MET ONE TECHNOLOGIES

Surgical Technique

Audere C Spinal Implant System

STG-1029-02 Rev A
11-2023

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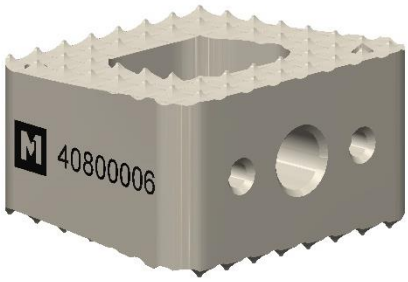
PRODUCT OVERVIEW

The Met One Technologies Audere C Spinal Intervetebral Body Fusion Device is a cervical intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. A variety of implant sizes is provided to accommodate individual patient anatomy. The implants are manufactured from VESTAKEEP® i4 PEEK per ASTM F2026 and have tantalum markers per ASTM F560.

The Met One Technologies Audere C Spinal Vertebral Body Replacement Device is a thoracolumbar vertebral body replacement device that is implanted to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. A variety of implant sizes is provided to accommodate individual patient anatomy. The implants are manufactured from VESTAKEEP® i4 PEEK per ASTM F2026 and have tantalum markers per ASTM F560.

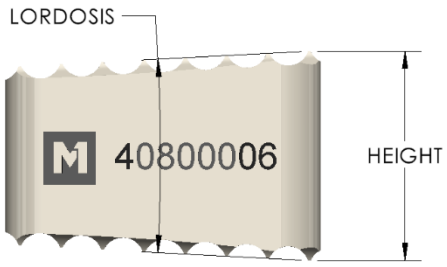


FEATURES

- Large graft windows create maximum contact between the graft and endplate
- Textured superior/inferior surfaces prevent expulsion in any direction
- Superior instrumentation for the most efficient application of implants
- Quick-release inserter prevents implant cross threading and allows for easier implant insertion
- Sizes available for all surgical needs

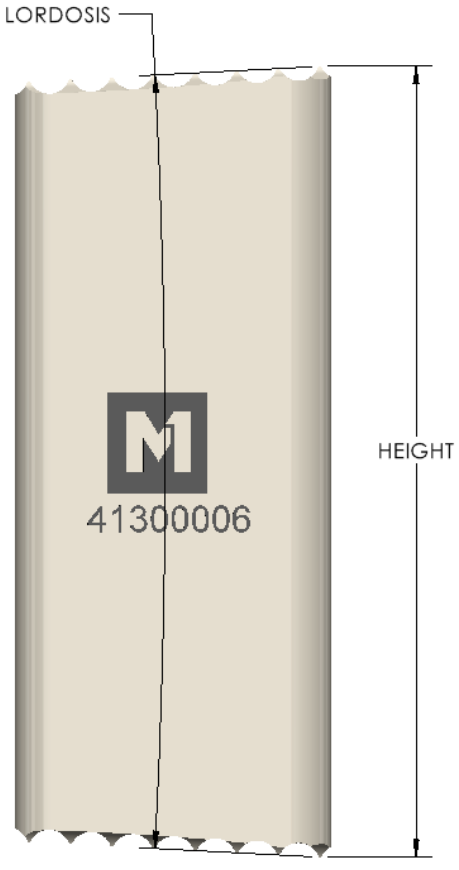
AUDERE C CERVICAL IMPLANT OVERVIEW

12mm x 14mm Footprint
Parallel (0°) & 6° Lordosis Angles
5mm – 10mm Heights



AUDERE C CORPECTOMY IMPLANT OVERVIEW

12mm x 14mm Footprint
Parallel (0°) & 6° Lordosis Angles
11mm – 60mm Heights

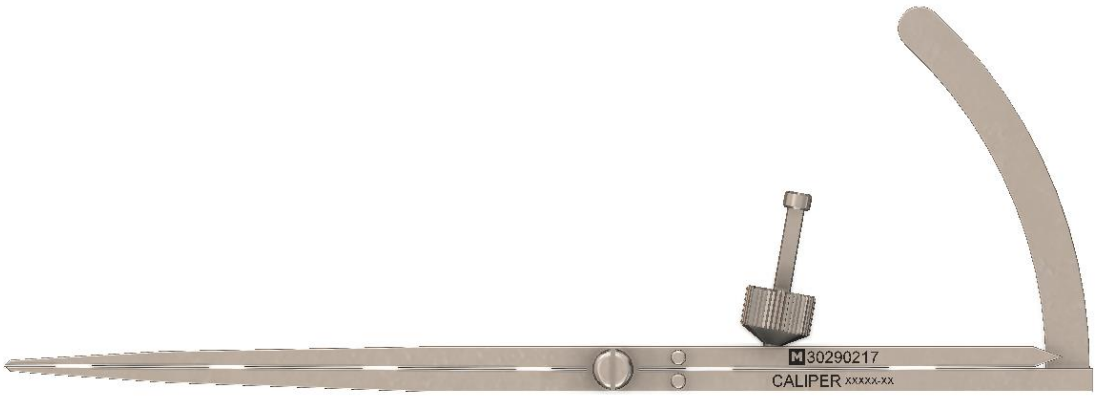


INSTRUMENT OVERVIEW

30290209 Lever Inserter

30290211 Tamp

30290217 Caliper



30290210 Corpectomy Trial

30290202 - 30290207 0° Cervical Trials

30290221 - 30290226 6° Cervical Trials

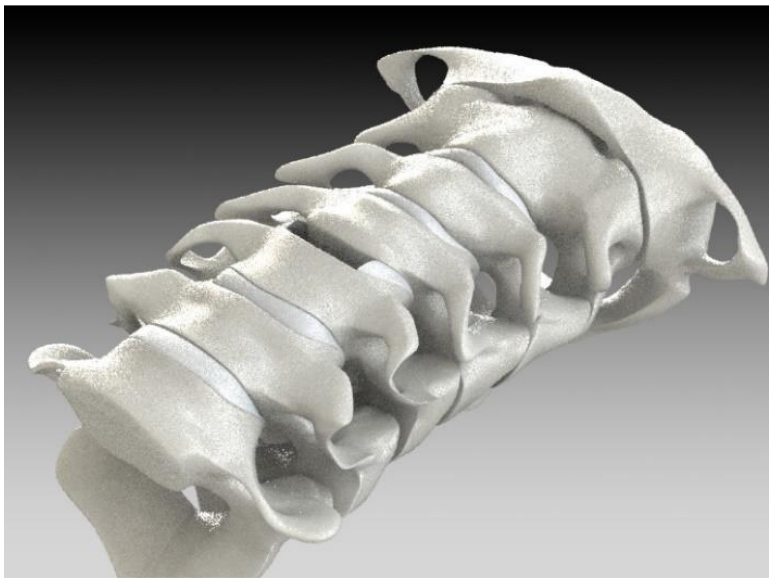
EXPOSURE OF THE INTERVETEBRAL SPACE

Locate the correct operative level using radiographic assistance. Expose the intervertebral disc and adjacent bodies through a standard anterior approach to the cervical spine. Carefully place retractors to provide sufficient access to the intervertebral space.

