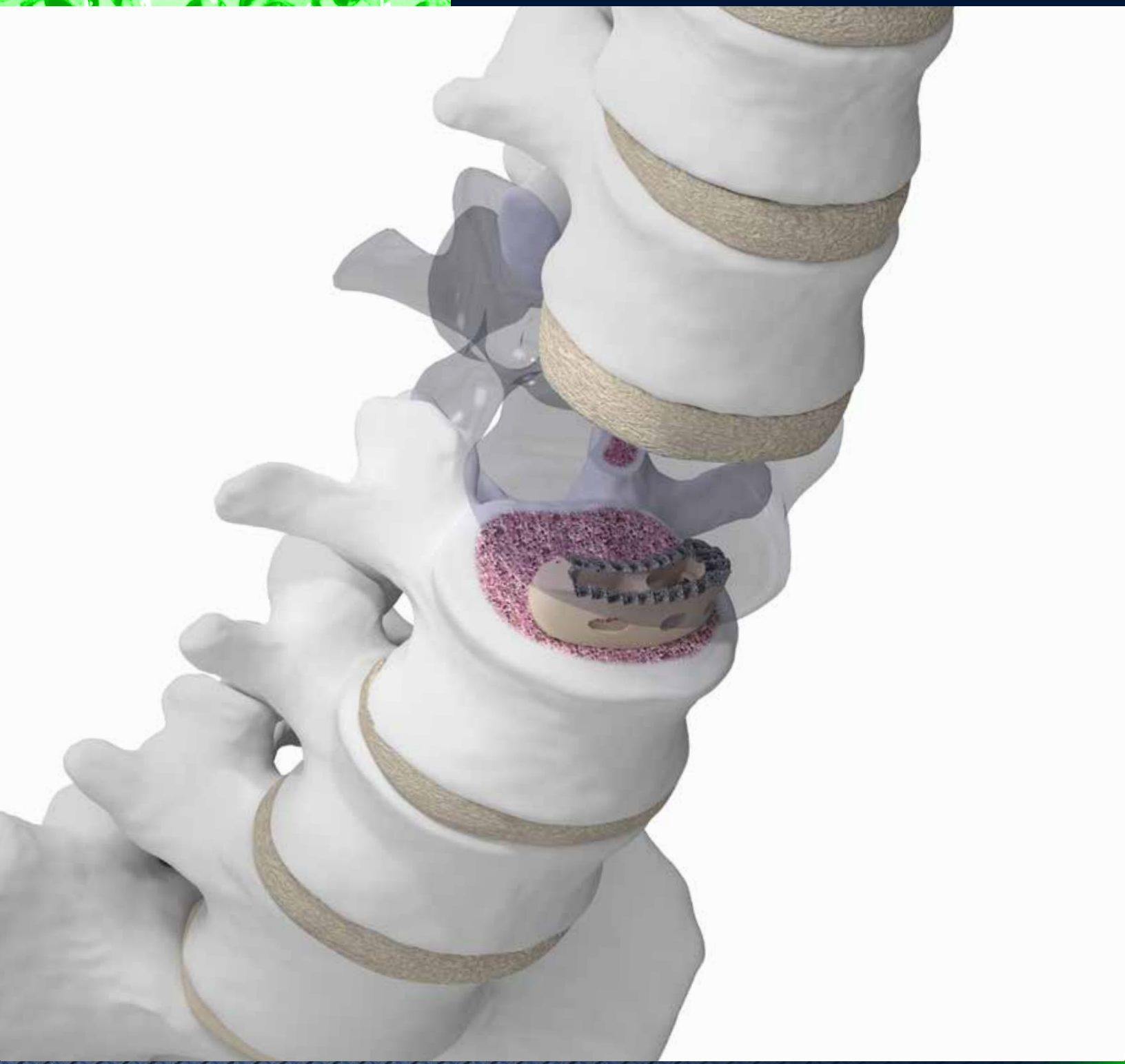
Battalion® PC

Universal Spacer System

POSTERIOR APPROACH | Surgical Technique Guide



PREFACE

Alphatec Spine is pleased to offer the Battalion® PC Universal Spacer System with curved implants and implant instrumentation. The Battalion PC system aims to provide surgeons with a range of implants and instrumentation necessary for achieving lumbar fusions. All implants are titanium-coated and are available in a wide variety of height and footprint options. The instrumentation offered in the PC Instrument Sets feature ergonomic, dual-patterned handles that allow for optimal comfort and tactile feel with both wet and dry gloves.

