Surgical Technique
The ThinLine System is the lowest profile plate in the SC-AcuFix® Anterior Cervical Plating System family at a very slim 1.8mm profile. The reduced profile and streamlined design is intended to minimize esophageal irritation and reduce the risk of dysphasia by having less metal protruding from the anterior surface of the cervical vertebral body. The ThinLine System is available in both one- and two-level plates with either spiked or spikeless implants and utilizes the proprietary SecureRing® Locking Mechanism technology with a one-piece, zero-step locking mechanism to secure the plate.

The ThinLine System was designed with patients in mind and is one option in a full range of anterior cervical solutions from the people of Zimmer Spine.
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Description

The Zimmer Spine SC-AcuFix® Anterior Cervical Plate System components are temporary implants and associated instruments that are used to stabilize the cervical spine during the development of a solid spinal fusion in patients with degenerative disease, trauma (including fractures), and tumor pathology. The SC-AcuFix System consists of single and multi-segmented titanium bone plates of various sizes and lengths, titanium bone screws in various diameters and lengths, and instrumentation for plate insertion. Fixation is provided by the insertion of bone screws through the two openings at each end of a plate segment into the vertebral bodies of the cervical spine. Fixation of the screws to the plate is accomplished by seating into the SecureRing® screw retention mechanism. Screws may also be inserted into additional adjacent screw holes of multi-segment plates if needed.

Implant components are manufactured of ASTM F136 implant quality titanium alloy (Ti-6Al-4V). Specifications are controlled for optimization of metallurgical properties and corrosion resistance, and are based on the strength and rigidity requirements of the individual component. Thus to achieve the best results, do not use any of the SC-AcuFix Anterior Cervical Plate System components with components from any other system or company. As with other orthopaedic implants, none of the SC-AcuFix System components should be reused or reimplanted under any circumstances.

Indications

The SC-AcuFix Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

1. Degenerative disc disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
2. Trauma (including fractures);
3. Tumor;
4. Spondylolisthesis;
5. Spinal stenosis;
6. Deformity (i.e., scoliosis, kyphosis, lordosis);
7. Pseudarthrosis; and
8. Failed previous fusions.
Contraindications

The SC-AcuFix Anterior Cervical Plate System is not designed or sold for any use except as indicated. Do not use SC-AcuFix implants in the presence of any contraindication.

Contraindications include, but are not limited to:

1. Presence of overt infection and/or localized inflammation.
2. Rapid joint disease, bone absorption, osteopenia and/or osteoporosis.
3. Suspected or documented metal allergy or intolerance.
4. Any patient having inadequate tissue coverage over the operative site.
5. Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
6. Severe comminuted fractures, such that segments may not be maintained in satisfactory approximate reduction.
7. Use in displaced, non-reduced fractures with bone loss.
8. The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
9. Any other medical or surgical condition that would preclude the potential benefit of surgery, such as elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), fever, leukocytosis or a marked left shift in the WBC differential count.
10. The physical contact of the SC-AcuFix System implants with metal implant made of anything other than implant grade titanium, such as stainless steel (ASTM F138) or MP35 N, or other dissimilar metal.
11. Situations with the absence or compromise of significant stabilizing elements.
12. Use in the presence of any neural or vascular deficits or other compromising pathology, which may be further injured by device intervention.
ThinLine Implants

