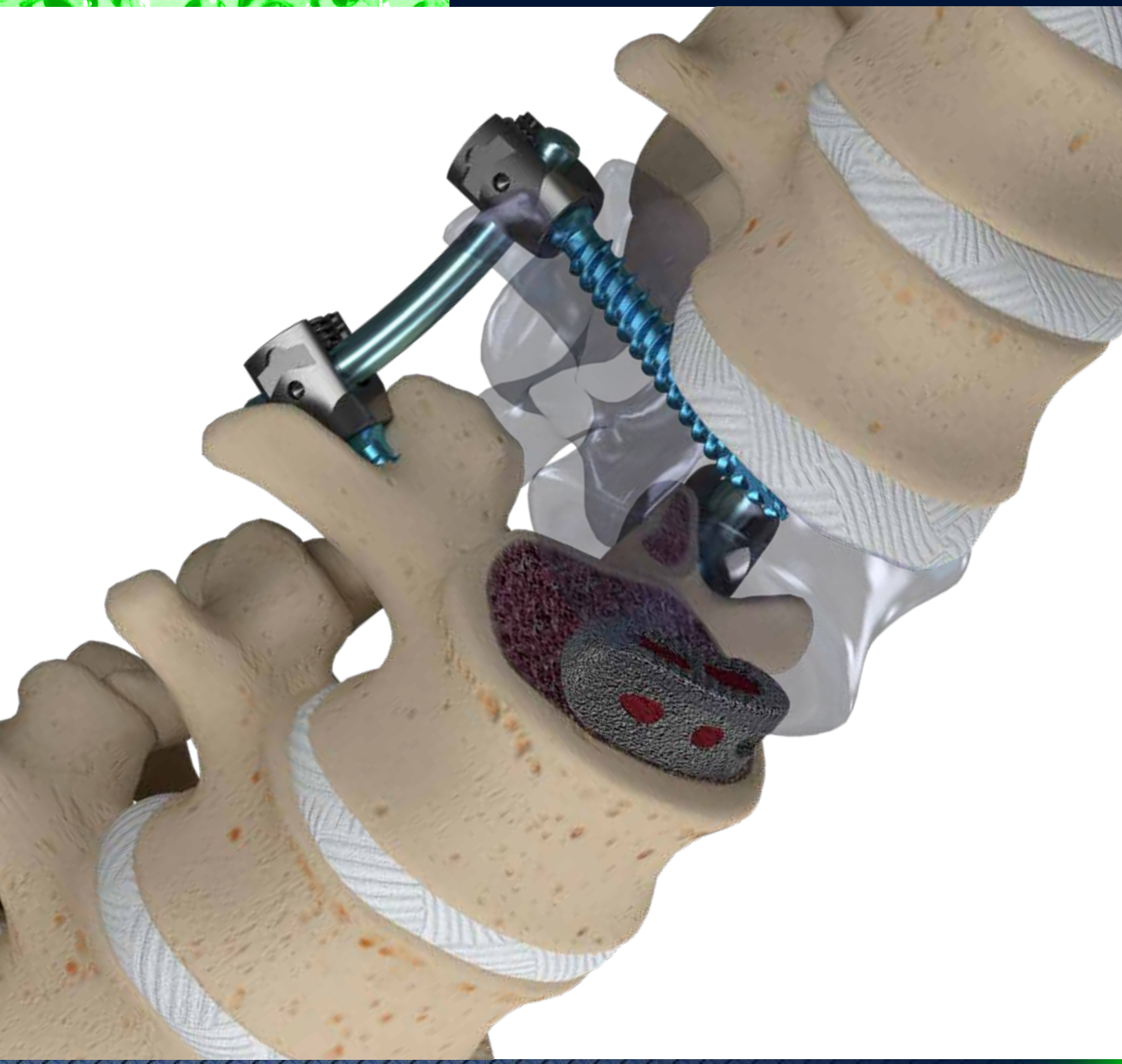
IdentiTi™

Posterior Curved Porous Ti Interbody System

POSTERIOR APPROACH | Surgical Technique Guide



PREFACE

ATEC Spine is pleased to offer the IdentiTi Posterior Curved Porous Ti Interbody System of curved implants and instruments. The system aims to provide surgeons with a range of implants and instrumentation necessary for achieving lumbar fusions from a posterior approach. All implants are made of porous titanium material and are available in a wide variety of height and footprint options.

CONTENTS

A SYSTEM OVERVIEW

Features

The IdentiTi-PC Posterior Curved Porous Ti Interbody System was designed to optimize the art of spinal fusion procedures by providing the following:

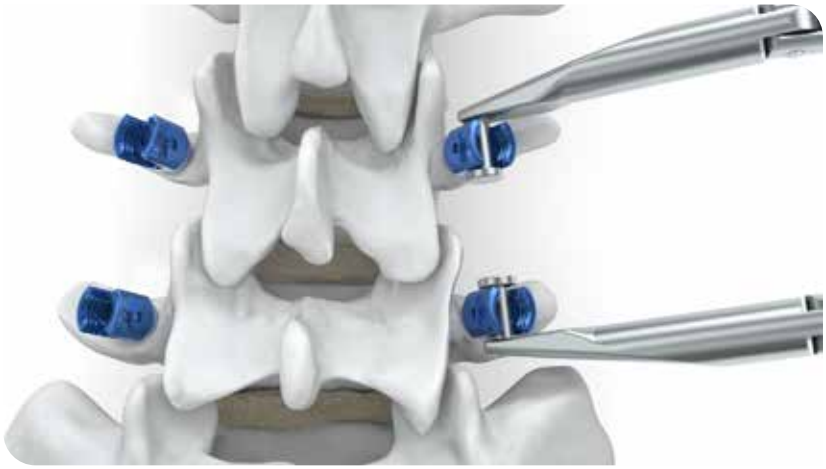
- A comprehensive system offering a wide variety of implants and instruments
- Ergonomically designed instrumentation
  - Light-weight materials
  - Tactile feel and comfort
- A wide variety of implant footprints and height options
  - Designed for varying patient anatomy
  - Bulleted nose for insertion
- Axial and Offset Inserters featuring a 180 degree ratchet style locking mechanism
  - Provides smooth implant/inserter interface
  - Allows for controlled insertion and detachment of the implant
- Instruments featuring 30 mm of TiN coating
  - Designed to maintain sharp cutting surfaces after multiple uses

1 PATIENT POSITIONING

- Place the patient in the prone position in standard fashion for posterior approach interbody fusion.

2 SURGICAL EXPOSURE

- An open, mini-open, or minimally invasive approach may be utilized.
- The inferior and superior facet, pars interarticularis, transverse process, and lamina on the side of implantation should be easily identified for this technique.
- Distraction may be accomplished by one of the following techniques:



Screw to Screw Distractor:

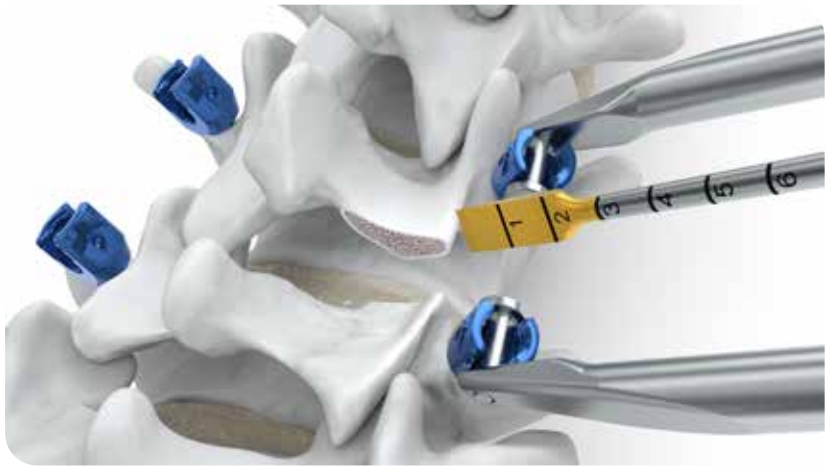
- Place Screw to Screw Distractor onto implanted pedicle screws. Insert provisionally tightened set screws for optimal distraction. Apply distraction on the pedicle screws using the Screw to Screw Distractor.