DISCECTOMY

Perform a complete discectomy at the desired level employing rongeurs and curettes as appropriate. Remove posterior rim and/or osteophytes as necessary. Take care to avoid damaging the vertebral body endplates to minimize the probability of implant subsidence.

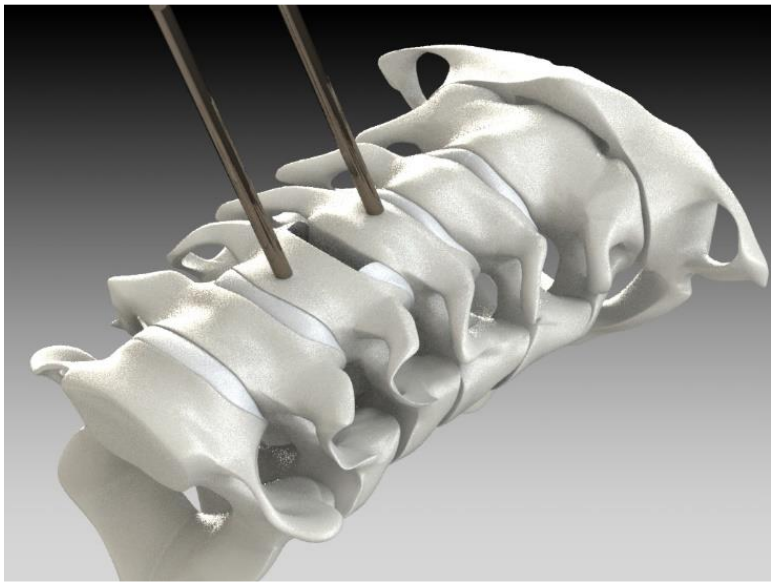
Cervical spine before discectomy



Cervical spine after discectomy

DISTRACTION

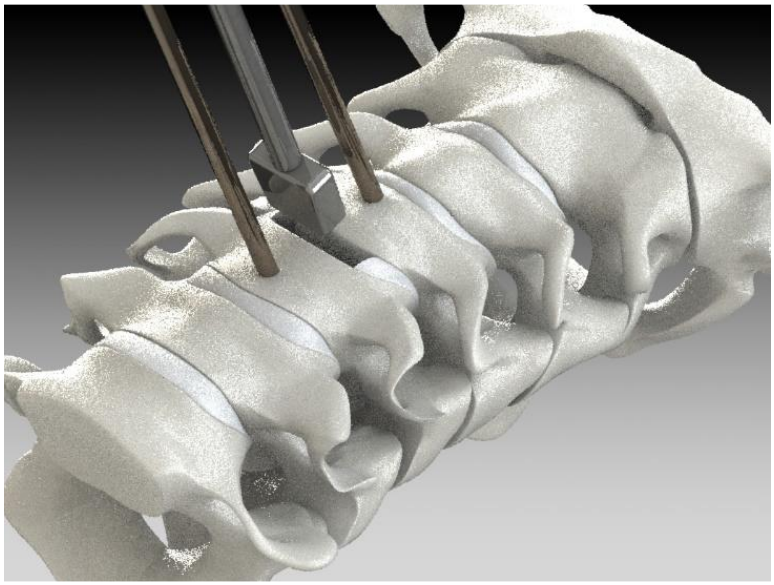
Place distraction screws in the adjacent vertebral bodies and attach a Caspar distractor.



Distraction

DETERMINE IMPLANT SIZE

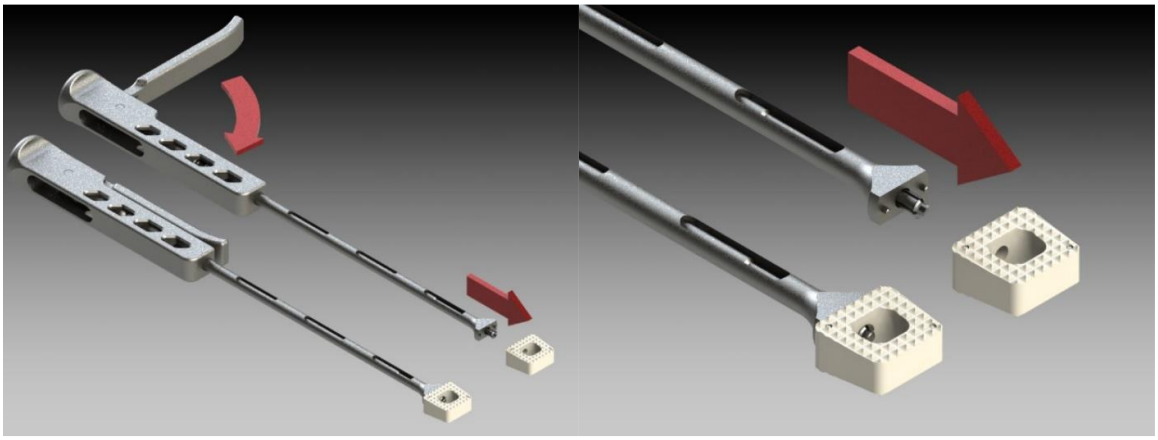
After ensuring proper distraction of the intervertebral space with a Caspar distractor, use the provided implant trials to determine the appropriate implant size for the procedure. Be sure to note the size marked on the trial. Slight impaction may be used to introduce the trial into the intervertebral space. Use a smaller trial if the fit is deemed too tight, or a larger trial if the fit is deemed too loose. Confirm fit of the trial radiographically.



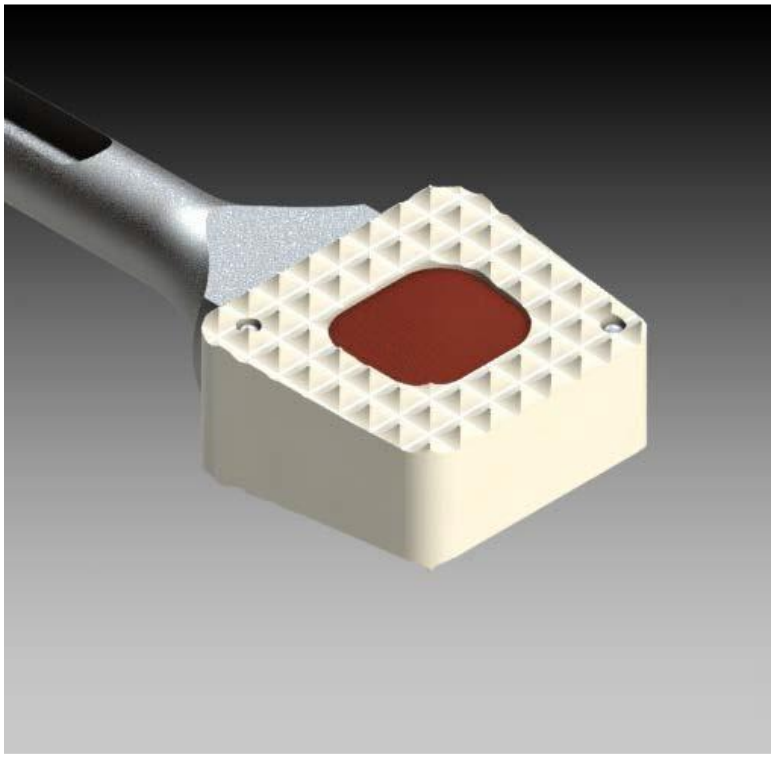
Trialing implant size

IMPLANT SELECTION AND PREPARATION

Select the implant that matches the appropriate implant trial. Attach the selected implant to the inserter, check again that it is the appropriate size and place it in the graft loading block. Fill the implant with bone graft or bone graft substitute and pack it down with the tamp. Do not use a mallet for packing down the bone graft as this may damage the structural integrity of the implant.



