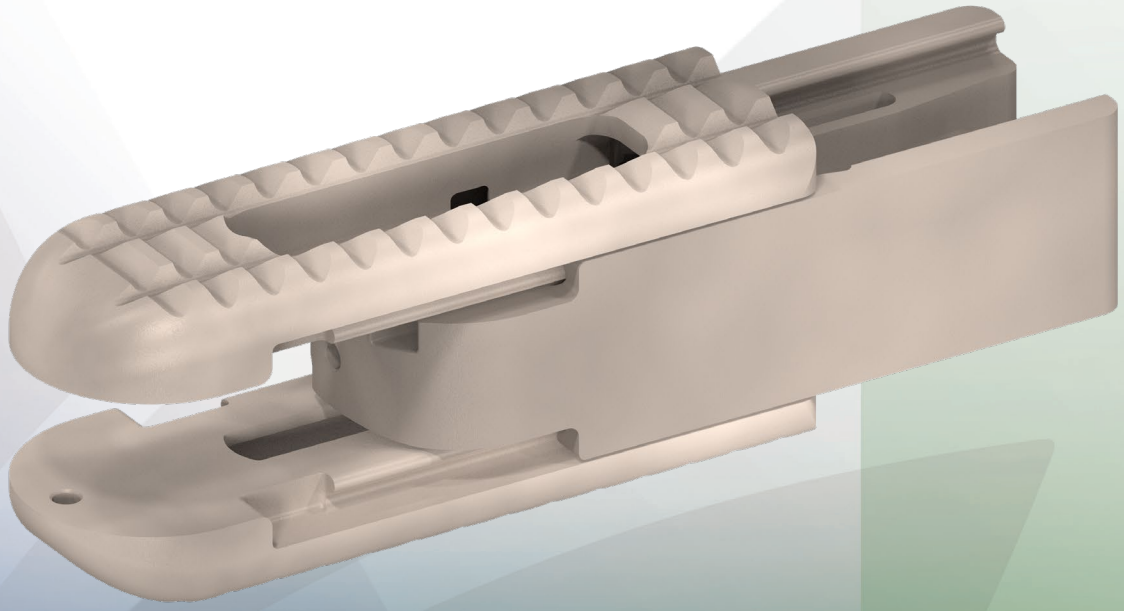
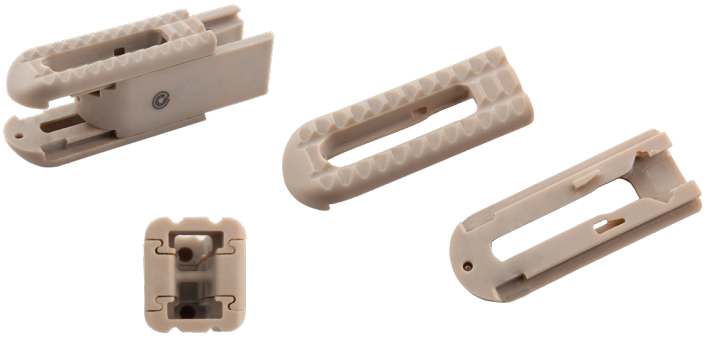
ChoiceSpine™
Propelling Spinal Surgery



OCTANE® M Surgical Technique

Modular Interbody System

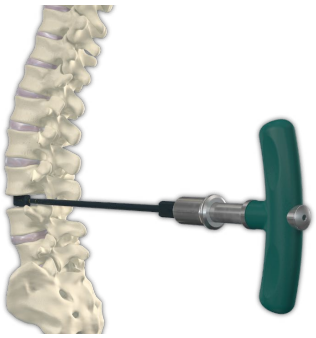


OCTANE® M

Octane M is a modular, self-distracting PEEK Spacer System designed to provide controlled delivery while minimizing impaction force.

