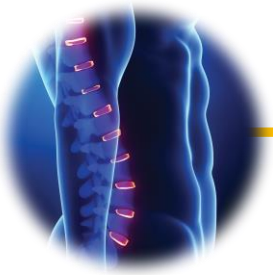


# SURGICAL TECHNIQUE

PRECISION SPINE

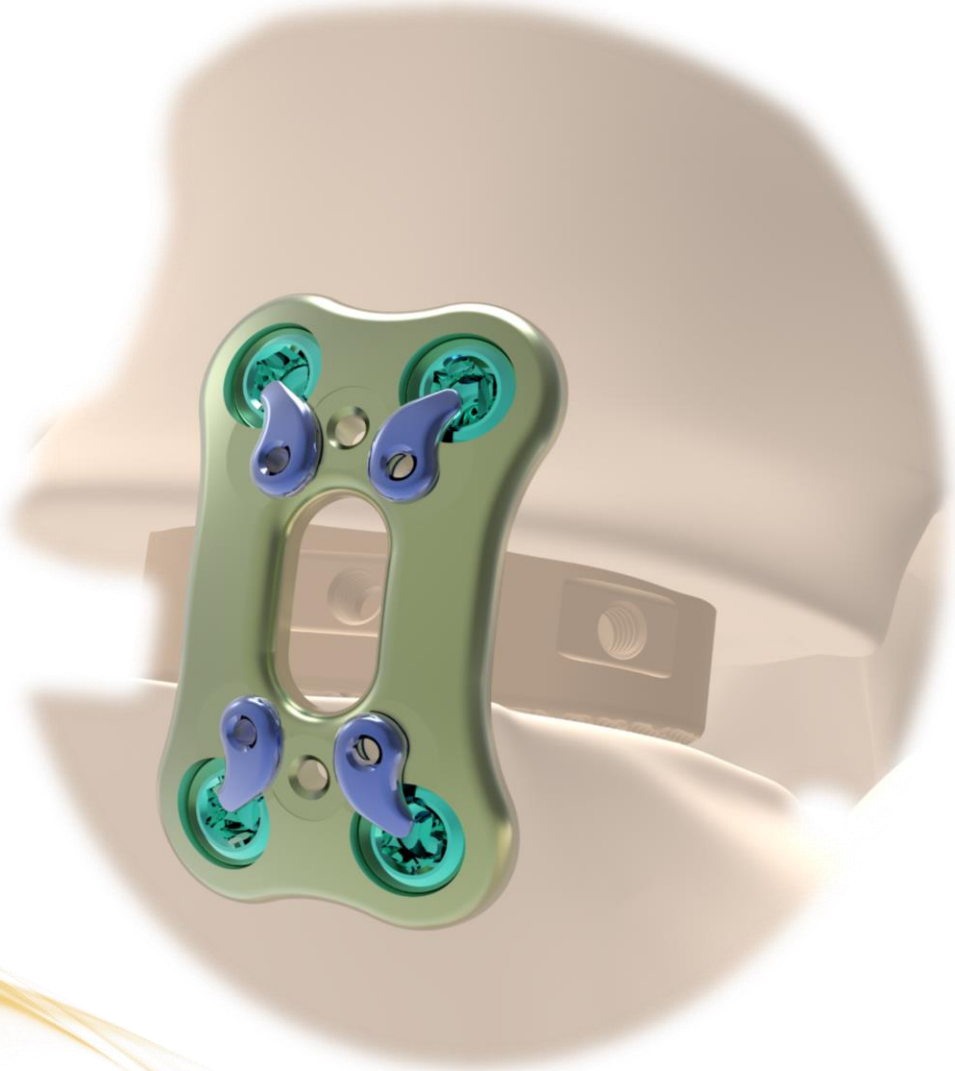
# AccuFit®

ALIF PLATE SYSTEM

PRECISION SPINE

# ShurFit®

ALIF INTERBODY CAGES



PRECISION SPINE®

*Discover the Difference*

Made in the USA

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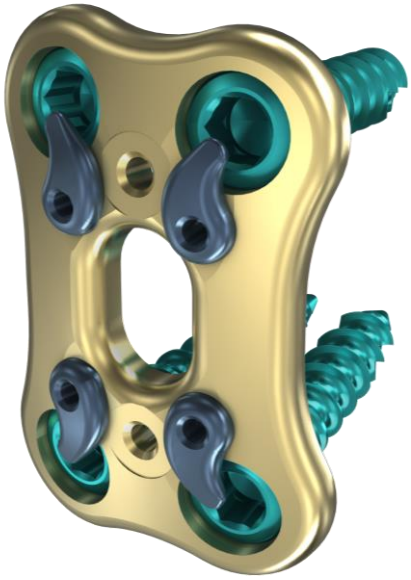
# OVERVIEW

## DESCRIPTION OF DEVICES

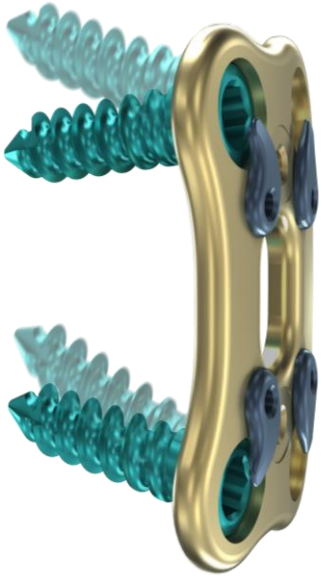
The ShurFit® ALIF Interbody Cage design offers a large contact area, optimizing vertebral body support while minimizing risk of subsidence. The large graft window allows for maximum biological coverage area, enhancing the opportunity for successful fusion. Simple instrumentation offers ease of implantation for surgeons, while the unique tooth pattern geometry minimizes the potential for expulsion. The polyetheretherketone (PEEK, per ASTM F2026) ShurFit Interbody cage is available in multiple sizes to accommodate varying anatomies and permit optimal patient matching.

The AccuFit® ALIF Plate System is a lumbosacral fixation system offering two low profile plate designs to facilitate anatomical fit and protect surrounding vascular structures. The AccuFit Plate features an intuitive one step locking system that provides visual locking confirmation and a large graft window for extensive visibility to the endplates, as well as the interbody spacer. Fixed and variable screws in 5.0 and 5.5mm sizes and 25, 30 and 35mm lengths are offered to accommodate patient anatomies.



## INDICATIONS

The ShurFit ALIF Anterior Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the system. It is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with supplemental fixation and autogenous autograft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.



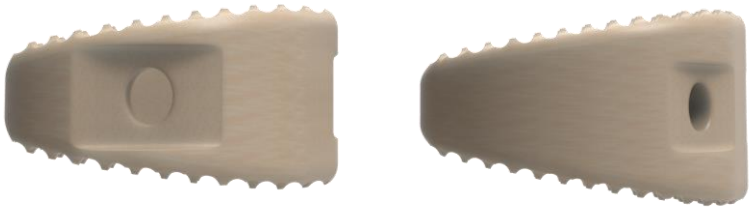
The AccuFit Anterior Lumbar Interbody Fusion Plate System is indicated for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved. The AccuFit Anterior Lumbar Interbody Fusion Plate System is intended for anterior lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD), defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion

# DESIGN FEATURES

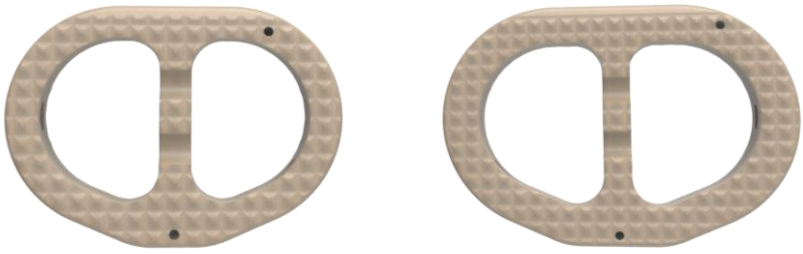
## SHURFIT® ALIF SYSTEM

**3 Points of Insertion**
facilitate anterior, anterolateral and direct lateral insertion


**Anatomical Shape & Central Strut**
provide a large surface area for anterior column support



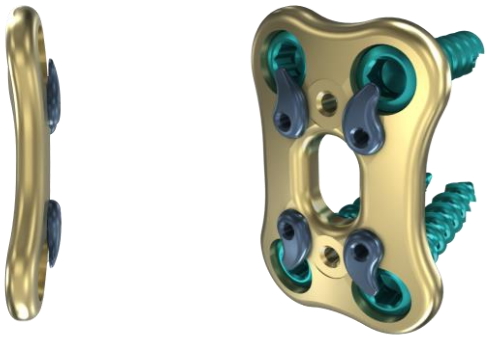
**Large Graft Windows**
allow for a large volume of biological ingrowth



# DESIGN FEATURES

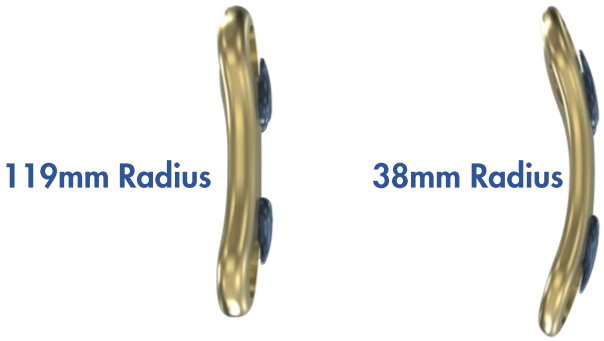
## ACCUFIT® ALIF PLATE

**Low Profile Design**
- (3.8mm) minimizes tissue disruption

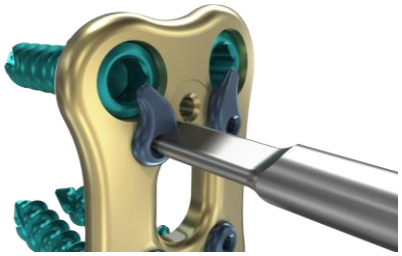


**Large Graft Window**
- Allows for optimal visualization of interbody

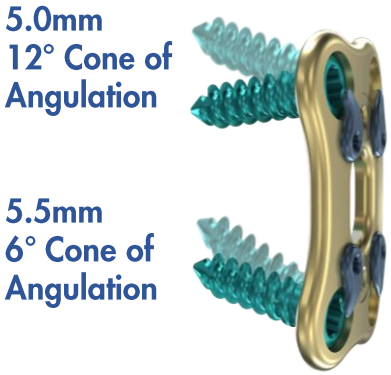
**Pre-Lordosed L5-S1 Plate**
- Contours to Sacral Anatomy