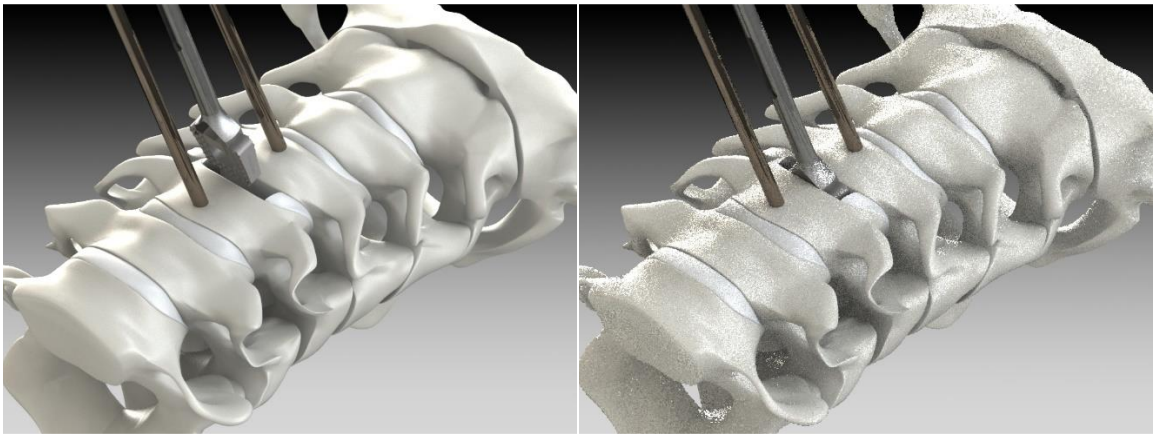
Attaching the implant to inserter



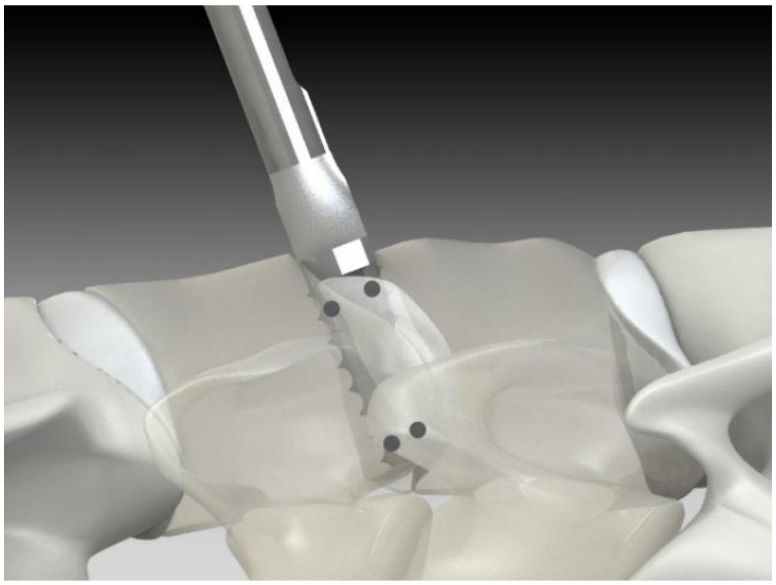
Implant packed with bone graft or bone graft substitute

IMPLANT INSERTION

Align the implant to the prepared intervertebral space and carefully insert the implant. Proper positioning may be facilitated by using slight impaction. Confirm the location of the implant radiographically. Once proper positioning has been achieved, disconnect the inserter from the implant and remove from the surgical site. Also remove the Caspar distractor and distractor pins. Verify correct positioning of the implant radiographically again.



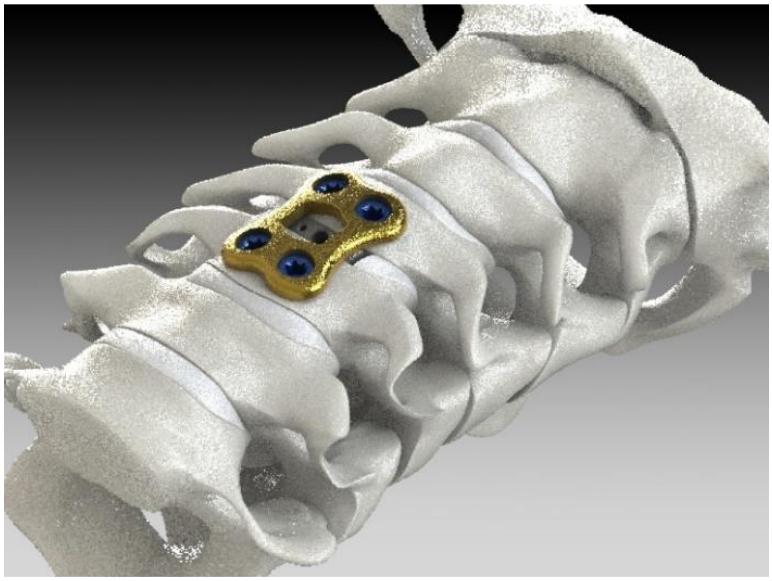
Implant insertion



Typical final position of implant

CERVICAL PLATE

Implant an approved cervical plate and screw system at the appropriate level to provide additional stabilization.



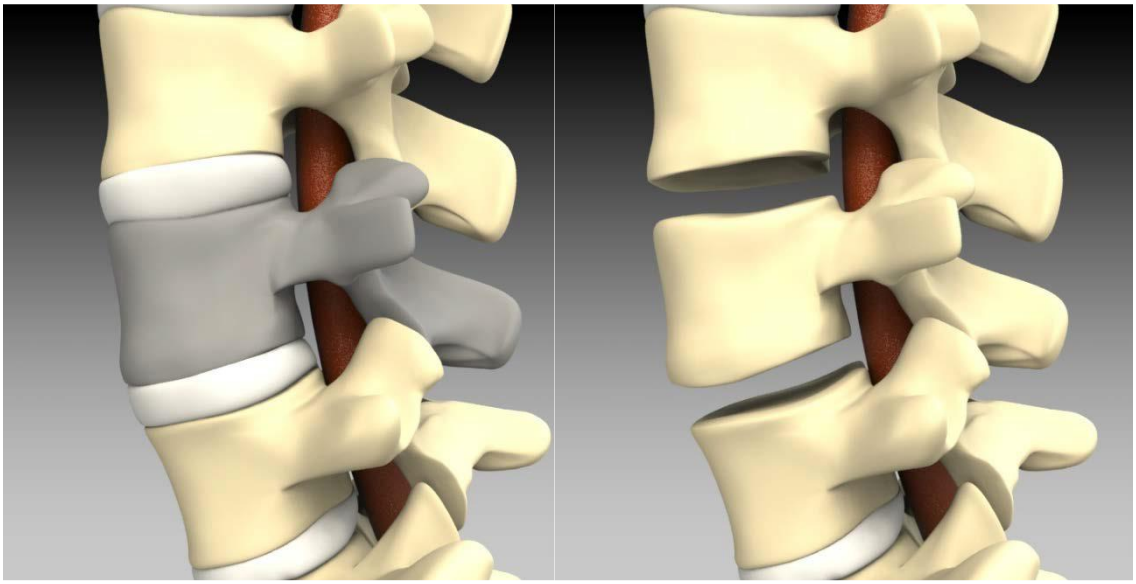
Cervical plate and screw system (example)