TABLE OF CONTENTS

OPERATIVE TECHNIQUE OVERVIEW

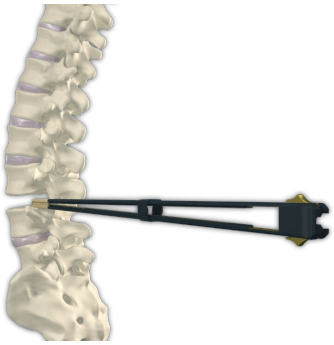


1

Insert Trial Spacer

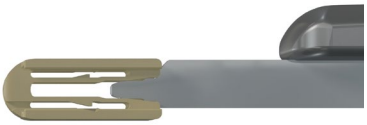
2

Attach Endplates to
Rail Assembly



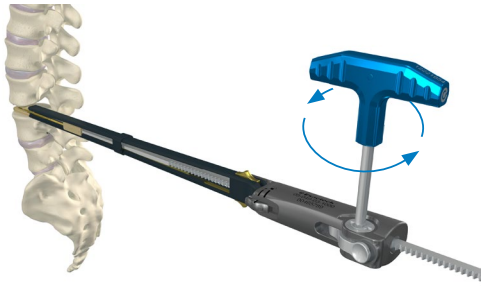
3

Guide the Endplates
into Position



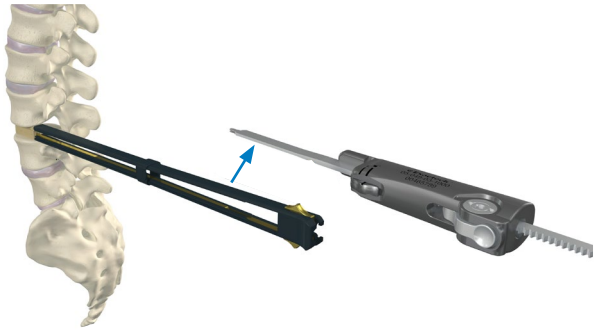
4

Attach Spacer



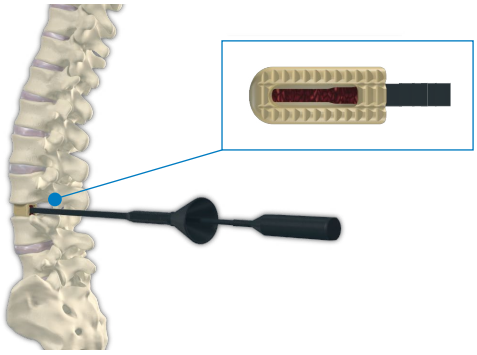
5

Advance the Spacer Using
the Gear Inserter



6

Disengage the Gear Inserter and
Rail Assembly



7

Insert the Bone Graft

DETAILED OPERATIVE TECHNIQUE

PREPARATION

Expose the posterior anatomy and perform the discectomy. A transforaminal approach is used for the 26mm and 30mm spacers.

A posterior disc preparation set of instruments is available upon request to supplement the Octane M Instrumentation.

IMPLANT SIZING

Choose the appropriate Trial Spacer and attach it to either the T or Straight Handle. Insert the Trial Spacer into the intervertebral space (Figure 1) and rotate it 90° in order to determine height adequacy (Figure 2). Repeat, using the next larger size trial if necessary, until the desired disc space height is obtained. Use A/P and lateral fluoroscopy to confirm proper placement and trajectory.

Note: If a height of smaller than 9mm is required, Octane Straight is available upon request. Lengths of 24, 28, & 32mm and heights ranging from 6-15mm are offered in both straight insertion and insert-and-rotate

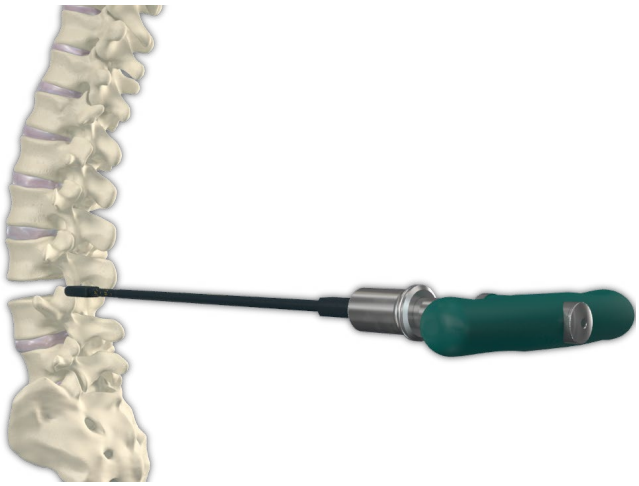


Figure 1
Insert the Trial Spacer

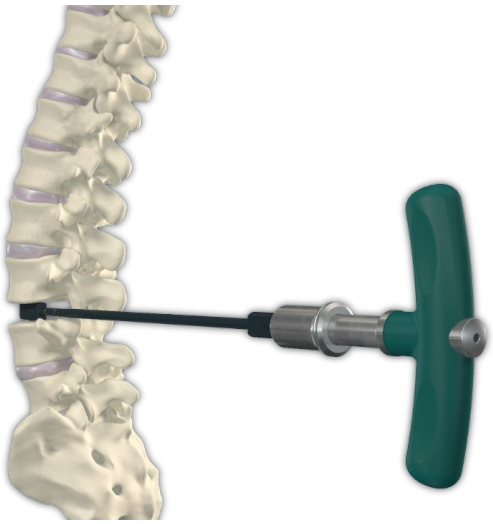


Figure 2
Determine Height Adequacy

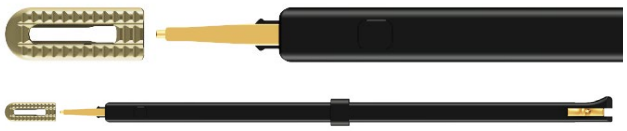


Figure 3
Attach Endplates to Rail Assembly

Figure 4
Endplates Attached to Inserter

IMPLANT INSERTION

Choose the appropriately sized implant based on the size determined during disc preparation and remove the Octane M Endplate implants from their sterile package.

To assemble the implant, first attach the endplates to the Inserter Rail Assembly by sliding the Rail Shafts into the Inserter Rail in the “unlocked” position (Figure 3 & 4).

Ensure that the (2) Rail Shafts on the Inserter Rail Assembly are in the unlocked position (Figure 5) and snap each Octane M Endplate over the dual hooks at the Assembly’s distal end. Make sure the teeth on the Endplates point outward.

