
SURGICAL TECHNIQUE



PRECISION  SPINE

AccuFIT[®]

LATERAL PLATE SYSTEM



LATERAL PLATE OVERVIEW

DEVICE DESCRIPTION:

The AccuFit® Lateral Plate System consists of non-sterile, single use, titanium alloy (Ti-6Al-4V ELI per ASTM F136) rigid plates and bone screws of varying sizes and lengths. The plate attaches by means of screws to the lateral portion of the vertebral body of the thoracolumbar spine (T1-L5). The system includes instrumentation which assists in the surgical implantation of the device. The AccuFit Lateral Plate System implants and instruments are provided non-sterile. They require sterilization prior to use.

INDICATIONS:

The AccuFit Lateral Plate System is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

Please refer to Instructions For Use (IFU) for complete system description, indications and warnings.

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IMPLANT FEATURES

FEATURES

- Low Profile Design
- Each plate is matched to 8, 10, 12, 14, & 16mm ShurFit® LLIF interbody cages
- Cephalad/Caudal 15 degree angulation
- Unique plate placement locking guide
- Single step, anti screw back out mechanism
- Variable screws-5.5 & 6.5mm, 30-60mm (5mm inc.)
- Temporary fixation to implant for ease of plate and screw placement.
- 30mm, 32mm, 34mm, 36mm and 38mm plate sizes.

IMPLANT INSERTION

The technique for using the AccuFit® Lateral Plate implant includes these basic steps:

1. Loading the implant onto the instrument
2. Inserting it through guidewire into the surgical site at the appropriate level
3. Temporarily locking plate to implant
4. Screw hole preparation
5. Screw Insertion
6. Final locking
7. Guidewire and lock screw removal

LATERAL PLATE PLACEMENT INSTRUMENTS

58-PH-0100 - Plate Holder



58-LS-0100 - Lock Screw



58-SD-0200 - Lock Screw Driver



58-HD-0400 - Torque Limiting Handle



LATERAL PLATE SCREW INSERTION AND LOCK

58-SD-0100 - Screw Driver



58-SD-0101 - Flexible Screw Driver



58-SD-0300 - Lock Unlock Driver



LATERAL PLATE SCREW PREPARATION INSTRUMENTS

58-HD-0100 - Ratcheting AO Handle



58-DG-0100 - Variable Guide



58-DA-0100 - Drill



58-DA-0200 - Bevel Awl



58-DA-0300 - Trocar Awl



58-DA-0101 - Flexible Drill



58-DA-0201 - Flexible Bevel Awl



58-DA-0301 - Flexible Trocar Awl



58-DA-0302 - Angled Trocar Awl



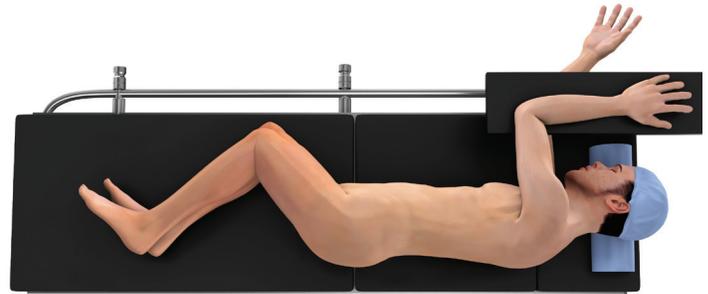
SURGICAL TECHNIQUE

1 LUMBAR APPROACH PATIENT POSITIONING

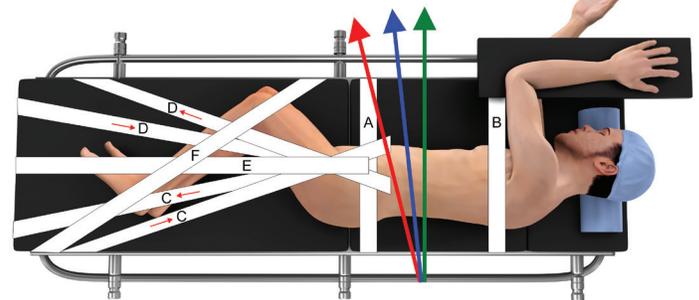
The patient is placed on a flexible surgical table in a true lateral decubitus (90°) position so that the patient's greater trochanter or iliac crest is directly over the table break. Place an auxiliary roll, bean bag or other device underneath the patient's greater trochanter. Place pillows under the head, between the knees and under the upper arm.