**Intuitive Single Step Locking Mechanism**
- Facilitates secure placement

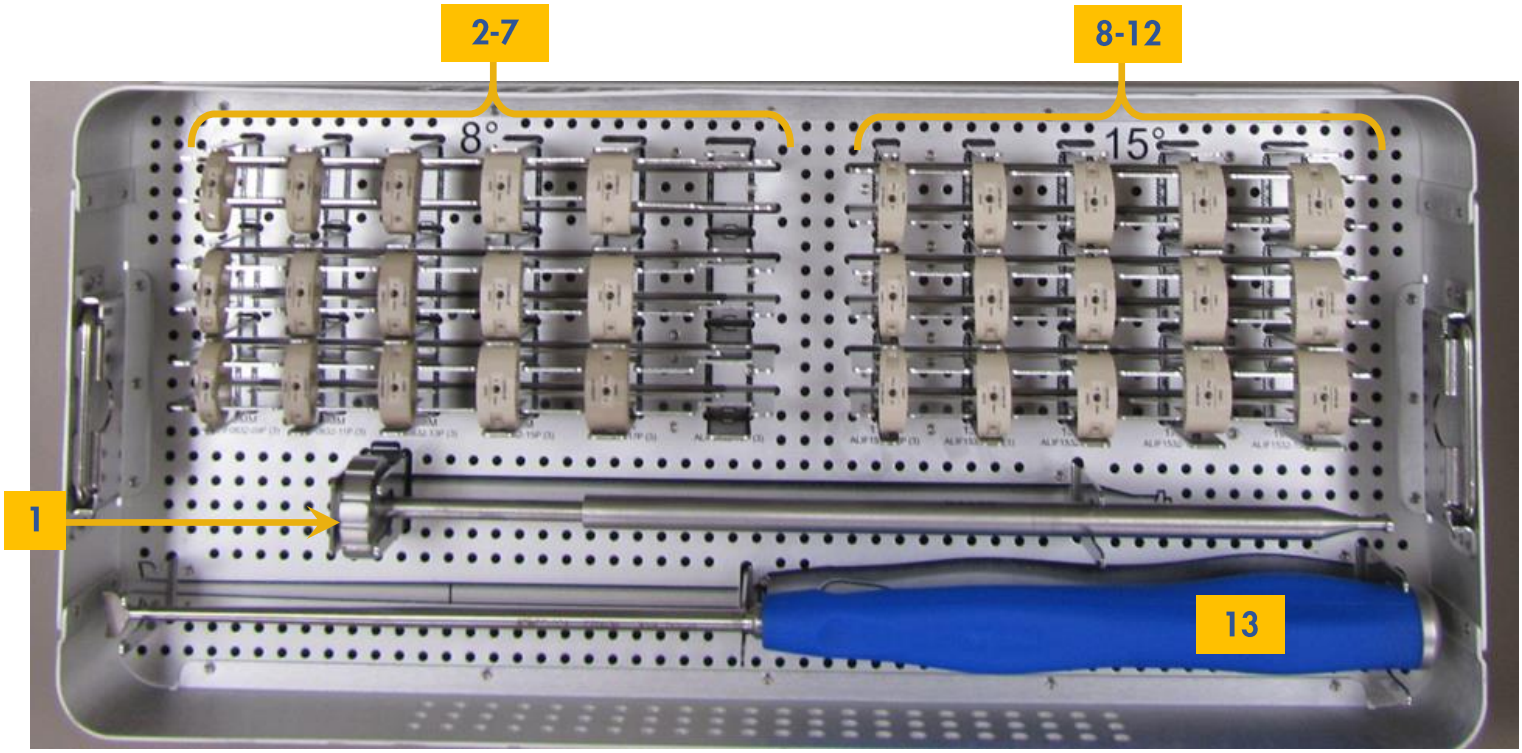


**ALIF Self-Drilling Bone Screws**
- 5.0 & 5.5mm screw diameters
- Variable & Fixed, 25, 30 & 35mm



# SHURFIT® ALIF – 26mm CAGES – TOP TRAY

## TRAY NUMBER 21-1026-CAT

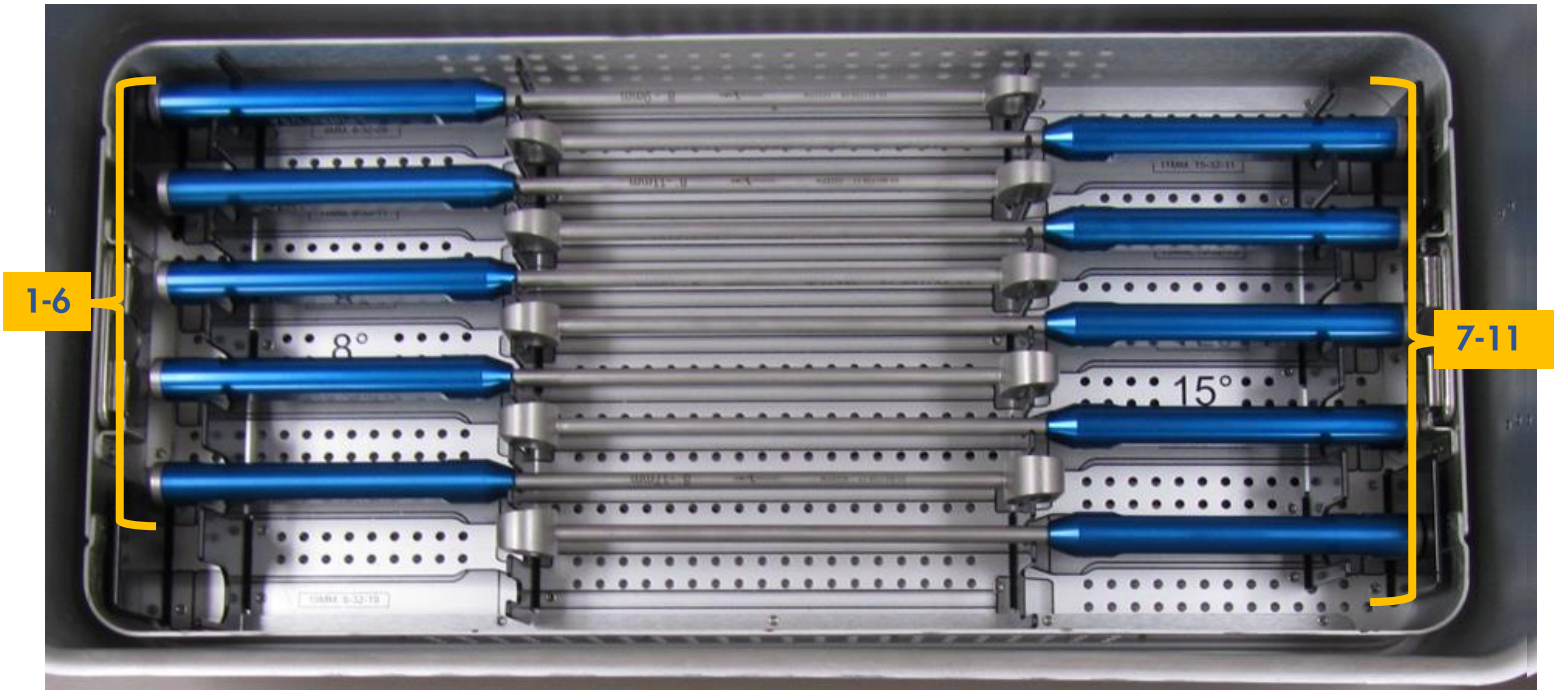



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALIFINS | ALIF Inserter, Small | 1 |
| 2. | ALIF0826-09P | ALIF Cage Peek 8 degree, 26mm x 9mm | 3 |
| 3. | ALIF0826-11P | ALIF Cage Peek 8 degree, 26mm x 11mm | 3 |
| 4. | ALIF0826-13P | ALIF Cage Peek 8 degree, 26mm x 13mm | 3 |
| 5. | ALIF0826-15P | ALIF Cage Peek 8 degree, 26mm x 15mm | 3 |
| 6. | ALIF0826-17P | ALIF Cage Peek 8 degree, 26mm x 17mm | 3 |
| 7. | ALIF0826-19P | ALIF Cage Peek 8 degree, 26mm x 19mm | 1 |
| 8. | ALIF1526-11P | ALIF Cage Peek 15 degree, 26mm x 11mm | 3 |
| 9. | ALIF1526-13P | ALIF Cage Peek 15 degree, 26mm x 13mm | 3 |
| 10. | ALIF1526-15P | ALIF Cage Peek 15 degree, 26mm x 15mm | 3 |
| 11. | ALIF1526-17P | ALIF Cage Peek 15 degree, 26mm x 17mm | 3 |
| 12. | ALIF1526-19P | ALIF Cage Peek 15 degree, 26mm x 19mm | 1 |
| 13. | ALN022 | Tamp | 1* |

