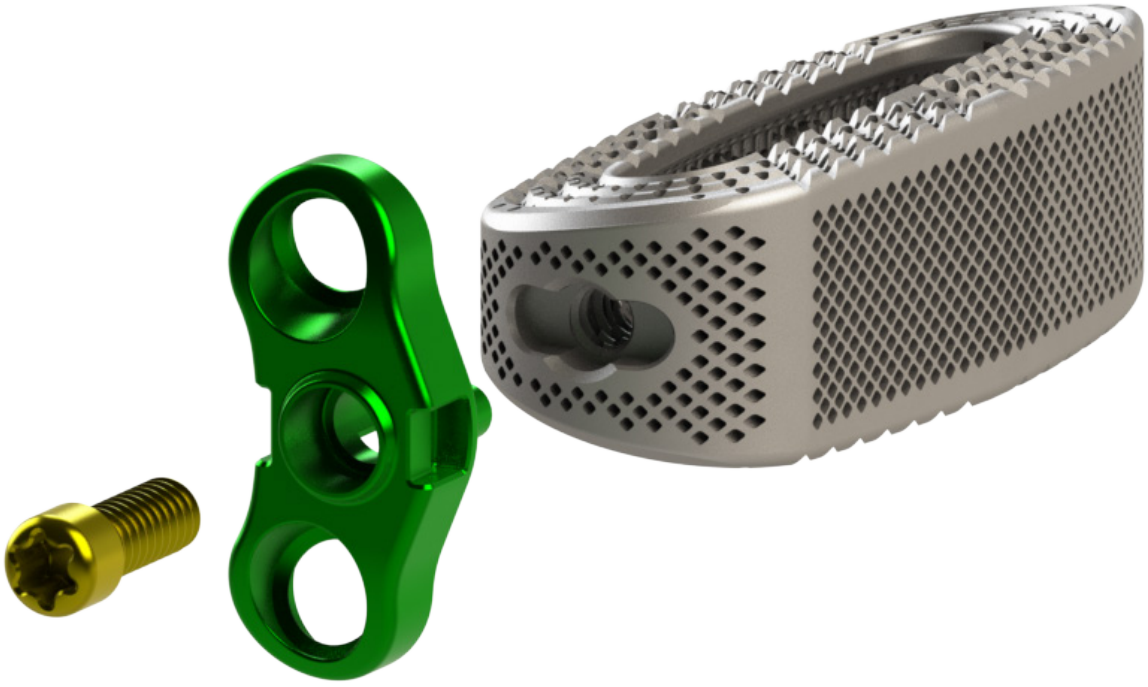
If keeping the Plate attached to the inserter during screw hole preparation and screw insertion is preferred, an Offset Inserter is provided, instead of the standard Plate Inserter.

To attach the Cayman United Plate, load the appropriate Plate to the Offset Inserter and thread the outer sleeve clockwise until the Plate is fully captured. Then the Plate can be inserted onto the interbody and screw preparation or screw insertion can be completed, with the Offset Inserter still attached.

Note: The Assembly Screw cannot be attached with the Offset Inserter still connected to the Plate.

Note: Both the Cayman United Plate and the Cascadia Lateral 3D interbody can be pre-attached on the back table and inserted with the Offset Inserter.





Product catalog

Plates

Catalog #	Description
*See special note	Cayman United Two-Hole Plate
*See special note	Cayman United One-Hole Plate, Right
*See special note	Cayman United One-Hole Plate, Left
*See special note	Plate Assembly Screw

*Unique catalog numbers exist for each level plate in each available length. Please contact your local sales representative with any questions you may have about ordering the Cayman United Plate System Plates.

Cayman United Two-Hole Plate

Lengths (mm): 16, 18, 20, 22, and 24

Cayman United One-Hole Plate, Right

Lengths (mm): 16, 18, 20, 22, and 24

Cayman United One-Hole Plate, Left

Lengths (mm): 16, 18, 20, 22, and 24

Plate Assembly Screw

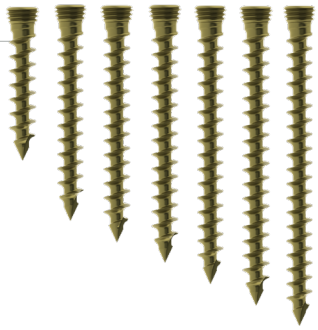
Catalog #	Description
*See special note	Ø5.0mm Self-starting Screws
*See special note	Ø5.5mm Self-starting Screws

*Unique catalog numbers exist for each screw in each available length. Please contact your local sales representative with any questions you may have about ordering the Cayman United Plate System screws.

**There may be more screw lengths available by request. Please contact your local sales representative for more information.

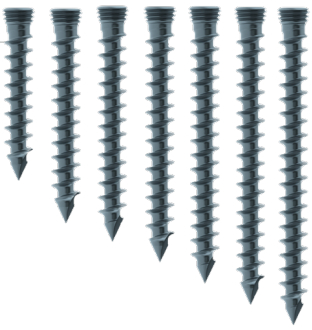
Ø5.0mm Self-starting Screws

Lengths (mm): 28, 40, 44, 48, 52, 56, and 60



Ø5.5mm Self-starting Screws

Lengths (mm): 28, 40, 44, 48, 52, 56, and 60



Instruments

Catalog #	Description
7902-90033	Cayman United Plate Inserter
7902-90102	Cayman United Angled Inserter
7902-90106	Tapered Plate Assembly Driver
7902-90062	Plate Assembly Final Tightener

Catalog #	Description
1208-90012	Ratcheting Hudson Handle
4508-90075	Spring Loaded Awl, 20mm
2008-90043	Torque Limiting Handle, 20 in-lbs

Note: Do not exceed recommended torque or damage to the instrument or implant may result.