Lock the Endplates onto the Inserter Rail Assembly by sliding the (2) Rail Shafts to the locked position (Figure 6).

Figure 5
Inserter in Unlocked Position

Figure 6
Inserter in Locked Position

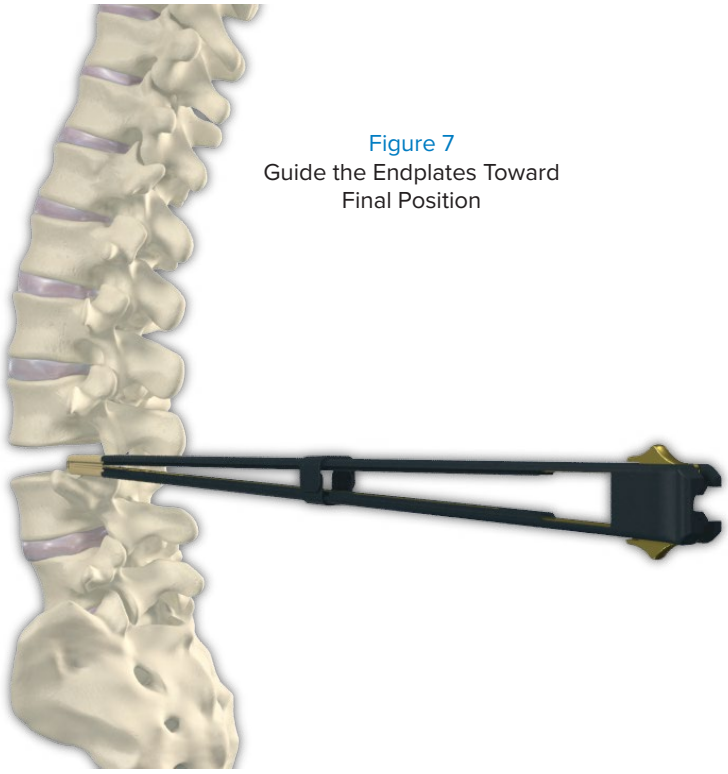


Figure 7
Guide the Endplates Toward Final Position

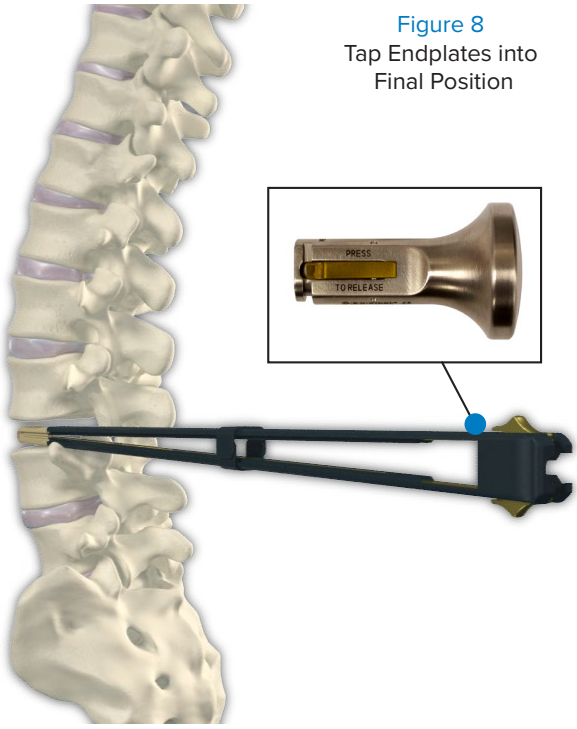


Figure 8
Tap Endplates into Final Position

application.

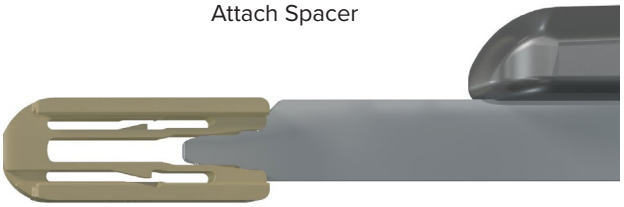
Implant Endplate Insertion

Orient the proximal U-channel opening of the Inserter Rail Assembly medially to guide the Endplates toward a final intervertebral position (Figure 7).

If necessary, slide the Impaction Cap into the proximal channel of the Inserter Rail Assembly and gently tap the Endplates into a final position (Figure 8). Once the Endplates are in the proper position, remove the Impaction Cap by pushing the release button and sliding it out of the Inserter Rail Assembly.

Remove the appropriately sized Octane M Spacer from its sterile package. Attach the Spacer to the distal end of the Gear Inserter's Shaft by sliding the forked tip over the spacer's center strut (Figure 9).

Figure 9
Attach Spacer



Implant Spacer Insertion

Ensure the Gear Inserter's shaft is in the retracted position.

Attach the Gear Inserter to the Inserter Rail Assembly by sliding it into the slot (Figure 10); the two instruments will lock together with the sliding lock featured on the Gear Inserter.