* Special Order

# SHURFIT® ALIF – 26mm SIZERS – BOTTOM TRAY

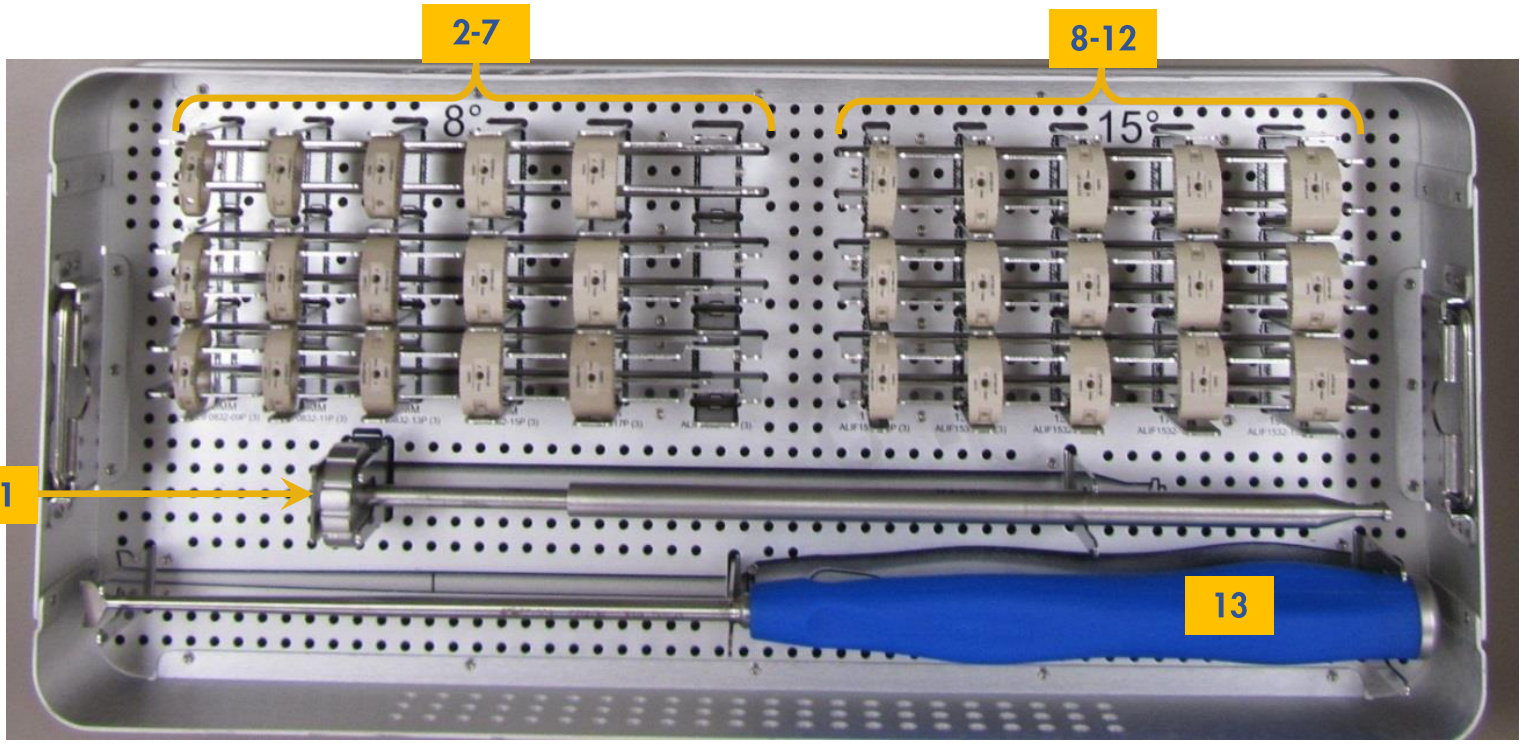
## TRAY NUMBER 21-1026-CAT




| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | 00-901608-09 | ALIF Sizer 8 degree, 26mm x 9mm | 1 |
| 2. | 00-901608-11 | ALIF Sizer 8 degree, 26mm x 11mm | 1 |
| 3. | 00-901608-13 | ALIF Sizer 8 degree, 26mm x 13mm | 1 |
| 4. | 00-901608-15 | ALIF Sizer 8 degree, 26mm x 15mm | 1 |
| 5. | 00-901608-17 | ALIF Sizer 8 degree, 26mm x 17mm | 1 |
| 6. | 00-901608-19 | ALIF Sizer 8 degree, 26mm x 19mm (Not shown) | 1 |
| 7. | 00-901615-11 | ALIF Sizer 15 degree, 26mm x 11mm | 1 |
| 8. | 00-901615-13 | ALIF Sizer 15 degree, 26mm x 13mm | 1 |
| 9. | 00-901615-15 | ALIF Sizer 15 degree, 26mm x 15mm | 1 |
| 10. | 00-901615-17 | ALIF Sizer 15 degree, 26mm x 17mm | 1 |
| 11. | 00-901615-19 | ALIF Sizer 15 degree, 26mm x 19mm | 1 |

# SHURFIT® ALIF – 32mm CAGES – TOP TRAY

## TRAY NUMBER 21-1032-CAT

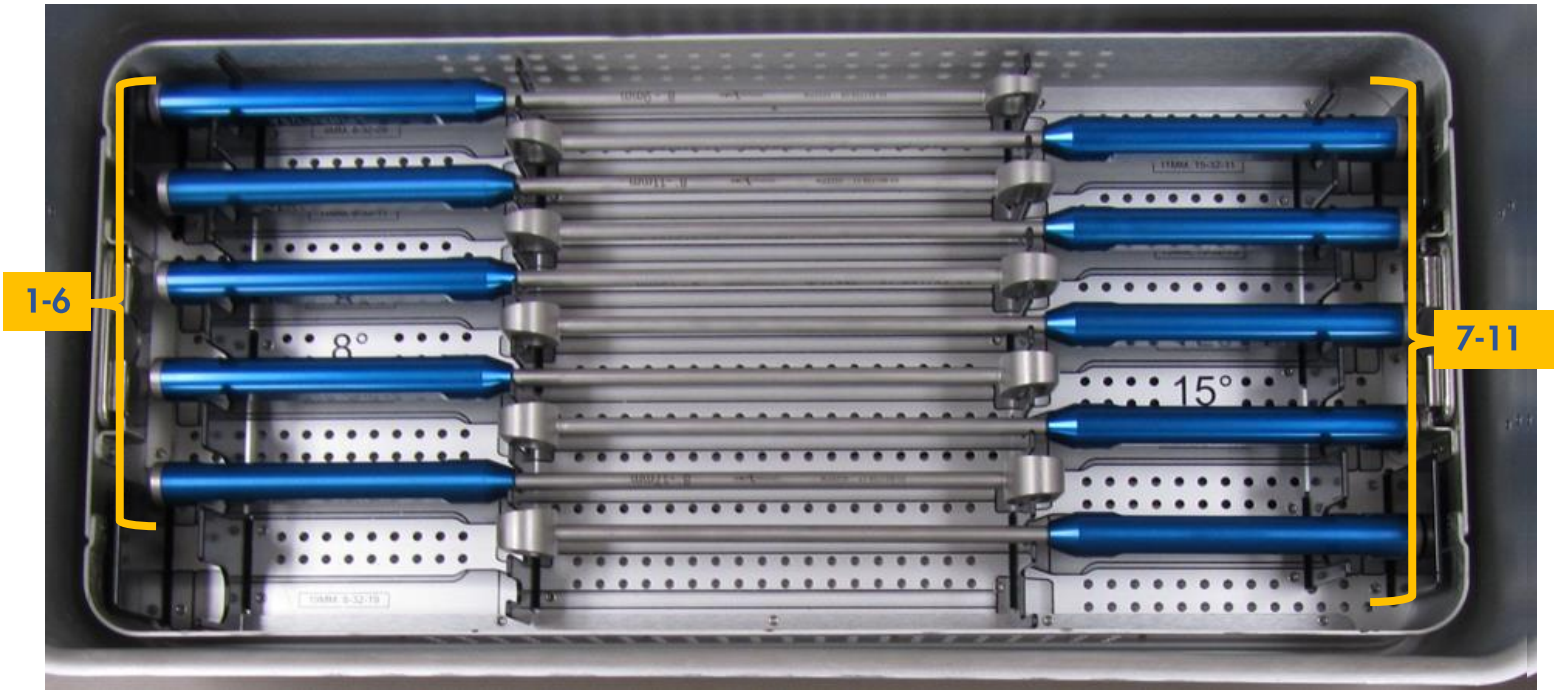



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALIFINS | ALIF Inserter, Small | 1 |
| 2. | ALIF0832-09P | ALIF Cage Peek 8 degree, 32mm x 9mm | 3 |
| 3. | ALIF0832-11P | ALIF Cage Peek 8 degree, 32mm x 11mm | 3 |
| 4. | ALIF0832-13P | ALIF Cage Peek 8 degree, 32mm x 13mm | 3 |
| 5. | ALIF0832-15P | ALIF Cage Peek 8 degree, 32mm x 15mm | 3 |
| 6. | ALIF0832-17P | ALIF Cage Peek 8 degree, 32mm x 17mm | 3 |
| 7. | ALIF0832-19P | ALIF Cage Peek 8 degree, 32mm x 19mm | 1 |
| 8. | ALIF1532-11P | ALIF Cage Peek 15 degree, 32mm x 11mm | 3 |
| 9. | ALIF1532-13P | ALIF Cage Peek 15 degree, 32mm x 13mm | 3 |
| 10. | ALIF1532-15P | ALIF Cage Peek 15 degree, 32mm x 15mm | 3 |
| 11. | ALIF1532-17P | ALIF Cage Peek 15 degree, 32mm x 17mm | 3 |
| 12. | ALIF1532-19P | ALIF Cage Peek 15 degree, 32mm x 19mm | 1 |
| 13. | ALN022 | Tamp | 1* |