Lamina Spreader/Distractor:

- Apply distraction on the base of the spinous processes using a Lamina Distractor before implantation of pedicle screws and rods.

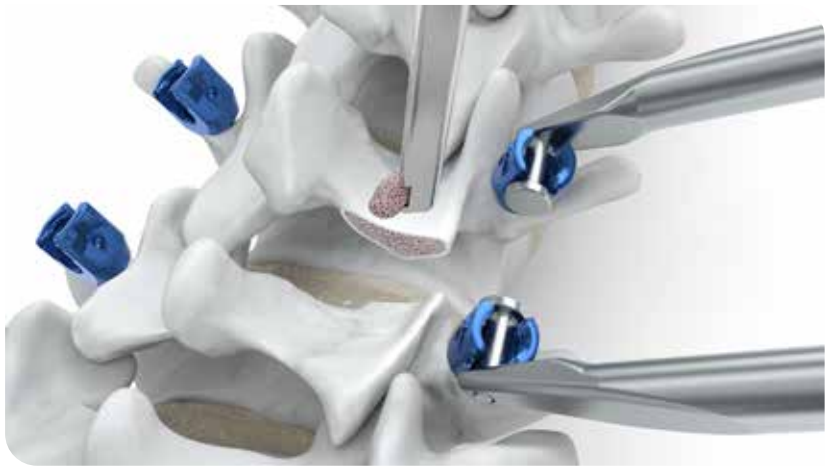
3 TRANSFORAMINAL WINDOW

- Resect the inferior facet of the cephalad vertebra with an Osteotome or high speed burr. Excise the superior facet of the caudal vertebra to the pedicle optimizing entry to the disc space. Care should be taken to avoid penetration of the pedicle cortex if using a high speed burr.



TIP: The local bone may be saved, decorticated and used as bone graft material.

TIP: The TiN coating (gold section) represents the distal 30 mm of the shaft of the Osteotome.



NOTE: A Kerrison Rongeur or drill may be used to perform additional resection as needed.

4 DISC SPACE PREPARATION

- Place Nerve Root Retractor to protect the exiting nerves, and create an annulotomy with a scalpel.
- Enter and prepare the disc space using preferred tools.
- Insert Rotating Shavers until the cutting edge is completely within the disc space.

TIP: The TiN coating (gold section) represents the distal 30 mm of the shaft of the Rotating Shavers.

NOTE: Rotating Shavers are available in heights of 5 mm – 15 mm in 1 mm increments. Custom shavers available upon request.

NOTE: Rotating Shavers are intended to resect and prepare the disc space for the insertion of an interbody cage; they should not be used for distraction.

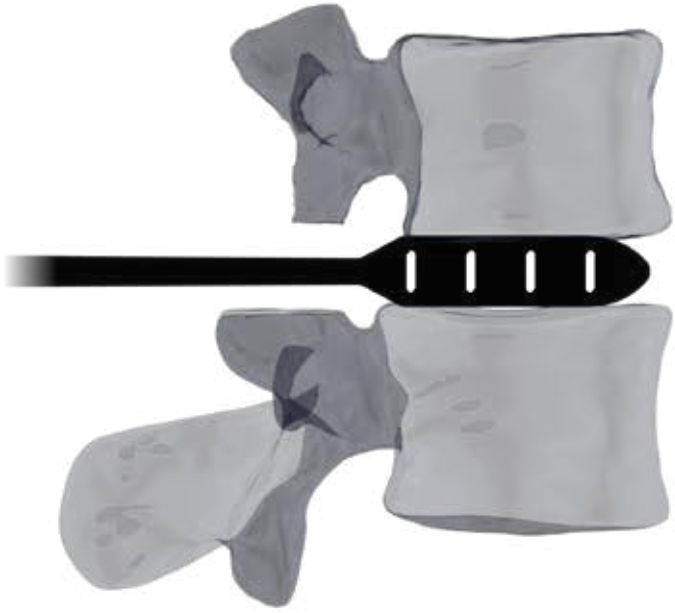
NOTE: Remove any loose disc material from the disc space with the Pituitary Rongeurs.

TIP: Up-Biting Pituitary Rongeurs can also function as Down-Biting Pituitary Rongeurs.

5 ROTATING DISTRACTION

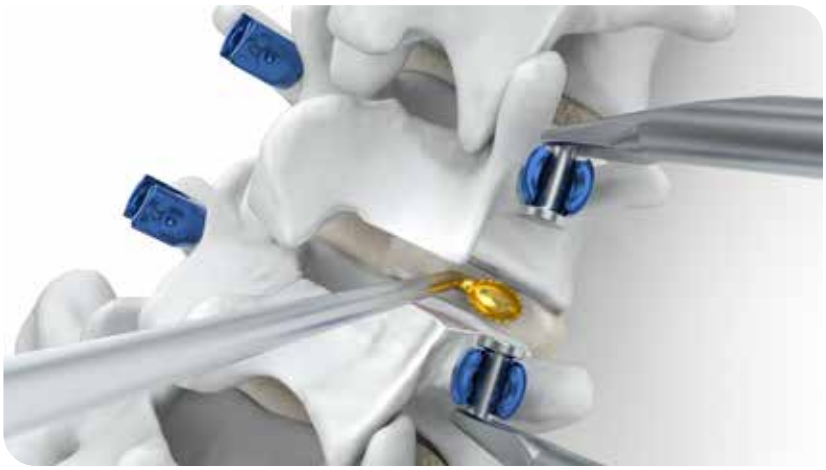
- Use the Rotating Distractors to distract the disc space to the desired height.
  - Fenestrations within the Rotating Distractors are visible under fluoro and are 10 mm apart.

NOTE: Rotating Distractors are available in heights of 5 mm – 15 mm in 2 mm increments (odd increments). Even increments available upon request.



6 ENDPLATE PREPARATION

- Roughen endplates to achieve cancellous bone bleeding using the tools from the Battalion® Disc Prep Set (BATPINT). The Battalion Disc Prep Set contains Rasps (Straight and Curved Double-Sided), Serrated Curettes (Straight, Right and Left Angled, Push and Pull) and teardrop-shaped Ringed Curettes (Straight and Angled).



TIP: The TiN coating (gold section) represents the distal 30 mm of the shaft of the Curette.

TIP: Smaller currette sizes available upon request.

TIP: Custom currettes available upon request.

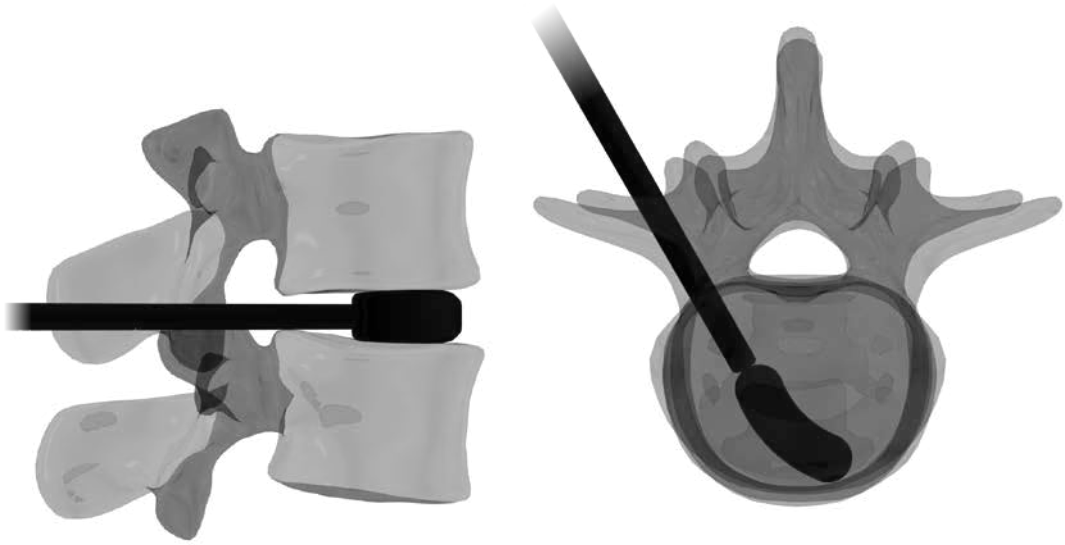
7 IMPLANT TRIALING

- Insert selected implant Trial into ¼" T-Handle square to confirm the correct height, footprint, and/or location within the disc space.
- AP and/or lateral fluoroscopy can be used to confirm position.
- Select the appropriate sized IdentiTi™-PC implant.
- The implant Trials are color coded.
  - Black 5 degree implant lordosis
  - Silver 10 degree implant lordosis
  - Gold 15 degree implant lordosis

Posterior Curved Trials

TIP: If implant Trial becomes lodged in the disc space, connect Slap Hammer to Trial handle or directly to the ¼" sq. to facilitate removal.