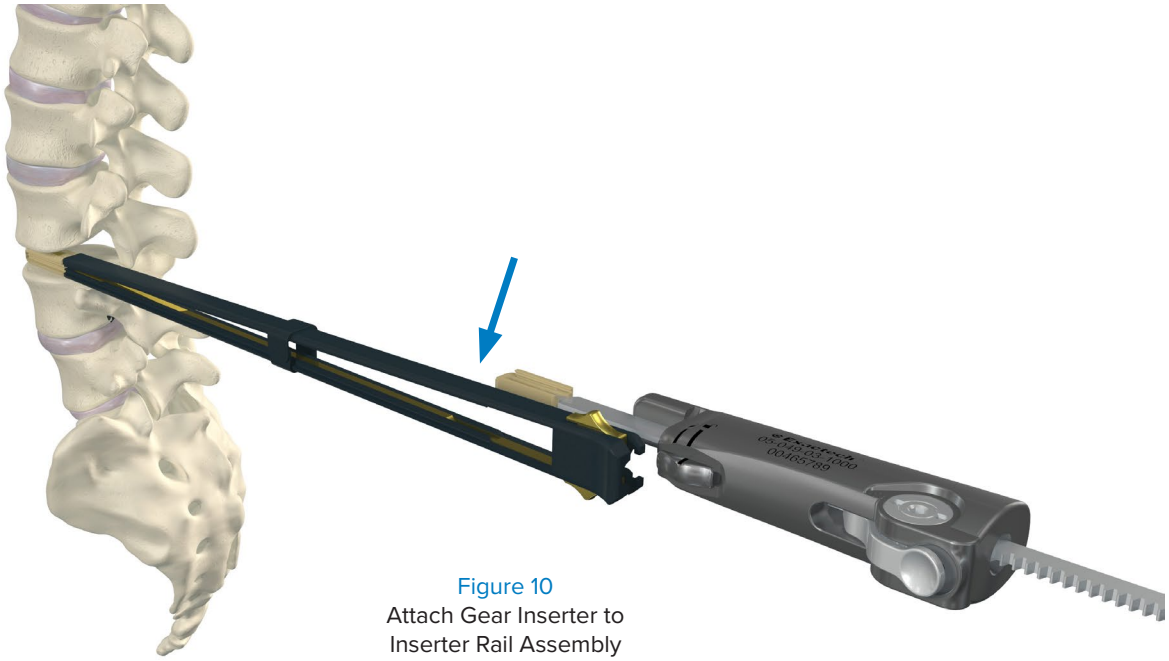


Figure 10
Attach Gear Inserter to Inserter Rail Assembly

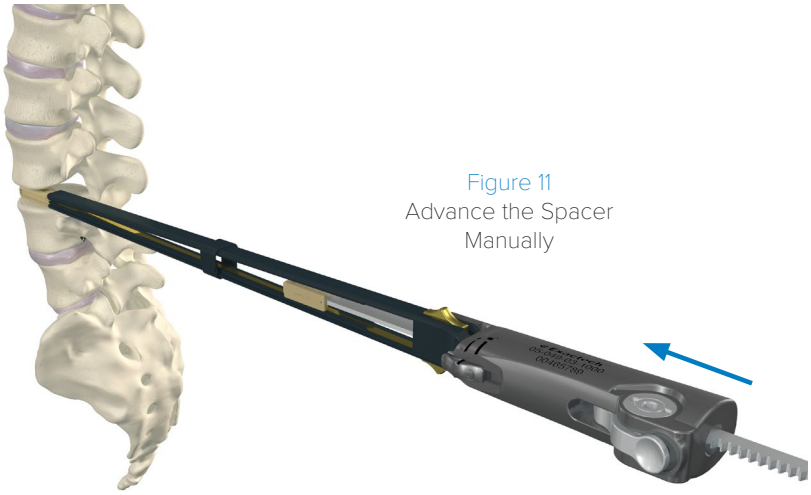
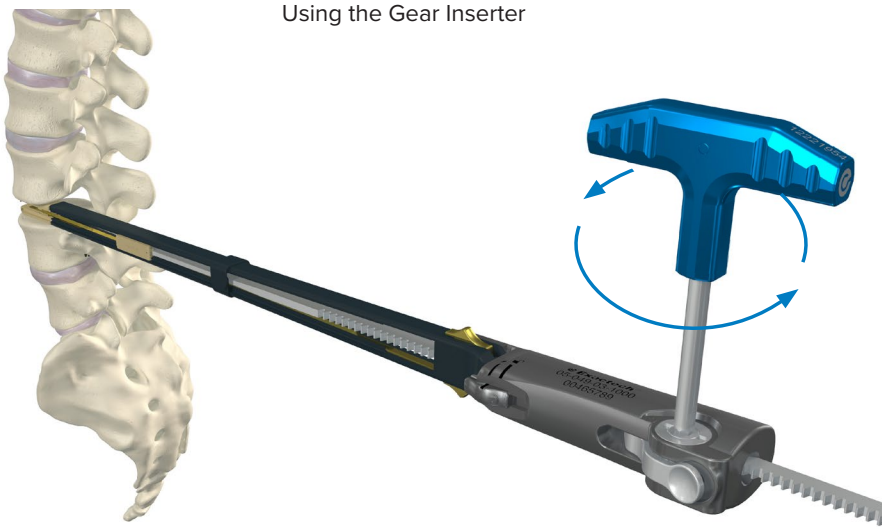


Figure 11
Advance the Spacer
Manually

Figure 12
Advance the Spacer
Using the Gear Inserter



Advance the Spacer down the Inserter Rail Assembly by hand as far as it will go without resistance (Figure 11). Then, introduce the Gear Inserter T-Handle to the Gear Inserter, turning downward from either side to further advance the Spacer down the Inserter Rails until the Spacer will no longer advance (Figure 12 & 13).