* Special Order

# SHURFIT® ALIF – 32mm SIZERS – BOTTOM TRAY

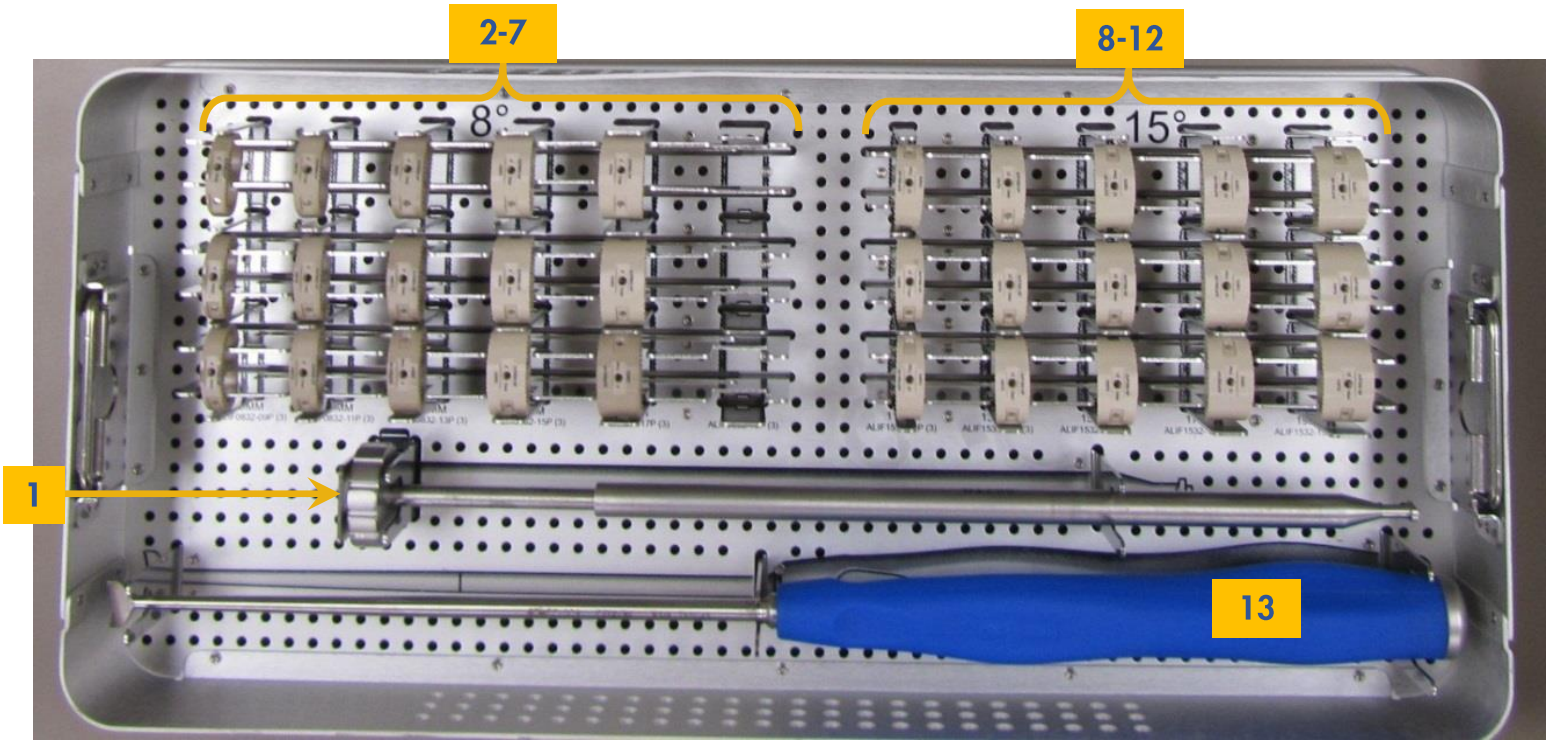
## TRAY NUMBER 21-1032-CAT




| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | 00-901708-09 | ALIF Sizer 8 degree, 32mm x 9mm | 1 |
| 2. | 00-901708-11 | ALIF Sizer 8 degree, 32mm x 11mm | 1 |
| 3. | 00-901708-13 | ALIF Sizer 8 degree, 32mm x 13mm | 1 |
| 4. | 00-901708-15 | ALIF Sizer 8 degree, 32mm x 15mm | 1 |
| 5. | 00-901708-17 | ALIF Sizer 8 degree, 32mm x 17mm | 1 |
| 6. | 00-901708-19 | ALIF Sizer 8 degree, 32mm x 19mm (Not shown) | 1 |
| 7. | 00-901715-11 | ALIF Sizer 15 degree, 32mm x 11mm | 1 |
| 8. | 00-901715-13 | ALIF Sizer 15 degree, 32mm x 13mm | 1 |
| 9. | 00-901715-15 | ALIF Sizer 15 degree, 32mm x 15mm | 1 |
| 10. | 00-901715-17 | ALIF Sizer 15 degree, 32mm x 17mm | 1 |
| 11. | 00-901715-19 | ALIF Sizer 15 degree, 32mm x 19mm | 1 |

# SHURFIT® ALIF – 39mm CAGES – TOP TRAY

## TRAY NUMBER 21-1039-CAT

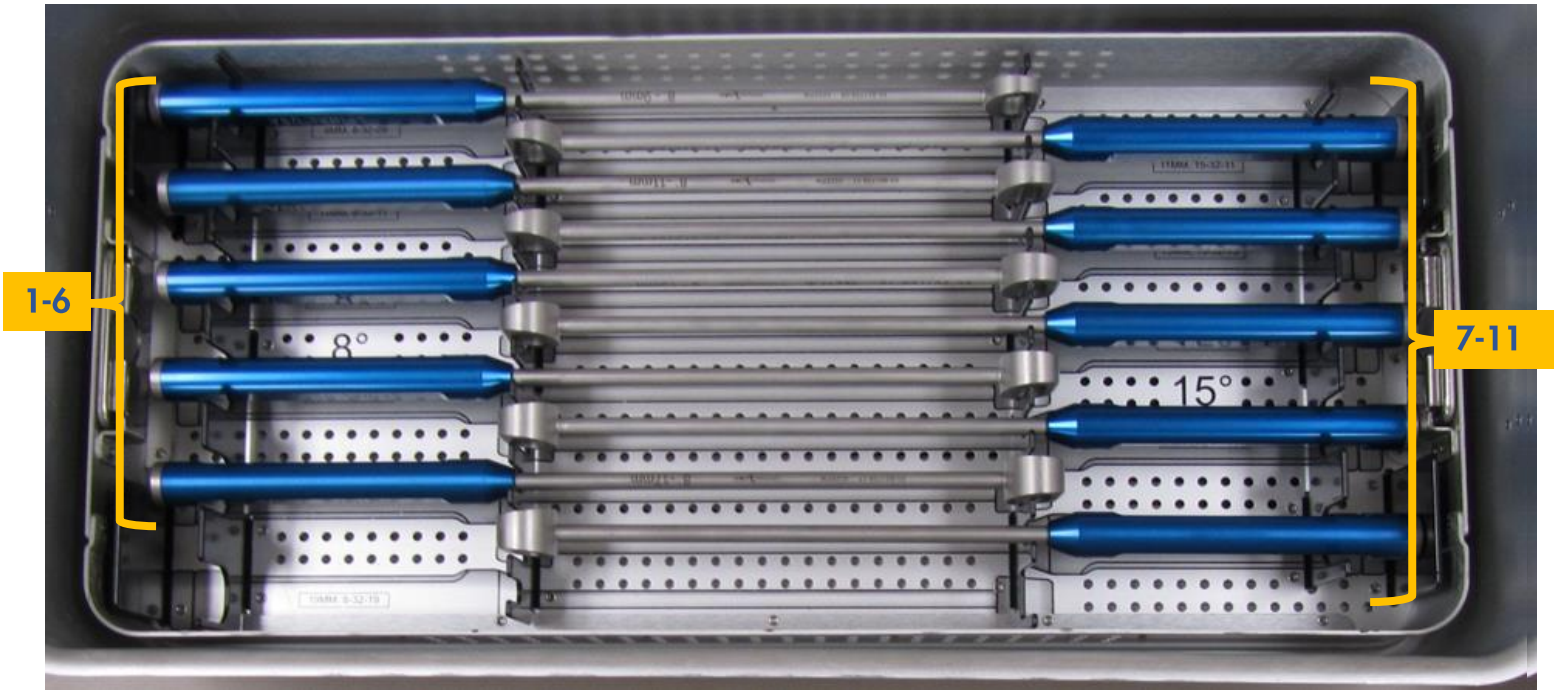



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALIFINS | ALIF Inserter, Small | 1 |
| 2. | ALIF0839-09P | ALIF Cage Peek 8 degree, 39mm x 9mm | 3 |
| 3. | ALIF0839-11P | ALIF Cage Peek 8 degree, 39mm x 11mm | 3 |
| 4. | ALIF0839-13P | ALIF Cage Peek 8 degree, 39mm x 13mm | 3 |
| 5. | ALIF0839-15P | ALIF Cage Peek 8 degree, 39mm x 15mm | 3 |
| 6. | ALIF0839-17P | ALIF Cage Peek 8 degree, 39mm x 17mm | 3 |
| 7. | ALIF0839-19P | ALIF Cage Peek 8 degree, 39mm x 19mm | 1 |
| 8. | ALIF1539-11P | ALIF Cage Peek 15 degree, 39mm x 11mm | 3 |
| 9. | ALIF1539-13P | ALIF Cage Peek 15 degree, 39mm x 13mm | 3 |
| 10. | ALIF1539-15P | ALIF Cage Peek 15 degree, 39mm x 15mm | 3 |
| 11. | ALIF1539-17P | ALIF Cage Peek 15 degree, 39mm x 17mm | 3 |
| 12. | ALIF1539-19P | ALIF Cage Peek 15 degree, 39mm x 19mm | 1 |
| 13. | ALN022 | Tamp | 1* |

* Special Order

# SHURFIT® ALIF – 39mm SIZERS – BOTTOM TRAY

## TRAY NUMBER 21-1039-CAT

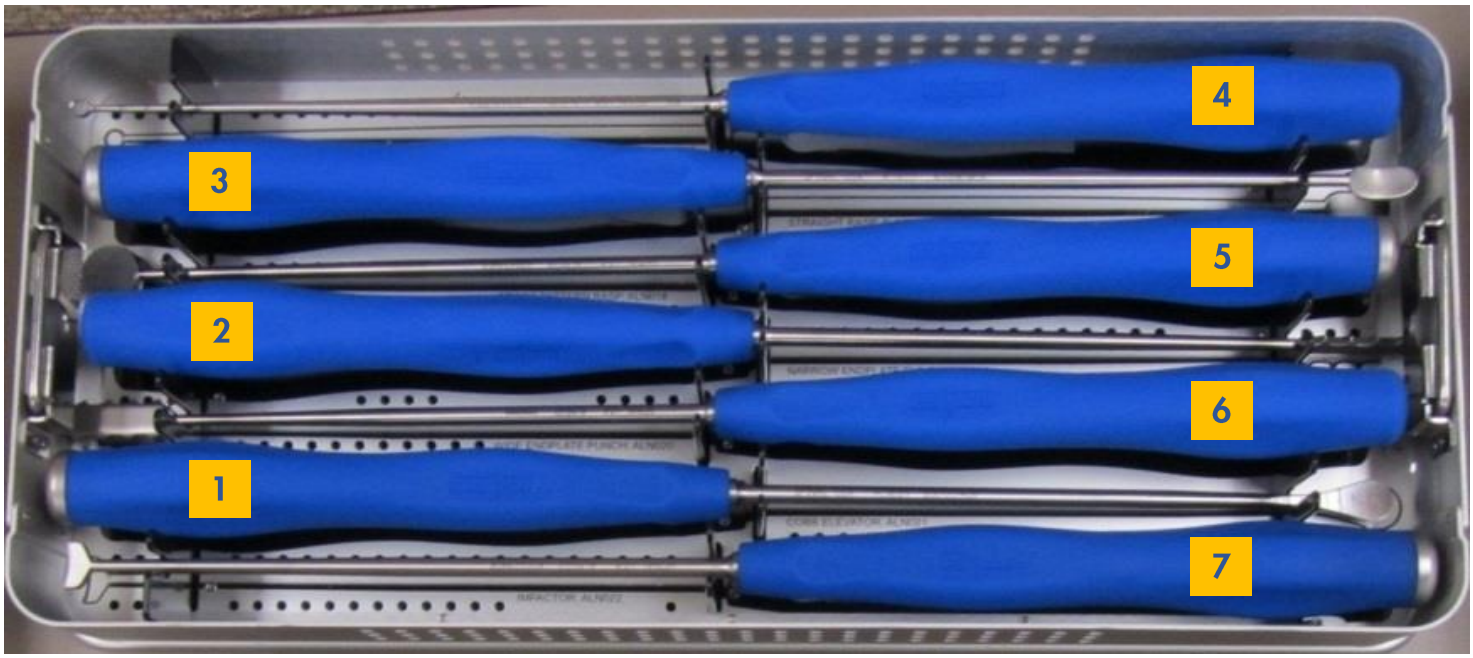



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | 00-901808-09 | ALIF Sizer 8 degree, 39mm x 9mm | 1 |
| 2. | 00-901808-11 | ALIF Sizer 8 degree, 39mm x 11mm | 1 |
| 3. | 00-901808-13 | ALIF Sizer 8 degree, 39mm x 13mm | 1 |
| 4. | 00-901808-15 | ALIF Sizer 8 degree, 39mm x 15mm | 1 |
| 5. | 00-901808-17 | ALIF Sizer 8 degree, 39mm x 17mm | 1 |
| 6. | 00-901808-19 | ALIF Sizer 8 degree, 39mm x 19mm (Not shown) | 1 |
| 7. | 00-901815-11 | ALIF Sizer 15 degree, 39mm x 11mm | 1 |
| 8. | 00-901815-13 | ALIF Sizer 15 degree, 39mm x 13mm | 1 |
| 9. | 00-901815-15 | ALIF Sizer 15 degree, 39mm x 15mm | 1 |
| 10. | 00-901815-17 | ALIF Sizer 15 degree, 39mm x 17mm | 1 |
| 11. | 00-901815-19 | ALIF Sizer 15 degree, 39mm x 19mm | 1 |