EXPOSURE OF THE INTERVERTEBRAL SPACE

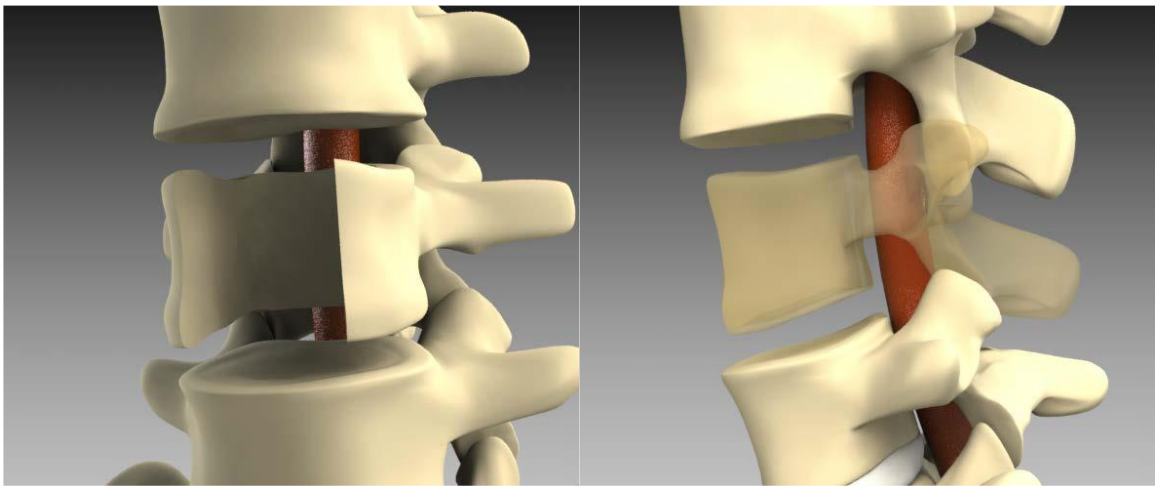
Locate the correct operative level using radiographic assistance. Expose the vertebral body being replaced as well as the adjacent vertebral discs via a standard anterior approach to the lumbar spine. Carefully place retractors to provide sufficient access to the surgical area.

DISCECTOMY AND CORPECTOMY

Perform a complete discectomy on the adjacent intervertebral discs employing rongeurs and curettes as appropriate. Take care to avoid damaging the endplates of the adjacent vertebral bodies in order to minimize the probability of implant subsidence.



Identify target vertebral body (highlighted body shown) and perform discectomies on caudal and cephalad intervertebral discs.

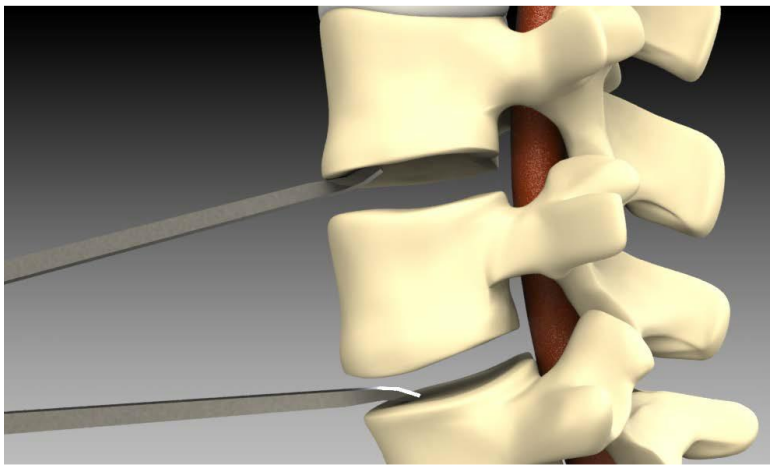


Perform corpectomy as necessary (corpectomy shown is for illustrative purposes only, actual procedures may have more or less bone removed).

DETERMINE IMPLANT SIZE

Determining the appropriate implant size may be achieved by employing the measurement caliper provided in the instrument set. Measure the distance from the endplates of the superior and inferior intact vertebrae respectively. If desired, the surgeon may apply traction to the spinal column to achieve proper spacing between intact vertebrae. Note the distance indicated on the measurement caliper and select the appropriately sized implant.

