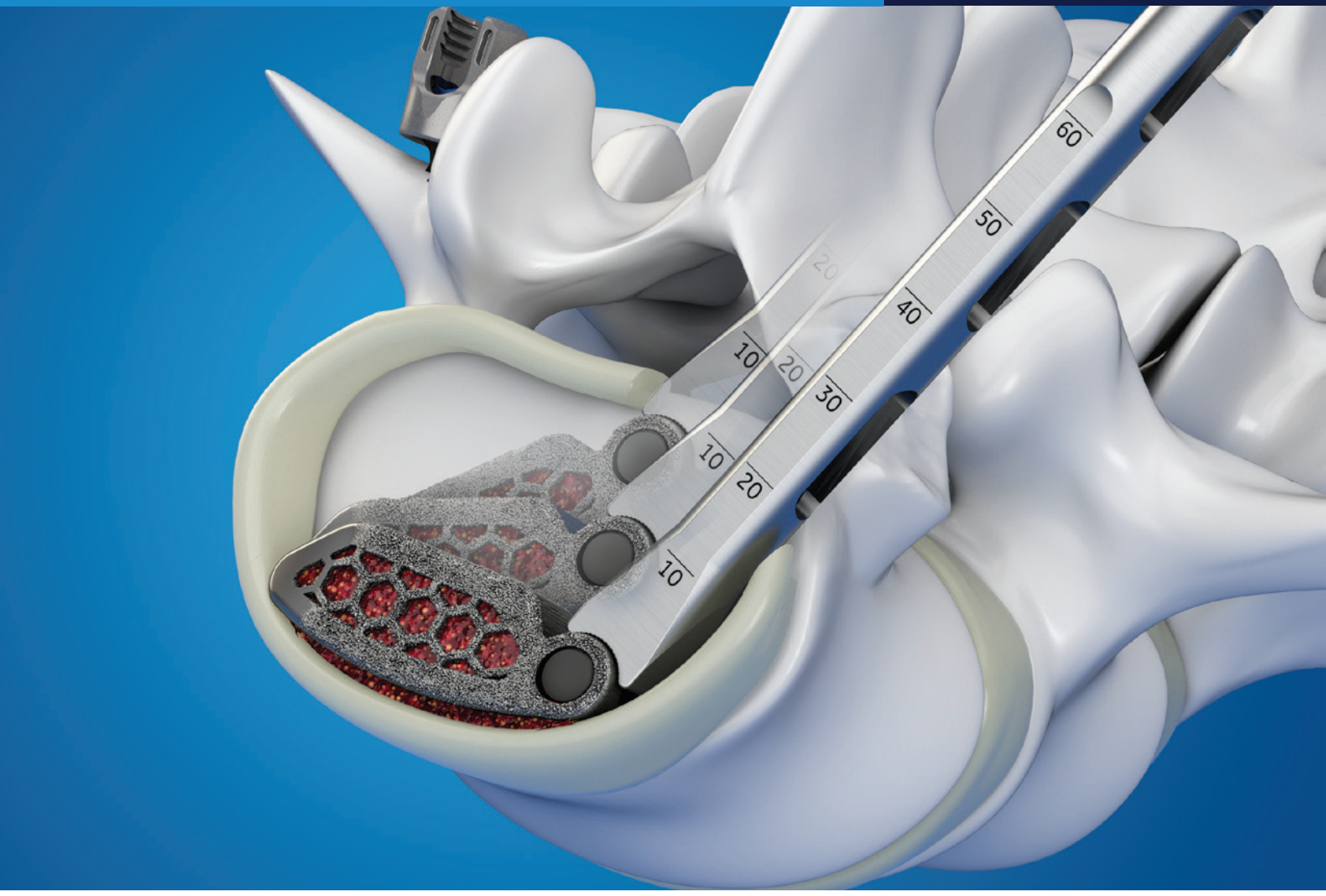
SURGICAL
TECHNIQUE
for TLIF

ARTiC-L™ 3D Ti Spinal System

with TiONIC™ Technology



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INTRODUCTION

The ARTiC-L™ 3D Ti Spinal System was developed as an implant for stabilization of the lumbar spinal column via an open or minimally invasive transforaminal lumbar interbody fusion (TLIF). This surgical technique is designed to familiarize healthcare professionals with the surgical procedure. Please carefully read this surgical technique and its appendix prior to the use of the implant.

ARTiC-L™ 3D TI Spinal System is an articulating titanium implant with a roughened surface that is designed for sagittal alignment restoration in the lumbar spine by offering multiple heights, lengths and lordotic angles for use in degenerative and deformity TLIF needs.

- Available in 5°, 10° and 20° lordosis sterile options to better address variations in patient anatomical needs
- Rough titanium surface with open honeycomb structure for graft material
- Implant design incorporates an internal articulating feature that allows seamless transition between insertion and final placement
- Smooth tapered tip to aid in ease of distraction during implant insertion
- Honeycomb lattice structure designed to minimize the stress load compared to an open cage design
- MAST™ Procedure compatible

Risks

Risks/potential risks associated with the device include, but are not limited to:

- Implant migration
- Loss of spinal curvature, correction, height, and/or reduction
- Bone fracture or stress shielding at, above, or below the level of surgery
- Bone graft donor site complication
- Loss of spinal mobility
- Endplate disruption
- Neurological impairment

See IFU for a full list of risks, warnings, and contraindications.

DISTINCTIVE FEATURES

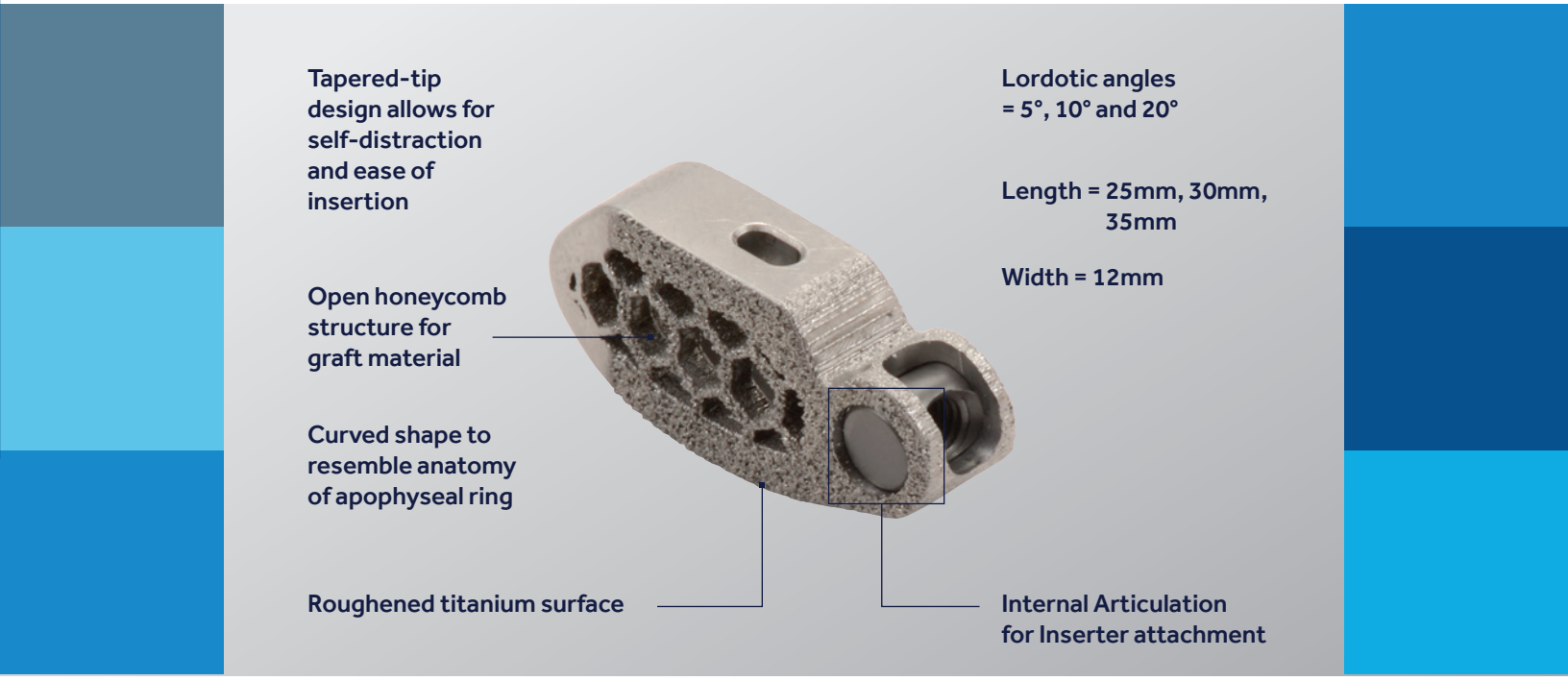
TiONIC™ Technology

A Laser Rapid Additive Manufacturing Technique.

- Features a rough titanium surface texture that promotes bone formation[1,2]
- Allows for a more unique topology compared to standard PEEK or machined Ti Alloy designs
- Creates high coefficient of friction to aid in initial fixation and to help prevent migration[3]
- Uses honeycomb design as an osteoconductive scaffold for bony growth into the implant[1,2]
- Features honeycomb lattice structure designed to minimize the stress load compared to an open cage design[4]

ARTiC-L 3D Spinal System Implant

TiONIC Technology enables a complex implant design.



1 Wennerberg, A., & Albrektsson, T. (2009). Effects of titanium surface topography on bone integration: a systematic review. *Clin Oral Implants Res*, 20 Suppl 4, 172-184.

2 Gittens, R.A., Olivares-Navarrete, R., Schwartz, Z, Boyan, B.D. (2014). Implant osseointegration and the role of microroughness and nanostructures: lessons for spine implants. *Acta Biomater.*, 10(8), 3363-71.