**ThinLine Spikeless Plate, One-Level**
407-6120 to 407-6132

**ThinLine Spiked Plate, One-Level**
407-6020 to 407-6032

**ThinLine Spikeless Plate, Two-Level**
407-7136 to 407-7150

**ThinLine Spiked Plate, Two-Level**
407-7036 to 407-7050

**ThinLine Self-Tapping Screw, Primary (12-14mm)***
402-44012 to 402-44014

**ThinLine Self-Drilling Screw, Primary (12-14mm)***
402-48112 to 402-48114

**ThinLine Self-Tapping Screw, Rescue (12-14mm)***
402-46012 to 402-46014

*Screw color varies by length
SC-AcuFix Instruments

**Temporary Fixation Pins**
457-1
Provides additional plate stability before screw insertion.

**Temporary Fixation Pin Inserter**
497-1
Places the Temporary Fixation Pins.

**Modular Drill Guide Handle**
462-1
Secures to the Restricted Angle Drill Tube and Fixed Angle Drill Guide.

**Modular AO Handle**
561-2
Secures to the Modular Hex Driver and 2.5mm Drills.

**Reduced Length 2.5mm Long Drill**
453-31
Drills holes for self-tapping screws in conjunction with the Freehand Drill Guide.

**Reduced Length Combo 2.5mm Drill/4.0mm Tap**
489-31
Drills and taps holes for screws in conjunction with the Freehand Drill Guide. **Power drilling is not recommended for use with this tap.**

**Multi-Angle Fixed Depth Drill Guide**
491-1
Allows for drilling, tapping and screw placement in intermediate screw holes.
**Modular 2.5mm Hex Driver**
450-2

Used with the Modular AO Handle to implant 2.5mm self-tapping or self-drilling screws. Tapered, self-securing tip allows easy retrieval and insertion of screws. **Do not use with Fixed Angle Guides; may cause screw misalignment.**

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**Fixed Angle 2.5mm Stop Drill (12 - 14mm)**
482-312 to 482-314

Used with the Fixed Angle Drill Guides to drill holes for screws. Available in lengths of 12, 13 and 14mm.

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**Fixed Angle Combo Stop 2.5mm Drill/4.0mm Tap (12 - 14mm)**
480-312 to 480-314

Used in conjunction with the Fixed Angle Drill Guide in cases where the surgeon identifies preference for tapping. Available in lengths of 12, 13 and 14mm. **Power drilling is not recommended for use with this tap.**

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**Rescue Driver**
474-1

Used for screw removal and revision. The Threaded Removal Driver may be substituted in cases of compromised bone purchase.

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**Threaded Removal Driver**
479-1

Recommended for screw removal and revision in cases of compromised bone purchase. Central threaded post secures to the internal threads of bone screws.
Bone Compass
481-1
Used to measure the appropriate length to span the disc space.

Plate Tamp
488-1
Used to set the posterior fixation spikes into the prepared surface.

Plate Holder
452-2
Used with the rotating handle to place the plate onto prepared surfaces. Attaches to the keyhole of the plate.
ThinLine Instruments

2.5mm Cortical Spring Punch, 13mm
440-13
Punches holes for the SC-AcuFix Screws; spares more bone than a traditional tap.

Restricted Angle Drill Tube (12 - 14mm)
473-12 to 473-14
Used with the 2.5mm Freehand Drill and Modular AO Handle to freehand drill for 12mm, 13mm and 14mm screws. Available in lengths of 12, 13, and 14mm.

Caudal Fixed Angle Drill Guide
446-60
Single cannula for drilling and screw placement. Provides consistent screw angulation and screw-to-plate trajectory.
Predetermined 6˚ medial and 0˚ cephalad/caudal bias guarantees placement within ROM.

Cephalad Fixed Angle Drill Guide
446-66
Single cannula for drilling and screw placement. Provides consistent screw angulation and screw-to-plate trajectory.
Predetermined 6˚ medial and 6˚ cephalad/caudal bias guarantees placement within ROM.

ThinLine Plate Bender
444-1
Used to increase the existing machined lordotic curve in the ThinLine Plate, if necessary.
Surgical Technique

**Step 1**

**Plate Sizing**
Use the Bone Compass to determine the plate size. Appropriately sized plates will not interfere with the adjacent, unfused disc space.

Handle the sharp tips of the Bone Compass carefully.

**Step 2**

**Plate Bending**
If plate contouring is necessary, use the ThinLine Plate Bender. Bending should be performed in small increments avoiding contact with the screw holes.