Measurement Caliper

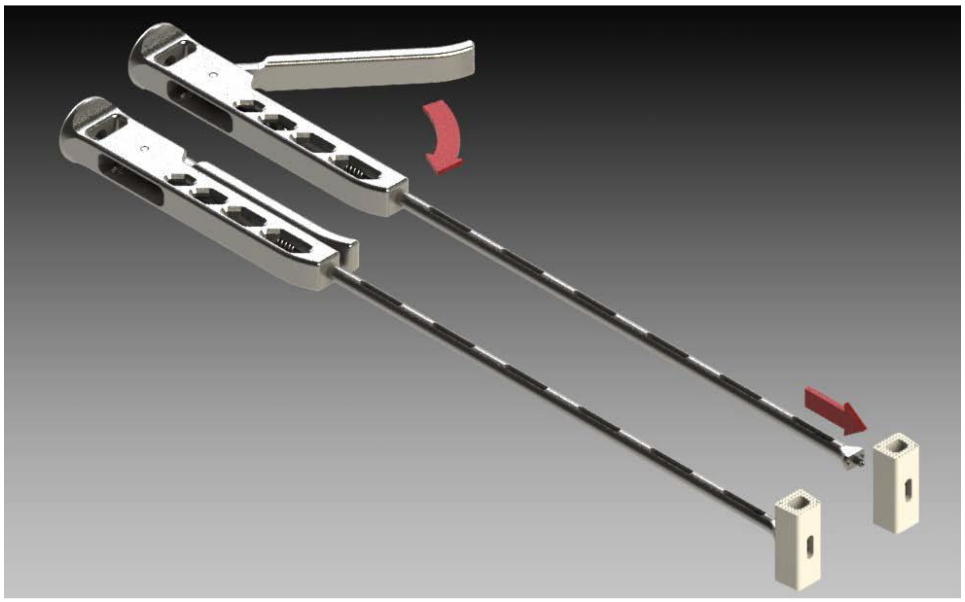


Employing caliper to measure space

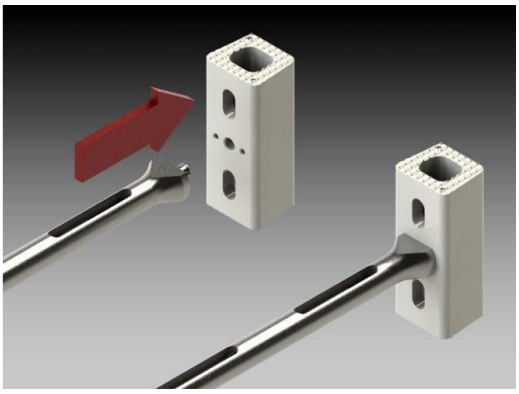
Reading Caliper

IMPLANT SELECTION AND PREPARATION

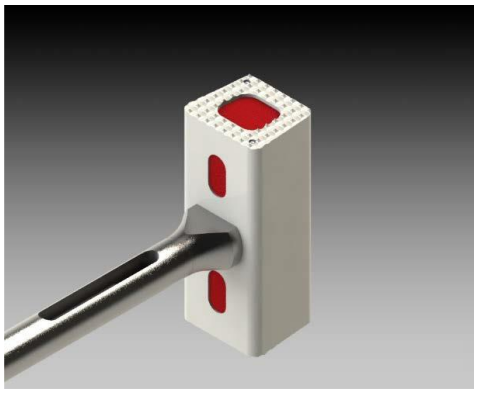
Select the implant that matches the appropriate implant trial. Attach the selected implant to the inserter, check again that it is the appropriate size and fill the implant with bone graft or bone graft substitute and pack it down with the impactor tool. Do not use a mallet for packing down the bone graft as this may damage the structural integrity of the implant.



Attaching implant to inserter, locking inserter



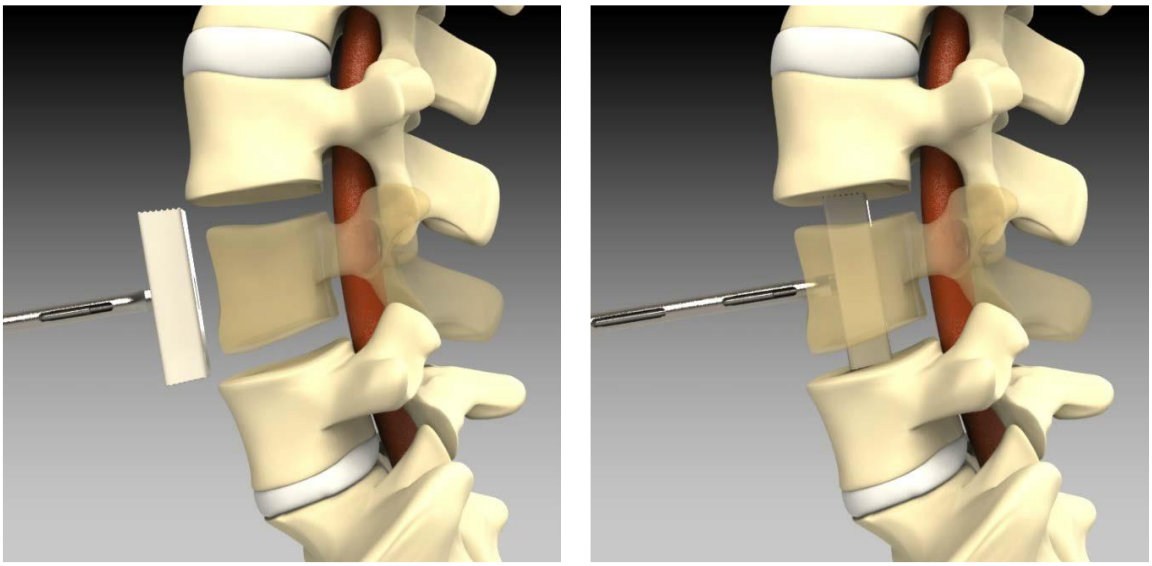
Attaching implant to inserter



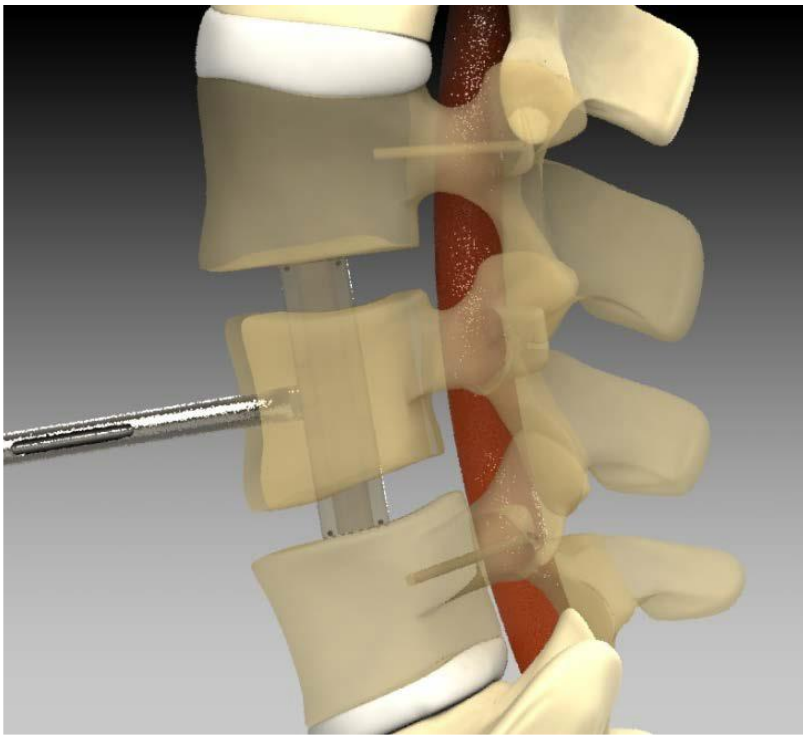
Packing bone graft in implant

IMPLANT INSERTION

Align the implant to the prepared space and carefully insert the implant. If desired, the surgeon may apply traction to the spinal column to distract the space between intact vertebrae. Proper positioning may be facilitated by using slight impaction. Confirm the location of the implant radiographically, being sure to identify the radiographic markers in the implant. Once proper positioning has been achieved, disconnect the inserter from the implant remove from the surgical site. Verify correct positioning of the implant radiographically again.