NOTE: Trials are sized 1:1 (line to line) with the implants, which includes the height of the teeth on the implants.



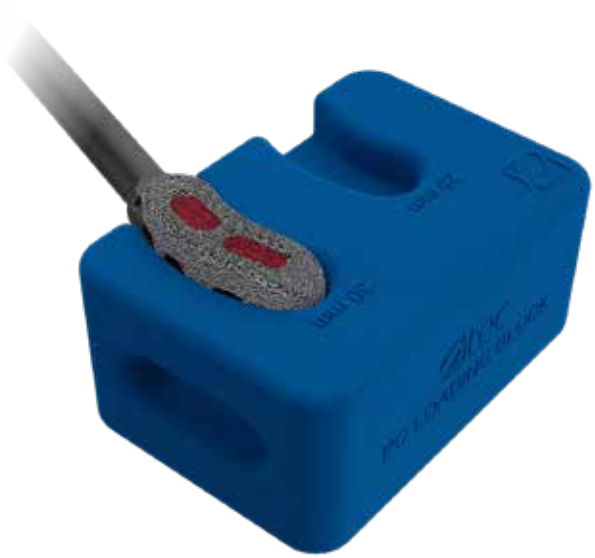
8 IMPLANT SELECTION

- Select the appropriate sized IdentiTi Posterior Curved Porous Ti implant.
- Load the implant onto either the Axial or Offset Inserter.

Posterior Curved Implant

9 BONE GRAFT APPLICATION

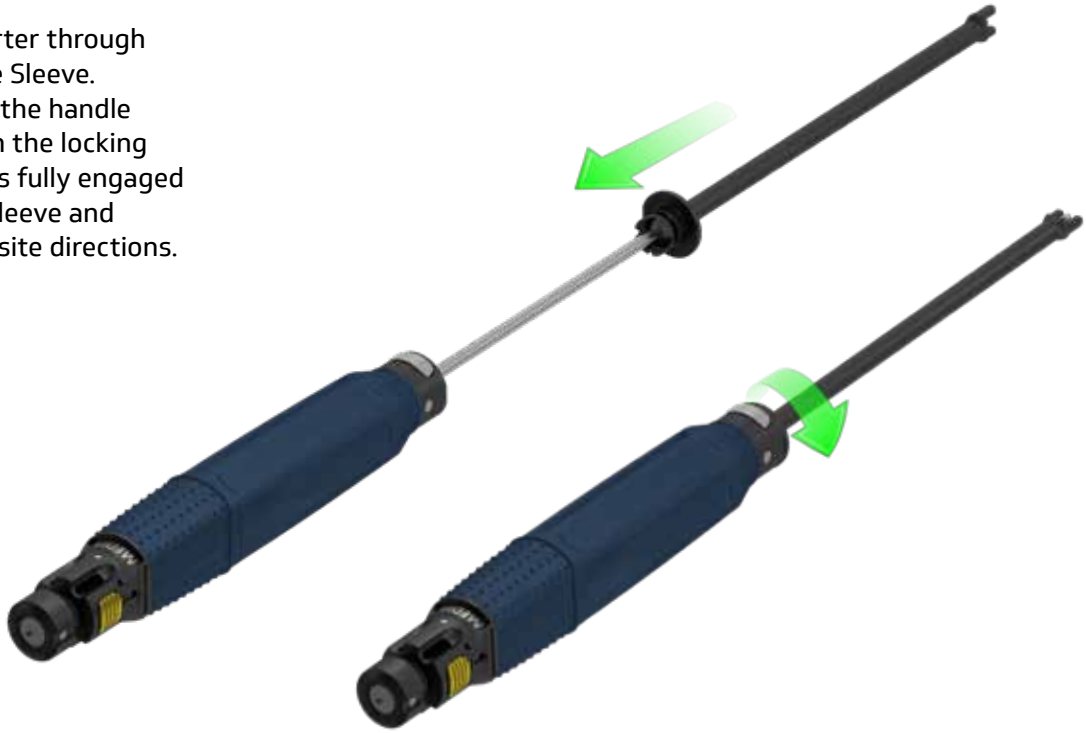
- Use the Implant Graft Packing Block to fill the implant's central chamber with bone graft material.
- After interbody implantation use the truncated Bone Graft Funnel to deploy bone graft into surrounding portions of the disc space.
- The Bone Tamp is designed to protrude from the funnel to assist with bone graft extrusion.



TIP: Apply saline solution to the footprint of the Packing Block to prevent graft material from sticking to the Packing Block.

10 ATTACHING THE SLEEVE TO THE INSERTER

- Insert shaft of the Inserter through the through-hole of the Sleeve. Spin the Sleeve around the handle until it is fully seated on the locking mechanism. Confirm it is fully engaged by slightly pulling the Sleeve and Inserter handle in opposite directions.



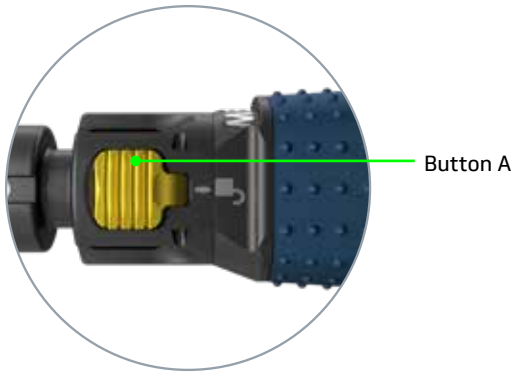
11 IMPLANT-INSERTER ENGAGEMENT

Attaching the Implant to the Inserter:

- To engage and attach the implant to the Inserter, check that the gold square large button “A” is aligned with the “unlocked” laser mark. Slide the implant on to the end of the Inserter, apply very light pressure to the implant, and begin rotating the most proximal part of the handle. An audible ratcheting or "clicking" will begin at 150 degrees; continue rotating until implant is fully engaged (approximately 180 degrees).

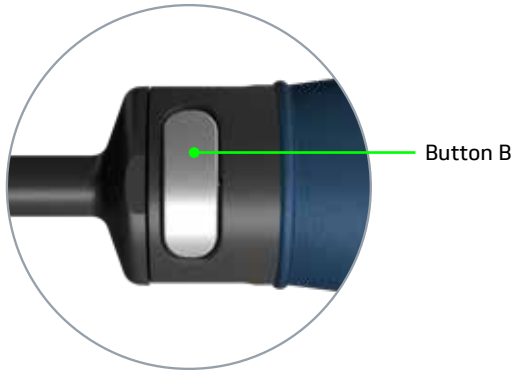
Disengaging the Implant from the Inserter:

- To disengage the implant from the Inserter, press and hold the gold square button and rotate the handle approximately 180 degrees until the square large button “A” reaches the “unlocked” laser mark and pull the Inserter away from the implant.