3 Data on file.

4 Data on file.

DISTINCTIVE FEATURES — ARTICULATING INSERTER

One Instrument to Insert and Position

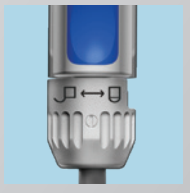
Thumbwheel

- Should be used ONLY for attachment and detachment of implants and Trials
- Should be turned in order to thread implant and Trial onto the Articulating Inserter
- The implant should be tightened as much as desired with the clutch handle closed
- To be used for engagement and/or disengagement of implant to Inserter
- Design incorporates Slap Hammer mating connection, as seen in Detail A

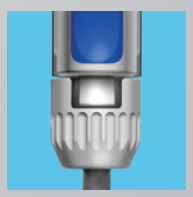
Detail A

Clutch Handle

- Manual depression creates ability to fix the implant at any angle
- Allows efficient workflow and one-hand implant positioning
- Lock allows implant to be fixed if desired



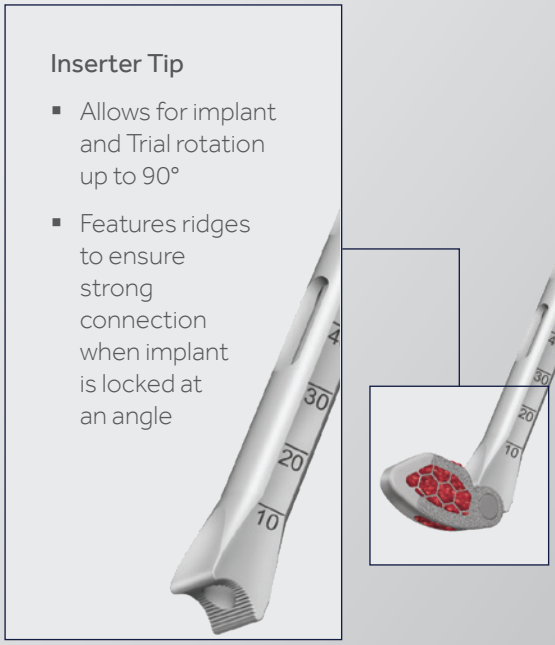
Locked Position



Unlocked Position

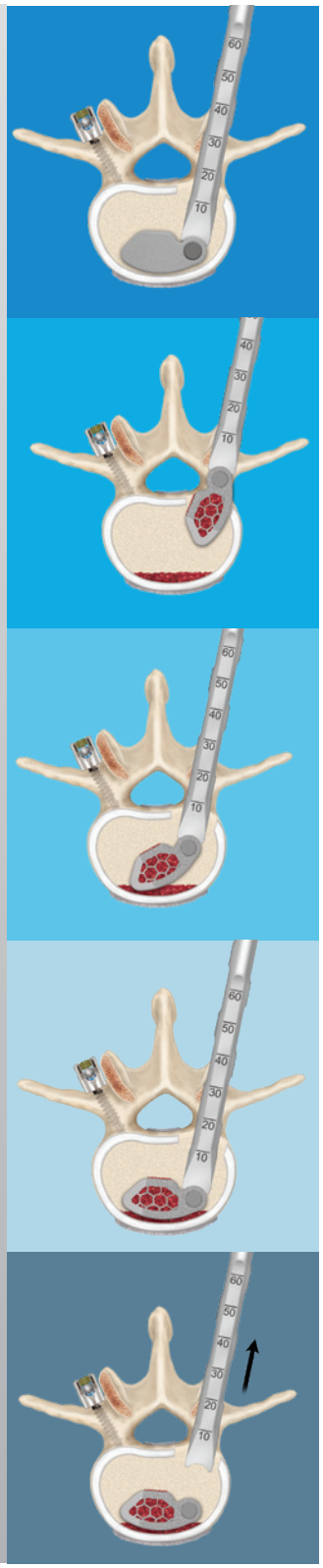
Inserter Tip

- Allows for implant and Trial rotation up to 90°
- Features ridges to ensure strong connection when implant is locked at an angle



Lock

- Fixes clutch handle in closed position so that implant can be tightened at any angle
- Laser marks indicate open and closed positions



DISTINCTIVE
FEATURES — TRIALS

To aid in determining final implant size and placement, ARTiC-L™ Implant Trialing is available in two separate intraoperative options based on surgeon preference: Fixed and Articulating Trials.

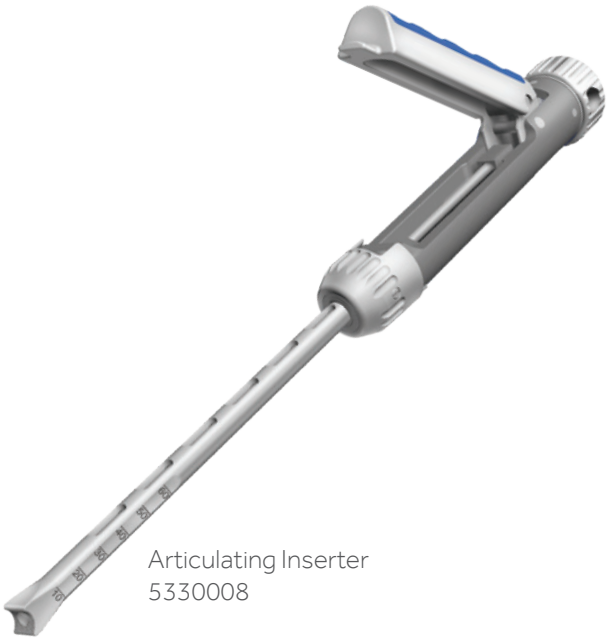
Fixed Trial

- Provides sequential distraction for selecting the height and length of the implant
- Available in 0° for height and length trialing
- Smooth for ease of insertion

Articulating Trial

- 1:1 Sizing in 5° and 20°
- Roughened for tactile feel
- Can be positioned in the same location as the implant to aid in determining final placement

INSTRUMENT **SET**



Articulating Inserter
5330008

Inserter Inner Shaft
5330009

Slap Hammer
5330021

Tamp
5330012

Removal Tool
5330020

INSTRUMENT
TRIAL SET

Articulating Trial
See page 14 for part numbers

Trial Handle
5330023

Fixed Trials
See page 19 for part numbers

TLIF APPROACH
OPEN AND MINIMALLY INVASIVE TECHNIQUES

Positioning

The prone position will allow a free abdomen to decrease abdominal pressure on the stomach vessels, creating temporary segmental kyphosis through positioning or spinous process/laminar distraction that will aid in disc access and implant placement. This can be achieved by using a positioning frame or padding. Use a well-padded prone support table that replicates physiological lordosis. This positioning may be tolerated by the patient for many hours and therefore may be suitable for extended spinal surgeries. Furthermore, it allows intraoperative imaging guidance in the A/P and lateral views. The O-Arm™ Imaging System can be used to provide imaging assistance.

For complete labeling for the navigation products please contact Medtronic Navigation, General Business at 800-580-8860 or visit medtronic.com.

PREOPERATIVE PLANNING
AND SET UP

Preoperative planning can be useful in determining the proper starting point and screw trajectory. An axial view demonstrates the distance lateral to the pedicle initially taken through the skin **(Figure 1)**. Mark the affected segment in the midline after imaging guidance. Make a skin incision 4cm lateral to the midline at the level of the affected segment.

Important

The starting point is rarely directly over the pedicle.Some tables have pedestals that make it difficult to get a true AP view of the pedicles, especially at the S1 level. While adjustments in patient positioning can be made, tables that limit good AP fluoroscopy should generally be avoided. A larger prep area is also necessary for intraoperative flexibility.

If desired, the skin incision can be made with PlasmaBlade™ on a setting of CUT 5. PlasmaBlade™ can dissect through multiple tissue types with low resistance and limited thermal damage.[6]

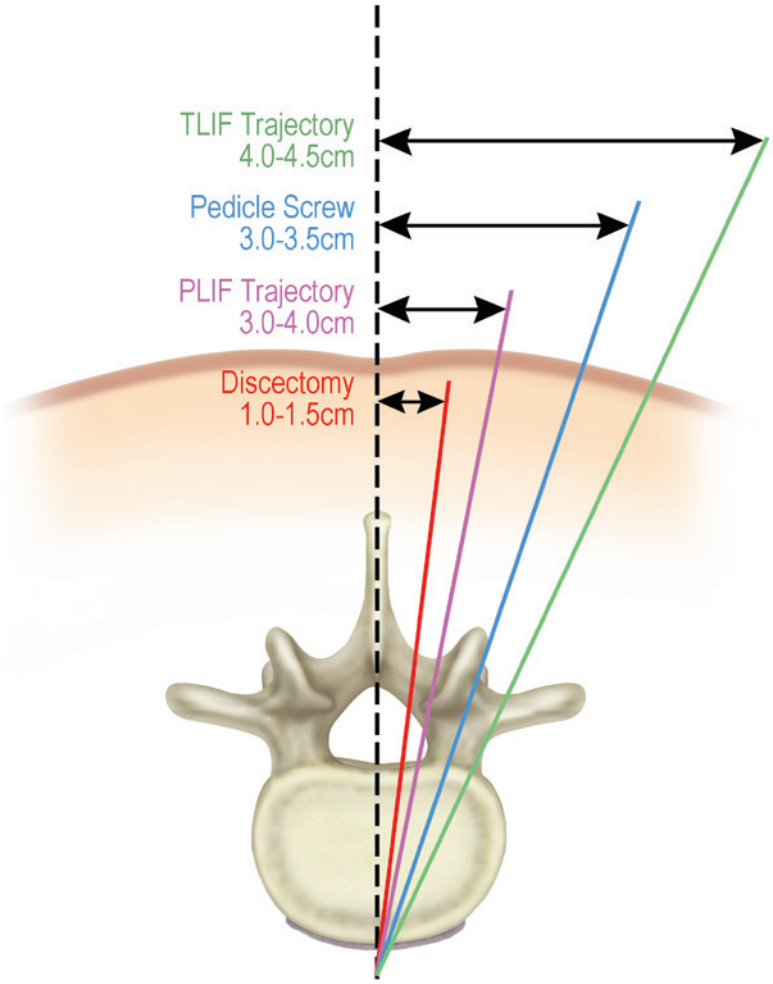


Figure 1

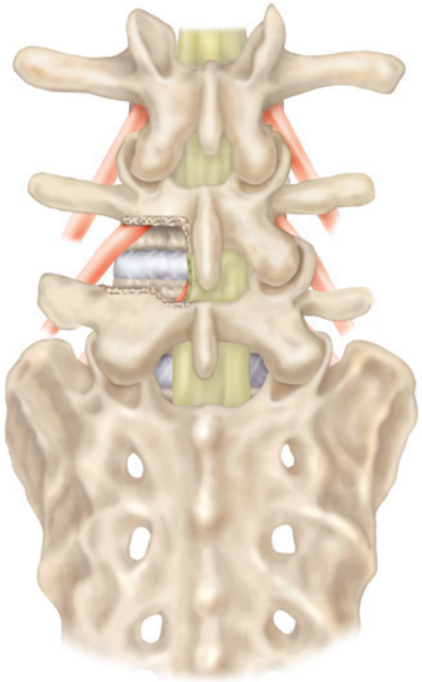
6 Ruidiaz ME, Messmer Dr, Atmodjo DY, et al. Comparative healing of human cutaneous surgical incisions created by the PEAK PlasmaBlade, conventional electrosurgery, and a standard scalpel. Plast Reconstr Surg. 2011;128(1):104-111.

FACETECTOMY

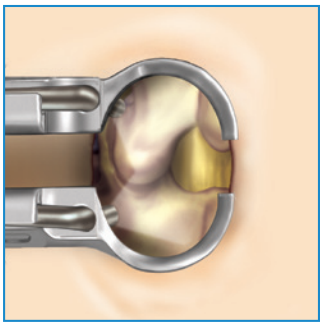
Expose the interlaminar window and the medial aspect of the facet joint. In general, a bony resection towards cranial and lateral is required in the area of the facet joints. Due to the design of the implants, a partial medial facetectomy is necessary to insert the implants into the disc space. In most of the cases, a resection of the spinous process is not required. The maintenance of the superior lamina is suggested to keep the interlaminar as well as the interspinous stability of the superior adjacent level and motion segment.