The patient is taped to the table at the following locations:

- Directly across the table just beneath the iliac crest.
- Over the thoracic region just under the shoulder.
- Superior and anterior to the iliac crest, down to the foot of the table, around the corner of the table and back to the iliac crest.
- Superior and posterior to the iliac crest, down to the foot of the table, around the corner of the table and back to the iliac crest.
- From the iliac crest, straight down to the end of the table.
- From the anterior edge of the table, over the knee and along the lower leg to the posterior, inferior corner of the table.

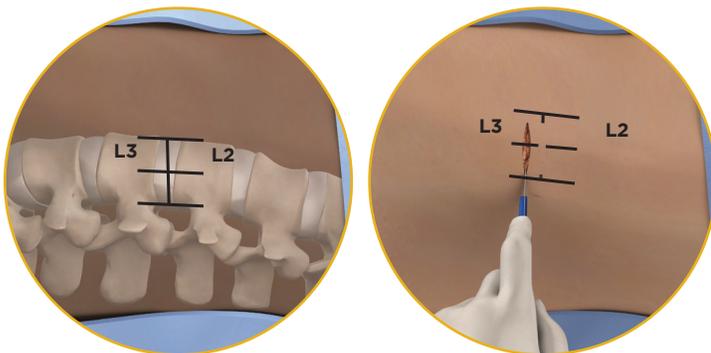


Match the lordotic angles of the spine



2 LUMBAR APPROACH SITE IDENTIFICATION AND INCISION

Under fluoroscopic guidance, flex the table to open the interval between the 12th rib and the iliac crest to provide direct access to the disc space. The table should be adjusted so that the c-arm provides true AP images when at 0° and true lateral images when at 90°. Use fluoroscopy to identify the level to be fused by laying two crossed Guidewires on the skin above the surgical site. Mark the skin at the anterior and posterior margins of the vertebral body, through the center and posterior third of the disc space.



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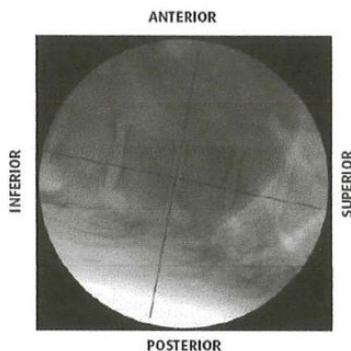
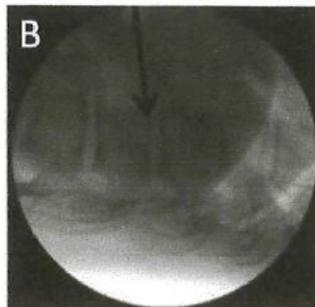
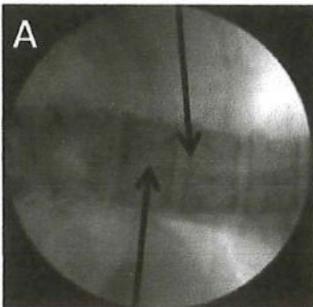
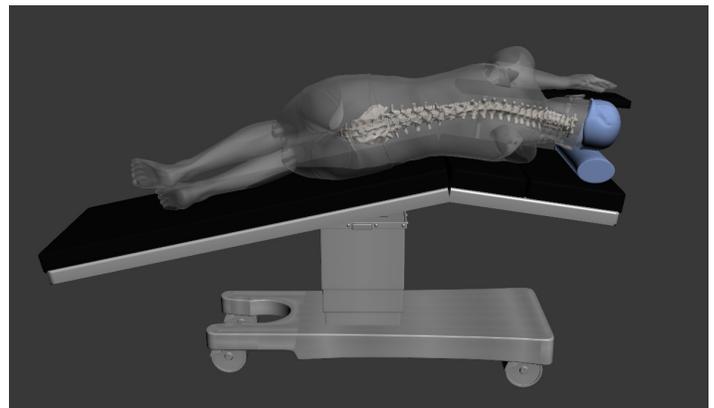
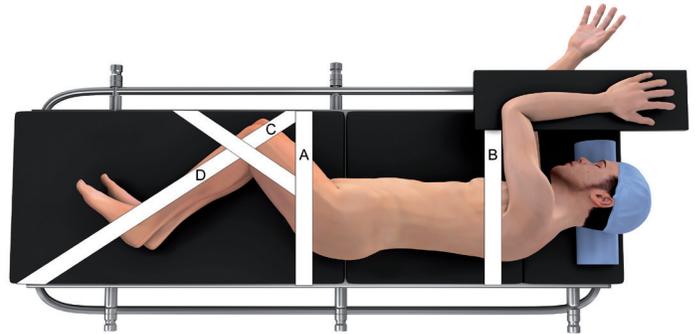
THORACIC APPROACH PATIENT POSITIONING