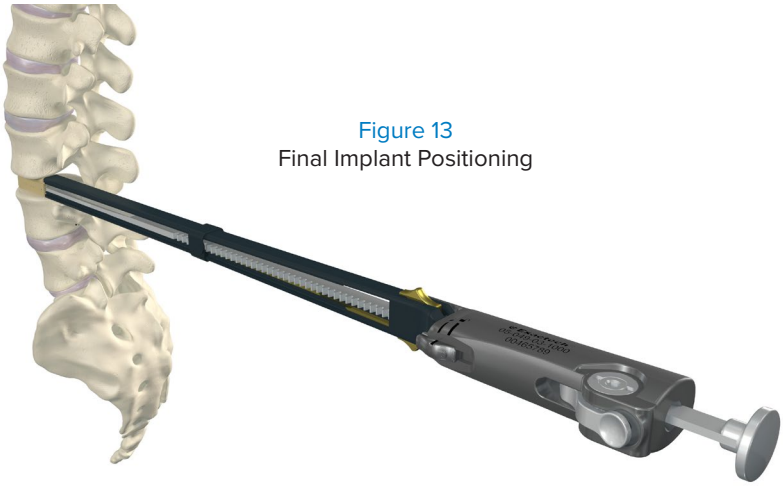


Figure 13
Final Implant Positioning

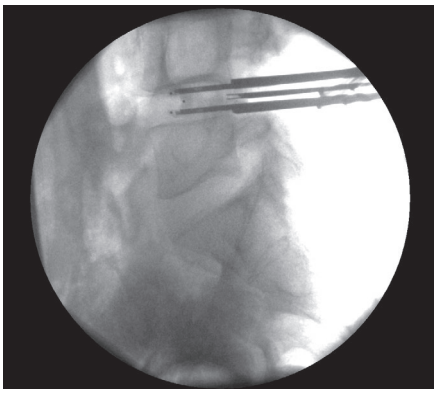


Figure 14
Verify Radiographic Markers

The implant is now assembled and locked. Successful assembly is verified when radiography shows that the three tantalum markers at the distal tip of the implant assembly are aligned (Figure 14 & 15).

Note: Do not attempt to pre-load the Spacer with autograft prior to assembly.

Note: Dural surface and traversing and exiting nerve roots must be protected at all times with appropriate technique and/or specific nerve root retractors based on the experience of the spinal surgeon.

DISENGAGING THE INSERTER

Firmly hold the Inserter Rail Assembly in a stationary position, and pull the Gear Inserter's shaft to the retracted position. This will disengage the Spacer (Figure 16).