Careful attention must be paid to removing a sufficient amount of the inferior portion of the inferior articulation facet and superior portion of the superior articulating facet to safely access the disc space **(Figures 2 and 2a)**.

Use an Osteotome, Box Chisel, or Kerrison to remove the inferior end plate ridge adjacent to the pedicle.



Open Technique
Figure 2



MAST™ Technique
Figure 2A

Aquamantys™ may be used to control bleeding from the paraspinous muscles during the exposure and to pretreat high risk vessels <1mm such as the parafacetal arteries. Aquamantys™ bipolar sealers can control and reduce blood loss leading to improved visibility and reduced surgical time.[7,8]

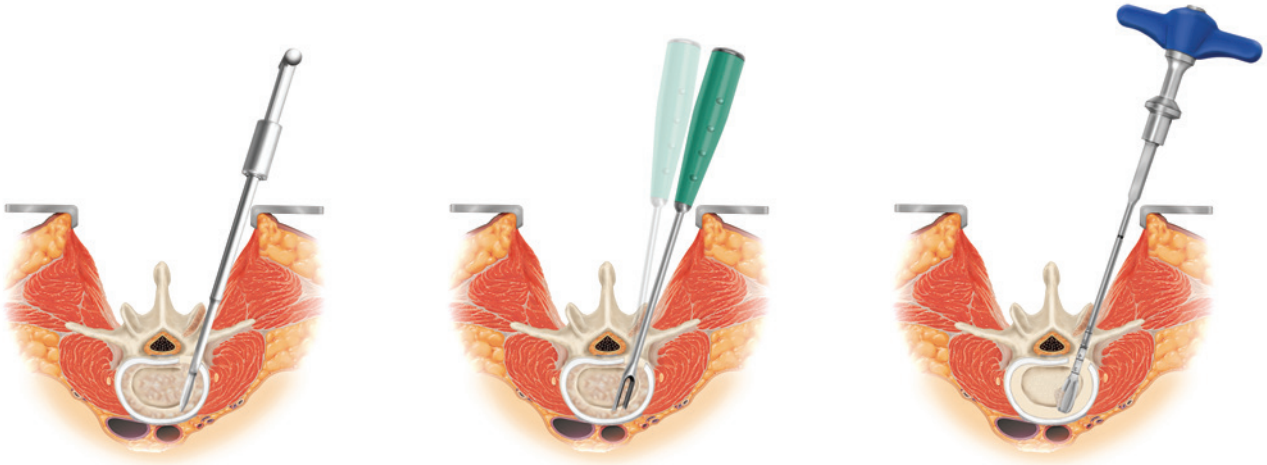
The Midas Rex™ high speed drilling system can be used to remove bone during spinal procedures.

7 Mankin KP, Moore CA, Miller LE, Block JE. Hemostasis with a bipolar sealer during surgical correction of adolescent idiopathic scoliosis. *J Spinal Disord Tech*. 2012;25(5):259-263.

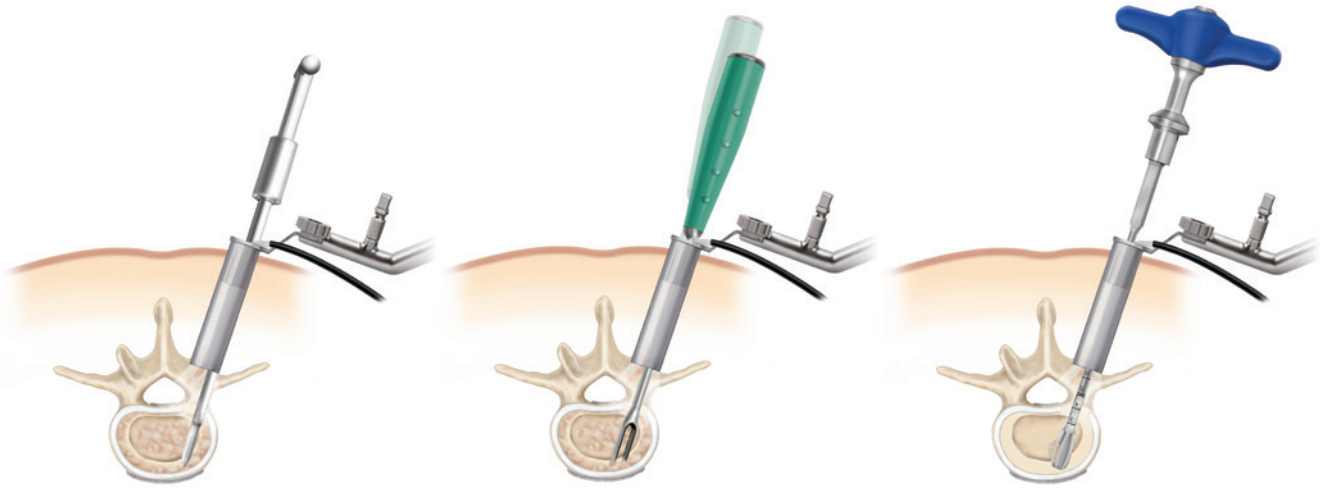
8 Snyder BD, Hedequist D, Shannon E. Hemostatic efficacy of bipolar wound sealer as adjunct to wound management in children with neuromuscular scoliosis. Poster presentation at Pediatric Orthopaedic Society of North America Annual Meeting 2007; Hollywood, FL.

DECOMPRESSION / DISCECTOMY

Open the annulus and resect the nucleus and the inner annulus as completely as possible. After discectomy, remove the endplate cartilage. Ensure that the bony endplates stay intact. Injuring bony endplates may lead to implant subsidence into the vertebrae.



Open Technique



Minimally Invasive Technique

TLIF APPROACH
DISTRACTION

The disc space is sequentially distracted until adequate disc space height is obtained and adequate foraminal size is restored. The surgeon may insert supplemental screw and rod fixation on contralateral side to maintain distraction during disc space preparation. The screw and rod construct should be provisionally tightened. To maintain implant distraction during minimally invasive and open spinal procedures, there are a variety of distraction instruments available to order with the CD Horizon™ Solera™ Spinal System. These include:

Open TLIF Distractor
- 4.75mm (5484327)
- 5.5/6.0 mm (5584327) **(Figure 3a)**

MIS TLIF Distractor
- 4.75mm (6640017)
- 5.5/6.0mm (6640019) **(Figure 3b)**.

Alternatively, the Scissor Jack™ Distractor is also available separately to order **(Figure 3c)**.

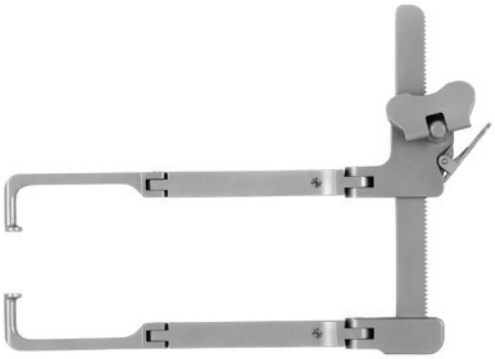


Figure 3a

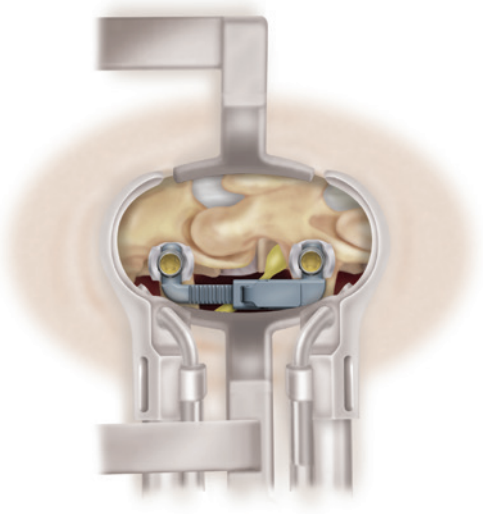


Figure 3b

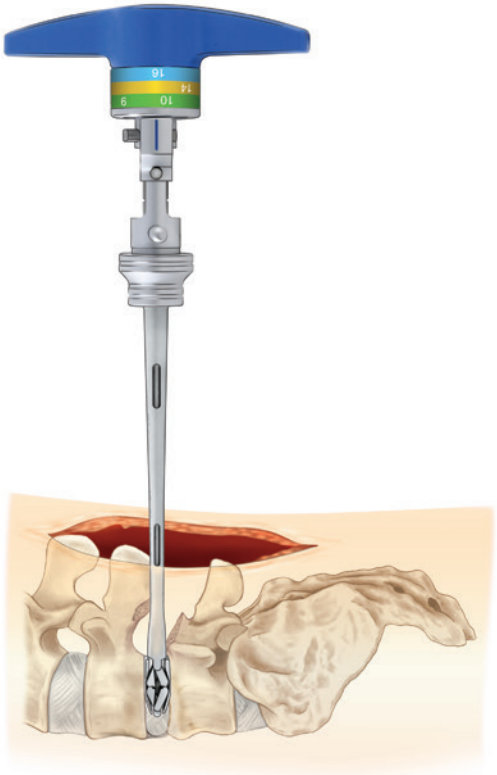


Figure 3c

ARTICULATING **INSERTER**

Assembly of the Articulating Inserter

For initial assembly, insert Inner Shaft (5330009) into the Articulating Inserter (5330008) with clutch handle closed as shown **(Figures 4)**. Ensure Inner Shaft is fully depressed into Inserter **(Figure 5)**.

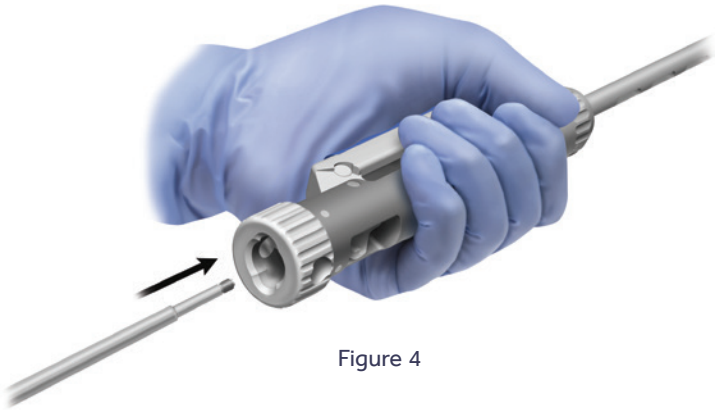


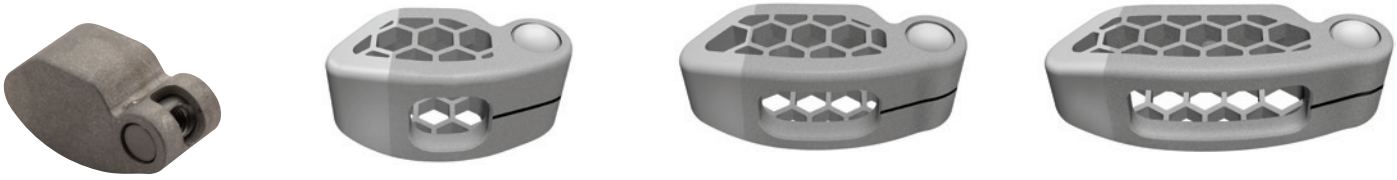
Figure 4

Figure 5

Important
If inner shaft is not fully depressed into Articulating Inserter, the trial or implant will not fully thread.