Disassembling for Cleaning:

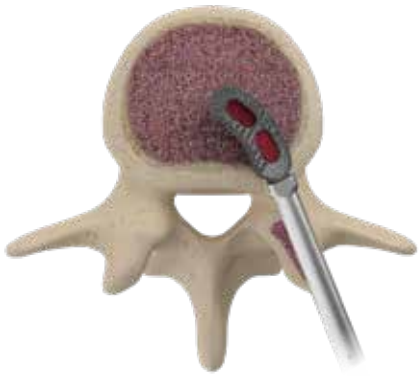
- To separate the outer sleeve from the main Inserter for cleaning, press the small oblong button “B” and slide the sleeve away from the Inserter. To reconnect, slide the sleeve down the main Inserter shaft. Rotate the sleeve until it is fully seated on Inserter and you hear a click.

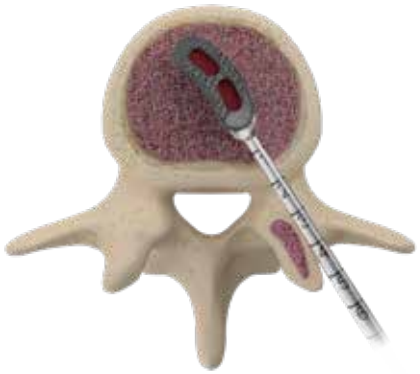


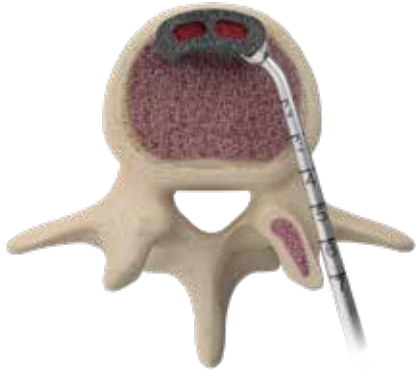
NOTE: Square large button “A” is only used to lock and unlock the implants from the Inserter.

Implant Verification

- Confirm implant position with AP and lateral fluoroscopy.
- The Straight or Curved Tamp or Straight or Curved Positioner can be used to manipulate the implant into final position.
- Pack additional bone graft material posteriorly as needed.
- Remove the distraction device, and create additional lordosis as needed by compressing on the posterior pedicle screw construct.







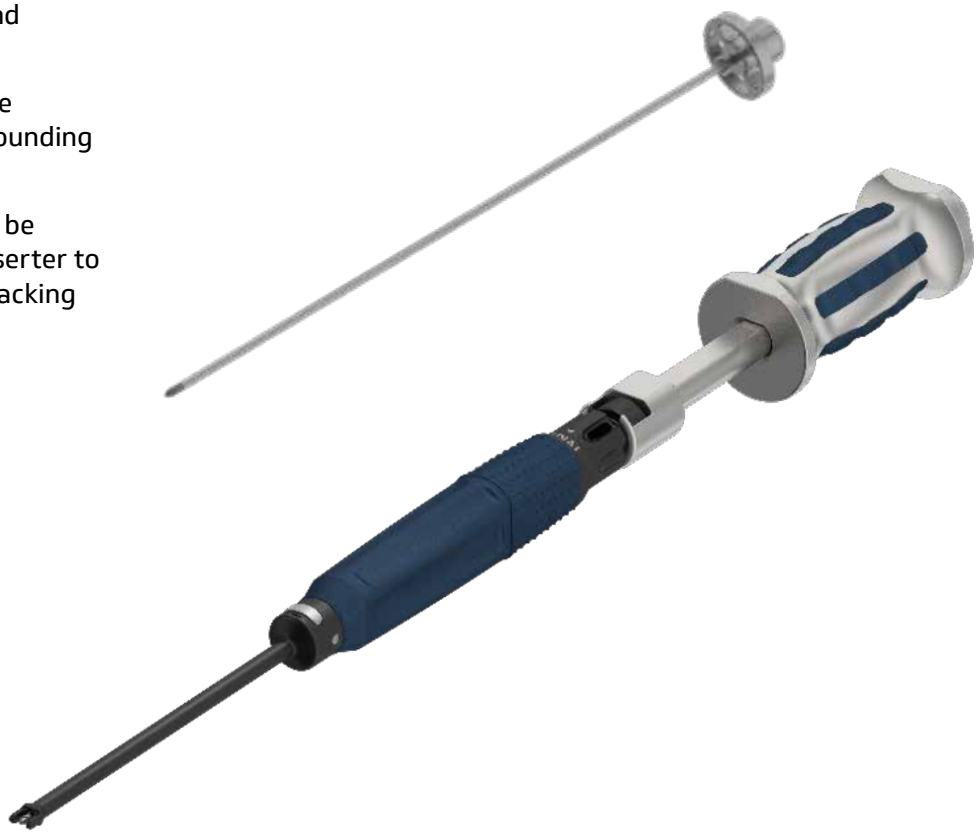
12 SUPPLEMENTAL FIXATION

- The IdentiTi Posterior Curved Porous Ti implants must be used with supplemental fixation for use in the thoracolumbar spine. Implant the supplemental fixation according to the recommended surgical technique for the fixation system.

NOTE: When used in the US, supplemental fixation systems must be cleared by the FDA per the indications for use.

13 IMPLANT REMOVAL/RETRIEVAL

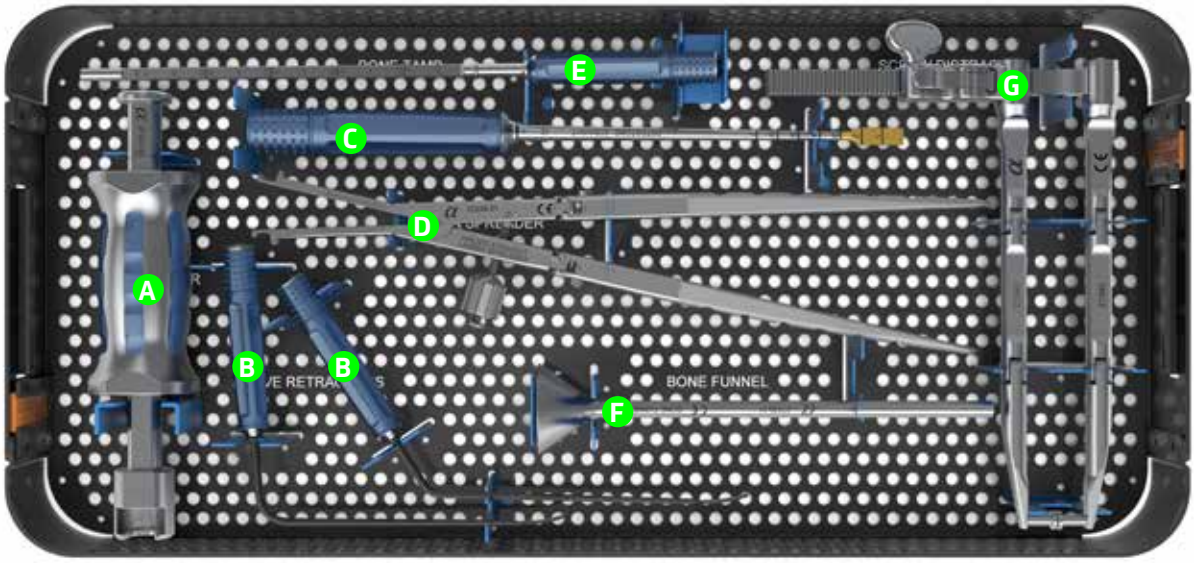
- Using the Implant Retriever, insert the threaded end of the Implant Retriever Instrument into the implant and gently remove.
- When removing the implant, be careful not to disturb the surrounding nerve root structures.
- Alternatively, the implant may be removed by connecting the Inserter to the Slap Hammer and slowly backing out the implant.