CONTENTS

A SYSTEM OVERVIEW

Features

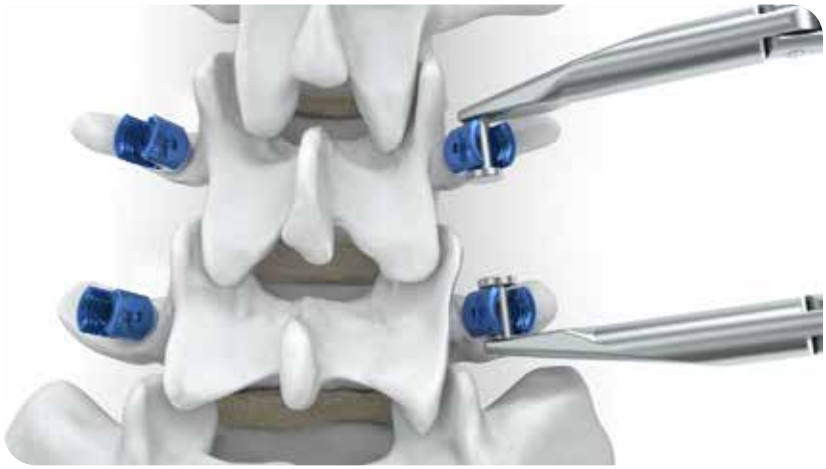
The Battalion Universal Spacer System was designed to optimize the art of spinal fusion procedures by providing surgeons the following:

- A comprehensive system offering a wide variety of implants and instruments
- Ergonomically designed instrumentation
  - Improved mechanical advantage with lighter-weight materials
  - Improved tactile feel and comfort
- Titanium-coated implants
- A wide variety of implant footprints and height options
  - Designed to match varying patient anatomy
  - Bullet nose for easy insertion
- Axial and Offset Inserters featuring a 180 degree locking mechanism
  - Creates smooth implant/inserter interface
  - Allows the surgeon to obtain controlled insertion and detachment of the implant
- Instruments featuring 30 mm of TiN coating
  - Keeps cutting surfaces sharp after multiple uses

1 PATIENT POSITIONING

- Place the patient in the prone position.

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.
- Per surgeon's preference, distraction can be done by the following:

Screw to Screw Distractor:

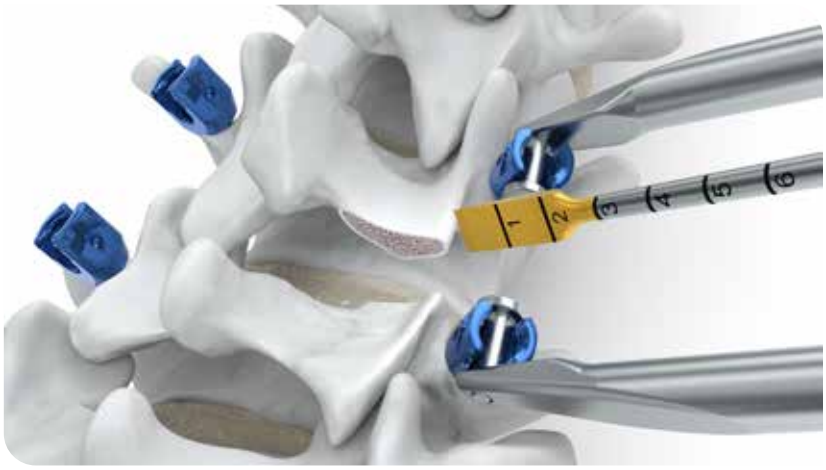
- Place Screw to Screw Distractor onto implanted pedicle screws. Insert provisionally tightened set screws for optimal distraction. Apply distraction on the pedicle screws using the Screw to Screw Distractor.