Articulating Inserter Attachments

The mating attachments to the Articulating Inserter include the Articulating Trials and sterile implant options.



IMPLANT
TRIALING METHODS

Intraoperative Implant trialing is available in two separate options based on preference:

- Articulating trials for standard implants.
  (Set Number SPS02924)

- Traditional fixed trialing for standard implants
  (Set Number SPS02924)

Note
It is not necessary to use BOTH trialing methods in a single procedure. Either method should be chosen based on surgeon preference. For either method, please use caution during retraction for the dura mater and the off-branching nerve roots. In order to choose the appropriate type and size of the Trial, use preoperative planning to determine the appropriate height and lordosis.

Method 1: Articulating Trials

Articulating trialing method is intended to provide a true trialing experience for size, lordosis, and final placement. Articulating trialing is a two-step process: first trialing for height and lordosis and then trialing for length.

Important
Articulating Trials are not intended to be implanted.

Step 1: Height and Lordosis Trialing

Part numbers 5250705-5251320 can be used with the Articulating Inserter to trial for height and lordosis. Articulating Trials are available in every height and in 5° and 20° of lordosis. The articulating nature of the Trials allows for assessment of true final placement. Insert Trials sequentially until desired disc space height, width and length are established. Use AP and lateral fluoroscopy to confirm proper placement and trajectory.

TLIF Articulating Trials

Part#	Description
5250705	L25 HT 7 DEG 5 ART
5250805	L25 HT 8 DEG 5 ART
5250905	L25 HT 9 DEG 5 ART
5251005	L25 HT 10 DEG 5 ART
5251105	L25 HT 11 DEG 5 ART
5251205	L25 HT 12 DEG 5 ART
5251305	L25 HT 13 DEG 5 ART
5251020	L25 HT 10 DEG 20 ART
5251120	L25 HT 11 DEG 20 ART
5251220	L25 HT 12 DEG 20 ART
5251320	L25 HT 13 DEG 20 ART

Step 2: Length Trialing

All height trials are represented in a 25mm length footprint. If this length is determined appropriate in step 1 then step 2 is NOT required.

After height and lordosis are determined, implant length can be trialed if desired.

Trials are available in two lengths to asses implant lengths of 30mm and 35mm.

Part#	Description
5300805	L30 HT 8 DEG 5 ART
5350805	L35 HT 8 DEG 5 ART

Utilization of the Articulating Trials

With the clutch handle in the closed position, put the Inserter Inner Shaft into the Inserter Tube then thread the Articulating Trial onto the Articulating Inserter, aligning the indicator line on the Articulating Inserter with its counterpart on the Trial **(Figure 6)**.

Note

Caddy can be used as loading block for both Articulating Trials and implants.

Figure 6

To fully connect the attachment, continute to rotate the thumbwheel until the attachment is as tight as possible. (The tightness will affect the Articulating Inserter's ability to lock the Trial in place.)

The thumbwheel is on the back end of the Articulating Inserter as shown **(Figure 7)**.

Important
The thumbwheel should NOT be utilized again until the surgeon is ready for complete detachment of the Trial. The thumbwheel is NOT intended to be used for articulation.

Ensure correct alignment so that the Articulating Inserter engages into the posterior aspect of the Trial **(Figure 8)**.

Figure 7

Figure 8

With the attachment fully tightened, the Articulating Trial should be locked and unable to articulate **(Figure 9)**.

To begin to utilize the articulation feature, the lock knob must be unlocked by rotating it. The locked and unlocked position are shown **(Figure 10)**. The lock knob rotation allows for the release of the clutch. Release of the clutch allows for free articulation of the implant **(Figure 11)**.

Figure 9

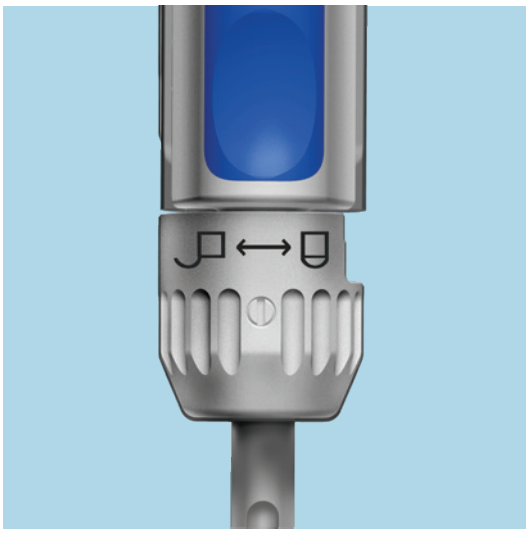


Figure 10

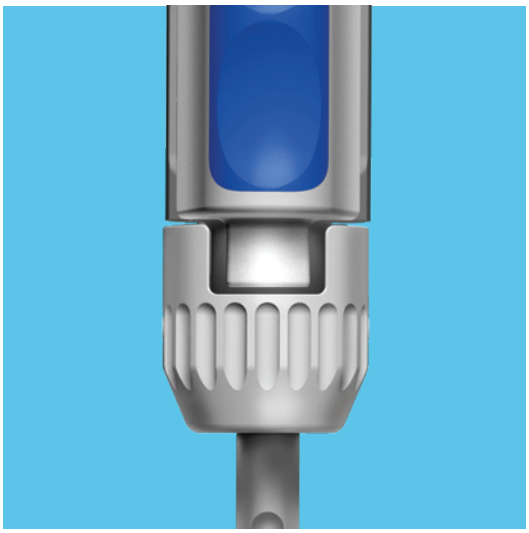


Figure 11

Depression of the clutch allows manual locking of the Attachment at a new fixed angle **(Figures 12 – 15)**.

Figure 12

Figure 13

Figure 14

Important
Articulating Inserter should only be impacted when handle is in closed position, making the trial locked and unable to articulate.

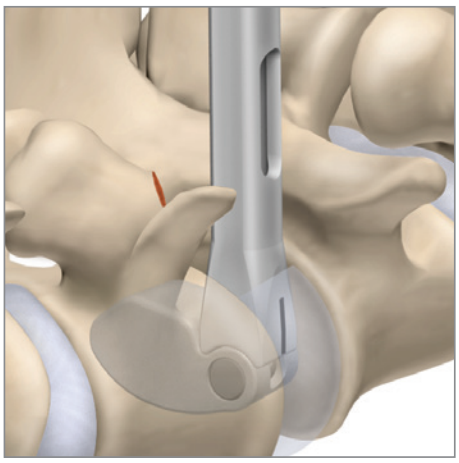


Figure 15

Method 2: Fixed Trials

Fixed trialing method is a more traditional method intended to provide trialing of height and length. Fixed trialing is a two-step process, first trialing for height and then trialing for length. The fixed trials are intended to be used interchangeably with the quick connect trial handles.

Step 1: Height Trialing

Part numbers 5250800-5251500 can be used with the trial handle to trial for height. Trials are available in every height. Insert Trials sequentially until desired disc space, height, width, and length are established. Use AP and lateral fluoroscopy to confirm proper placement and trajectory.

Step 2: Length Trialing

***All height trials are represented in a 25mm length footprint. If this length is determined appropriate in step 1 then step 2 is NOT required.**

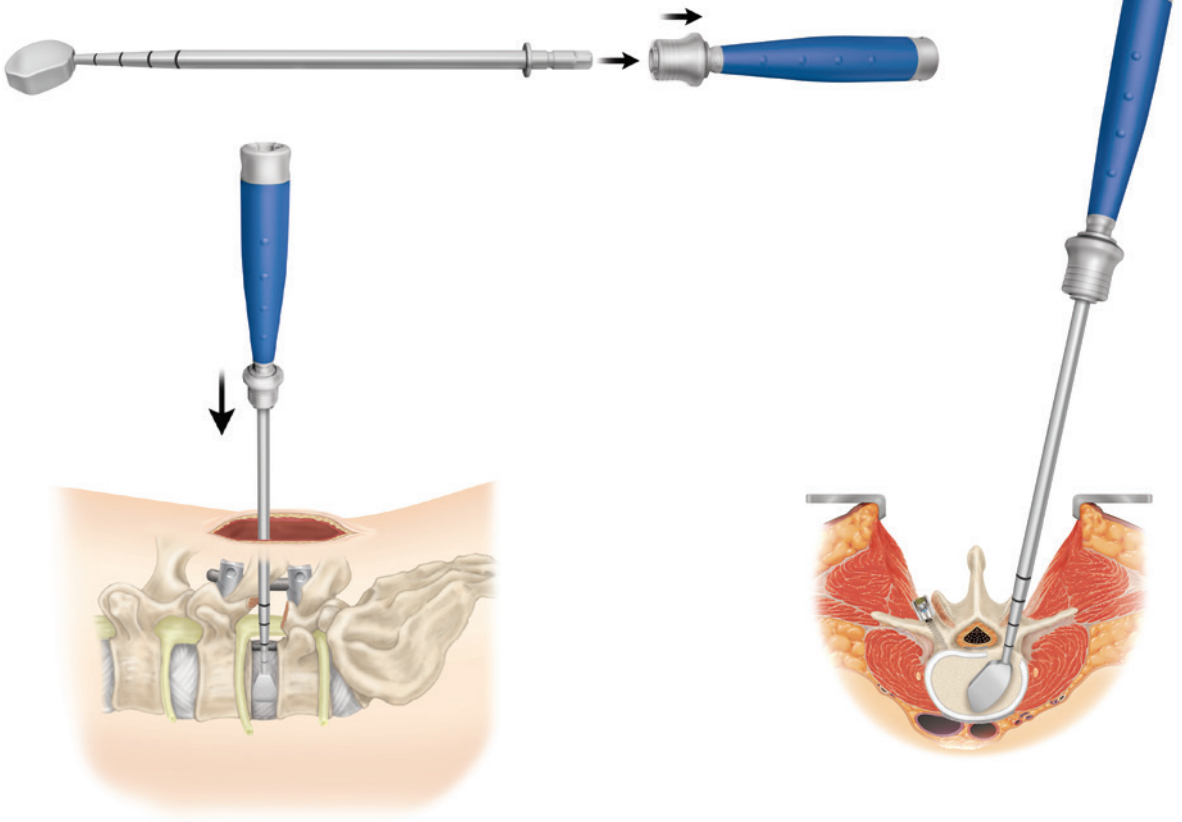
After height is determined, implant length can be trialed if desired.