14 TRAY CONFIGURATION

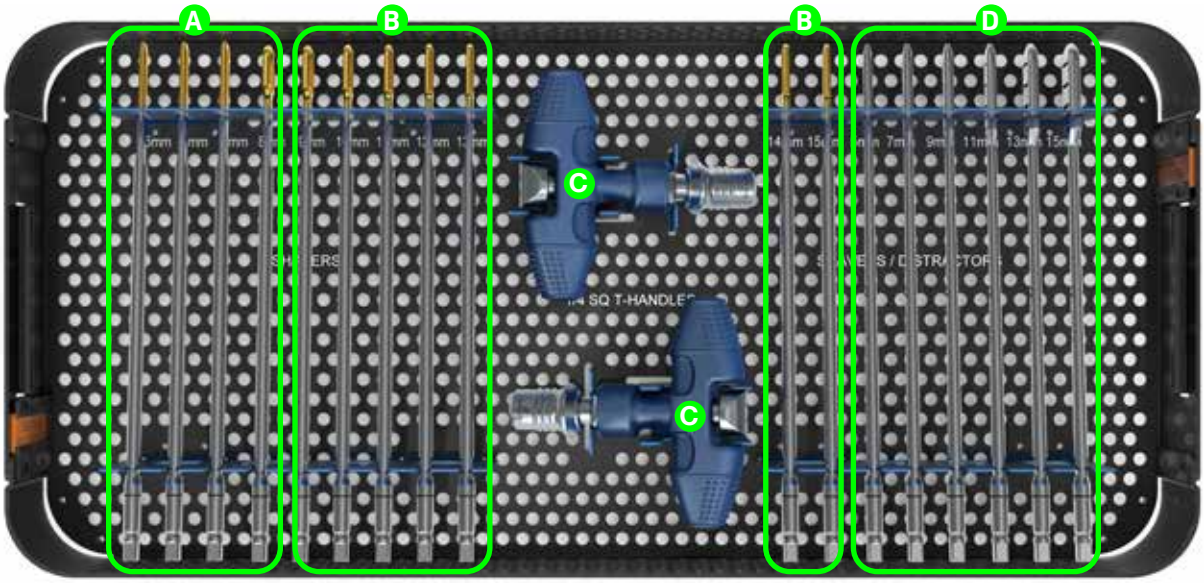
SKIF: 27500-01 Set ID: BATGEN

Top Tray



- **A** Slap Hammer
  Part #: 27241-01
- **B** Nerve Root Retractors (Qty 2)
  Part #: 27232-27 & 27232-22
- **C** Straight Osteotome
  Part #: 27204-01-08
- **D** Hinged Straight Lamina Spreader
  Part #: 27234-01
- **E** Bone Graft Tamp
  Part #: 27239-02
- **F** Bone Graft Funnel
  Part #: 27239-01
- **G** Screw to Screw Distractor
  Part #: 27240

Bottom Tray

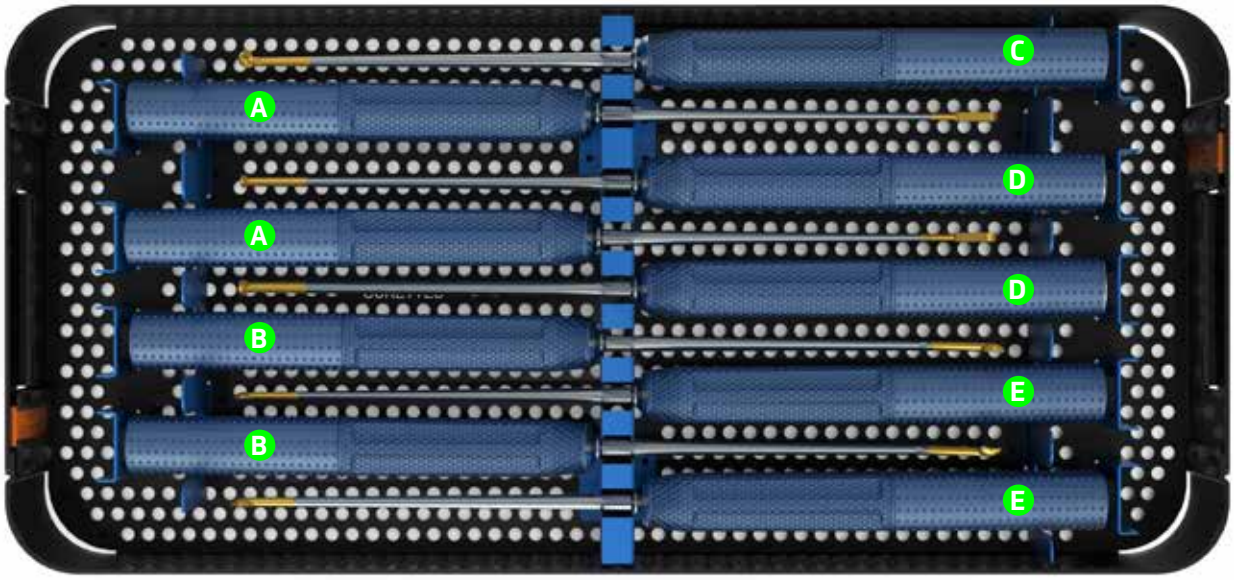


- **A** Rotating Shaver Standard (5 – 8 mm)
  Part #: 27222-01-XX, 27222-02-08
- **B** Rotating Shaver Parallel (9 – 15 mm)
  Part #: 27222-04-XX
- **C** Silicone Handle (Qty 2)
  Part #: 86904-0210
- **D** Fenestrated Rotating Distractors
  Part #: 27233-23-XX

14 TRAY CONFIGURATION

SKIF: 27550-01 Set ID: BATPINT

Top Tray



A Teardrop Curette, Straight and Angled, Size 2
Part #: 27223-10-021-05 & 27223-11-021-05

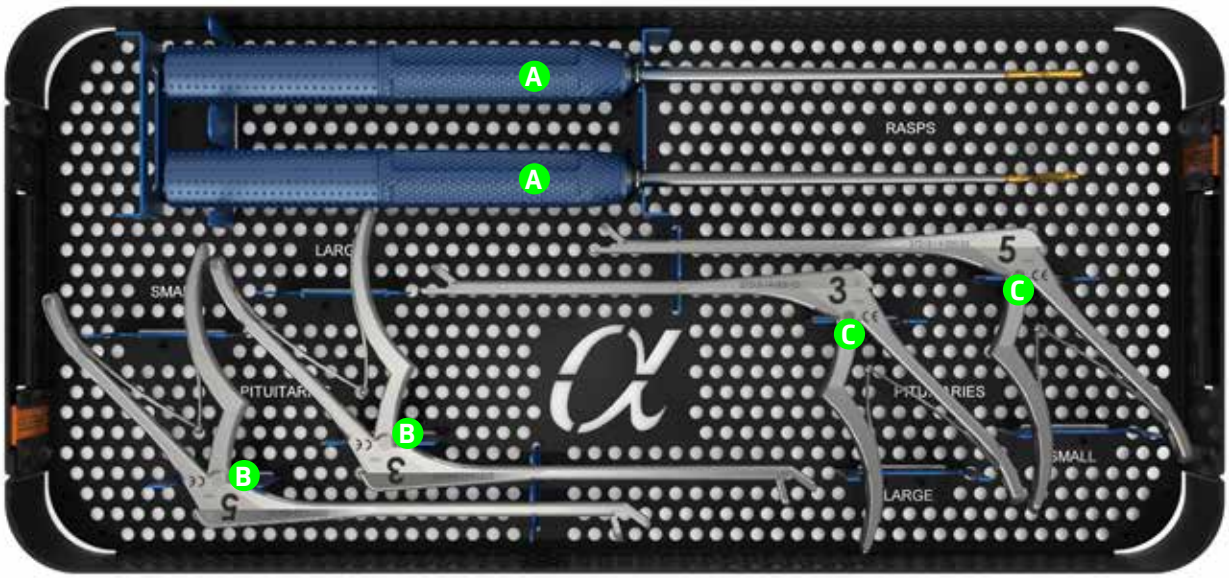
B Serrated Right and Left Angled Curette, Size 4
Part #: 27223-XX-022-XX