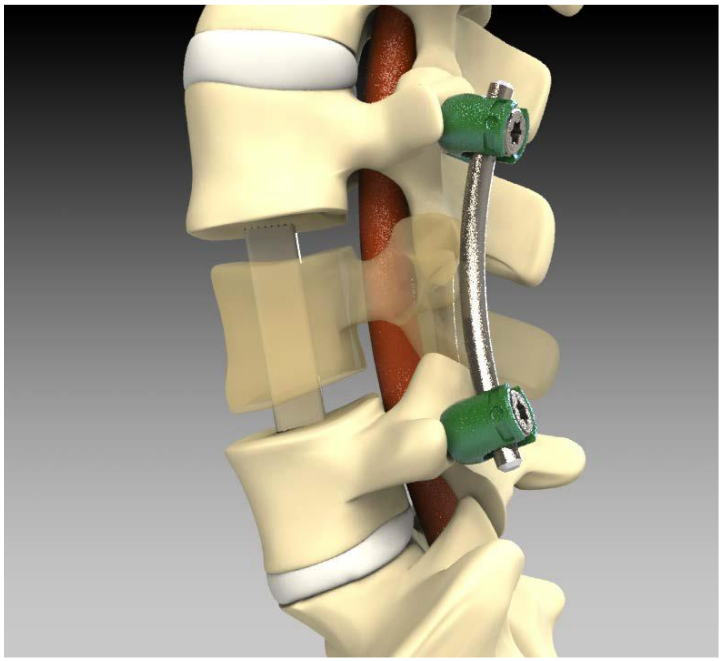
Insert implant – approach and final position



Radiographic check of implant position

SUPPLEMENTAL FIXATION

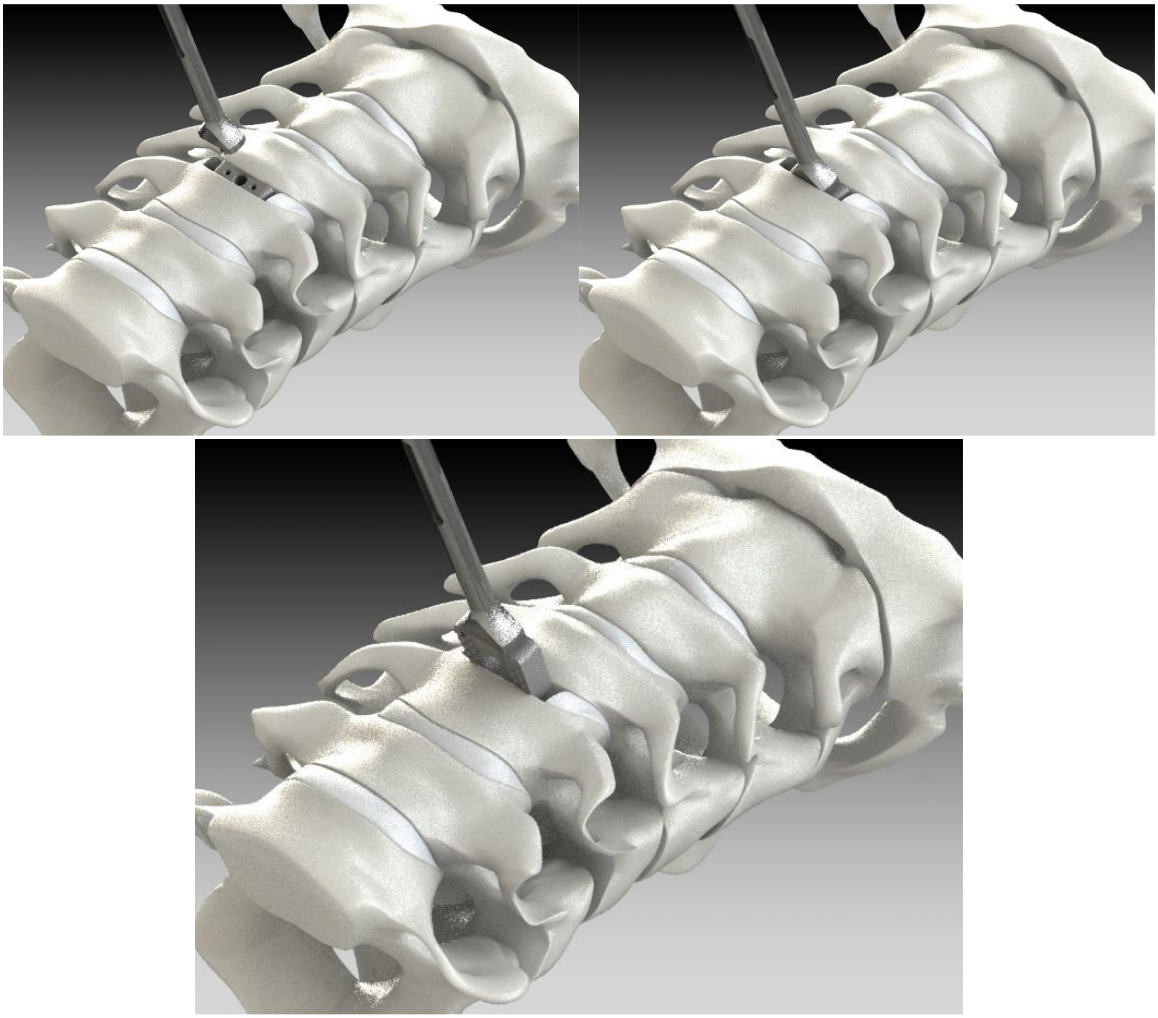
Supplemental posterior fixation is achieved through the use of an approved pedicle screw system as shown.



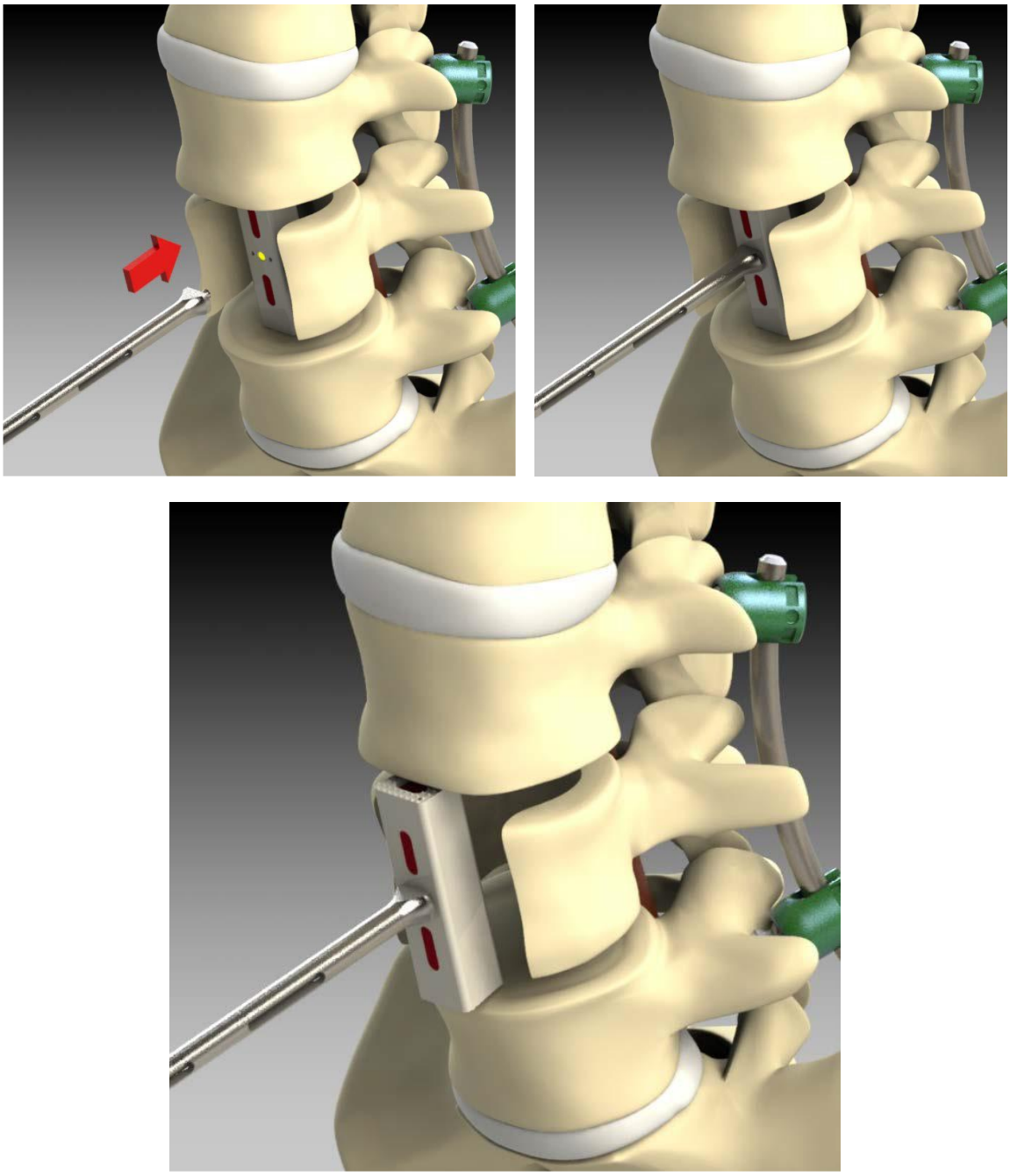
Final construct with pedicle screw in place.
(L4 vertebral body transparent for illustrative purposes.)