Two length trials are available to asses implant lengths of 30mm and 35mm.

TLIF Fixed Trials

Part#	Description
5250800	L25 HT 8 DEG 0 FIXED
5250900	L25 HT 9 DEG 0 FIXED
5251000	L25 HT 10 DEG 0 FIXED
5251100	L25 HT 11 DEG 0 FIXED
5251200	L25 HT 12 DEG 0 FIXED
5251300	L25 HT 13 DEG 0 FIXED

Part#	Description
5300800	L30 HT 8 DEG 0 FIXED
5350800	L35 HT 8 DEG 0 FIXED



IMPLANT **FILLING**

The implant can be filled with either autograft, allograft, demineralized allograft with bone marrow aspirate, or a combination of both. Autograft can be collected from the surgical site and morselized using the Midas Rex™ Electric Bone Mill System (Figure 16a) or can be recovered from a secondary site using the Corex™ minimally invasive bone harvester **(Figure 16b)**.

Allograft material such as cancellous and/or corticocancellous bone graft may be used. This can also be hydrated with CBMA using the Marrow Cellutions advanced bone marrow aspirate system.

Demineralized allograft bone may also be used. The demineralized allograft bone must be hydrated with bone marrow aspirate that can be harvested using the Marrow Cellutions.

To fill the cage, all holes (even the honeycomb structure) can be used **(Figures 17 and 18)**.

Figure 16a

Figure 16b

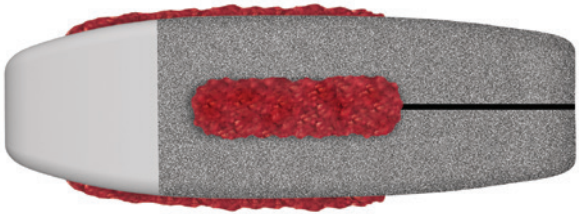


Figure 17

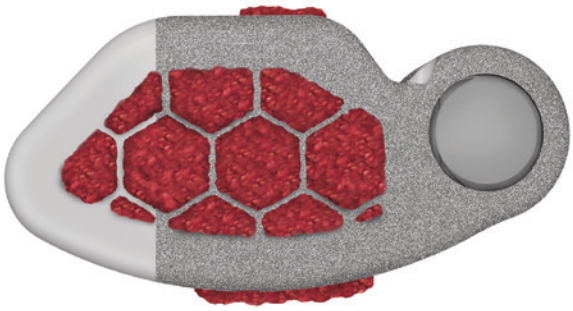


Figure 18

IMPLANT ATTACHMENT

The appropriate size implant is chosen from the trialing step. Remove the appropriate size implant out of the sterile packing, taking care to select the correct implant size. Then firmly attach the implant to the Inserter.

With the clutch handle in the closed position, put the Inserter. Inner Shaft into the InserterTube then thread the articulating implant onto the Inserter, aligning the indicator line on the Articulating Inserter with its counterpart on the implant. **(Figure 19)**.

Note

To fully connect the attachment, continute to rotate the thumbwheel until the attachment is fully tightened. (The tightness will affect the Inserter's ability to lock the implant in place.)

The thumbwheel is on the back end of the Inserter as shown **(Figure 20)**.

Important

The thumbwheel should NOT be utilizied again until the surgeon is ready for complete detachment of the implant. The thumbwheel is NOT intended to be used for articulation.

With the attachment fully tightened, the Articulating Trial or implant should be locked and unable to articulate **(Figure 21)**.

Figure 19

Figure 20

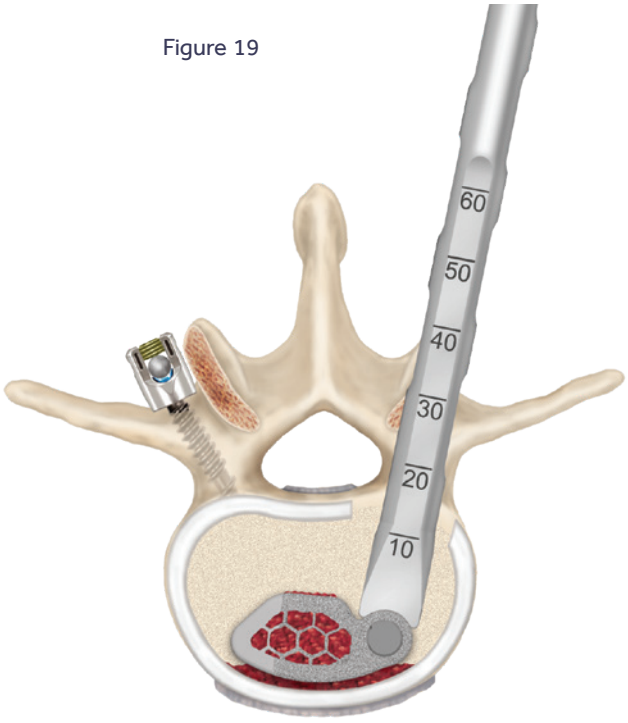


Figure 21

To begin to utilize the articulation feature, the lock knob must be unlocked by rotating it . The locked and unlocked positions are shown **(Figure 22)**. The lock knob rotation allows for the release of the clutch as shown. Release of the clutch allows for free articulation of the implant **(Figures 23 and 24)**.

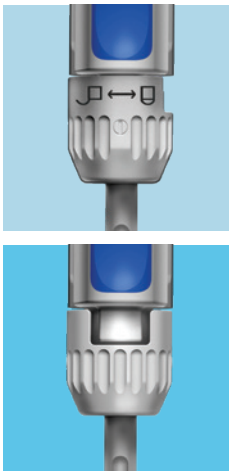


Figure 22

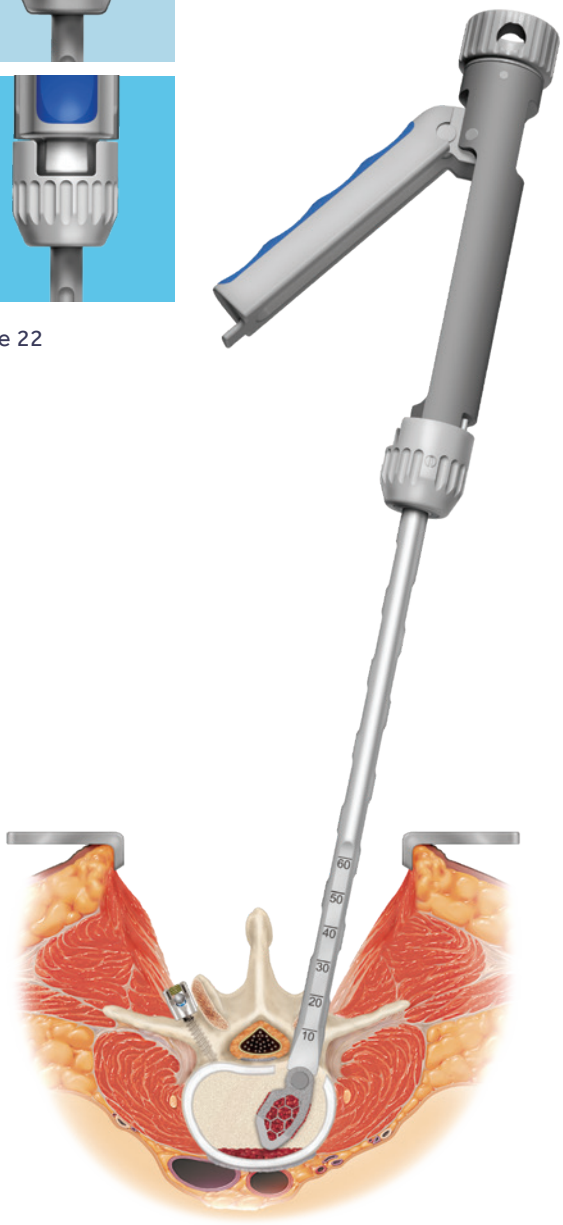


Figure 23

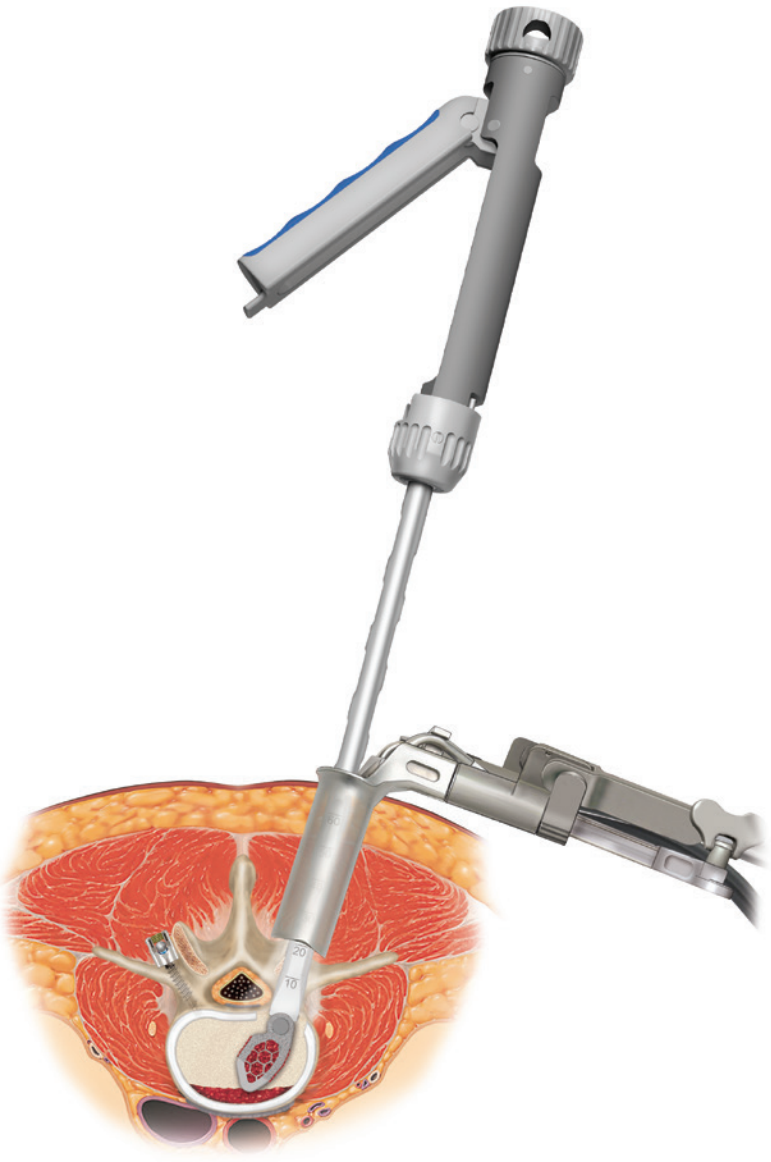


Figure 24

Depression of the clutch allows manual locking of the attachment at a new fixed angle **(Figures 25 – 27)**.