Lamina Spreader/Distractor:

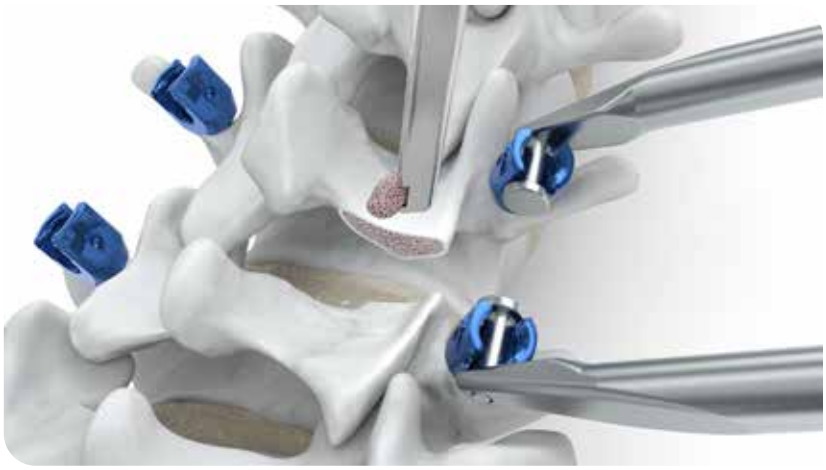
- Apply distraction on the base of the spinous processes using a Lamina Distractor before implantation of pedicle screws and rods.

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 point to the disc space. Care should be taken to prevent 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.

4 DISC SPACE PREPARATION

- Place a Nerve Root Retractor to protect the exiting nerves, and create an annulotomy with a scalpel.
- Enter and prepare the disc space using the surgeon's 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.

- 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.

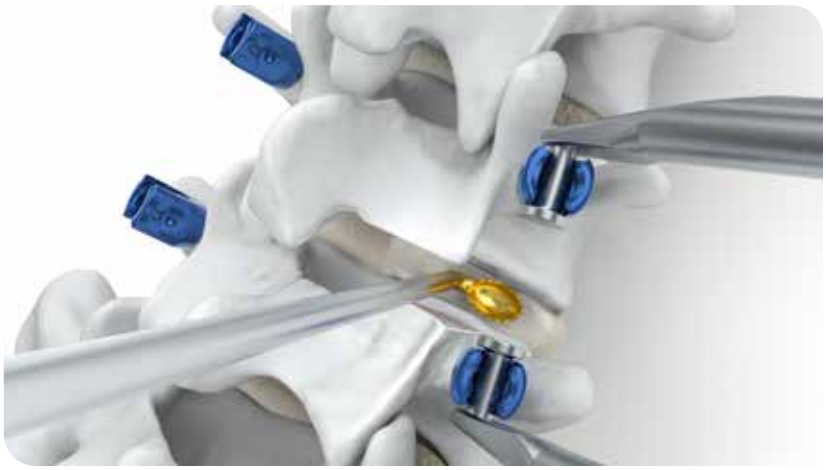
5 ROTATING DISTRACTION

- Use the Rotating Distractors to distract the disc space to the desired height.
  - Fenestrations within the Rotating Distractors are able to be seen 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) or the surgeon's preferred tools. The Battalion Disc Prep set contains Rasps (Straight and Curved Double-Sided), Serrated Curettes (Straight, Right and Left Angled, Push and Pull), and tear-drop-shaped Ringed Curettes (Straight and Angled). These instruments are available in the BATPINT set.



TIP: TiN coating (gold coating) is Measured from the tip 30 mm up the shaft of all Rasps and Curettes.

7 IMPLANT SIZING

- Insert selected implant Trial to confirm the correct height, footprint, and/or location within the disc space.
- AP and/or lateral fluoroscopy can be used to confirm position.
- The implant Trials are color-coded.
  - Orange 25 mm implant length
  - Yellow 30 mm implant length
  - Green 35 mm implant length

Posterior Curved Trial

TIP: If implant Trial becomes lodged in the disc space, connect Slap Hammer (Part #: 27241-01) to Trial handle or directly to the ¼" sq. to facilitate removal.

NOTE: Trials are sized 1:1 with the implants, which accounts for teeth height and the Ti coating of the implants.

8 IMPLANT SELECTION

- Select the appropriate sized Battalion PC 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.
- Use the truncated Bone Graft Funnel to deploy bone graft into the affected area sequentially in the anterior and contralateral portions of the disc space.
- The Bone Tamp is designed to protrude from the funnel to identify that all bone graft material has been extruded.