*Note:* Reverse bending should not be performed. Do not use the SC-AcuFix Plate Bender to bend a ThinLine plate.
Plate Positioning
Attach the ThinLine Plate to the Plate Holder by pressing down on the proximal end of the Plate Holder while inserting its distal tip into the plate’s keyhole. Release the pressure on the Plate Holder to lock the plate into the keyhole. The plate can now be placed into the surgical site. Proper orientation of the plate is indicated by the “CEPHALAD” notation. Recommended placement is centered midline with the plate’s screw holes 3.0 - 3.5mm from the edge of the vertebral endplates or as close as possible to the graft site without compromising the vertebral endplates.

Note: If using a spiked plate, utilize the Plate Tamp to set the spikes into the anatomy.

Temporary Fixation
Temporary Fixation Pins are used to hold the ThinLine Plate in position. Pull back on the center ring of the Temporary Fixation Pin Inserter and insert a Fixation Pin into the inserter’s distal end. Release the center ring to lock the pin to the inserter.

The range of motion for the screw holes are as follows:

<table>
<thead>
<tr>
<th>Orientation</th>
<th>Range of Motion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cephalad</td>
<td>~ Constrained (1˚)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>~ 4˚</td>
</tr>
<tr>
<td>Caudal</td>
<td>~ 8˚</td>
</tr>
</tbody>
</table>

Turn the pin clockwise until it’s firmly seated in the screw hole. Remove the Temporary Fixation Pin from the inserter by pulling up on its outer sleeve.

Note: The use of Temporary Fixation Pins may affect the screws’ fixation. Fixation Pins should be removed prior to inserting screw and prior to closing the incision.
Screw Placement - Fixed Angle Drill Guide Option, Self-Tapping Screws

**Prepare Drill Guide**
Use the Fixed Angle Drill Guides for consistent screw angulations and for drill and screw placement.

Assemble the Modular Drill Guide Handle to the appropriate *ThinLine* Fixed Angle Drill Guide. The distal end of the Fixed Angle Drill Guide fits directly into the two holes on each end of the *ThinLine* plate. The Multi-Angle Fixed Drill Guide is used for intermediate screw placement with the two-level *ThinLine* plates.

**Screw Preparation**
Assemble the Fixed Angle 2.5mm Diameter Short Stop Drill or the Fixed Angle Combo Stop 2.5mm Drill/4.0mm Tap to the Modular AO Handle. Insert the assembly into the Fixed Angle Drill Guide. When using the drill, carefully rotate the handle clockwise until the drill depth stop contacts the Drill Guide. When using the combo drill/tap, advance it just short of the depth stop to mitigate stripping. To remove the drill or combo drill/tap turn its handle counterclockwise while gently pulling up.

**Screw Placement**
Assemble the Fixed 2.5mm Hex Driver/Modular AO Handle. Select a screw length consistent with your drill size. Secure the screw to the driver and insert a bone screw into the Drill Guide cannula. Tighten the screw into the plate until the hard stop of the Hex Driver makes contact with the top of the guide. It will automatically disengage from the screw, leaving the top of the screw head 1 - 1.5mm proud of the *SecureRing* Mechanism.

To prevent the plate from ‘twisting’ during screw insertion, insert a second screw contralateral to the first.

*Power tapping is not recommended. The 2.5mm Cortical Spring Punch, 13mm can be used through the Fixed Angle Drill Guide.*
Screw Preparation
Assemble the Fixed Angle 2.5mm Hex Driver to the Modular AO Handle. Select a screw length consistent with the drill length used for the screw hole. Secure the screw to the Hex Driver and insert the assembly into the Drill Guide cannula.

Note: The use of the 2.5mm Modular Hex Driver and the Multi-Angle Fixed Drill Guide is discouraged for cephalad screws due to the increased risk of screw misalignment outside the range of motion for the screw holes.