Figure 25

Figure 26

Figure 27

IMPLANT INSERTION

When the handle is in closed position and the implant is locked, gently impact the implant until it is 3mm to 4mm below the posterior margin of the annulus **(Figures 28 and 29)**.

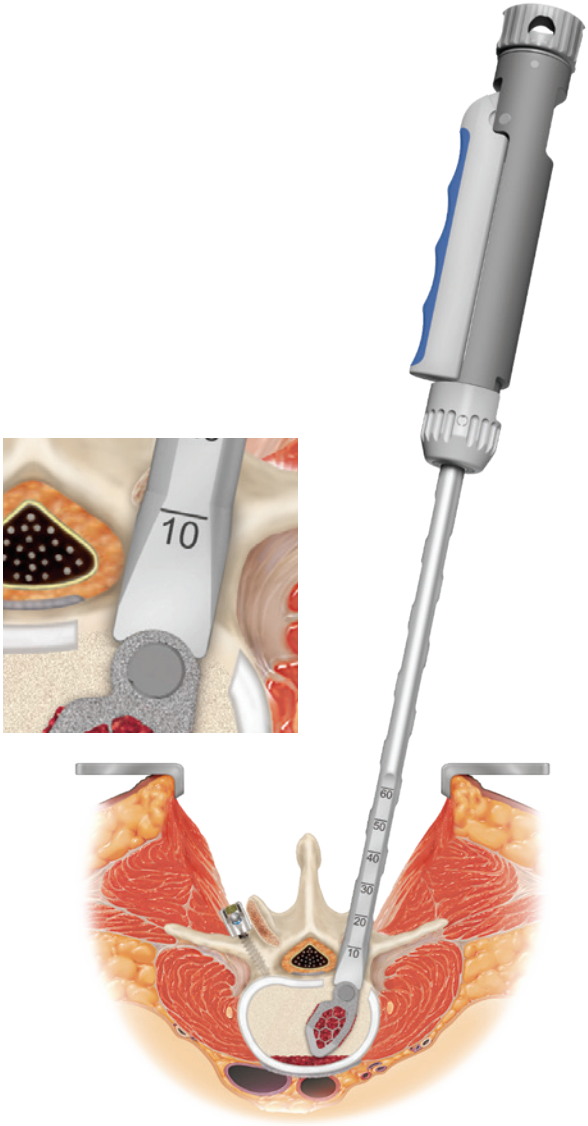


Figure 28

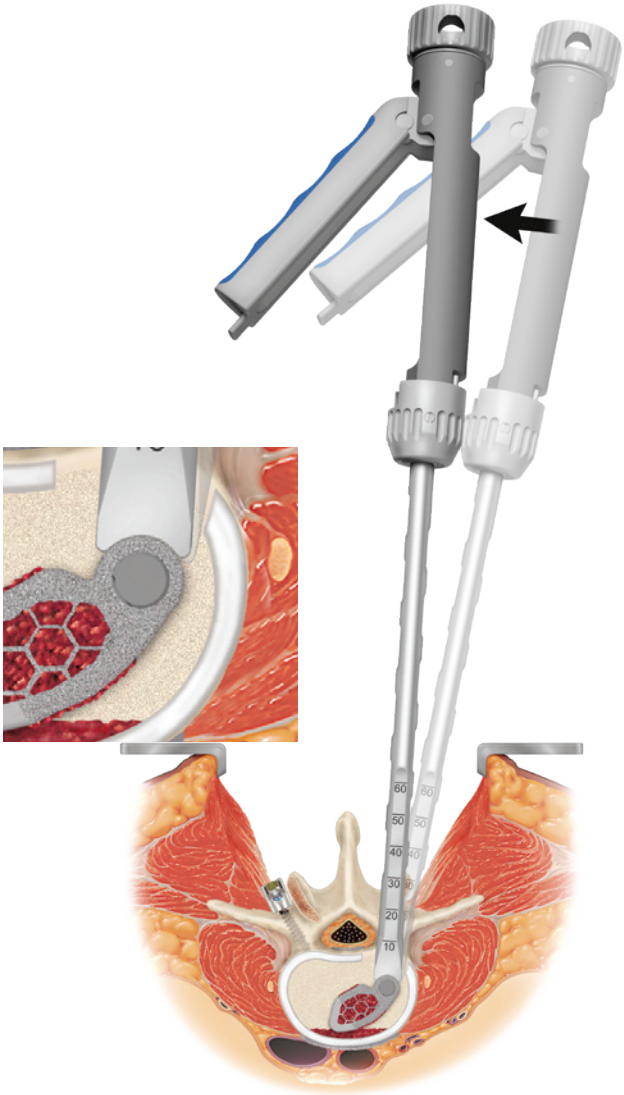


Figure 29

A mallet may be used on the Inserter as a tamp to help facilitate final position **(Figure 30)**.

A combination of the articulation steps and impaction steps should allow for the implant to be inserted straight but be eventually fully rotated and placed anteriorly **(Figures 31 – 33)**.

Important
Articulating Inserter should only be impacted when handle is in closed position, making the implant locked and unable to articulate.

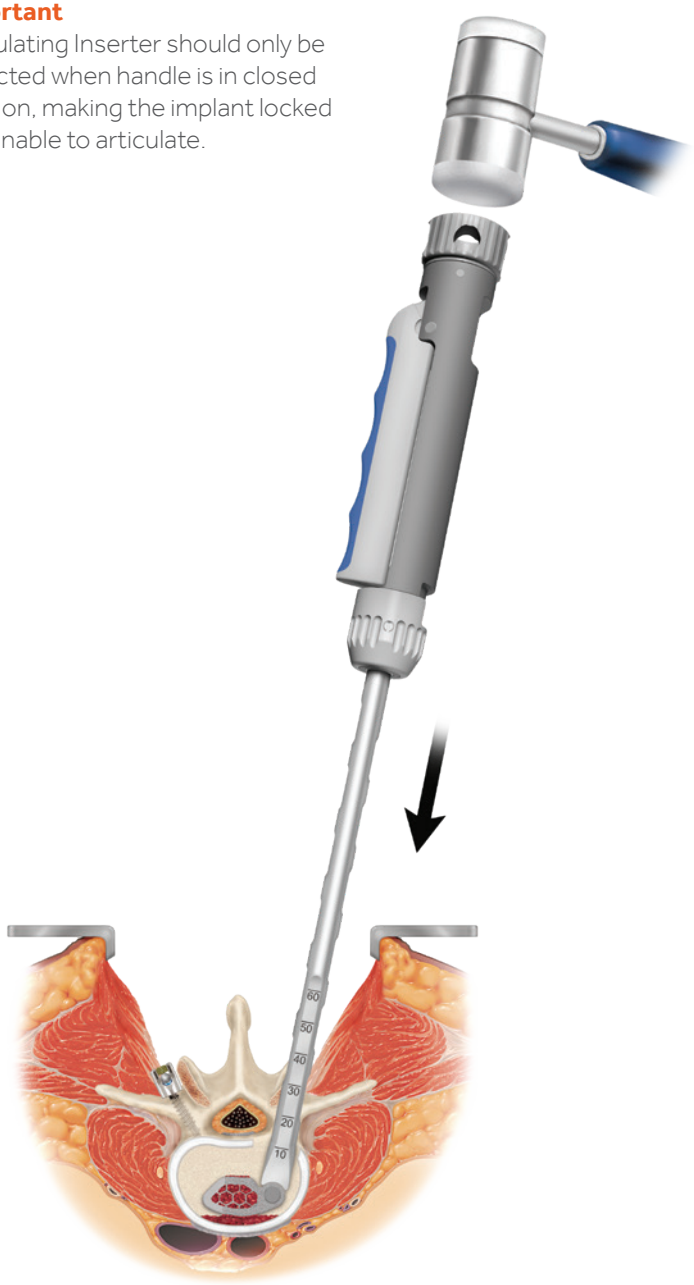


Figure 30

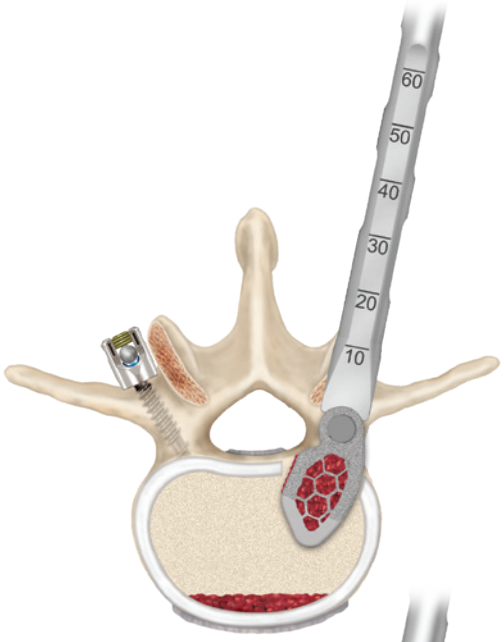


Figure 31

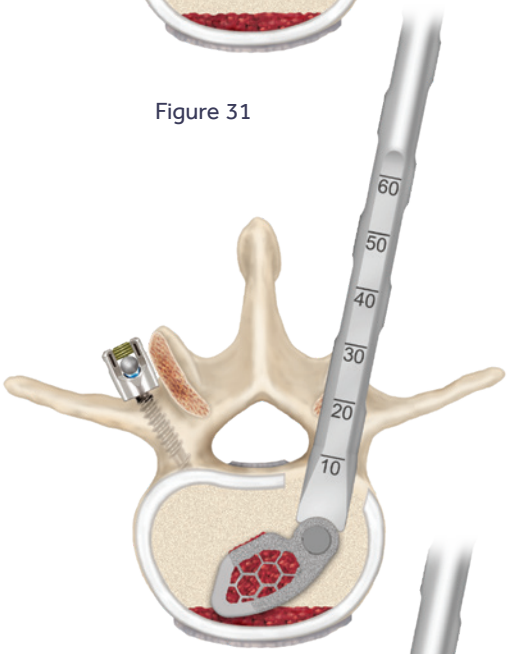


Figure 32

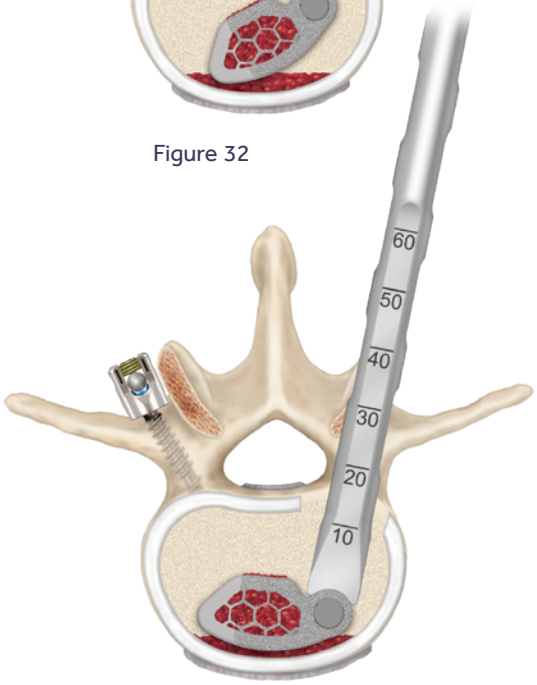


Figure 33

FINAL
PLACEMENT

It is recommended to place the cage anteriorly along the apophyseal ring in order to get maximal biomechanical stability of the construct. To induce lordosis with rod and screw compressors, the surgeon may compress posteriorly.