The patient is placed on a bendable surgical table in a direct lateral decubitus (90°) position. If the surgery involves lumbar and thoracic level, the patient is positioned so the table break is directly under the greater trochanter. If the surgery includes only thoracic levels, the patient is positioned with the table break under the mid-surgical level.

The table should be break at the targeted level to increase the distance between the ribs and facilitate the access to the disc space.

The patient is taped to the table at the following locations:

- Tape just below the iliac crest.
- Tape over the thoracic region (ensuring tape does not interfere with the surgical exposure of the level of interest).
- Tape from the iliac crest to the knee, then secured to the table.
- Tape from one side of the table to the knee, past the ankle, then secured to the other side of the table.



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THORACIC APPROACH SITE IDENTIFICATION

Once the patient is taped, the fluoroscopy is utilized to confirm targeted disc space location and adjust the table to provide true AP and lateral images when the C-Arm is horizontal or vertical, respectively. Proper disc location:

A) Spinous Process centered between pedicles and distinct endplates (black arrows).

B) Lateral view showing distinct endplates (black arrow).

The table should be independently adjusted for every approached level in order to maintain this relationship.

A K-Wire is placed perpendicular to the spine at the index level.

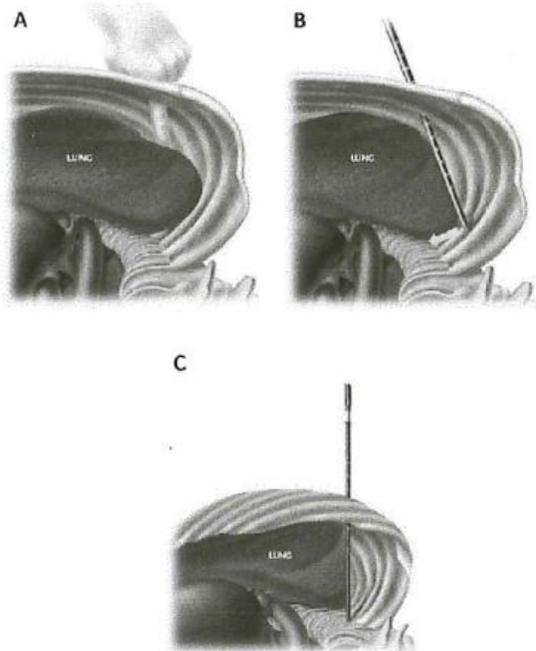
The other K-Wire is placed parallel to the spine at the posterior middle-third of the disc space or vertebra. Two marks will be made to define the location of the skin incision.

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THORACIC APPROACH SKIN INCISION AND SURGICAL APPROACH

The incision will be made parallel to the ribs at the intersection of the skin markings. The surgeon will be able to access a single level by passing between the ribs. For expanded access, utilized in multilevel cases, it will be necessary to dissect a small section of the rib head. Care should be taken to preserve the neurovascular bundle that lies under the inferior aspect of each rib. Dissection will be performed through the subcutaneous tissue down to the ribs or intercostal space.