Screw Placement
Rotate the screw clockwise until the depth stop on the screwdriver meets the top of the guide. The driver will automatically disengage from the screw head leaving the screw head 1 – 1.5mm proud of the SecureRing Mechanism. To prevent plate rotation during screw insertion, insert a second screw contralateral to the first. Place remaining screws in the same manner, remembering to remove fixation pins prior to insertion.

Follow the Multi-Angle Fixed Drill Guide instructions when placing intermediate screws.

Proceed to Final Tightening.
Screw Placement - Multi-Angle Fixed Drill Guide Option

**Step 5 Option 3a**

**Prepare Drill Guide**
Assemble the Modular Drill Guide Handle to the Multi-Angle Fixed Drill Guide.

The distal end of the Multi Angle Drill Guide sits directly into the caudal or intermediate screw holes. Once seated, adjust the assembly to the desired angle, not to exceed the 8˚ range of motion (ROM) in the caudal screw holes or 4˚ ROM in the intermediate screw hole.

*Note: Multi-Angle Fixed Drill Guide is not recommended for use in the constrained cephalad screw holes on the ThinLine plate due to the increased risk of screw misalignment.*

**Step 5 Option 3b**

**Drill/Tap Screw Holes**
Assemble the Fixed Angle 2.5mm Diameter Short Stop Drill or the Fixed Angle Combo Stop 2.5mm Drill/4.0mm Tap to the Modular AO Handle and insert into the seated Multi-Angle Fixed Drill Guide. When using the drill, advance it carefully by rotating the handle clockwise until the drill depth stop contacts the Drill Guide. When using the combo drill/tap, advance to just short of the depth stop to mitigate stripping.

To remove the drill or combo drill/tap, turn handle counterclockwise while gently pulling up.

*Power tapping is not recommended. The 2.5mm Cortical Spring Punch, 13mm can be used through the Multi-Angle Fixed Drill Guide.*
Screw Preparation
Assemble the Fixed Angle 2.5mm Hex Driver to the Modular AO Handle.
Select a screw length consistent with the drill length used for the screw holes. Secure the screw to the Hex Driver and insert the assembly into the Drill Guide cannula. Adjust the assembly to the desired angle, not to exceed the 8° ROM in the caudal screw holes or 4° ROM in the intermediate screw hole.

Note: The use of the 2.5mm Modular Hex Driver and the Multi-Angle Fixed Drill Guide is discouraged for cephalad screws due to the increased risk of screw misalignment and/or alignment outside the ROM for the screw holes.

Screw Placement
Rotate the screw clockwise until the depth stop on the driver meets the top of the guide. The screwdriver will automatically disengage from the screw head leaving it 1 – 1.5mm proud of the SecureRing Mechanism. To prevent plate rotation during screw insertion, insert a second screw contralateral to the first. Place the remaining screws in the same manner, remembering to remove the Fixation Pins prior to insertion.
Follow the Fixed Angle Drill Guide instructions when placing cephalad screws.
Proceed to Final Tightening.
Screw Placement - Freehand Drill/Fixed Depth Drill Guide Option

Drill Guide Preparation
Assemble the 2.5mm Reduced Length Long Drill or Reduced Length Combo 2.5mm Drill/4.0mm Tap to the Modular AO Handle and appropriate ThinLine Restricted Angle Drill Tube to the Modular Drill Guide Handle.

The distal end of the Restricted Angle Drill Tube sits directly into the screw holes capturing the SecureRing swivel. Adjust the guide to its desired angle, not to exceed the 8˚ ROM in caudal screw holes or 4˚ ROM in the intermediate screw hole. Cephalad screw holes are constrained and have a 6˚ medial and cephalad bias.

Drill/Tap
Insert drill or drill/tap into the Drill Guide. When using the drill, advance it carefully by rotating the handle clockwise until the drill stop contacts the Drill Guide. When using the combo drill/tap, advance it to just short of the depth stop to mitigate stripping.