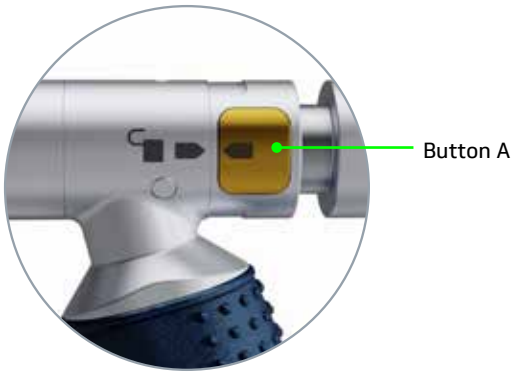
TIP: Apply saline solution to the footprint of the Packing Block to prevent graft material from sticking to the Packing Block.

10 IMPLANT INSERTION

NOTE: Square large button A: is only used to Lock and Unlock the implants from the Inserter.

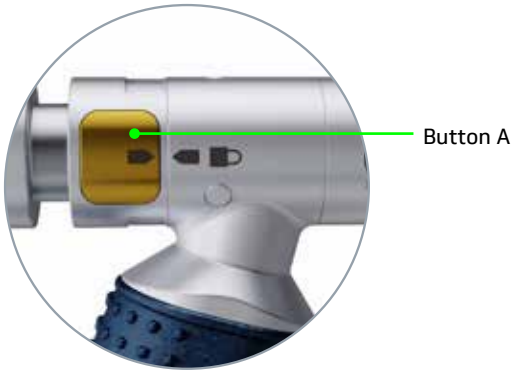
Attaching the implant to the Inserter:

- To engage and attach the implant to the Inserter, check that the 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, press the square large button “A” and rotate the handle 180° until the you hear & feel the “click” when the square large button “A” aligns with the “LOCKED” laser mark.



Disengaging the implant from the Inserter:

- To disengage the implant from the Inserter, simply press the square large button and rotate the handle 180° until the square large button “A” reaches the “Unlocked” laser mark and simply pull the Inserter away from the implant.

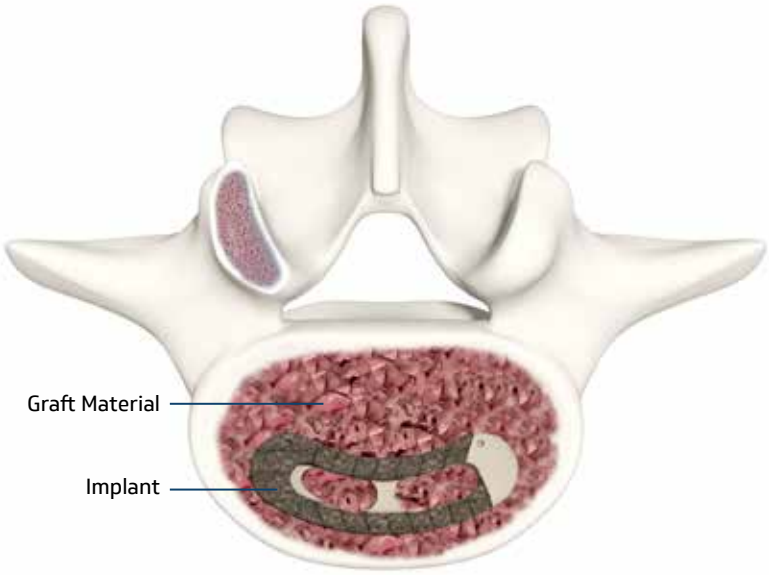


Cleaning:

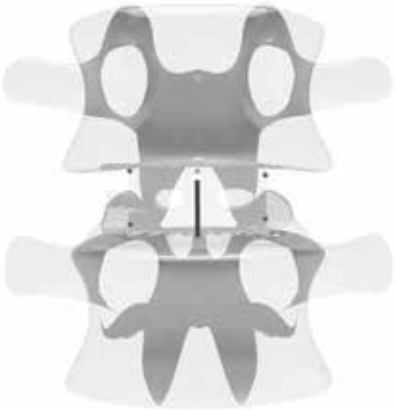
- To separate the outer sleeve from the main Inserter for cleaning, press the small round button “B” (Note: Laser marking around button that reads: “FOR CLEANING”). To reconnect, slide sleeve back onto the main Inserter to attach. No need to push the small round button to reattach.
- Round small button “B” is only used to detach the outer sleeve from the main Inserter for cleaning.