# SHURFIT® ALIF – INSTRUMENT SET 1 of 3 – TOP TRAY

## TRAY NUMBER 21-1004-CAT

**BY REQUEST ONLY**

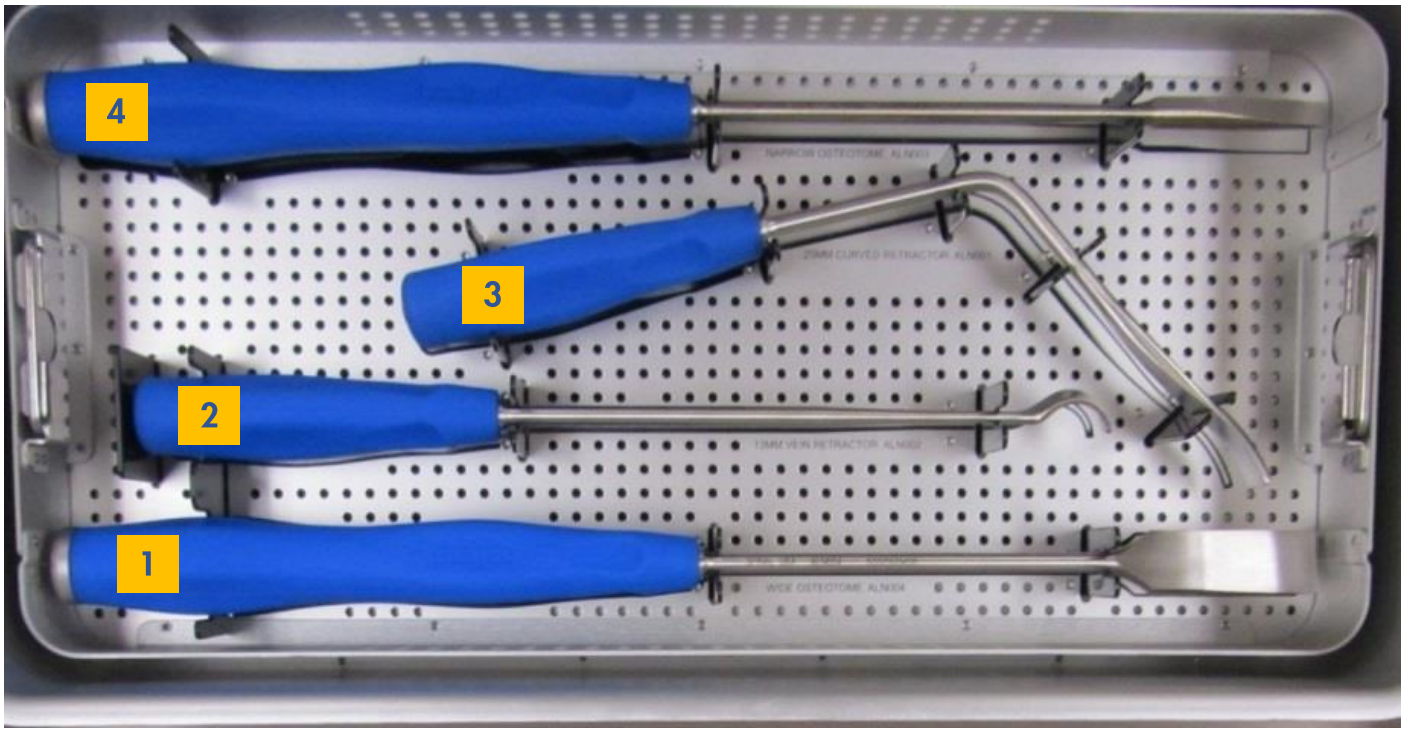



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALN021 | Cobb Elevator 18.5mm | 1 |
| 2. | ALN019 | Narrow Endplate Punch – 12 x 5mm | 1 |
| 3. | ALN017 | Rasp Curved Serrated | 1 |
| 4. | ALN015 | Curette Ring, Straight 8mm | 1 |
| 5. | ALN018 | Cross-Pattern Serrated Rasp | 1 |
| 6. | ALN020 | Wide Endplate Punch – 20 x 7mm | 1 |
| 7. | ALN022 | Impactor Curved Serrated 20mm | 1 |

# SHURFIT® ALIF – INSTRUMENT SET 1 of 3 – BOTTOM TRAY

## TRAY NUMBER 21-1004-CAT

**BY REQUEST ONLY**




| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALN004 | Osteotome Wide, 1″ | 1 |
| 2. | ALN002 | Vein Retractor 13mm | 1 |
| 3. | ALN001 | Curved Retractor, 25mm 1″ | 1 |
| 4. | ALN003 | Osteotome Narrow ½″ | 1 |

# SHURFIT® ALIF – INSTRUMENT SET 2 of 3 – TOP TRAY

## TRAY NUMBER 21-1005-CAT

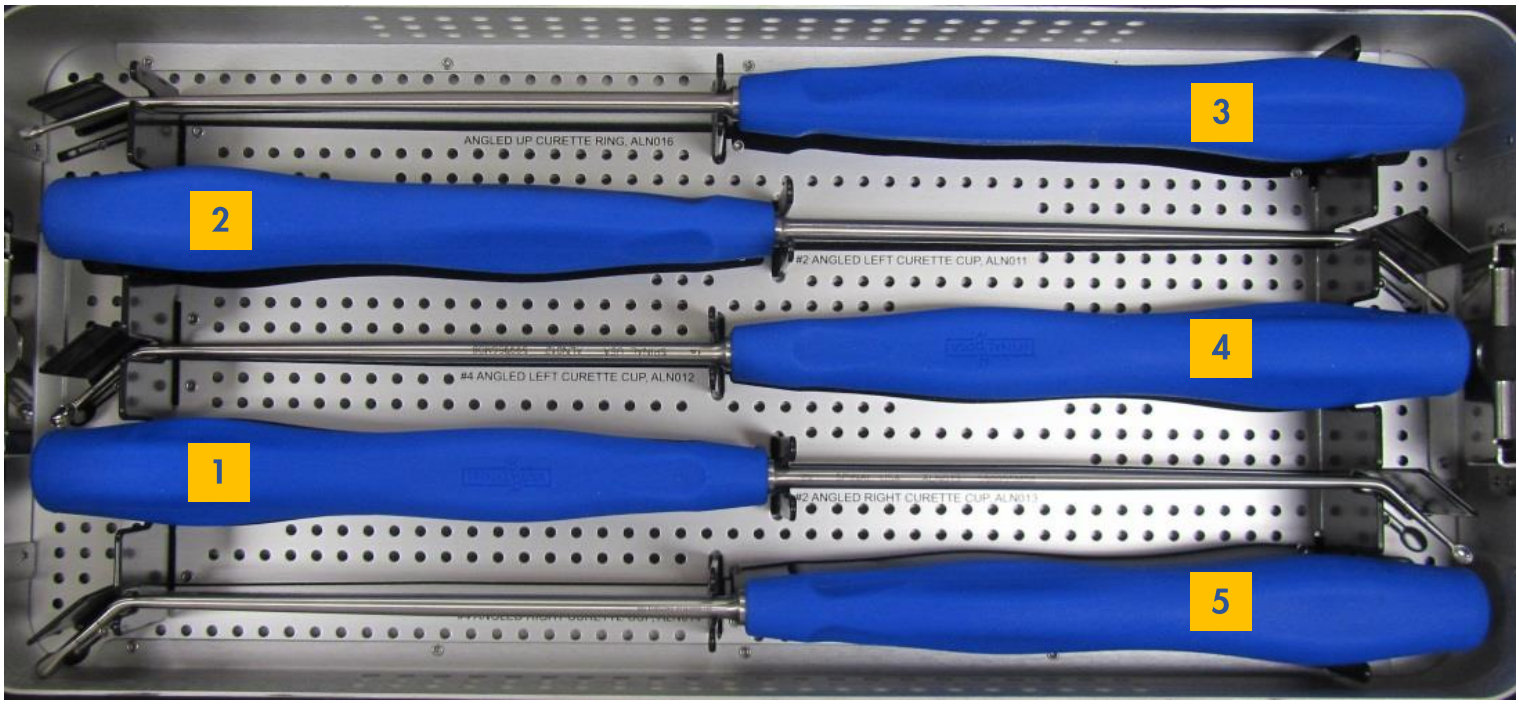
**BY REQUEST ONLY**


| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALN009 | Curette Cup Angle Up #2 | 1 |
| 2. | ALN008 | Curette Cup Angle Down #4 | 1 |
| 3. | ALN006 | Curette Cup Angle Straight #4 | 1 |
| 4. | ALN005 | Curette Cup Angle Straight #2 | 1 |
| 5. | ALN007 | Curette Cup Angle Down #2 | 1 |
| 6. | ALN010 | Curette Cup Angle Up #4 | 1 |