- Index finger palpating and displacing the thoracic cavity structures.
- Introduction of the first dilator. Note the posterior direction of the dilator.
- Slide down the dilator to access the intersection of the rib head and the vertebral body.



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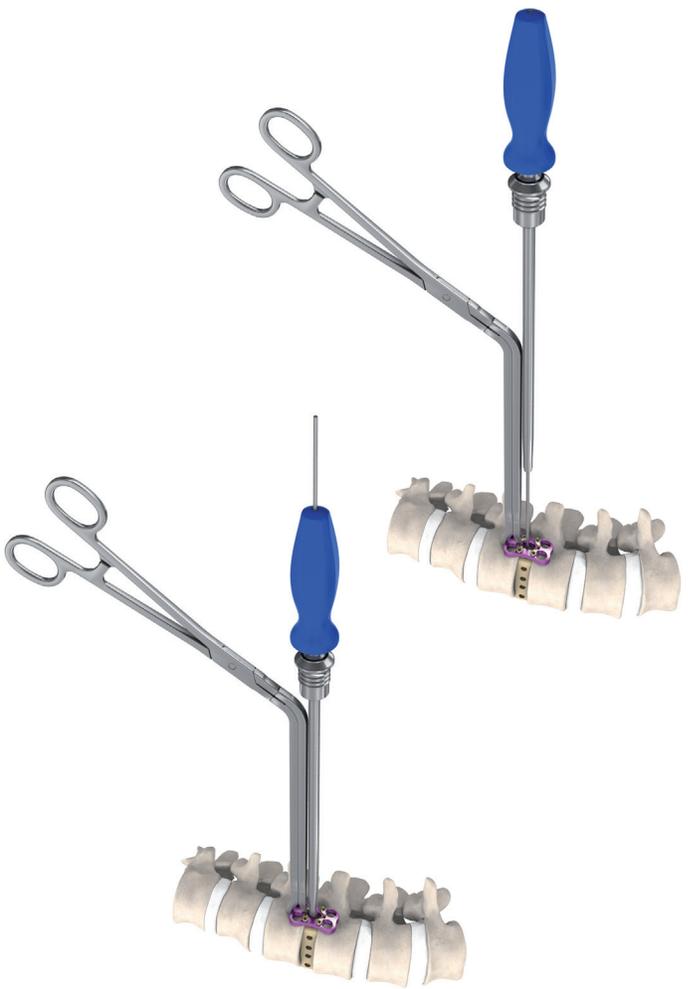
PLATE INSERTION

Determine the appropriate size plate. Grab the **Plate (58-LP-00XX)** using the **Plate Holder (58-PH-0100)** by placing the pin of the plate holder through one of the two small center holes and the second arm into the corresponding groove. Insert the Plate into the surgical site by placing the center hole of the plate over the guidewire.

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LOCK SCREW INSERTION AND TIGHTENING

Connect the **Lock Screw Driver (58-SD-0200)** to the **Torque Limiting Handle (58-HD-0400)**. Using the **Lock Screw Driver (58-SD-0200)** grab the **Lock Screw (58-LS-0100)** and slide it over the guidewire. Lower the lock screw until it engages with the guidewire threads. Use the lock screw driver to screw the lock screw until it mates with the inner shelf of the center plate hole. Torque Limiting Handle will click when required Locking Torque has been applied. Ensure plate is situated as intended.



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PILOT HOLE PREPARATION

Several instruments are available in the AccuFit® Lateral Plate System set to create pilot holes. The selected technique will be based on surgeon preference and surgical requirements.