11 VERIFYING IMPLANT POSITION

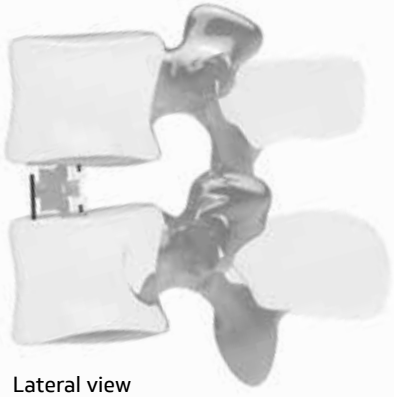
- Confirm implant position with AP and lateral fluoroscopy.
- The Straight or Curved Tamp or Straight or Curved Positioner can be used to manipulate the implant into final position.
- Pack additional bone grafting material posteriorly as needed.
- Remove the distraction device, and create lordosis by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



NOTE: Implant position and alignment can be confirmed by noting the radiographic markers (beads and wires) in AP and lateral fluoroscopic views. Ideal positions shown to the right.



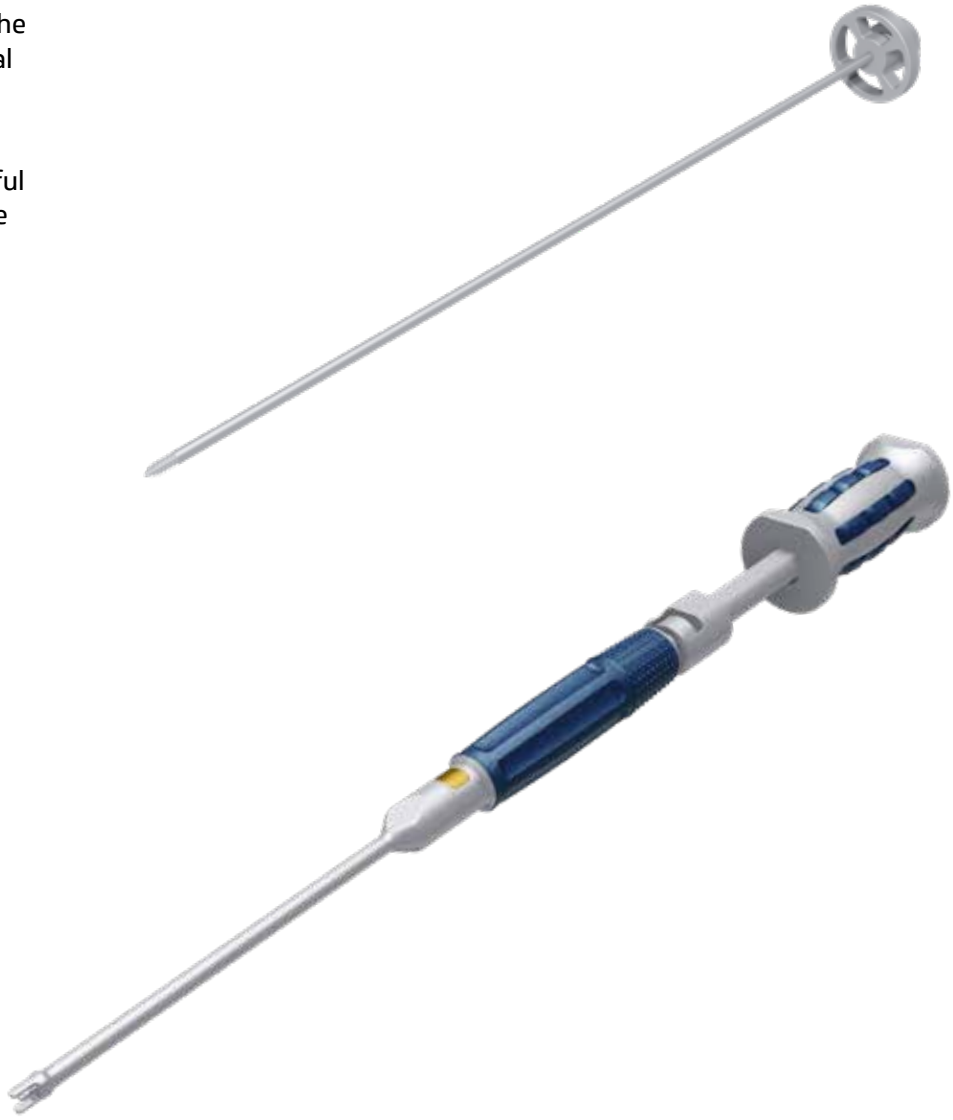
A/P view



Lateral view

12 REMOVING/RETRIEVING THE IMPLANT

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



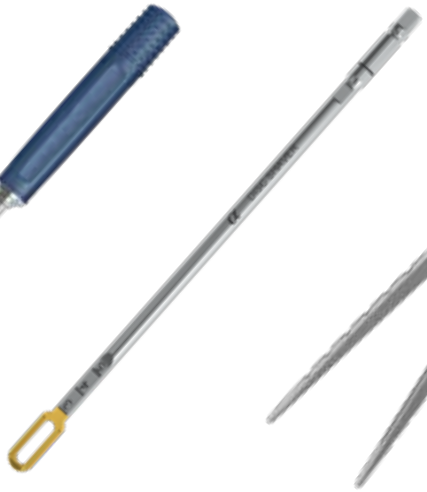
13 INSTRUMENTS

Slap Hammer
Part # 27241-01

Nerve Root Retractor
Part # 27232-27

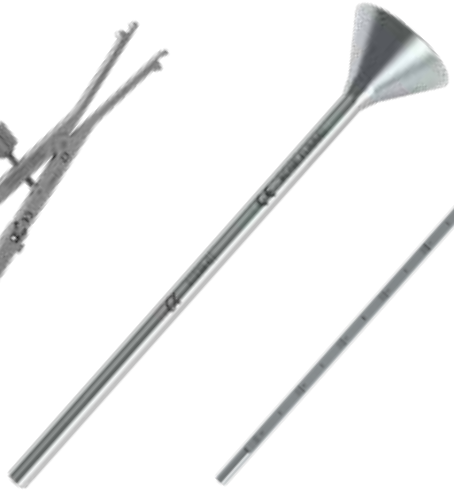
Nerve Root Retractor
Part # 27232-22

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

13 INSTRUMENTS

Screw To Screw Distractor
Part # 27240

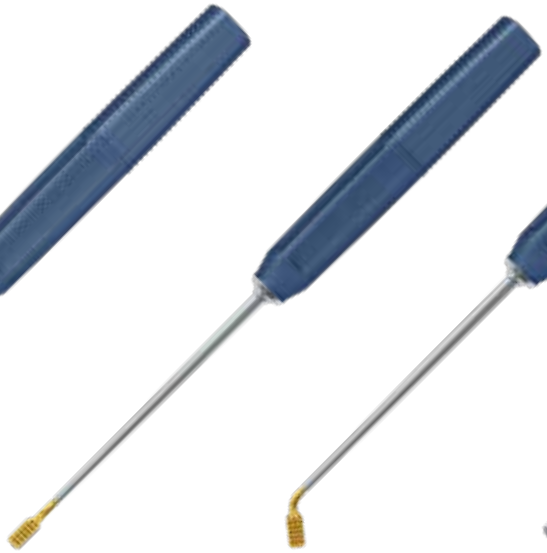
Silicone Handle, Large T,
¼" SQ., Impacting
Part # 86904-0210