C Serrated Pull Curette, Size 4
Part #: 27223-XX-022-XX

D Serrated Push Curette, Size 2 & 4
Part #: 27223-XX-022-XX

E Serrated Straight Curette, Size 2 & 4
Part #: 27223-XX-022-XX

Bottom Tray



A Straight and Curved Rasp, Two Sided
Part #: 27221-02 & 27221-08

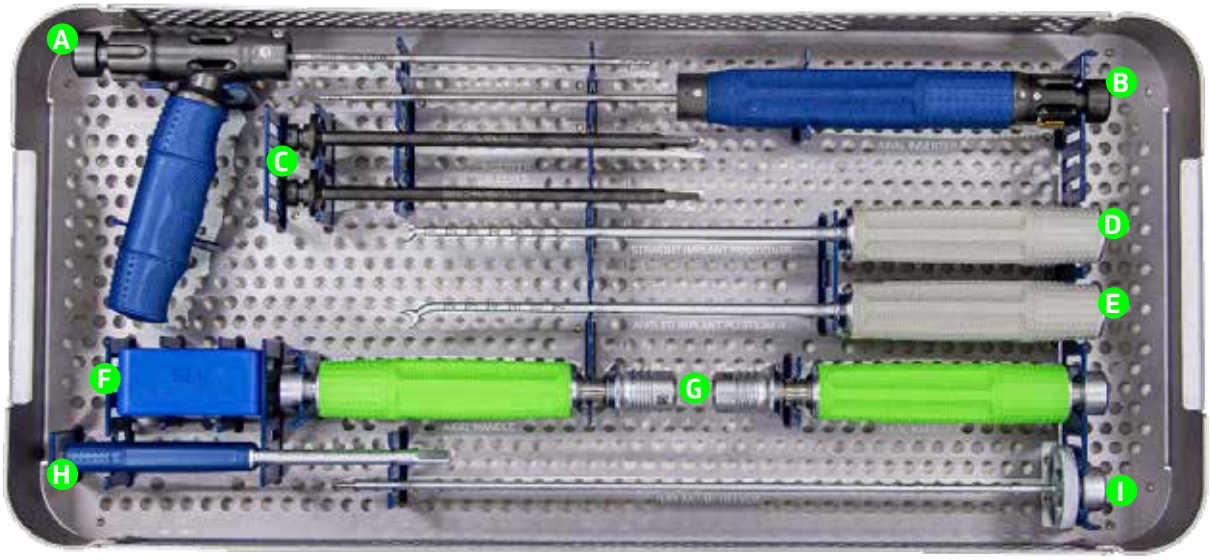
B Pituitary, Up - Biting, 3 and 5 mm
Part #: 27213-02-000-03 & 27213-02-000-05

C Pituitary, Straight Biting, 3 and 5 mm
Part #: 27213-14-000-03 & 27213-14-000-05

14 TRAY CONFIGURATION

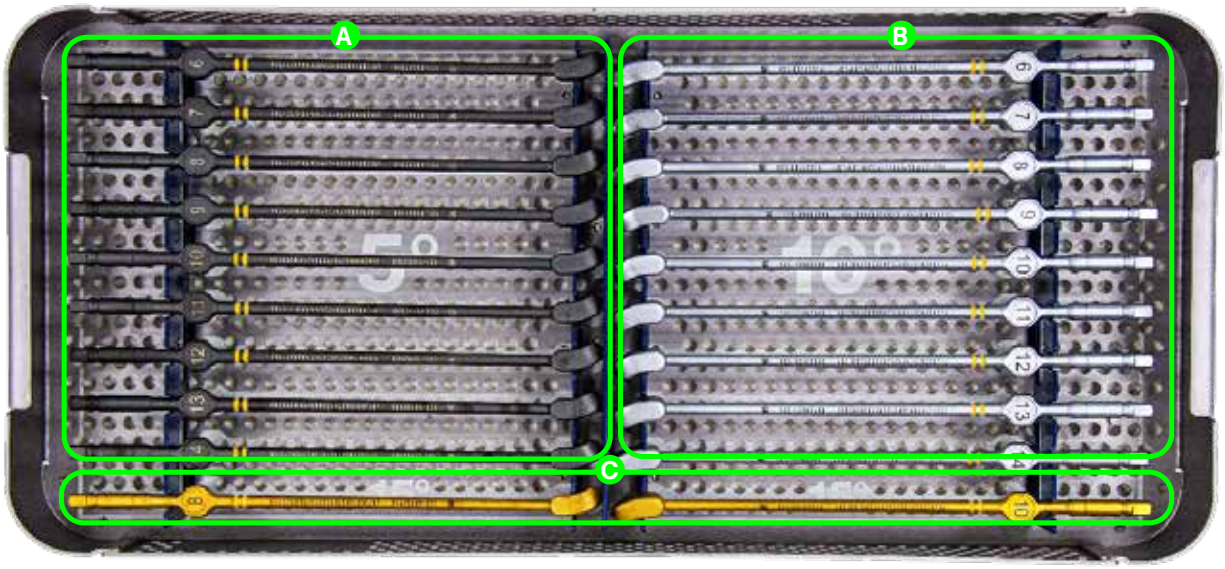
SKIF: 123-01 Set ID: IDPCINT

Top Tray



- **A** PO Offset Inserter
  Part # 125-200
- **B** PO Inserter
  Part # 125-100
- **C** PC Inserter Sleeve
  Part # 123-100-50
- **D** Implant Positioner, Straight
  Part # 123-300
- **E** Implant Positioner, Angled
  Part # 123-310
- **F** PC Loading Block
  Part # 123-400
- **G** Silcone Handle, Axial, Large, 1/4" QC Modular, Impacting, Non-Cannulated
  Part # 86003-0231
- **H** Bone Tamp
  Part # 27809
- **I** Implant Retriever
  Part # 27804

Bottom Tray



- **A** IdentiTi PC Porous Ti Trial
  XX x 10 x 25 mm 5°
  Part # 123-XX102505
- **B** IdentiTi PC Porous Ti Trial
  XX x 10 x 25 mm 10°
  Part # 123-XX102510
- **C** IdentiTi PC Porous Ti Trial
  XX x 10 x 25 mm 15°
  Part # 123-XX102515