# SHURFIT® ALIF – INSTRUMENT SET 2 of 3 – BOTTOM TRAY

## TRAY NUMBER 21-1005-CAT

**BY REQUEST ONLY**

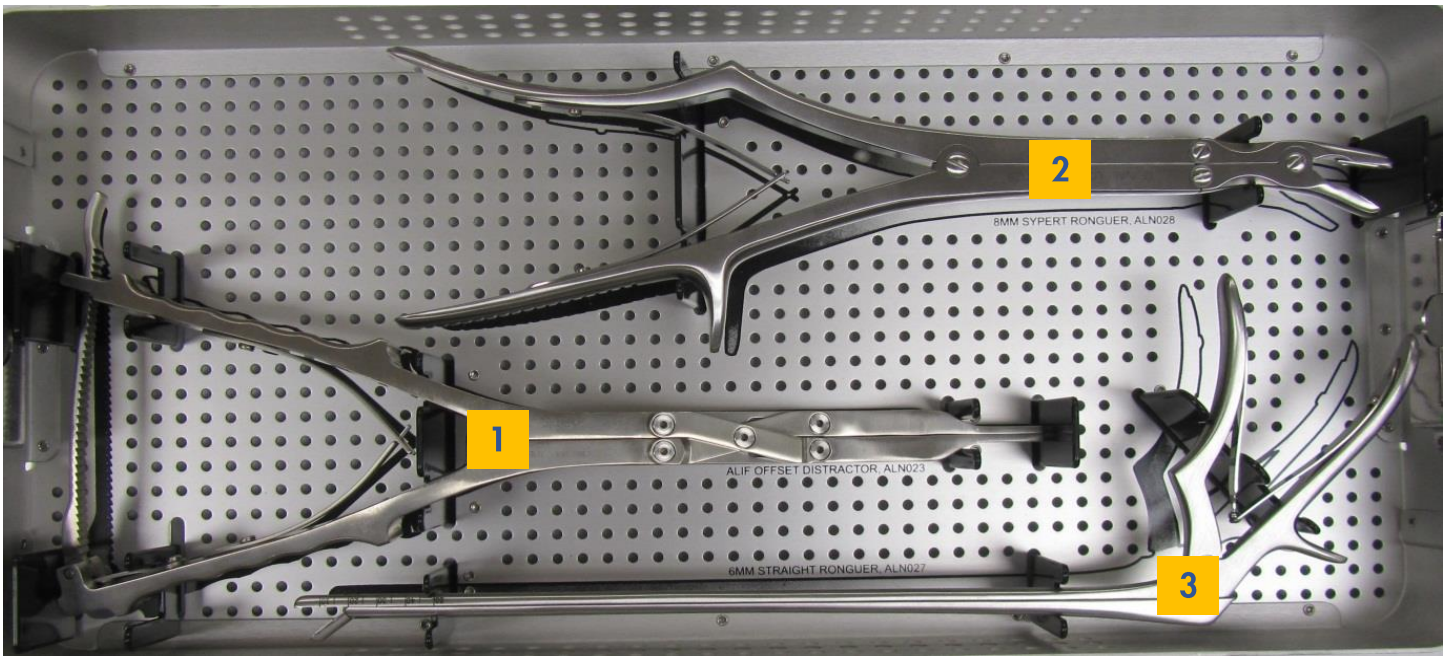



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALN013 | Curette Cup Angle Right #2 | 1 |
| 2. | ALN011 | Curette Cup Angle Left #2 | 1 |
| 3. | ALN016 | Curette Ring Angle Up 8mm | 1 |
| 4. | ALN012 | Curette Cup Angle Left #4 | 1 |
| 5. | ALN014 | Curette Cup Angle Right #4 | 1 |

# SHURFIT® ALIF – INSTRUMENT SET 3 of 3 – TOP TRAY

## TRAY NUMBER 21-1006-CAT

**BY REQUEST ONLY**

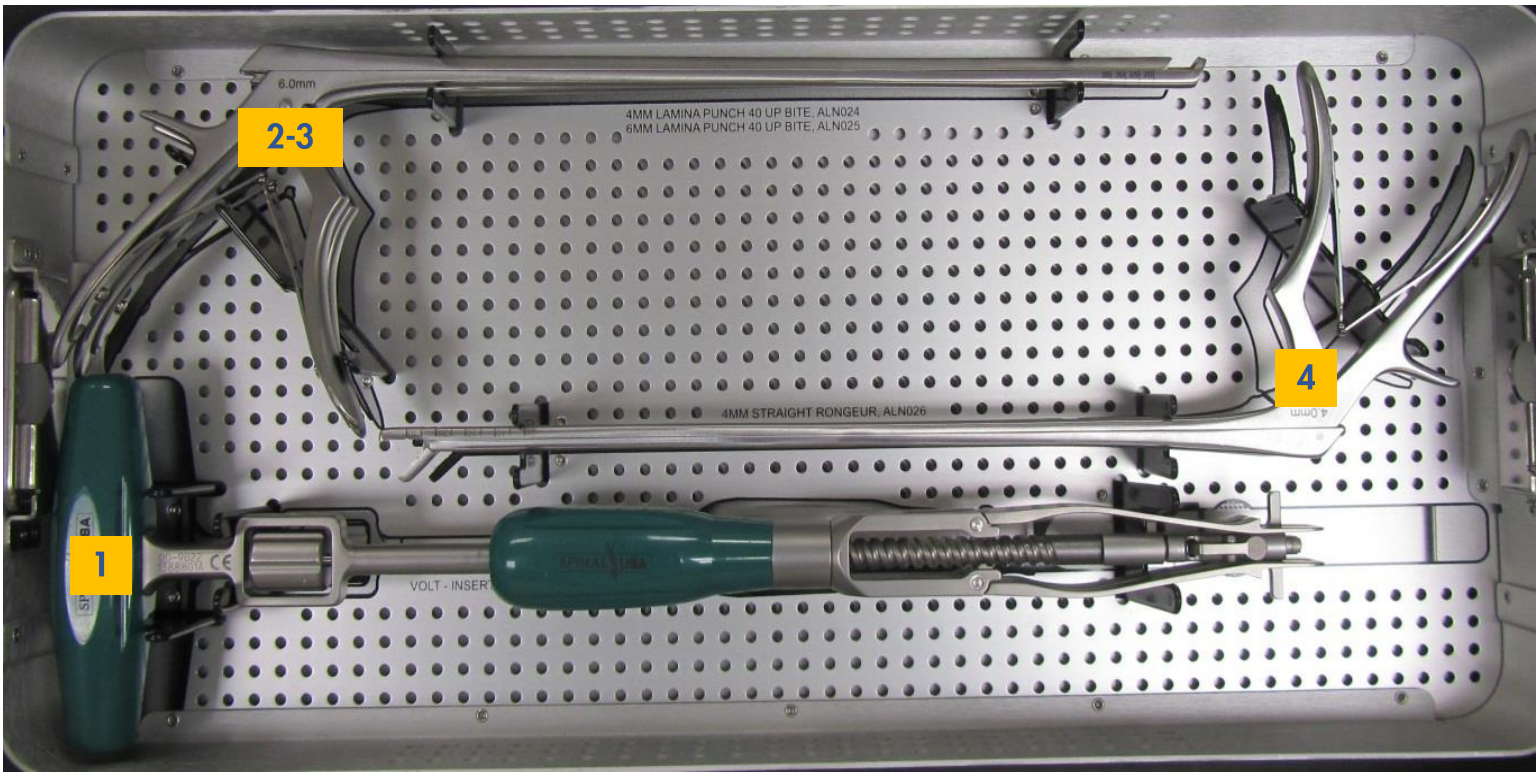



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALN023 | Distractor ALIF Offset (Ti Handles, SS Components) | 1 |
| 2. | ALN028 | Rongeurs Sypert 8mm Slight Angle 14½" | 1 |
| 3. | ALN027 | Pituitary Rongeur Straight 6mm x 330mm | 1 |

# SHURFIT® ALIF – INSTRUMENT SET 3 of 3 – BOTTOM TRAY

## TRAY NUMBER 21-1006-CAT

## BY REQUEST ONLY

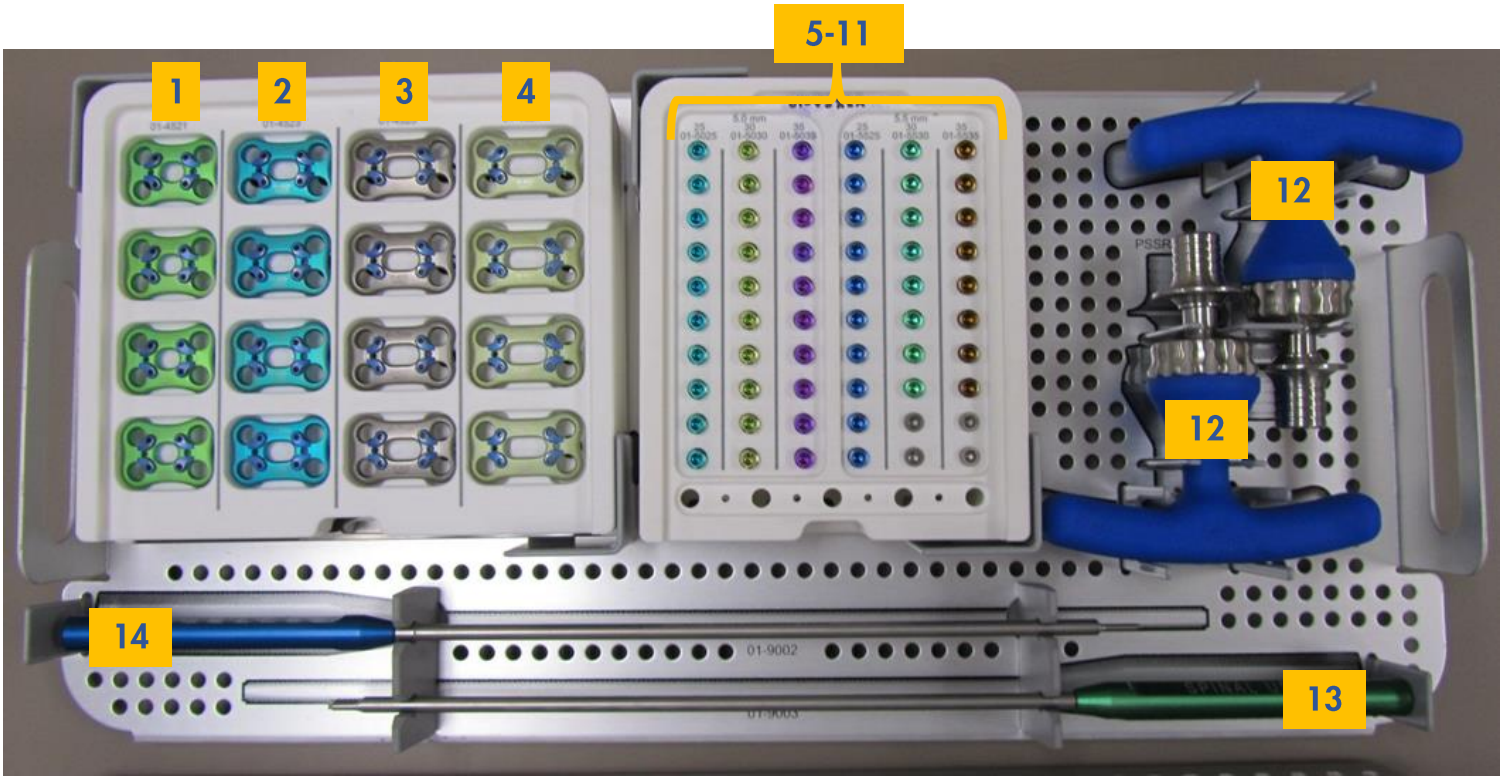



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | 00-9022 | Volt Inserter, Green Gator Squid | 1* |
| 2. | ALN024 | Punch Kerrison 40 degree Up bite 4mm x 330mm | 1 |
| 3. | ALN025 | Punch Kerrison 40 degree Up bite 6mm x 330mm | 1 |
| 4. | ALN026 | Pituitary Rongeur Straight 4mm x 330mm Length | 1 |