Cayman United Plate Inserter

Cayman United Angled Inserter

Cayman United Offset Inserter

Tapered Plate Assembly Driver

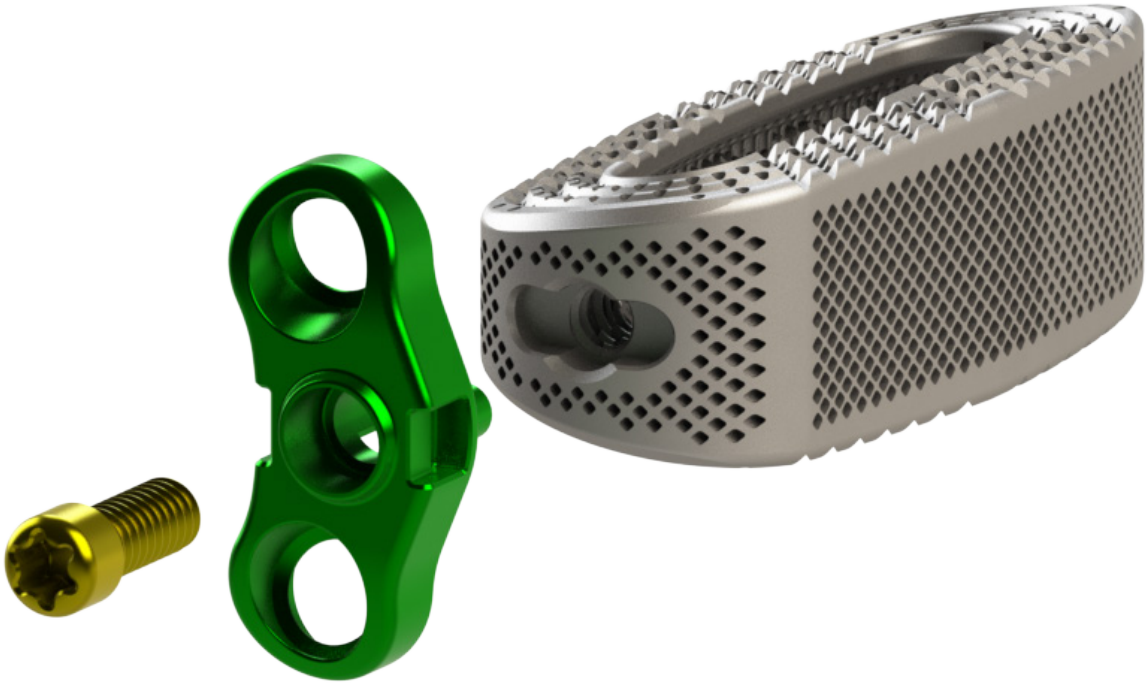
Plate Assembly Final Tightener

Ratcheting Hudson Handle

Spring Loaded Awl, 20mm

Torque Limiting Handle, 20 in-lbs

Catalog #	Description	Torque values and accuracy
2008-90043	Torque Handle, 20 in-lbs (2.3 N-m)	2.3 ± 0.23 Nm (10%)



Instructions for use

Instructions for use

Cascadia Interbody System
IFU Reference Number: PI051-2EN-01 Rev 0

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.
The CASCADIA non-hyperlordotic lateral lumbar implants may optionally be used with CAYMAN United plates, in addition to supplemental spinal fixation systems.

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
Unless specifically labeled as STERILE, K2M reusable devices are supplied non-sterile must be thoroughly cleaned prior to sterilization.

Point of Use
Contaminated instruments should be wiped clean of visible soil at the point of use, to prevent drying of soil and contaminants in and on the device. Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris on the inside.

Manual Cleaning Steps
1. PREPARE low foaming pH neutral enzymatic detergent per manufacturer's recommendation. Presoak the instruments for the specified time or a minimum of 5 minutes, whichever is longer.
2. MANUALLY clean instruments using a soft-bristled brush and/or soft lint-free cloth.
3. PAY ATTENTION to instruments with crevices, interfaces, cannulations and moving parts. Actuate device (if applicable) and use an approximately sized lumen brush to clean all cannulas.
4. RINSE parts under warm running tap water for 1 minute.
5. REPEAT the process until no visible debris remains.
6. PREPARE pH neutral detergent for ultrasonic cleaning* per manufacturer's recommendations. Immerse the articles into the prepared detergent solution and allow the articles to sonicate for 10 minutes.
7. REMOVE the instruments from the sonicator and rinse under warm tap water for a minimum of 1 minute.
8. RINSE the instrument under running reverse osmosis/deionized (RO/DI) water for a minimum of 1 minute.
9. VISUALLY inspect each instruments for visible soil. If visible soil is noticed contact the sponsor.
10. DRY using a clean, soft, lint-free single use cloth.

*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 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.

US
Autoclave Cycle: Prevacuum
Temperature: 270°F (132°C)
Time: 4 minutes
Drying Time: 30 minutes

OUS
Autoclave Cycle: Prevacuum
Temperature: 273°F (134°C)
Time: 3 minutes
Drying Time: 30 minutes

Usage of an FDA cleared 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).

Warning (Outside the U.S.A. only):
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
Components labeled as STERILE were sterilized by gamma radiation.

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.

Instructions for use

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 or migration 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. Check expiration date and integrity of sterile packaging.

3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.

4. An adequate inventory of implant sizes should be available at the time of the surgery.

5. All components should be clean and sterilize before use.

6. 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.

Notes

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Spine division

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