Fenestrated Rotating
Distractor
Part # 27233-23-XX

Axial Handle
Part # 86003-0230

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

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

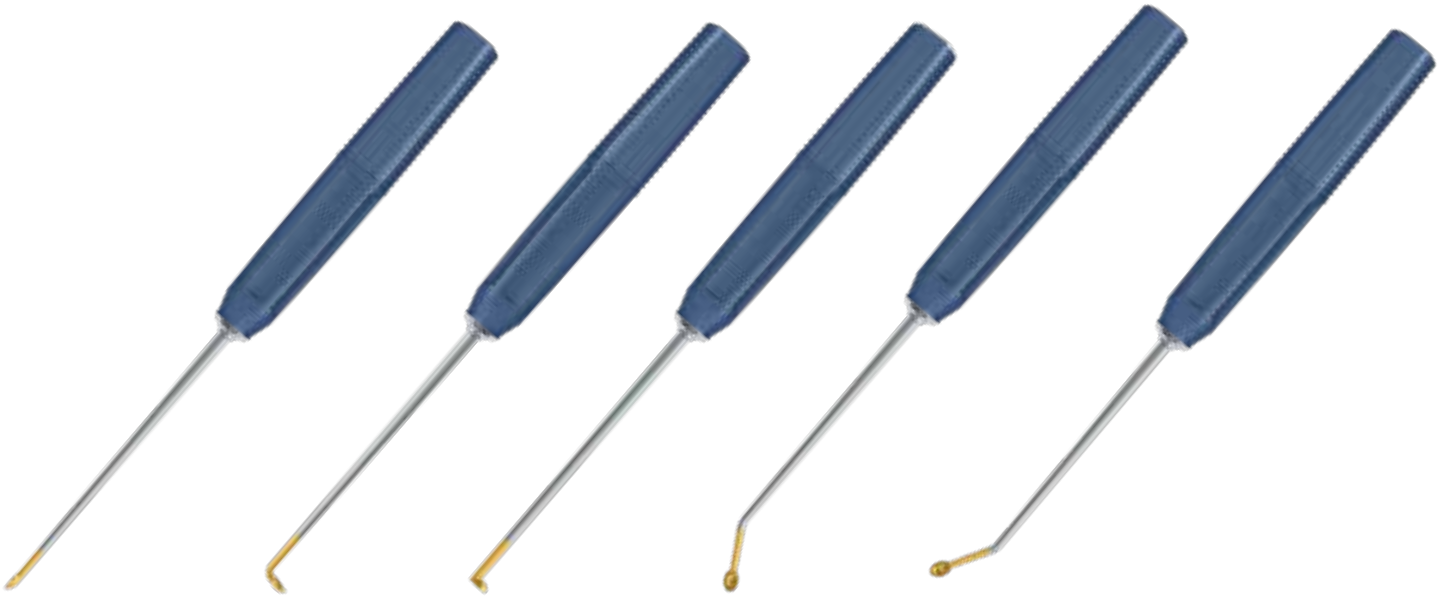


Straight Rasp
Part # 27221-02

Curved Rasp
Part # 27221-08

Bone Tamp
Part # 27809

13 INSTRUMENTS



Curettes
Part #
27223-XX-022-XX

Curettes
Part #
27223-XX-022-XX

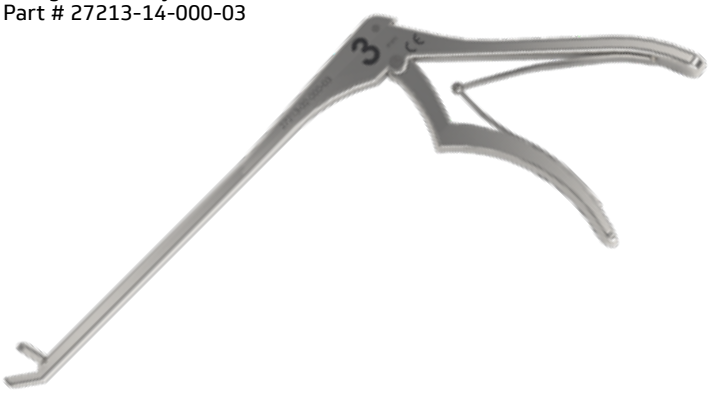
Curettes
Part #
27223-XX-022-XX

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

13 INSTRUMENTS

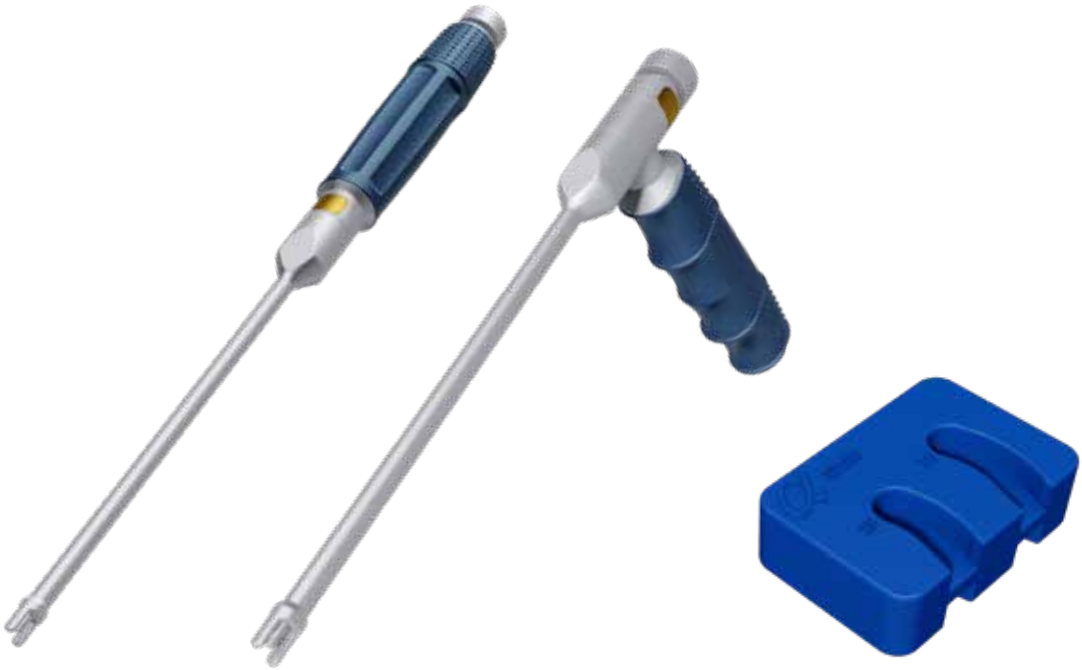
Straight Tamp
Part # 27805

Angled Tamp
Part # 27806

Implant Positioner
Straight
Part # 27810-01

Implant Positioner
Angled
Part # 27810-02

Curved Trials
Part # 27003-056-064 (small) and
Part # 27003-084-092 (large)



Curved Axial Inserter
Part # 27811

Curved Offset
Inserter
Part # 27812

Bone Graft Packing Block
Part # 27808

14 IMPLANTS

Battalion PC Implants
Part # 27013-XXX-S

Footprint (width & length) - All Implants are 5° lordotic

Height	10 mm x 25 mm	10 mm x 30 mm	10 mm x 35 mm
7 mm	27013-014-S	27013-056-S	27013-098-S
8 mm	27013-015-S	27013-057-S	27013-099-S
9 mm	27013-016-S	27013-058-S	27013-100-S
10 mm	27013-017-S	27013-059-S	27013-101-S
11 mm	27013-018-S	27013-060-S	27013-102-S
12 mm	27013-019-S	27013-061-S	27013-103-S
13 mm	27013-020-S	27013-062-S	27013-104-S
14 mm	27013-021-S	27013-063-S	27013-105-S
15 mm	27013-022-S	27013-064-S	27013-106-S

Battalion® Universal Spacer System

GENERAL INFORMATION:
The Battalion Universal Spacer System (Battalion System) is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. The implants are manufactured from PEEK Optima LT1 with/without titanium coated endplates and tantalum markers. All materials are surgical grade conforming to ASTM F2026 (PEEK), ASTM F1580 (titanium coating), and ASTM F560 (tantalum).
Use with supplemental fixation systems from Alphatec Spine such as: Zodiac® Polyaxial Spinal Fixation System, Arsenal® Spinal Fixation System, Illico® MIS Posterior Fixation System, Illico FS Facet Fixation System, BridgePoint® Spinous Process Fixation System, or InvictusTM Spinal Fixation System.

INDICATIONS FOR USE:
The Battalion 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). The lateral approach is limited to levels T5-6 to T11-T12.
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 Battalion 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 that are cleared by FDA for use in the thoracic and lumbar spine.
LIF Anti-Migration Plate (AMP) may be used with Battalion LLIF interbody spacers to provide integrated fixation.

CONTRAINDICATIONS:
The Battalion 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 PEEK, titanium, or tantalum.
4. Patients resistant to following post-operative 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. 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, pseudoarthrosis (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. AMP Anti-Migration Plate is not designed to be used with Battalion LLIF 14 mm wide cages.

PRECAUTIONS:
1. 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.
2. 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.
3. 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.
4. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
5. Resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the LLIF 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.

MRI SAFETY INFORMATION:
The Battalion 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 Battalion 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.

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 the 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.

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

Excerpt from INS-078

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

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