* Special Order

# ACCUFIT® PLATE – IMPLANTS & INSTRUMENTS– BOTTOM TRAY

## TRAY NUMBER 21-1009

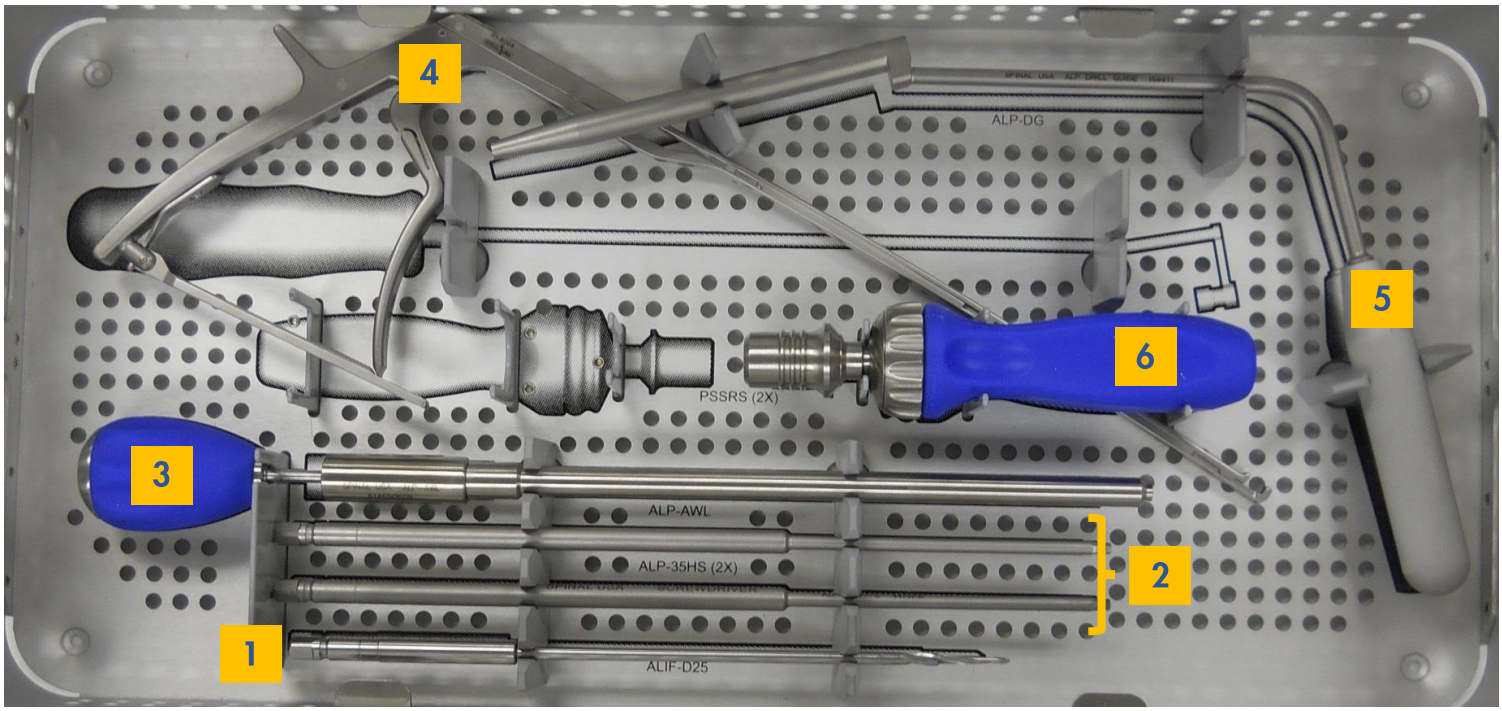



| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | 01-4521 | ALIF Plate 21mm for L4-L5 | 3 |
| 2. | 01-4523 | ALIF Plate 23mm for L4-L5 | 3 |
| 3. | 01-4525 | ALIF Plate 25mm for L4-L5 | 3 |
| 4. | 01-4527 | ALIF Plate 27mm for L4-L5 | 3 |
| 5. | 01-V5025 | 5.0mm x 25mm Self-Drilling, Variable Screw | 10 |
| 6. | 01-V5030 | 5.0mm x 30mm Self-Drilling, Variable Screw | 10 |
| 7. | 01-V5035 | 5.0mm x 35mm Self-Drilling, Variable Screw | 6 |
| 8. | 01-V5525 | 5.5mm x 25mm Self-Drilling, Variable Screw | 6 |
| 9. | 01-V5530 | 5.5mm x 30mm Self-Drilling, Variable Screw | 6 |
| 10. | 01-V5535 | 5.5mm x 35mm Self-Drilling, Variable Screw | 6 |
| 11. | 01-9005 | ALIF Fixation Pin | 4 |
| 12. | PSSRT | Ratchet T-Handle | 1 |
| 13. | 01-9003 | ALIF Plate Lock/Unlock Tool | 1 |
| 14. | 01-9002 | ALIF Plate Locking Tool | 1 |
| In Separate Caddy Under Main Caddy: | | | |
| | 01-5121 | ALIF Plate 21mm for L5-S1 | 3 |
| | 01-51213 | ALIF Plate 23mm for L5-S1 | 3 |
| | 01-51215 | ALIF Plate 25mm for L5-S1 | 3 |
| | 01-51217 | ALIF Plate 27mm for L5-S1 | 3 |
| | 01-F5025 | 5.0mm x 25mm Self-Drilling, Fixed Screw | 10* |
| | 01-F5030 | 5.0mm x 30mm Self-Drilling, Fixed Screw | 10* |
| | 01-F5035 | 5.0mm x 35mm Self-Drilling, Fixed Screw | 6* |
| | 01-F5525 | 5.5mm x 25mm Self-Drilling, Fixed Screw | 6* |
| | 01-F5530 | 5.5mm x 30mm Self-Drilling, Fixed Screw | 6* |
| | 01-F5535 | 5.5mm x 35mm Self-Drilling, Fixed Screw | 6* |

* Special Order

# ACCUFIT® PLATE – IMPLANTS & INSTRUMENTS– BOTTOM TRAY

## TRAY NUMBER 21-1009




| # | Part No. | Description | Qty |
|---|---|---|---|
| 1. | ALIF-D25 | ALIF Drill 25mm | 1 |
| 2. | ALP-35HS | ALP 3.5 Hex Screwdriver Shaft | 2 |
| 3. | ALP-AWL | Anterior Lumbar Plate Bone Awl | 1 |
| 4. | 01-9004 | ALIF Plate Holder | 1 |
| 5. | ALP-DG | Drill Guide | 1 |
| 6. | PSSRS | Ratchet Straight | 1 |

# SURGICAL TECHNIQUE

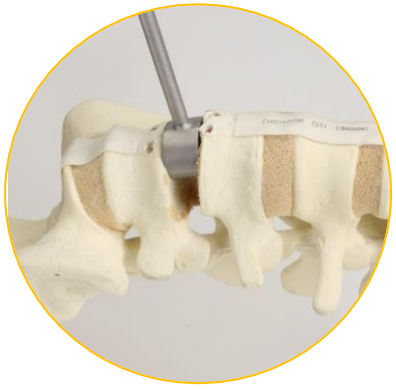
## 1 PATIENT POSITIONING/ EXPOSURE

Place the patient supine in a slight Trendelenburg position for an anterior approach to lower lumbar levels of the spine. Prep and drape in the usual manner for anterior lumbar spinal fusion. Expose and prepare the intended anterior lumbar spinal elements to be fused.

## 2 IMPLANT SELECTION

Use the appropriate ALIF Sizer which should be determined during pre-operative planning. Insert the ALIF Sizer into the intervertebral disc space using distraction as necessary. Fluoroscopy can be of assistance in confirming the fit and geometry of the ALIF Sizer.

If the desired amount of distraction is not achieved with the initial ALIF Sizer, repeat the process using incrementally larger or smaller Sizers until the desired amount of distraction is attained.



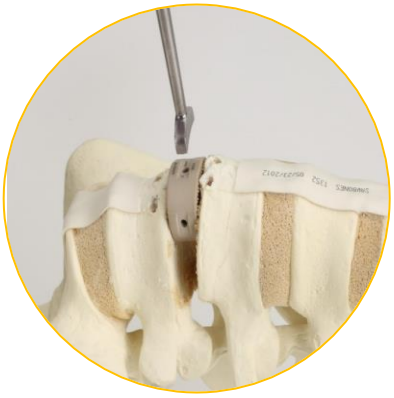
# SURGICAL TECHNIQUE

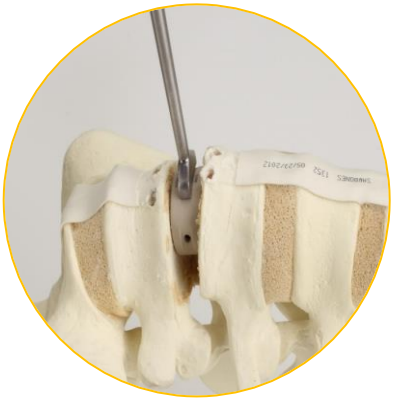
## 3 IMPLANT INSERTION (Option 1)

Place the appropriate size implant onto the ALIF Inserter (ALFINS) and tighten by turning the threaded knob clockwise until fully seated. Pack the implant and disc space with bone graft material.

Introduce the ALIF into the intervertebral disc space, ensuring that the orientation of the implant is correct.

Remove the inserter from the implant by turning the threaded knob counterclockwise until it is free from the implant. Final positioning of the implant can be achieved using the Impactor (ALN022)





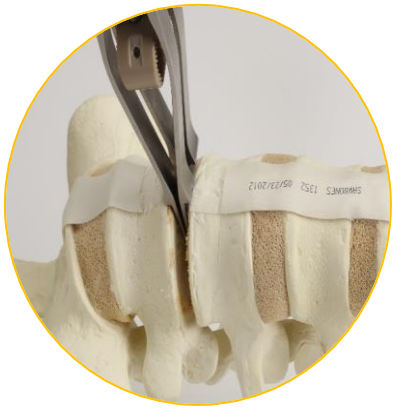
# SURGICAL TECHNIQUE

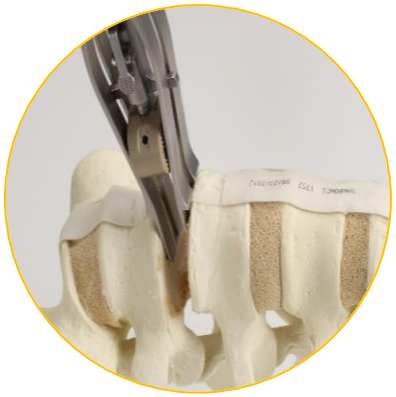
## 4 IMPLANT INSERTION (Option 2)

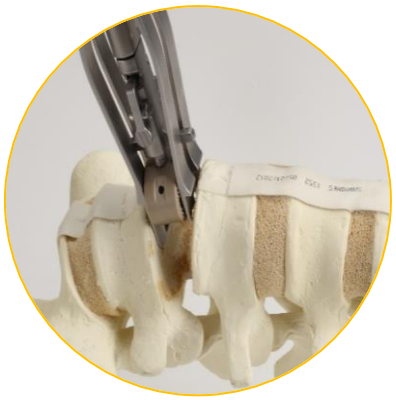
Place the appropriate size implant onto the ALIF Inserter (00-9022). The distractor blades at the most distal end should be closed when securing the ALIF implant to the Inserter. Tighten clockwise with the silver knob located just distal to the green T-handle to secure the implant. Pack the implant and disc space with bone graft material.