When satisified with the final implant placement, ensure the lock knob is fully locked and continue to unscrew the thumbwheel until the implant is detatched **(Figure 34)**. It is recommended to NOT disengage the Inserter until the implant is fully positioned and checked with a fluoro image.

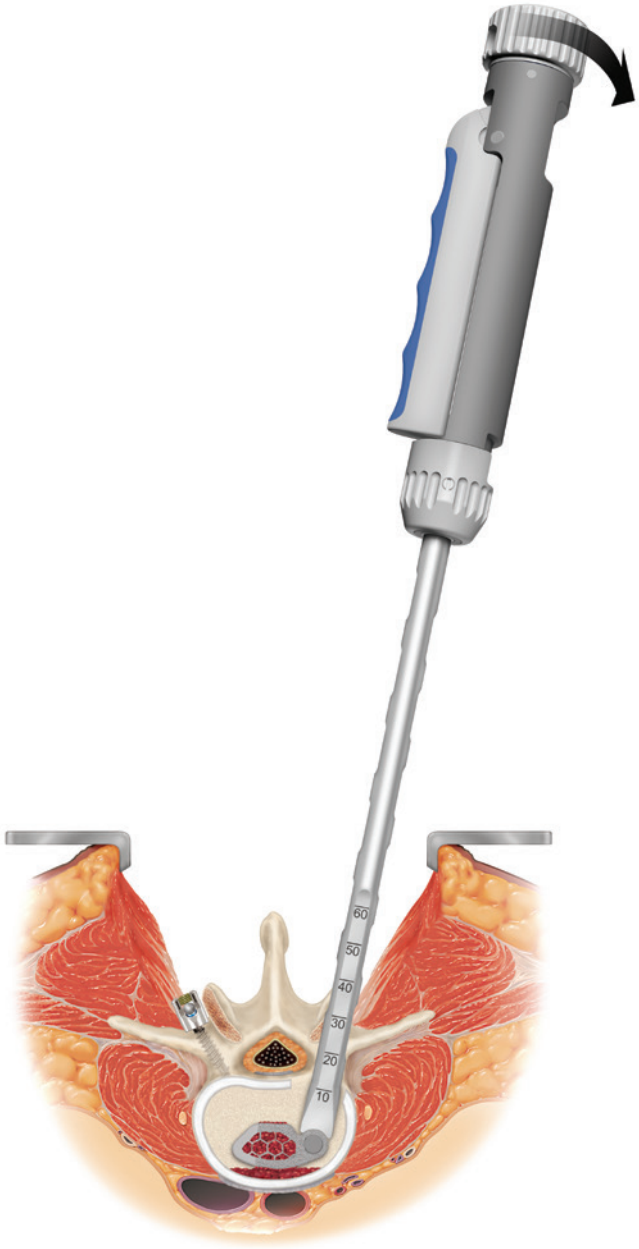


Figure 34

The extradural space and foramina are probed to ensure adequate decompression of the neural elements. Finally, check the integrity of the anterior annulus using the surgeon's preferred method.

To facilitate satisfactory immobilization of the autogenous bone grafted interspace, segmental internal fixation is applied using the standard technique **(Figures 35 and 36)**.

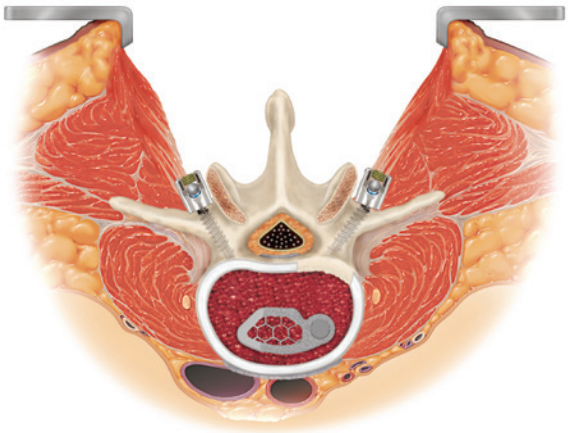


Figure 35

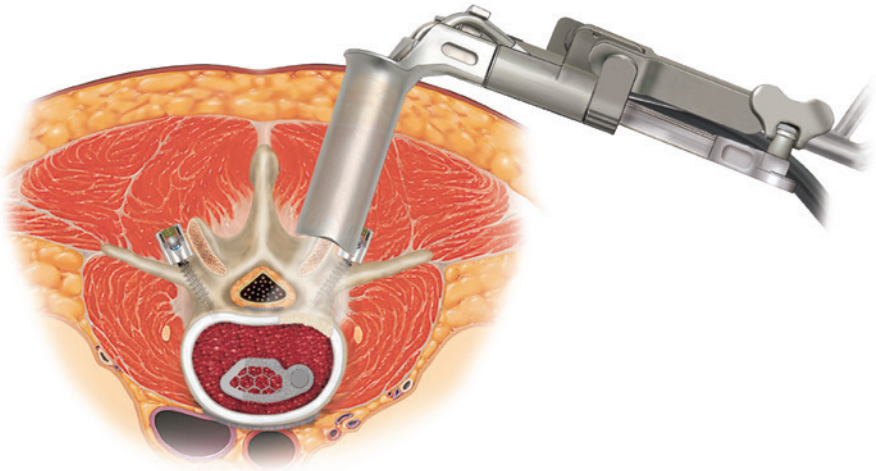


Figure 36

Disassembly of the Articulating Inserter

For post-operative dissasembly, release the clutch and manually slide inner shaft out of the Articulating Inserter. The inner shaft should be removed for sterilization purposes **(Figure 37)**.

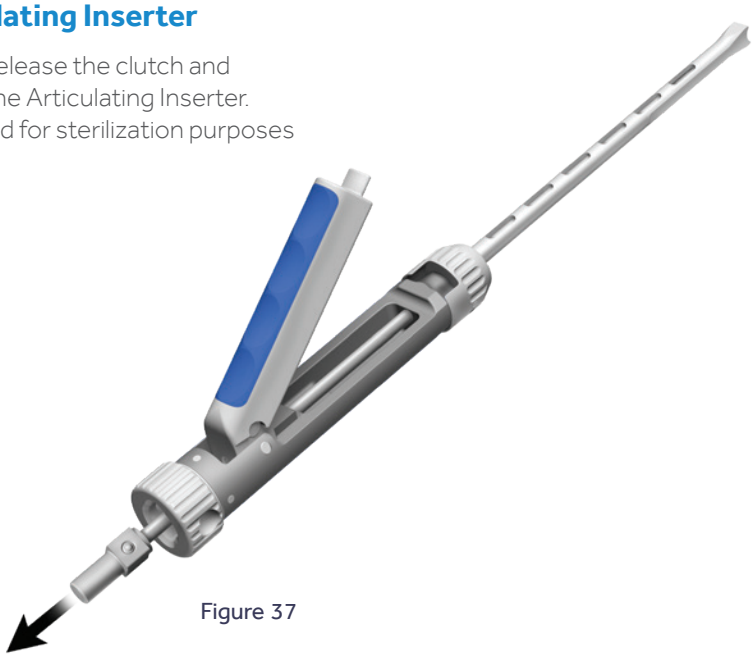


Figure 37

Tamping Option

A straight Tamp is available for implant placement **(Figure 38)**.

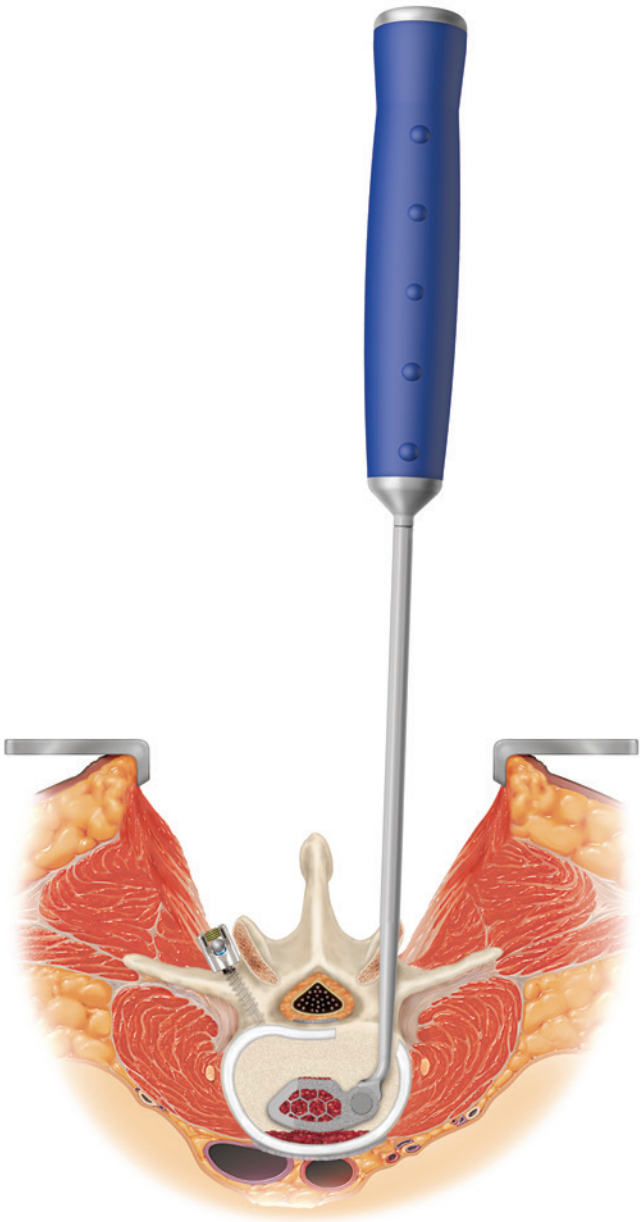


Figure 38

EXPLANTATION OF IMPLANT

If the implant must be removed from the disc space, use the supplied Removal Tool. Thread the Removal Tool into the implant and remove using in conjunction with the Slap Hammer **(Figures 39 and 40)**.