DRILL or AWL

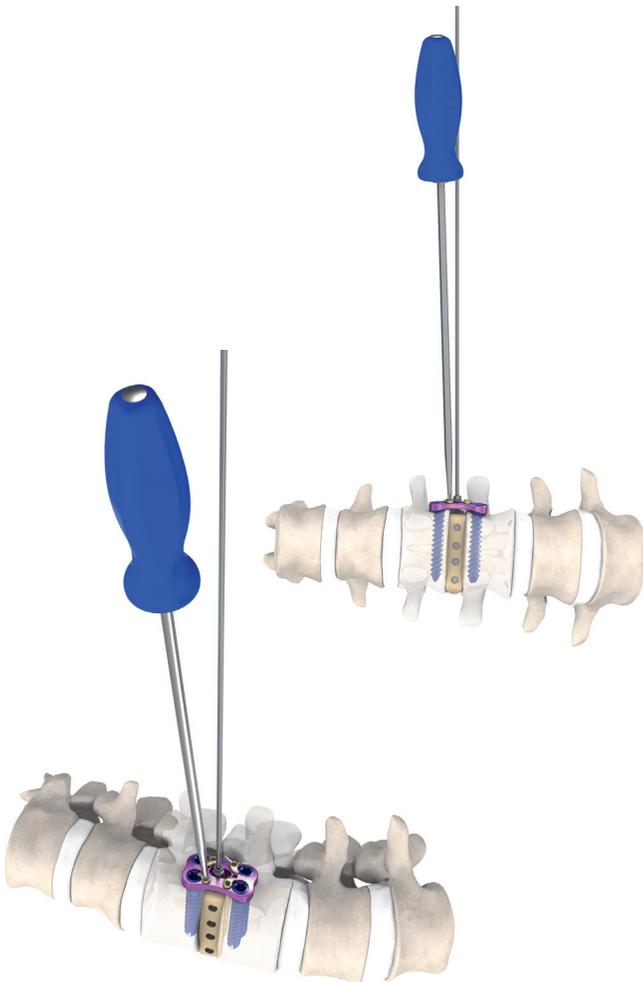
Adjust **Variable Guide (58-DG-0100)** to appropriate length based on surgeon preference. Place the Variable Guide into the screw hole of the plate and determine appropriate screw trajectory. Connect **Drill (58-DA-0100)** or **Awl, Bevel Tip (58-DA-0200)** or **Trocar Tip (58-DA-0300)** to **Ratcheting AO Handle (58-HD-0100)** and insert through variable guide and drill or awl to depth. Repeat for remaining pilot holes.

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SCREW INSERTION

Screw length is determined using interbody length and pilot hole depth for reference. Add additional length if bicortical purchase is desired. Insert the appropriate length **5.5mm screw (58-VS-55XX)** onto the tip of the **Screw Driver (58-SD-0100)** or **Flexible Screw Driver (58-SD-0101)** and thread inner shaft of the driver into the screw to rigidly attach screw to the driver.

Insert the screw into the plate screw hole. Drive the screw through the bone following the pilot hole. Drive screw until the head of the screw is fully inserted in the plate screw hole. Unthread bone screw driver inner shaft and release screw driver from screw. Repeat screw insertion procedure on remaining segments.