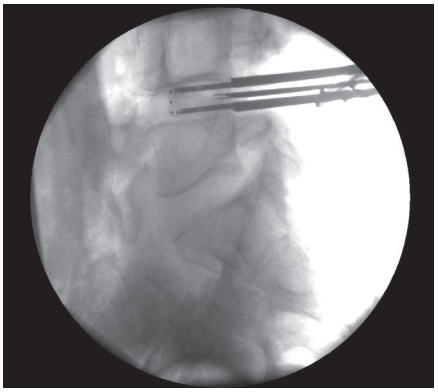


Figure 15
Verify Radiographic Markers

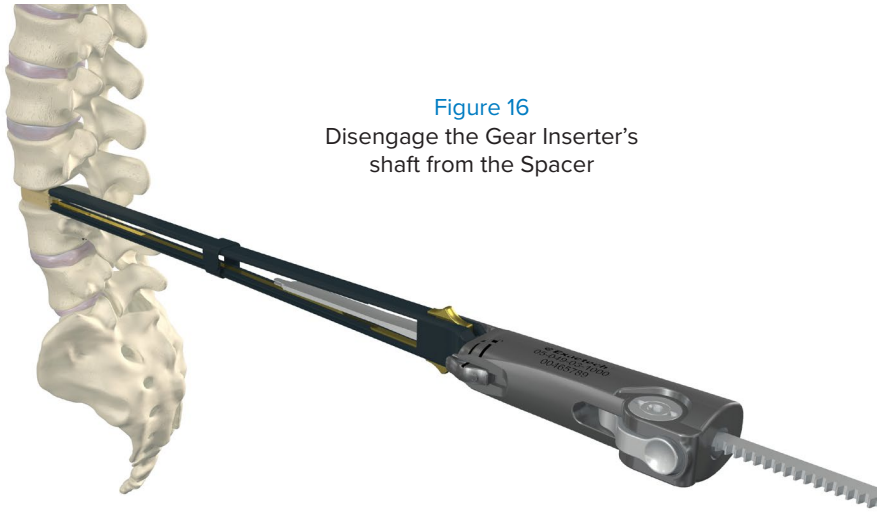


Figure 16
Disengage the Gear Inserter's shaft from the Spacer

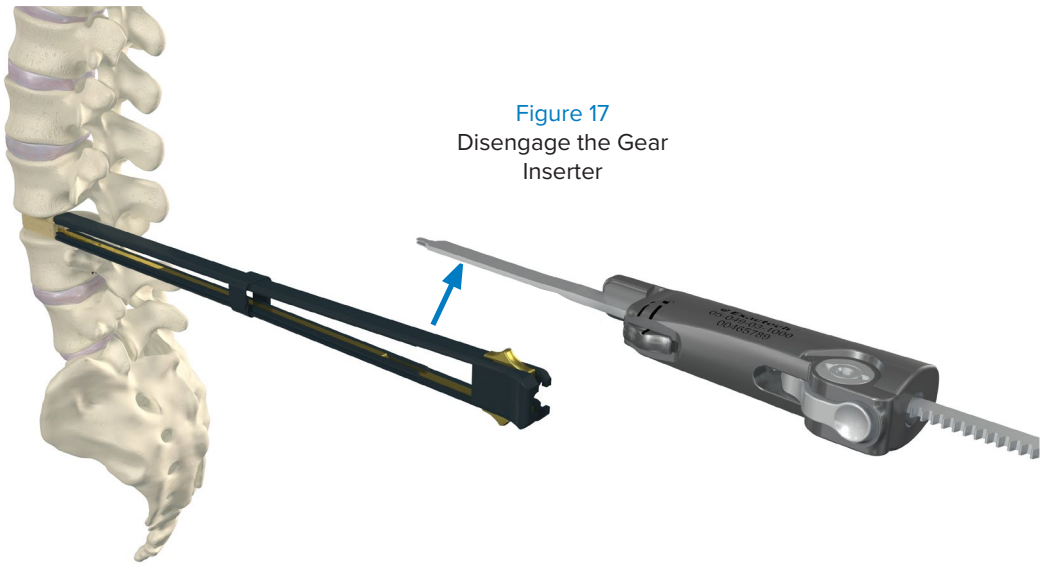


Figure 17
Disengage the Gear Inserter

Next, to unlock the Gear Inserter from the Inserter Rail Assembly, unlock the sliding lock located on the underside of the inserter and lift the inserter out of the Inserter Rail Assembly slot (Figure 17).

To remove the Inserter Rail Assembly from the implant, disengage the Rail Shafts by sliding them to the unlocked position (Figure 18)—the Rail Shaft Release Tool can be used for leverage if needed—then pull back on the Inserter Rail Assembly slowly to disengage the forked tip from the implant.

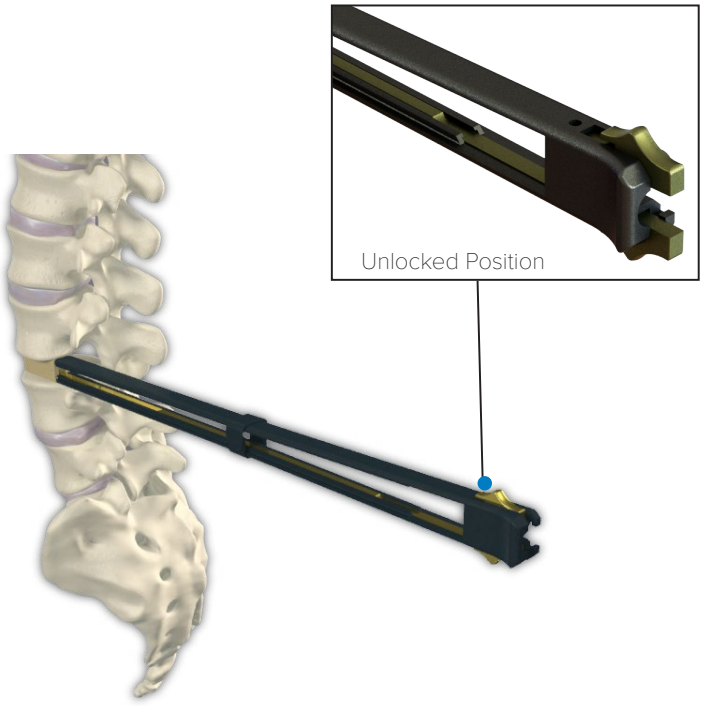


Figure 18
Inserter Rail Assembly in Locked Position

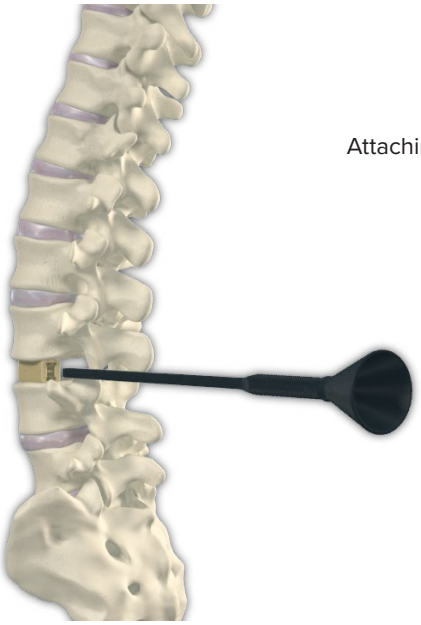


Figure 19
Attaching the Graft Funnel

BONE GRAFT PLACEMENT

After implant has been fully inserted, the openings in rear of the implant should be packed with autogenous bone —this should be performed prior to any further repositioning of the implant. The Graft Funnel and Graft Funnel Tamp can be used to facilitate placing autogenous bone graft as needed (Figure 19-20).