IMPLANT REMOVAL

This procedural step is only to be conducted if it is necessary to remove the implant from the intervertebral space. Being careful not to push the implant any further into the intervertebral space, attach the implant inserter to the implant ensuring that the alignment holes are engaged. Close the lever to ensure proper attachment of the instrument to the inserter. Applying an upward force and being careful not twist or bend the attachment between the implant and the inserter, remove the implant from the intervertebral space. Gentle tapping from a tap hammer is permissible.



Cervical Implant Removal

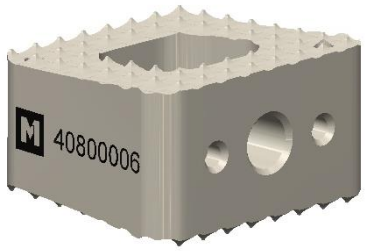


Corpectomy Implant Removal

CERVICAL IMPLANTS

The following implant sizes are indicated for use as an Intervertebral Body Fusion Device:

DESCRIPTION	CATALOG #	IMPLANT SIZE
Audere C Cervical Implant	40050000	5x0°
Audere C Cervical Implant	40060000	6x0°
Audere C Cervical Implant	40070000	7x0°
Audere C Cervical Implant	40080000	8x0°
Audere C Cervical Implant	40090000	9x0°
Audere C Cervical Implant	40100000	10x0°
Audere C Cervical Implant	40050006	5x6°
Audere C Cervical Implant	40060006	6x6°
Audere C Cervical Implant	40070006	7x6°
Audere C Cervical Implant	40080006	8x6°
Audere C Cervical Implant	40090006	9x6°
Audere C Cervical Implant	40100006	10x6°



Audere C Cervical Implant

CORPECTOMY IMPLANTS

The following implant sizes are indicated for use as a Vetebral Body Replacement Device:

DESCRIPTION	CATALOG #	IMPLANT SIZE
Audere C Corpectomy Implant	41110000	11x0°
Audere C Corpectomy Implant	41120000	12x0°
Audere C Corpectomy Implant	41130000	13x0°
Audere C Corpectomy Implant	41140000	14x0°
Audere C Corpectomy Implant	41150000	15x0°
Audere C Corpectomy Implant	41160000	16x0°
Audere C Corpectomy Implant	41170000	17x0°
Audere C Corpectomy Implant	41180000	18x0°
Audere C Corpectomy Implant	41190000	19x0°
Audere C Corpectomy Implant	41200000	20x0°
Audere C Corpectomy Implant	41210000	21x0°
Audere C Corpectomy Implant	41220000	22x0°
Audere C Corpectomy Implant	41230000	23x0°
Audere C Corpectomy Implant	41240000	24x0°
Audere C Corpectomy Implant	41250000	25x0°
Audere C Corpectomy Implant	41260000	26x0°
Audere C Corpectomy Implant	41270000	27x0°
Audere C Corpectomy Implant	41280000	28x0°
Audere C Corpectomy Implant	41290000	29x0°
Audere C Corpectomy Implant	41300000	30x0°
Audere C Corpectomy Implant	41310000	31x0°
Audere C Corpectomy Implant	41320000	32x0°
Audere C Corpectomy Implant	41330000	33x0°
Audere C Corpectomy Implant	41340000	34x0°
Audere C Corpectomy Implant	41350000	35x0°
Audere C Corpectomy Implant	41360000	36x0°
Audere C Corpectomy Implant	41370000	37x0°

Audere C Corpectomy Implant

IMPLANT OVERVIEW

DESCRIPTION	CATALOG #	IMPLANT SIZE
Audere C Corpectomy Implant	41380000	38x0°
Audere C Corpectomy Implant	41390000	39x0°
Audere C Corpectomy Implant	41400000	40x0°
Audere C Corpectomy Implant	41410000	41x0°
Audere C Corpectomy Implant	41420000	42x0°
Audere C Corpectomy Implant	41430000	43x0°
Audere C Corpectomy Implant	41440000	44x0°
Audere C Corpectomy Implant	41450000	45x0°
Audere C Corpectomy Implant	41460000	46x0°
Audere C Corpectomy Implant	41470000	47x0°
Audere C Corpectomy Implant	41480000	48x0°
Audere C Corpectomy Implant	41490000	49x0°
Audere C Corpectomy Implant	41500000	50x0°
Audere C Corpectomy Implant	41510000	51x0°
Audere C Corpectomy Implant	41520000	52x0°
Audere C Corpectomy Implant	41530000	53x0°
Audere C Corpectomy Implant	41540000	54x0°
Audere C Corpectomy Implant	41550000	55x0°
Audere C Corpectomy Implant	41560000	56x0°
Audere C Corpectomy Implant	41570000	57x0°
Audere C Corpectomy Implant	41580000	58x0°
Audere C Corpectomy Implant	41590000	59x0°
Audere C Corpectomy Implant	41600000	60x0°
Audere C Corpectomy Implant	41110006	11x6°
Audere C Corpectomy Implant	41120006	12x6°
Audere C Corpectomy Implant	41130006	13x6°
Audere C Corpectomy Implant	41140006	14x6°
Audere C Corpectomy Implant	41150006	15x6°
Audere C Corpectomy Implant	41160006	16x6°
Audere C Corpectomy Implant	41170006	17x6°
Audere C Corpectomy Implant	41180006	18x6°
Audere C Corpectomy Implant	41190006	19x6°
Audere C Corpectomy Implant	41200006	20x6°
Audere C Corpectomy Implant	41210006	21x6°
Audere C Corpectomy Implant	41220006	22x6°
Audere C Corpectomy Implant	41230006	23x6°
Audere C Corpectomy Implant	41240006	24x6°
Audere C Corpectomy Implant	41250006	25x6°
Audere C Corpectomy Implant	41260006	26x6°
Audere C Corpectomy Implant	41270006	27x6°
Audere C Corpectomy Implant	41280006	28x6°
Audere C Corpectomy Implant	41290006	29x6°
Audere C Corpectomy Implant	41300006	30x6°
Audere C Corpectomy Implant	41310006	31x6°
Audere C Corpectomy Implant	41320006	32x6°
Audere C Corpectomy Implant	41330006	33x6°