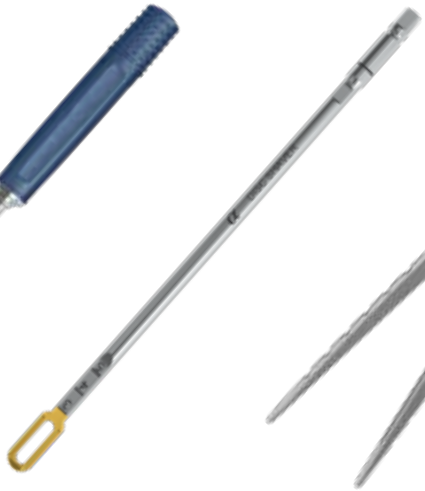
15 INSTRUMENTS

Slap Hammer
Part # 27241-01

Nerve Root Retractor
Part # 27232-27

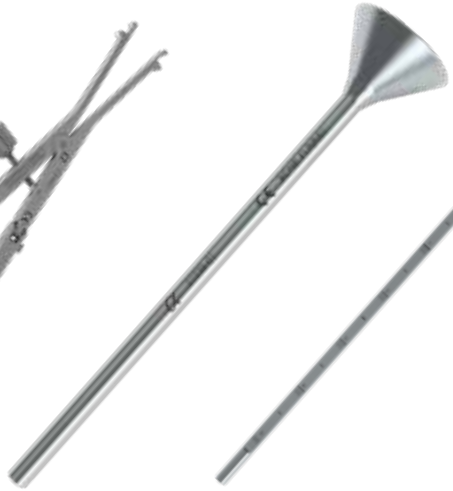
Nerve Root Retractor
Part # 27232-22

Osteotome, Straight
Part # 27204-01-XX



Rotating Shavers
Part # 27222-01-XX,
27222-02-08,
27222-04-XX

Hinged Straight
Lamina Distractor
Part # 27234-01



Bone Graft Funnel
Part # 27239-01

Bone Graft Tamp
Part # 27239-02

15 INSTRUMENTS

Screw To Screw Distractor
Part # 27240

Silicone Handle, Large T,
¼" SQ., Impacting
Part # 86904-0210

Fenestrated Rotating
Distractor
Part # 27233-23-XX

Axial Handle
Part # 86003-0231

Straight Teardrop
Curette
Part # 27223-10-021-05

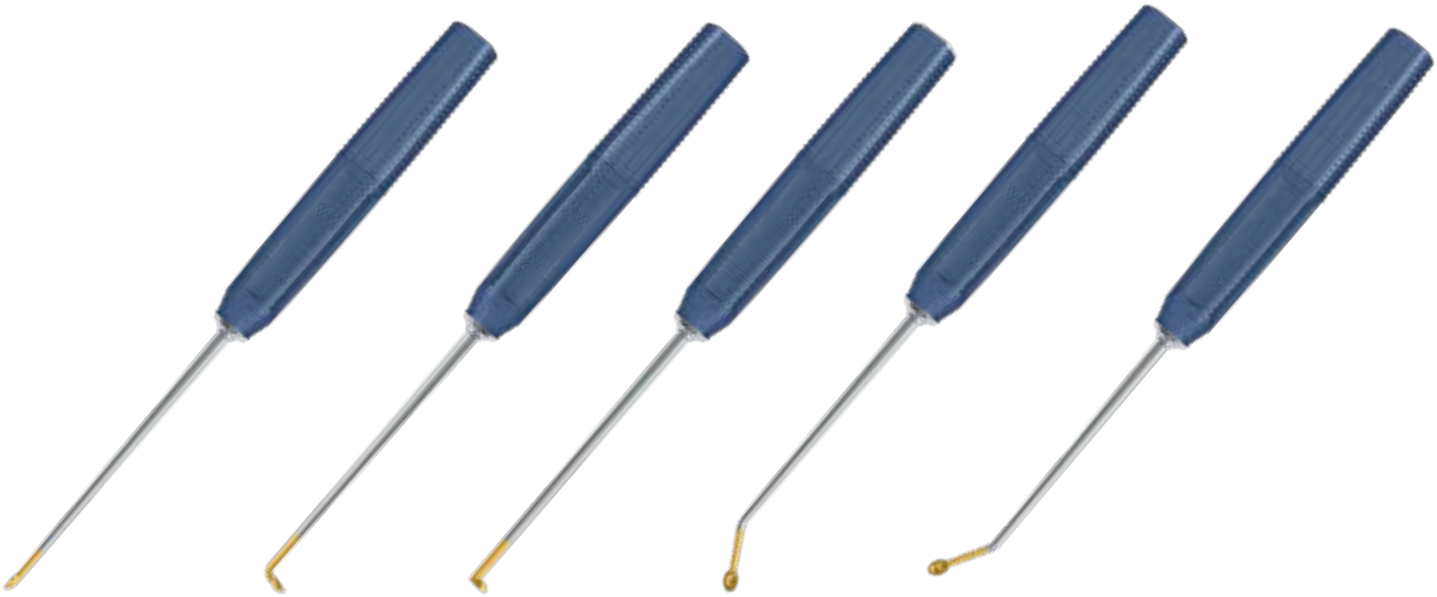
Angled Teardrop Curette
Part # 27223-11-021-05

Straight Rasp
Part # 27221-02

Curved Rasp
Part # 27221-08

Bone Tamp
Part # 27809

15 INSTRUMENTS



Curettes
Part #
27223-XX-022-XX

Curettes
Part #
27223-XX-022-XX

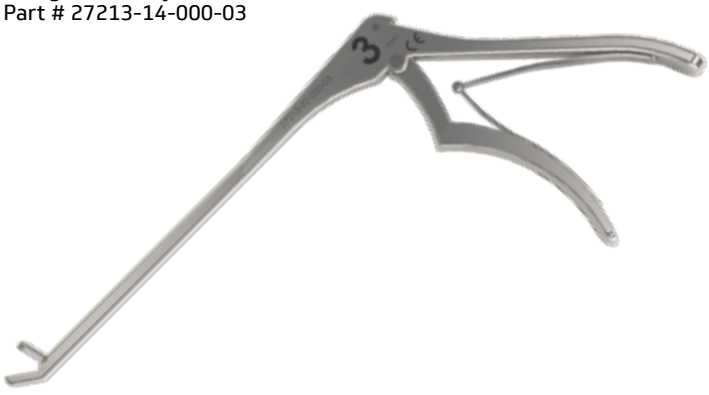
Curettes
Part #
27223-XX-022-XX

Curettes
Part #
27223-XX-022-XX

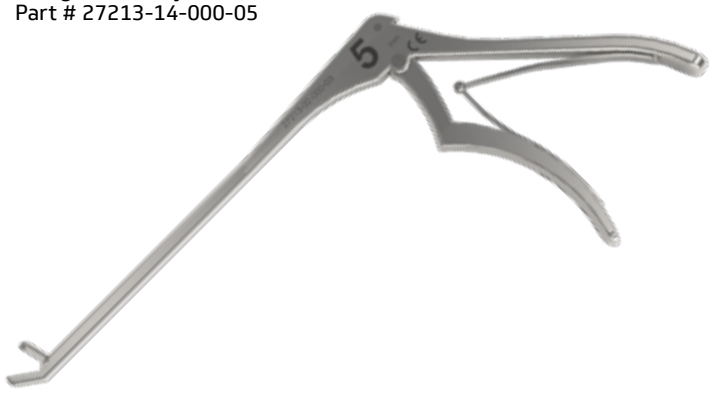
Curettes
Part #
27223-XX-022-XX

Straight Pituitary
Part # 27213-14-000-03

Straight Pituitary
Part # 27213-14-000-05



Up-Biting Pituitary
Part # 27213-02-000-03



Up-Biting Pituitary
Part # 27213-02-000-05

15 INSTRUMENTS

Implant Positioner
Straight
Part # 123-300

Implant Positioner
Angled
Part # 123-310

IdentiTi Inserter,
Curved Sleeve
Part # 123-100-50

IdentiTi
Inserter Axial
Part # 125-100

IdentiTi
Inserter Offset
Part # 125-200

Curved Trials
Part #
123-XXXXXXXX
15° Lordosis

Curved Trials
Part #
123-XXXXXXXX
10° Lordosis

Curved Trials
Part #
123-XXXXXXXX
5° Lordosis

Implant
Retriever
Part # 27804

Bone Graft Packing Block
Part # 123-400

16 IMPLANTS

IdentiTi Posterior Curved
Porous Ti Implants
Part # 122-XXXXXXXX-S

IdentiTi™ Porous Ti Interbody System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The IdentiTi Porous Ti Interbody System is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. The IdentiTi interbody spacers are manufactured from commercially pure titanium Grade 2 per ASTM F67. The IdentiTi Porous Ti cervical platform includes sub-system IdentiTi Cervical (IdentiTi-C). The IdentiTi Porous Ti thoracolumbar platform includes the following sub-systems: IdentiTi PS, IdentiTi PC, IdentiTi PO, IdentiTi ALIF, and IdentiTi LIF.

Use IdentiTi cervical interbody spacers with supplemental fixation systems from Alphatec Spine such as: Trestle Luxe® Cervical Plate System or Invictus® OCT Spinal Fixation System.

Use IdentiTi thoracolumbar interbody spacers with supplemental fixation systems from Alphatec Spine such as: Zodiac® Polyaxial Spinal Fixation System, Arsenal® Spinal Fixation System, Illico® MIS Posterior Fixation System, BridgePoint® Spinous Process Fixation System, or Invictus® Spinal Fixation System.