IMPLANT REMOVAL

To attach the Inserter Rail Assembly to the implant, first ensure that the Rail Shafts are in the unlocked position. Align the dual hooks at the distal end of the Inserter Rail Assembly with the mating feature in the posterior end of the implant and slide the shafts into the implant.

Lock the Inserter Rail Assembly to the implant by sliding both Rail Shafts to the locked position. The Inserter Rail Assembly is now securely connected to the implant. Using gentle force, slowly back out the implant from the disc space. Distraction of the segment may facilitate implant removal.

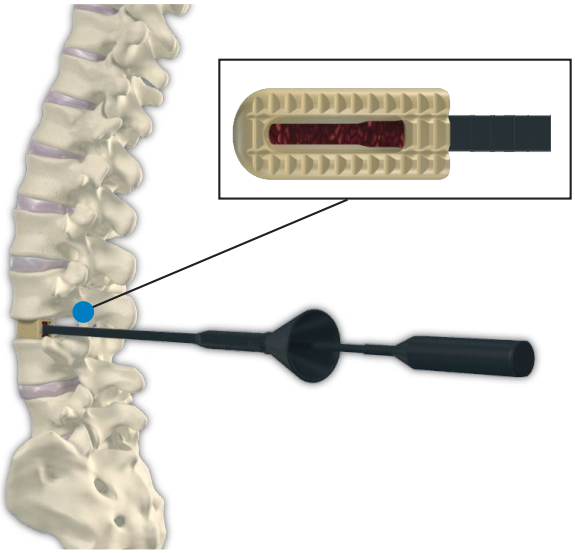


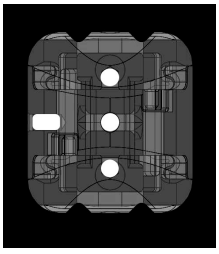
Figure 20
Inserting the Bone Graft

IMPLANT LISTING

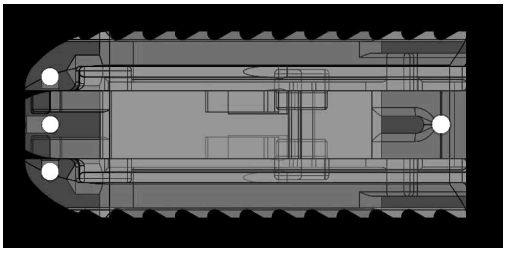
Catalog Number	Part Description	Graft Volume Graft not included
05-041-01-2609	Octane M 26x10x9mm	0.51cc
05-041-01-2610	Octane M 26x10x10mm	0.55cc
05-041-01-2611	Octane M 26x10x11mm	0.59cc
05-041-01-2612	Octane M 26x10x12mm	0.64cc
05-041-01-2613	Octane M 26x10x13mm	0.68cc
05-041-01-2614	Octane M 26x10x14mm	0.72cc
05-041-01-2615	Octane M 26x10x15mm	0.76cc
05-041-02-3009	Octane M 30x10x9mm	0.64cc
05-041-02-3010	Octane M 30x10x10mm	0.55cc
05-041-02-3011	Octane M 30x10x11mm	0.59cc
05-041-02-3012	Octane M 30x10x12mm	0.64cc
05-041-02-3013	Octane M 30x10x13mm	0.68cc
05-041-02-3014	Octane M 30x10x14mm	0.72cc
05-041-02-3015	Octane M 30x10x15mm	0.76cc