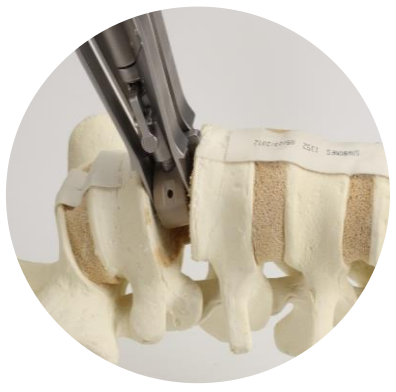
Introduce the ALIF into the intervertebral disc space using the green T-handle at the most proximal end of the Inserter. Ensure that the orientation of the implant is correct before disengaging the Inserter.

Remove the inserter from the implant by turning the threaded knob counterclockwise until it is free from the implant. Final positioning of the implant can be achieved using the Impactor (ALN022)









# SURGICAL TECHNIQUE

## 5 PLATE SELECTION

Once discectomy has been completed and an intervertebral device has been implanted, plate height can be determined intra-operatively. The ideal plate length should be when the screw holes are approximately 5mm caudal to the superior lip of the endplate and when the screw holes are approximately 5mm cephalad to the inferior endplate.

## 6 AWL INSERTION

The Awl (ALP-AWL) is inserted through the plate and into the screw holes until the awl bottoms out against the plate.

**(Optional)**
The ALIF Fixation Pin (01-9005) can be used to provisionally hold the plate in place while the initial screw is placed.) Insert the appropriate length screw in each of the 4 screw holes.

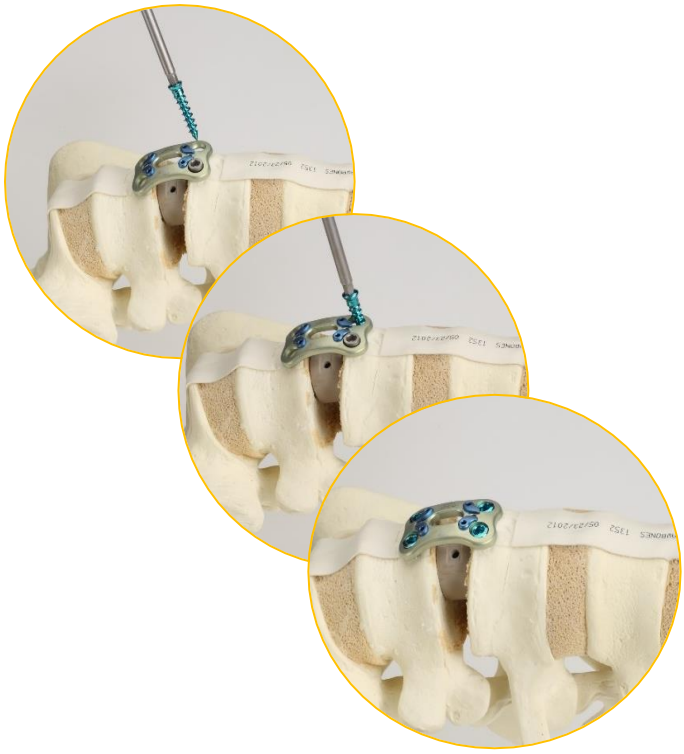
## 7 DRILL GUIDE & DRILL (Optional)

The Drill Guide (ALP-DG) is inserted into the screw holes on the plate. Assemble the Ratchet T-Handle (PSSRT) or Ratchet Straight Handle (PSSRS) to the Drill (ALIF-D25) and insert through the Drill Guide. Drill until desired depth or until the collar on the Drill prevents advancement.

# SURGICAL TECHNIQUE

## 8 SCREW INSERTION

Assemble the Ratchet T-Handle (PSSRT) or Ratchet Straight Handle (PSSRS) to the 3.5mm Hex Screw Driver (ALP-35HS) and firmly seat the appropriate length screw on the Hex Screw Driver.

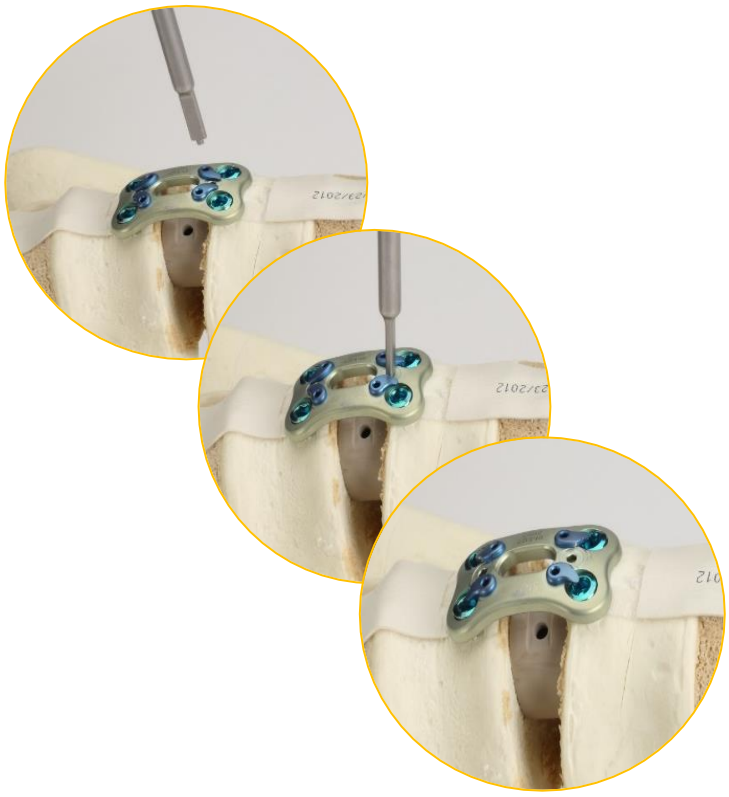


## 9 LOCKING PLATE

Once the screws have been securely positioned and tightened the locking feature can be employed.

If using the ALIF Plate Locking Tool (01-9002) insert it between the two locking features on each end of the plate and turn 360° until the locking feature covers both screw heads on each end of the plate. Every screw head should be covered by the locking feature.

**Note: Do not rotate the locking feature more than two times as this has the potential to weaken the locking mechanism.**



# SURGICAL TECHNIQUE

## 9 LOCKING PLATE (continued)

If using the ALIF Plate Lock/Unlock Tool (01-9003) Insert the long arm of the tool into the locking feature and turn until the locking feature covers the screw head securely.

**Note: Do not rotate the locking feature more than two times as this has the potential to weaken the locking mechanism.**

## 10 PLATE REMOVAL

Use the ALIF Plate Lock/Unlock Tool (01-9003) to rotate the locking feature until the screw head is no longer covered. Assemble the Ratchet T-Handle (PSSRT) or Ratchet Straight Handle (PSSRS) to the 3.5 mm Hex Screw Driver (ALP-35HS) and back out the screws securing the device. Remove Plate.

## 11 ALIF REMOVAL

Place the ALIF Inserter (ALFINS) into the ALIF Interbody Device and tighten by turning the threaded knob clockwise until fully seated. Remove the Implant.

# INDICATIONS, SHURFIT® ALIF INTERBODY CAGE

**CONTRAINDICATIONS:**
The ShurFit Interbody Fusion Devices contraindications include, but not limited to:

1. Prior fusion at the level(s) to be treated
2. Any condition not described in the indications for use
3. Previous vascular approach
4. Iliofemoral arteriosclerosis
5. Morbid obesity
6. Mental illness
7. Pregnancy
8. Local infection or inflammation
9. Any case needing to mix metals from different components
10. Any patient unwilling to cooperate with postoperative instructions
11. All cases not stated in the indications
12. Reuse, or multiple use

**POTENTIAL ADVERSE AFFECTS:**
The following potential adverse affects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse affects. The following are potential adverse effects, but not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Non-Union or delayed union
4. Foreign body reaction to the implants
5. Hemorrhaging
6. Loss of neurological function, dural tear, pain, and/or discomfort
7. Autograft fracture, vertebral body fracture or discontinued growth of fused at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of the components
9. Pain or discomfort
10. Change in mental status
11. Bursitis
12. Bone loss and/or bone fracture due to stress shielding
13. Inability to resume activities of normal daily activities
14. Revision surgery
15. Death

**WARNINGS:**
The following are warnings of this device.

1. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
2. Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, necrosis of the bone, neurological injury, and/or vascular or visceral injury.
3. The benefit of spinal fusions utilizing any interbody fusion device has not been adequately established in patients with stable spines.
4. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.
5. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
6. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters.
7. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions may compromise the results.
8. Never reuse an internal fixation device under any circumstances.
9. This device is not intended to be the sole means of spinal support. The ShurFit Interbody Fusion Devices must be used with additional anterior and/or posterior instrumentation to augment stability.
10. Only surgeons trained and experienced in spinal decompression and autografting techniques should use the ShurFit Interbody Fusion Devices. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.
11. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
12. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **AN IMPLANT SHOULD NEVER BE RE-USED.** Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.

# INDICATIONS, ACCUFIT® ALIF PLATE SYSTEM

**CONTRAINDICATIONS:**
The AccuFit Anterior Lumbar Interbody Fusion Plate System contraindications include but are not limited to:

1. A systemic infection
2. A local inflammation at the bone site
3. Rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis,
4. Known or suspected metal allergies
5. With any other medical, surgical, or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count
6. Previous vascular approach
7. Iliofemoral arteriosclerosis
8. Morbid obesity
9. Mental illness
10. Pregnancy
11. Any case needing to mix metals from different components
12. Any patient unwilling to cooperate with postoperative instructions
13. All cases not stated in the indications
14. Reuse
15. Multiple use

**POTENTIAL ADVERSE EFFECTS:**
The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects. The following are potential adverse effects, but not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Non-Union or delayed union
4. Foreign body reaction to the implants
5. Hemorrhaging
6. Loss of neurological function, dural tear, pain, and/or discomfort
7. Bone graft fracture, vertebral body fracture or discontinued growth of fused at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of the components
9. Pain or discomfort
10. Change in mental status
11. Bursitis
12. Bone loss and/or bone fracture due to stress shielding
13. Inability to resume activities of normal daily activities
14. Revision surgery
15. Death

**WARNINGS:**
The following are warnings for this device.

1. Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, necrosis of the bone, neurological injury, and/or vascular or visceral injury.
2. The AccuFit Anterior Lumbar Interbody Fusion Plate System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
3. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.
4. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
5. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters.
6. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions may compromise the results.
7. Never reuse an internal fixation device under any circumstances.
8. Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the AccuFit Anterior Lumbar Interbody Fusion Plate System. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.
9. Physicians note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
10. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **AN IMPLANT SHOULD NEVER BE RE-USED**. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

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