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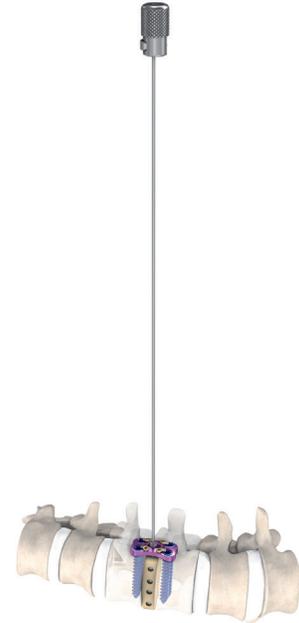
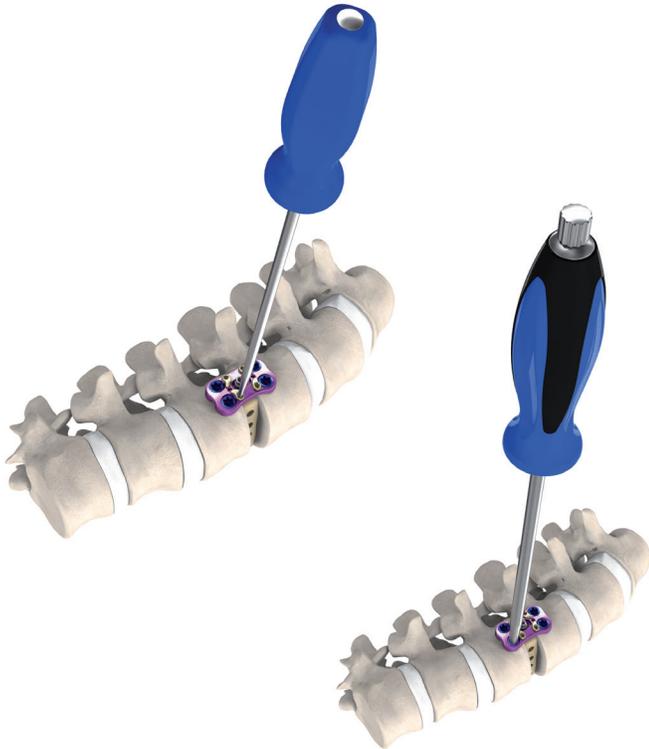
SCREW ANTI-BACK OUT

Insert tip of **Lock Unlock Driver (58-SD-0300)** into rivet and turn until flange of rivet is over the screw head. Repeat for all screws.

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GUIDE WIRE AND LOCK SCREW REMOVAL

After implant is locked connect the guidewire handle to the guide wire and unthread guide wire from cage. Lock screw will also remove along with guide wire.



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IMPLANT REMOVAL

Using the **Lock Unlock Driver**, insert the driver into the rivet. Turn until head of screw is fully unobstructed. Repeat for remaining rivets.

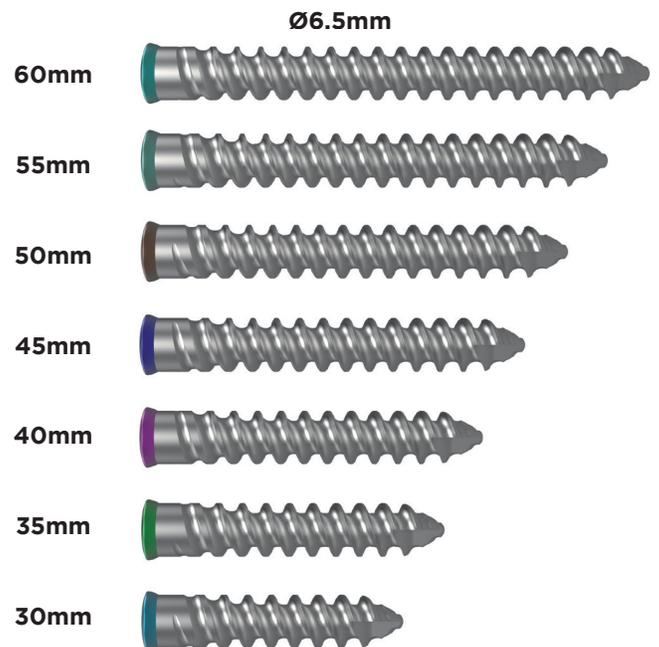
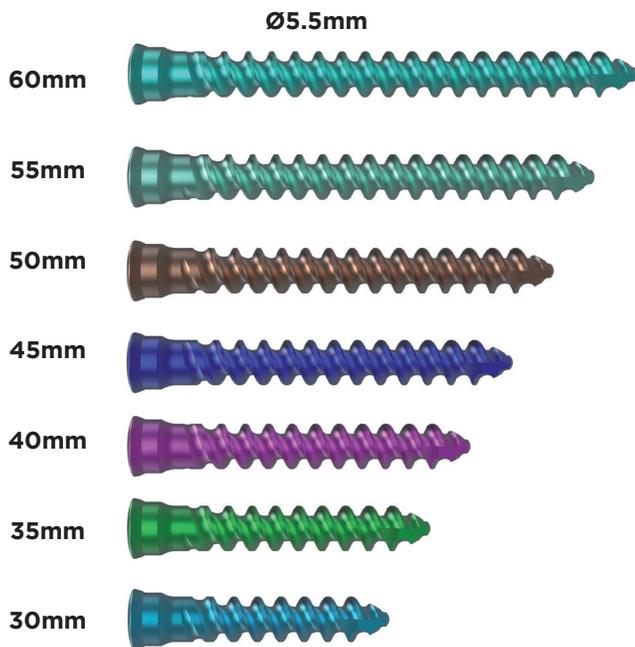
Using the **Screw Driver**, insert the **Screw Driver** into the screw and thread the inner shaft into the screw. Turn counterclockwise to remove the screw from the plate. Repeat for remaining screws.