Radiographic Markers

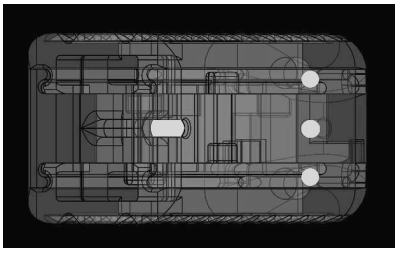
Anterior Posterior View

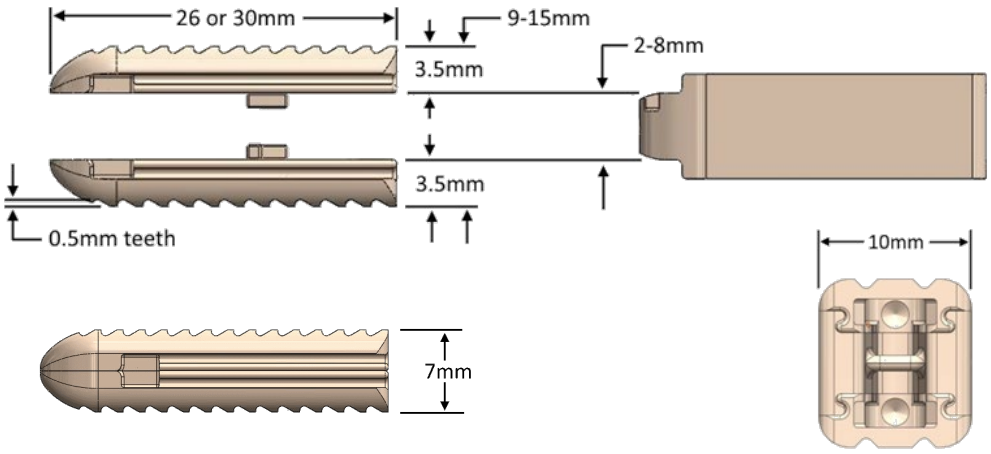


Lateral View



Oblique View





INSTRUMENT LISTING

Catalog Number	Part Description
05-049-01-0006	Trial Spacer, 6mm
05-049-01-0007	Trial Spacer, 7mm
05-049-01-0008	Trial Spacer, 8mm
05-049-01-0009	Trial Spacer, 9mm
05-049-01-0010	Trial Spacer, 10mm
05-049-01-0011	Trial Spacer, 11mm
05-049-01-0012	Trial Spacer, 12mm
05-049-01-0013	Trial Spacer, 13mm
05-049-01-0014	Trial Spacer, 14mm
05-049-01-0015	Trial Spacer, 15mm

05-049-02-0006	Paddle Scraper, 6mm
05-049-02-0007	Paddle Scraper, 7mm
05-049-02-0008	Paddle Scraper, 8mm
05-049-02-0009	Paddle Scraper, 9mm
05-049-02-0010	Paddle Scraper, 10mm
05-049-02-0011	Paddle Scraper, 11mm
05-049-02-0012	Paddle Scraper, 12mm
05-049-02-0013	Paddle Scraper, 13mm
05-049-02-0014	Paddle Scraper, 14mm
05-049-02-0015	Paddle Scraper, 15mm

28278	T-Handle

28277	Straight Handle

05-049-12-0000	Box Chisel

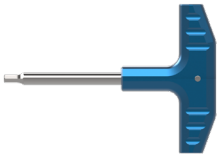
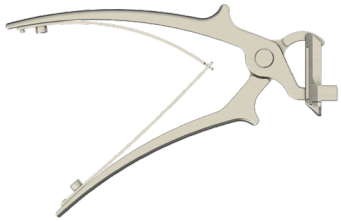
05-049-16-0000	Straight Rasp

05-049-17-0000	Angled Rasp

05-049-03-1000	Gear Inserter

05-049-04-0000	Inserter Rail

INSTRUMENT LISTING

Catalog Number	Part Description	
200-9027	Gear Inserter T-Handle	
05-049-05-0000	Rail Shaft	
05-049-08-0000	Graft Funnel	
05-049-09-0000	Graft Funnel Tamp	
05-049-10-0000	Straight Positioner	
05-049-11-0000	Angled Positioner	
05-049-13-0000	Impaction Cap	
05-049-18-0000	Rail Shaft Release Tool	
05-049-06-0001	Threaded Inserter, Outer	
05-049-06-0002	Threaded Inserter, Inner	

INDICATIONS FOR USE

GENERAL DESCRIPTION

The ChoiceSpine Octane-M Spinal Implant is an intervertebral body fusion device constructed of medical grade Polyetheretherketone (PEEK) as described by ASTM F2026. The implant incorporates ridges on the superior and inferior surfaces to resist expulsion. The device is provided in various configurations and heights and contains a hollow core to receive autogenous bone graft. The device incorporates tantalum markers conforming to ASTM F560 to permit verification of position.

INDICATIONS FOR USE

The Octane-M Spinal Implant is an intervertebral body fusion device intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The device is intended for use with autogenous bone graft and with supplemental internal fixation systems (i.e. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) cleared for use in the lumbosacral spine.

CONTRAINDICATIONS

Contraindications include, but are not limited to

- systemic, spinal, or localized infection;
- morbid obesity;
- active pregnancy;
- signs of local inflammation;
- fever or leukocytosis;
- prior fusion surgery at the involved level(s);
- cardiovascular complications;
- sensitivity/allergies to implant materials;
- any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
- grossly distorted anatomy due to congenital abnormalities;
- rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft);
- any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
- any case not described in the indications;
- any patient unwilling to cooperate with the postoperative instructions;
- any time implant utilization would interfere with anatomical structures or expected physiological performance.

WARNINGS AND PRECAUTIONS

The implantation of the Octane-M Spinal Implant is a technically demanding procedure presenting a risk of serious injury to the patient and should only be performed by experienced spinal surgeons with specific training in the use of this system. In addition, based on the fatigue test results, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions (e.g., smoking, occupation), which may impact on the performance of the implants.

The ChoiceSpine Octane-M Spinal Implant 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 Octane-M in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ChoiceSpine™
Propelling Spinal Surgery

400 Erin Drive, Knoxville, TN 37919 | O: 865.246.3333 | F: 865.246.3334 | choicespine.com

LIT# Octane M STG | REV00 | 6/19