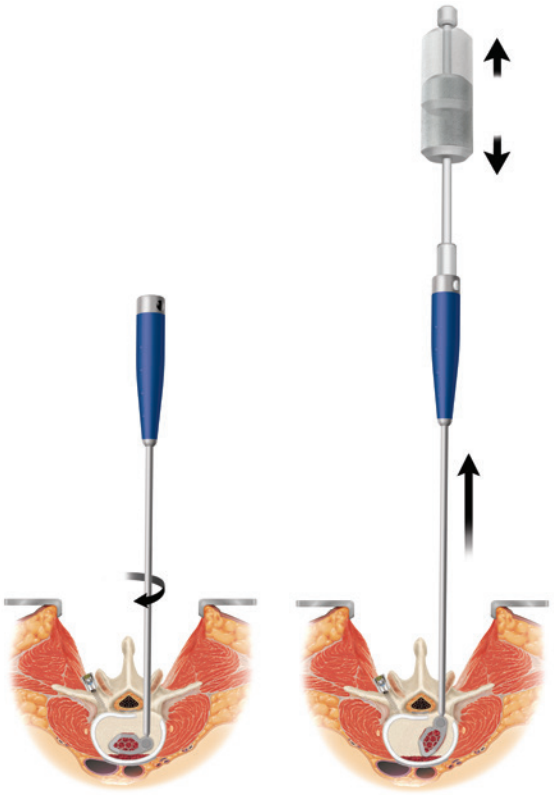


Figure 39

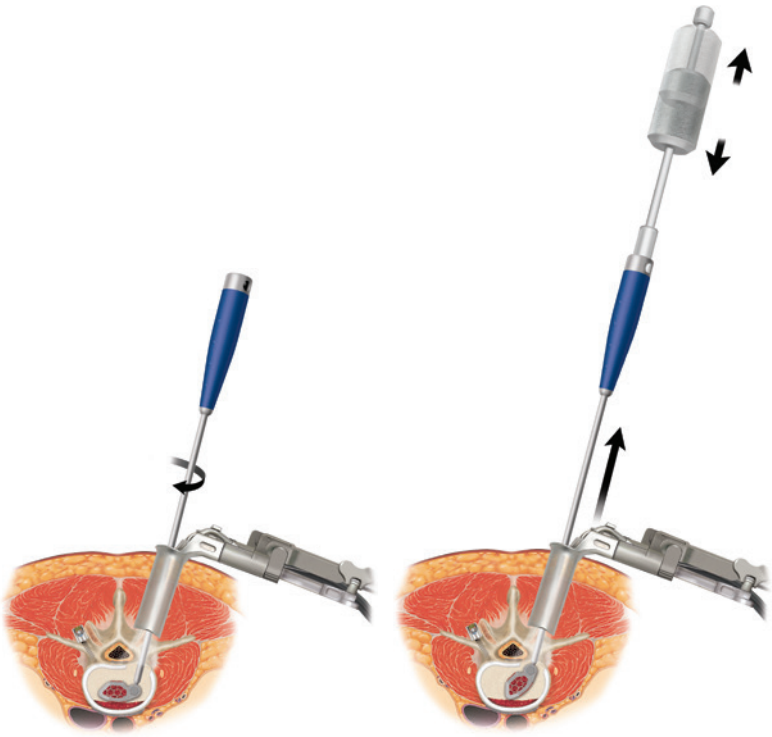


Figure 40

In addition, you may utilize the Slap Hammer that mates with the back end of the Articulating Inserter. Insert the Slap Hammer into the Articulating Inserter and rotate 90° to fully engage **(Figure 41)**.

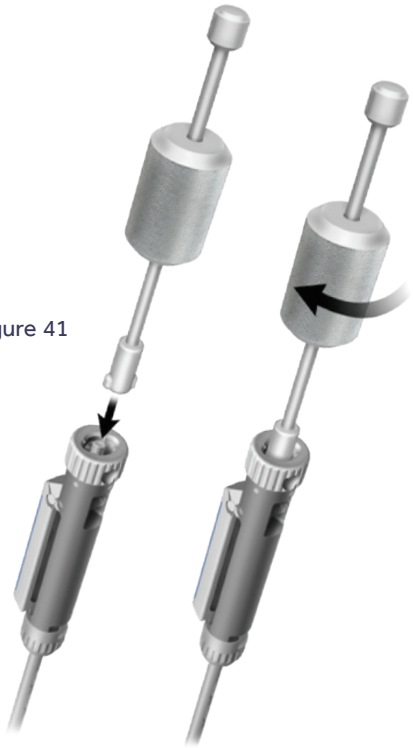


Figure 41

PRODUCT ORDERING INFORMATION

ARTiC-L™ 3D Ti Spinal System Instrument Set		
SPS02918		
Part Number	Item Description	Qty
5330008	Articulating Inserter	2
5330009	Inserter Inner Shaft	3
5330012	Straight Tamp	1
5330020	Removal Tool	1
5330021	Slap Hammer	1
5332030	Instrument Tray	1

ARTiC-L™ 3D Ti Spinal System Trial Instrument Set				
SPS02924				
Part Number	Length	Degree	Item Description	Qty
Fixed Trials				
5330023			Trial Handle	2
5250800	25	0°	Height 8	1
5250900	25	0°	Height 9	1
5251000	25	0°	Height 10	1
5251100	25	0°	Height 11	1
5251200	25	0°	Height 12	1
5251300	25	0°	Height 13	1
5300800	30	0°	Height 8	1
5350800	35	0°	Height 8	1
Articulating Trials				
5250805	25	5°	Height 8	1
5250905	25	5°	Height 9	1
5251005	25	5°	Height 10	1
5251020	25	20°	Height 10	1
5251105	25	5°	Height 11	1
5251205	25	5°	Height 12	1
5251305	25	5°	Height 13	1
5251120	25	20°	Height 11	1
5251220	25	20°	Height 12	1
5251320	25	20°	Height 13	1
5300805	30	5°	Height 8	1
5350805	35	5°	Height 8	1
5332033			Trials Tray	1
5332034			Articulating Trials Caddy	1
5332035			Articulating Trials Lid	1

ARTiC-L™ 3D Ti Spinal System Sterile 5 & 10 Degree Implants				
SPS02925				
Part Number	Length	Height	Degree	Qty
56250805	25mm	8mm	5°	1
56250905	25mm	9mm	5°	1
56251005	25mm	10mm	5°	2
56251105	25mm	11mm	5°	2
56251205	25mm	12mm	5°	2
56251305	25mm	13mm	5°	1
56250810	25mm	8mm	10°	2
56250910	25mm	9mm	10°	2
56251010	25mm	10mm	10°	2
56251110	25mm	11mm	10°	2
56251210	25mm	12mm	10°	1
56251310	25mm	13mm	10°	1
56300805	30mm	8mm	5°	2
56300905	30mm	9mm	5°	2
56301005	30mm	10mm	5°	1
56301105	30mm	11mm	5°	1
56301205	30mm	12mm	5°	1
56301305	30mm	13mm	5°	1
56300810	30mm	8mm	10°	2
56300910	30mm	9mm	10°	2
56301010	30mm	10mm	10°	2
56301110	30mm	11mm	10°	2
56301210	30mm	12mm	10°	2
56301310	30mm	13mm	10°	1
56350805	35mm	8mm	5°	2
56350905	35mm	9mm	5°	2
56351005	35mm	10mm	5°	2
56351105	35mm	11mm	5°	2
56351205	35mm	12mm	5°	2
56351305	35mm	13mm	5°	2
56350810	35mm	8mm	10°	1
56350910	35mm	9mm	10°	1
56351010	35mm	10mm	10°	1
56351110	35mm	11mm	10°	1
56351210	35mm	12mm	10°	1
56351310	35mm	13mm	10°	1

ARTiC-L™ 3D Ti Spinal System Sterile 20 Degree Implants				
SPS02926				
Part Number	Length	Height	Degree	Qty
56251020	25mm	10mm	20°	2
56251120	25mm	11mm	20°	2
56251220	25mm	12mm	20°	2
56251320	25mm	13mm	20°	2
56301020	30mm	10mm	20°	2
56301120	30mm	11mm	20°	2
56301220	30mm	12mm	20°	2
56301320	30mm	13mm	20°	2
56351020	35mm	10mm	20°	1
56351120	35mm	11mm	20°	1
56351220	35mm	12mm	20°	1
56351320	35mm	13mm	20°	1

Other devices that are not a part of the ARTiC-L System, such as Aquamantys™ and Midas Rex™ can be ordered to enable an ARTiC-L procedure.

Aquamantys: Advanced Energy Dissection and Hemostasis Devices		
Part Number	Item Description	Qty
PS210-0205	PlasmaBlade™ 3.0S	1
23-113-1	Aquamantys™ 2.3	1
23-312-1	Aquamantys™ SBS	1
40-4-4-1	AEX™ Generator	1

Midas Rex: Powered Surgical Solutions		
Part Number	Item Description	Qty
EM200	Legend™ EHS Stylus Motor	1
EC300	Integrated Power Console	1
BM110	Midas Rex™ Bone Mill Base	1
BM120	Midas Rex™ Bone Mill Console	1
BM210	Midas Rex™ Dual Blade, Disposable	1

BONE GRAFT VOLUME

BONE GRAFT VOLUME

Part Number	cc
56251020	0.6023
56251120	0.6976
56251220	0.7913
56251320	0.87988
56250810	0.49493
56250910	0.58849
56251010	0.68251
56251110	0.77803
56251210	0.86704
56251310	0.96026
56250805	0.53433
56250905	0.62777
56251005	0.72189
56251105	0.81731
56251205	0.9064
56251305	0.99962
56301020	0.84957
56301120	0.98636
56301220	1.11418
56301320	1.24929
56300810	0.6947
56300910	0.83038
56301010	0.96469
56301110	1.1014

BONE GRAFT VOLUME

Part Number	cc
56301210	1.20232
56301310	1.36444
56300805	0.75106
56300905	0.88673
56301005	1.02104
56301105	1.15785
56301205	1.28568
56301305	1.4209
56350810	0.90087
56350910	1.08149
56351010	1.26184
56351110	1.44349
56351210	1.61655
56351310	1.79661
56350805	0.9744
56350905	1.15494
56351005	1.3354
56351105	1.51705
56351205	1.69011
56351305	1.87017
56351020	1.11857
56351120	1.2991
56351220	1.47286
56351320	1.65471

IMPORTANT
PRODUCT INFORMATION

INDICATIONS

The ARTiC-L™ 3D Ti Spinal System with TiONIC ™ technology is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Additionally, the ARTiC-L™ 3D Ti Spinal System with TiONIC ™ technology can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine using autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft , and/or demineralized allograft bone with bone marrow aspirate. When used as an interbody fusion device, these implants are intended for use with supplemental internal fixation systems.

CONTRAINDICATIONS

This device is not intended for cervical spine use. Contraindications include, but are not limited to:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, or where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration and/or retropulsion of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous spinal surgery.

A device that has been implanted should never be re-used or re-processed under any circumstances. Sterile packaged devices are never to be re-sterilized. Re-use or reprocessing may compromise the structural integrity of the implants and create a risk of contamination of the implants.

Physician note: although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA For US Audiences Only

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

NOTES

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For PEAK PlasmaBlade™ Products and Aquamantys® bipolar sealers, please call Medtronic Advanced Energy Customer Service at 866-777-9400.

For Medtronic Powered Surgical Solutions, please call Customer Service at 1-800-433-7080.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.