INDICATIONS FOR USE:
IdentiTi Cervical Platform
The IdentiTi Cervical Porous Ti Interbody System is an anterior cervical interbody fusion system intended for spinal fusion procedures in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2-T1. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems. The system is designed for use with autograft, allograft comprised of cortical, cancellous, and/or corticocancellous bone graft, demineralized allograft with bone marrow aspirate, or a combination thereof.

IdentiTi Thoracolumbar Platform
The IdentiTi Porous Ti Interbody System is indicated for spinal fusion procedures from T1 to S1 in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, and/or thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain) at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

Additionally, the IdentiTi Porous Ti System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The IdentiTi Porous Ti Interbody System is intended for use on patients who have had at least six months of non operative treatment. It is intended to be used with autograft and/or allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate and supplemental fixation systems that are cleared by FDA for use in the thoracic and lumbar spine.

CONTRAINDICATIONS:
The IdentiTi Porous Ti Interbody System is contraindicated for:
1. Patients with bone resorption related disease (e.g., osteopenia), bone and/or joint disease, or deficient soft tissue at the wound site.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients with allergy or intolerance to titanium.
4. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
5. Patients with prior fusion at the level(s) to be treated.
6. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
7. Reuse or multiple uses of the implant.

WARNINGS/CAUTIONS/PRECAUTIONS:
1. Interbody implants and single-use instruments are provided sterile.
   a. Inspect the packaging for signs of damage. Do not use devices if package is opened, damaged, or past the expiry date.
   b. Do not re-sterilize implants.
   c. Do not use scratched or damaged devices.
2. Components of this system should not be used with components from other systems or manufacturers.
3. Do not comingle dissimilar materials (e.g., titanium and stainless steel) within the same construct.
4. All instruments except the single-use instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU. Sterile single-use instruments are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.
5. Implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
6. These implants are used only to provide internal fixation, in conjunction with graft and supplemental fixation, during the bone fusion process. A successful result may not be achieved in every instance.
7. Potential risks identified with the use of these fusion devices, which may require additional surgery, include device component failure, loss of fixation, pseudarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and/or vascular or visceral injury.
8. Risk factors that may affect successful surgical outcomes include: alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
9. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may affect the performance of this system.
10. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
11. Implantation 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.
12. Placement and positional adjustment of implants must only be performed with system-specific instruments. They must not be used with other instrumentation unless specifically recommended by Alphatec Spine Inc., because the combination with other instrumentation may be incompatible.
13. Resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the IdentiTi-LIF implant for greater sagittal correction, when used with AMP Anti-Migration Plate and supplemental fixation per the indications, and aid in preventing potential endplate damage. To minimize risk to surrounding anatomy when resecting the ALL, do not extend the resection past the medial wall of the contralateral pedicle as identified on true AP fluoroscopy.
14. The Center Screw - Back Table (116-5-01, green) must be assembled to the AMP and interbody prior to insertion, and must not be assembled in situ.

MRI SAFETY INFORMATION:
The IdentiTi Porous Ti Interbody System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the IdentiTi Porous Ti Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:
Possible adverse effects include:
1. Initial or delayed loosening, bending, dislocation, and/or breakage of device components.
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, seroma, and possible tumor formation.
3. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
4. Infection and/or hemorrhaging.
5. Non-union and/or pseudarthrosis.
6. Neurological disorder, pain and/or abnormal sensations caused by improper placement of the device, and/or instruments.
7. Subsidence of the device into the vertebral body.
8. Revision surgery.
9. Death.

PREOPERATIVE MANAGEMENT:
1. Only patients meeting the criteria listed in the indications for the use section should be selected.
2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include implantation strategy and a verification of required inventory for the case.
4. The condition of all implants and instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.
5. Cervical, LIF, and ALIF interbody implant anterior heights provided on product labels are theoretical calculations from other geometry (e.g., posterior height, width, lordosis). PS and PO interbody implant anterior heights provided on product labels reflect the maximum apex height. Anterior heights should be considered reference only. Use trials to assess implant sizing prior to implantation.

INTRAOPERATIVE MANAGEMENT:
1. The surgical technique manual should be followed carefully.
2. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times. Fluoroscopy should be employed where view of device is obstructed.
3. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.

POSTOPERATIVE MANAGEMENT:
Postoperative management by the surgeon is essential. This includes instructing, warning, and monitoring the compliance of the patient.
1. Patient should be informed regarding the purpose and limitations of the implanted devices.
2. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implanted devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibratory motion, falls, jolts or other movements preventing proper healing and/or fusion development.
3. Implanted devices should be revised or removed if bent, dislocated, or broken.
4. Immobilization should be considered in order to prevent bending, dislocation, or breakage of the implanted device in case of delayed, malunion, or nonunion of bone. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
5. Postoperative patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.

Excerpt from INS-100

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

SYMBOLS:
For a listing of Symbols and Explanations, see **atecspine.com/eifu**

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008 USA
Ph: (760) 431-9286
Ph: (800) 922-1356
atecspine.com

IdentiTi™ Porous Ti Interbody System
INSTRUCTIONS FOR USE (International)

GENERAL INFORMATION:
The IdentiTi Porous Ti Interbody System is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. The IdentiTi interbody spacers are manufactured from commercially pure titanium Grade 2 per ASTM F67. The IdentiTi Porous Ti cervical platform includes sub-system IdentiTi Cervical (IdentiTi-C). The IdentiTi Porous Ti thoracolumbar platform includes the following sub-systems: IdentiTi PS, IdentiTi PC, IdentiTi PO, IdentiTi ALIF, and IdentiTi LIF.
Use IdentiTi cervical interbody spacers with supplemental fixation systems from Alphatec Spine such as: Trestle Luxe® Cervical Plate System or Invictus® OCT Spinal Fixation System.
Use IdentiTi thoracolumbar interbody spacers with supplemental fixation systems from Alphatec Spine such as: Zodiac® Polyaxial Spinal Fixation System, Arsenal® Spinal Fixation System, Illico® MIS Posterior Fixation System, BridgePoint® Spinous Process Fixation System, or Invictus® Spinal Fixation System.

INDICATIONS FOR USE:
IdentiTi Cervical Platform
The IdentiTi Cervical Porous Ti Interbody System is intended for spinal fusion procedures at one or two levels from C2 – T1 in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The IdentiTi Cervical Porous Ti Interbody System is intended for use with supplemental fixation systems and with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Patients should have had six weeks of non-operative treatment.

IdentiTi Thoracolumbar Platform
The IdentiTi Porous Ti Interbody System is indicated for spinal fusion procedures in skeletally mature patients at one or two contiguous levels in the thoracolumbar spine.
Thoracic: T1-T2 to T11-T12, or at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic degenerative disc disease (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).
Lumbar: L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I 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.
The IdentiTi Porous Ti Interbody System is intended for use on patients who have had at least six months of non-operative treatment. It is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation systems for use in the thoracic and lumbar spine.

AMP™ Anti-Migration Plate may be used with IdentiTi LIF interbody spacers to provide integrated fixation. IdentiTi LIF spacers with >20° lordosis must be used with AMP Anti-Migration Plate in addition to supplemental fixation. IdentiTi ALIF interbody spacers with >20° lordosis must be used with an anterior plate as the form of supplemental fixation.

CONTRAINDICATIONS:
The IdentiTi Porous Ti Interbody System is contraindicated for:
1. Patients with bone resorption related disease (e.g., osteopenia), bone and/or joint disease, or deficient soft tissue at the wound site.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients with allergy or intolerance to titanium.
4. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
5. Patients with prior fusion at the level(s) to be treated.
6. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
7. Reuse or multiple uses of the implant.

WARNINGS/CAUTIONS:
1. Interbody implants and single-use instruments are provided sterile.
   a. Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
   b. Do not re-sterilize implants.
   c. Do not use scratched or damaged devices.
2. Components of this system should not be used with components from other systems or manufacturers.
3. Do not comingle dissimilar materials (e.g., titanium and stainless steel) within the same construct.
4. All instruments except the single-use instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU. Sterile single-use instruments are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.
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9. Death.

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Excerpt from INS-100-01

Australian Sponsor:
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