Remove plate by placing the pin of the plate holder on arm one through one of the two small center holes and the second arm into the corresponding groove. Remove plate from surgical site. As an alternative forceps can be used.

PLATE SIZES

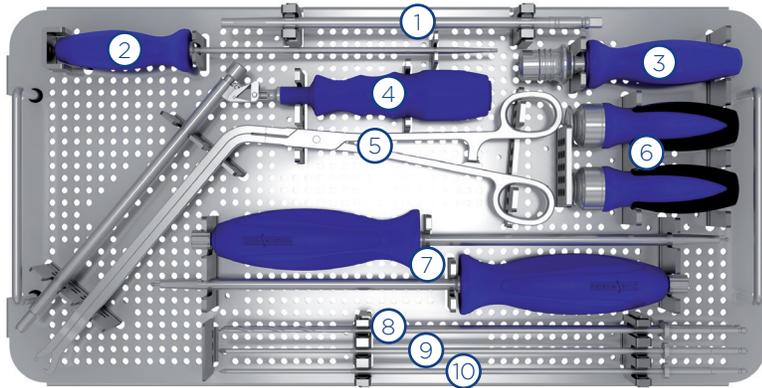


SCREW SIZES



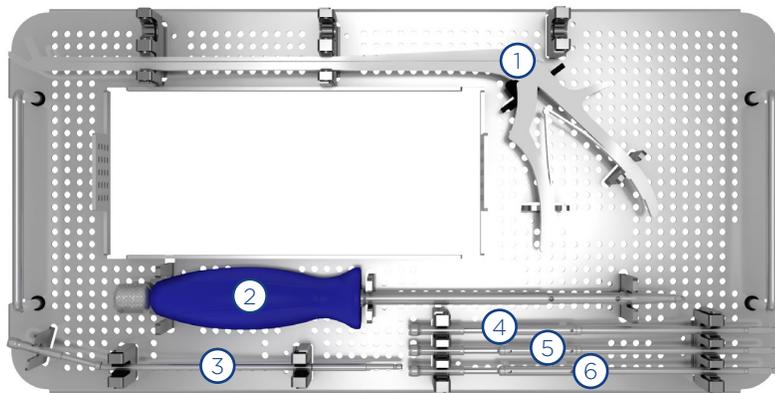
LATERAL PLATE INSTRUMENTS TRAYS

Top Level



- | ITEM NO. | DESCRIPTION |
|----------|------------------------|
| ① | Lock Screw Driver |
| ② | Lock/Unlock Driver |
| ③ | Torque Limiting Handle |
| ④ | Adjustable Guide |
| ⑤ | Plate Holder |
| ⑥ | Ratcheting AO Handle |
| ⑦ | Screw Driver |
| ⑧ | Drill |
| ⑨ | Awl, Bevel Tip |
| ⑩ | Awl, Trocar Tip |