Audere C Corpectomy Implant

IMPLANT OVERVIEW

DESCRIPTION	CATALOG #	IMPLANT SIZE
Audere C Corpectomy Implant	41340006	34x6°
Audere C Corpectomy Implant	41350006	35x6°
Audere C Corpectomy Implant	41360006	36x6°
Audere C Corpectomy Implant	41370006	37x6°
Audere C Corpectomy Implant	41380006	38x6°
Audere C Corpectomy Implant	41390006	39x6°
Audere C Corpectomy Implant	41400006	40x6°
Audere C Corpectomy Implant	41410006	41x6°
Audere C Corpectomy Implant	41420006	42x6°
Audere C Corpectomy Implant	41430006	43x6°
Audere C Corpectomy Implant	41440006	44x6°
Audere C Corpectomy Implant	41450006	45x6°
Audere C Corpectomy Implant	41460006	46x6°
Audere C Corpectomy Implant	41470006	47x6°
Audere C Corpectomy Implant	41480006	48x6°
Audere C Corpectomy Implant	41490006	49x6°
Audere C Corpectomy Implant	41500006	50x6°
Audere C Corpectomy Implant	41510006	51x6°
Audere C Corpectomy Implant	41520006	52x6°
Audere C Corpectomy Implant	41530006	53x6°
Audere C Corpectomy Implant	41540006	54x6°
Audere C Corpectomy Implant	41550006	55x6°
Audere C Corpectomy Implant	41560006	56x6°
Audere C Corpectomy Implant	41570006	57x6°
Audere C Corpectomy Implant	41580006	58x6°
Audere C Corpectomy Implant	41590006	59x6°
Audere C Corpectomy Implant	41600006	60x6°

Audere C Corpectomy Implant

EXCEPTIONAL SERVICE. SUPERIOR PRODUCTS. INNOVATIVE MINDS.

The physicians we work with are Renaissance thinkers. Their mastery, scientific insight and innovative minds inspire our product development. Met One puts advanced technology to work for physicians who artfully transform patients' lives.

INDICATIONS FOR USE

When used as an Intervertebral Body Fusion Device

The Audere C cervical spine devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine (C2-T1). The Audere C device is intended to be used with autograft and/or allograft bone (allogenic bone graft comprised of cancellous and/or corticocancellous bone graft). The Audere C device is intended to be used with an FDA-cleared cervical supplemental fixation system. Patients should receive six weeks of nonoperative treatment prior to treatment.

When used as a Vertebral Body Replacement Device

The Audere C device is indicated for use in the thoracolumbar spine (T1-L5) for partial or total replacement of a damaged, collapsed, or unstable vertebral body due to trauma/fracture or tumor to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Audere C device is intended to be used with autograft and/or allograft bone. The Audere C device is intended to be used with an FDA cleared supplemental fixation device such as a lumbar pedicle screw system.

For additional product information including warnings, precautions and adverse effects concerning spinal fixation implants refer to the product insert.

CONTRAINDICATIONS

These systems are contraindicated for use in patients with the following:

1. Active infectious process or significant risk of infection (immunocompromised)
2. Signs of local inflammation
3. Fever or leukocytosis
4. Osteoporosis or similar loss of bone density
5. Morbid obesity
6. Pregnancy
7. Gross distorted anatomy caused by congenital abnormalities

8. Suspected or documented metal allergy or intolerance
9. Prior fusion at the level being treated
10. Any case not described in the indications

WARNINGS

Potential risks identified with the use of this intervertebral body-fusion device, 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.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Never reuse an internal fixation device under any circumstances.

Only surgeons trained in and experienced with spinal-fusion and bone-grafting techniques should use the Audere C Spinal Implant System. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants, are essential considerations in the utilization of this device.

Do not reuse implants. Discard used, damaged or otherwise suspect implants. AN IMPLANT SHOULD NEVER BE REUSED. Any implant, once used, should be discarded.

PRECAUTIONS

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body-fusion device.

The implantation of the intervertebral body fusion device and/or vertebral body replacement device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Accepted medical practices, in addition to any local and national requirements, should be employed in the handling and disposal of all contaminated implants.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

MRI SAFETY INFORMATION

The Audere C Spinal Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Audere C Spinal Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING

Implants are provided clean but not sterile. ISO 8828 or ACORN recommended practices for in-hospital sterilization should be followed for all components.

Once an implant comes in contact with any human tissue or bodily fluid, it should not be resterilized and used. Please discard all contaminated implants.

1. Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions.
2. Immediately after the procedure, soak and manually agitate the soiled instruments in the solution for the minimum recommended time specified by the solution manufacturer or 10 minutes, whichever is longer.
3. Using a soft bristle scrub brush, scrub instruments to remove all traces of blood and debris from the instrument surfaces. Employ a soft bristle brush or pipe cleaner to reach the entire length of all instrument lumens.
4. Rinse instruments with warm 85°F-104°F (30°C-40°C) tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
5. Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions.
6. Rinse instruments again with warm 85°F-104°F (30°C-40°C) tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
7. Dry the instruments immediately after final rinse with a clean towel or clean, dry compressed air until visibly dry.

INSPECTION

1. Carefully inspect all instruments before sterilization to ensure all visible blood and soil have been removed from surfaces, lumens, holes and moveable parts.
2. If damage or biological residue is observed on an implant, the implant must be discarded.

STERILIZATION

All implants should be placed in the provided implant caddies. All instruments should be placed in their appropriate locations within the instrument case(s).

Instrument case(s) to be double wrapped with FDA approved 1-ply polypropylene wrap (Kimguard KC600 or equivalent) with a surgical towel placed between the tray and the wrap.

Sterilization type:	Pre-vacuum
Preconditioning Pulses:	3
Exposed Temperature:	270°F (132°C)
Full Cycle Time:	4 min.
Minimum Dry Time:	20 min

LIMITED WARRANTY

Met One Technologies products are sold with a limited warranty to the original purchaser against defects in the workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than two years have elapsed between the date of issue/revision of this insert and the date of consultation, contact Met One Technologies for current information.

MANUFACTURED BY

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