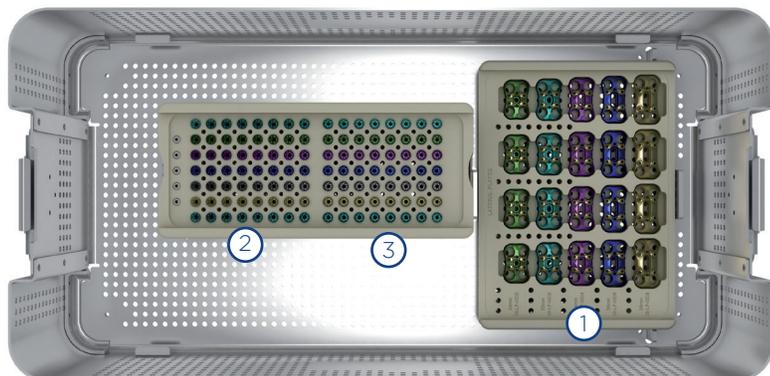
Mid Level



- | ITEM NO. | DESCRIPTION |
|----------|--------------------------|
| ① | Up-biting Rongeur |
| ② | Flexible Screw Driver |
| ③ | Angled Awl, Trocar Tip |
| ④ | Flexible Drill |
| ⑤ | Flexible Awl, Bevel Tip |
| ⑥ | Flexible Awl, Trocar Tip |

LATERAL PLATE IMPLANT TRAYS

Bottom Level



- | ITEM NO. | DESCRIPTION |
|----------|---|
| ① | Plate (30, 32, 34, 36, 38mm) |
| ② | Variable Screw Ø5.5
(30, 35, 40, 45, 50, 55, 60mm) |
| ③ | Variable Screw Ø6.5
(30, 35, 40, 45, 50, 55, 60mm) |

BILL OF MATERIALS

ITEM NUMBER	DESCRIPTION	QTY
58-LP-0030	30mm Plate	3
58-LP-0032	32mm Plate	4
58-LP-0034	34mm Plate	4
58-LP-0036	36mm Plate	4
58-LP-0038	38mm Plate	3
58-LS-0100	Lock Screw	5
58-VS-5530	Ø5.5 x 30mm Variable Screw	8
58-VS-5535	Ø5.5 x 35mm Variable Screw	8
58-VS-5540	Ø5.5 x 40mm Variable Screw	8
58-VS-5545	Ø5.5 x 45mm Variable Screw	8
58-VS-5550	Ø5.5 x 50mm Variable Screw	8
58-VS-5555	Ø5.5 x 55mm Variable Screw	8
58-VS-5560	Ø5.5 x 60mm Variable Screw	8
58-VS-6530	Ø6.5 x 30mm Variable Screw	8
58-VS-6535	Ø6.5 x 35mm Variable Screw	8
58-VS-6540	Ø6.5 x 40mm Variable Screw	8
58-VS-6545	Ø6.5 x 45mm Variable Screw	8
58-VS-6550	Ø6.5 x 50mm Variable Screw	8
58-VS-6555	Ø6.5 x 55mm Variable Screw	8
58-VS-6560	Ø6.5 x 60mm Variable Screw	8
58-DA-0100	Drill	2
58-DA-0101	Flexible Drill	1
58-DA-0200	Awl, Bevel Tip	1
58-DA-0201	Flexible Awl, Bevel Tip	1
58-DA-0300	Awl, Trocar Tip	1
58-DA-0301	Flexible Awl, Trocar Tip	1
58-DA-0302	Angled Awl, Trocar Tip	1
58-DG-0100	Adjustable Guide	1
58-HD-0100	Ratcheting AO Handle	2
58-HD-0400	Torque Limiting Handle	1
58-PH-0100	Plate Inserter	1
58-RD-1375	7.5mm Up-Biting Rongeur, Disc 13"	1
58-SD-0100	Screw Driver	2
58-SD-0101	Flexible Screw Driver	1
58-SD-0200	Lock Screw Driver	1
58-SD-0300	Lock/Unlock Driver	1
58-SC-1000	Lateral Plate Instrument and Implant Case	1

CONTRAINDICATIONS:

The AccuFit Lateral 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
9. Pain or discomfort
10. Change in mental status
11. Bursitis
12. Bone loss and/r bone fracture due to stress shielding
13. Inability to resume 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® Lateral 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 Lateral 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.

Discover the Difference



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PRECISION SPINE
AccuFIT®
LATERAL PLATE SYSTEM

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