To remove the drill or combo drill/tap, turn handle counterclockwise while gently pulling up.

Note: Power tapping is not recommended.
**Screw Placement**

Remove the Drill Guide assembly prior to inserting the screws. A Drill Guide is not for the freehand technique.

Assemble the Fixed Angle 2.5mm Hex Driver to the Modular AO Handle.

Select a screw length consistent with the Restricted Angle Drill Tube used for the screw hole. Secure the screw to the Hex Driver. Adjust the screw to the desired angle, not to exceed the 8˚ ROM in caudal screw holes, 4˚ ROM in intermediate screw hole, or 1˚ ROM on cephalad screw holes. Cephalad screw holes are constrained and have a 6˚ medial and cephalad bias.

Rotate screw clockwise until 1 – 1.5mm proud of the SecureRing Mechanism; screwdriver will automatically disengage from the screw head. To prevent plate rotation during screw insertion, insert a second screw contralateral to the first. Place remaining screws in the same manner, remembering to remove Fixation Pins prior to insertion.

Proceed to Final Tightening.
Screw Preparation - Cortical Spring Punch Option

**Step 5 Option 5a**

**Screw Preparation**
The distal end of the 2.5mm Cortical Spring Punch, 13mm sits directly into the screw holes of the SecureRing Mechanism swivel. Adjust the punch to the desired angle, not to exceed the 8˚ ROM in caudal screw holes, 4˚ ROM in the intermediate screw hole or 1˚ ROM in fixed cephalad screw holes. Cephalad screw holes are constrained and have a 6˚ medial and cephalad bias. Apply downward force to the punch’s handle in order to extend the punch’s distal end and pierce the cortical wall of the vertebral body.

**Step 5 Option 5b**

**Screw Placement**
Assemble the Fixed Angle 2.5mm Hex Driver to the Modular AO Handle.

Select a screw length consistent with the punch depth used to prepare the screw hole. Secure the screw to the Hex Driver. Adjust the screw to your desired angle, not to exceed the 8˚ ROM in caudal screw holes, 4˚ ROM in the intermediate screw hole or 1˚ ROM in cephalad screw holes. Cephalad screw holes are constrained and have a 6˚ medial and cephalad bias.

Rotate screw clockwise until 1 – 1.5mm proud of the SecureRing Mechanism; the screwdriver will automatically disengage from the screw head. To prevent plate rotation during screw insertion, insert a second screw contralateral to the first. Place remaining screws in the same manner, remembering to remove the Fixation Pins prior to insertion.

Proceed to Final Tightening.
**Final Tightening**

**Step 6**

**Securing the Plate**
A minimum of four screws (two in the cephalad and two in the caudal screw holes) are required for proper plate fixation. When possible, screws should also be placed in the plate’s intermediate screw holes for optimal stabilization.

Using the 2.5mm Modular Hex Driver/Modular AO Handle assembly, position the plate flush to the anterior cortex of the cervical spine by tightening the screws flush or below the proximal surface of the ThinLine Plate.

**Step 7**

**SecureRing Verification**
Proper SecureRing Mechanism deployment can be verified by using fluoroscopy and direct visualization. Prior to closing the wound, a lateral radiographic image should be taken to confirm that all screw heads are flush or below the plate’s proximal plane. If properly deployed, the SecureRing Hooks can also be seen capturing the top of the screw heads.
Screw Removal Option

The SecureRing Screw Locking Mechanism can be locked and unlocked up to three times without compromising strength. Use either the Rescue Driver or the Threaded Removal Driver to remove the plate’s screws.

**Step 8 Option 1**

**Hex Rescue Driver (If Necessary)**
Insert the driver tip into the screw head. Rest the driver’s handle in the palm while applying downward pressure and rotating the driver’s head in a 2-inch circle. This will release the SecureRing Hooks and allow the screw to be removed by maintaining downward pressure and rotating the driver counterclockwise.

**Step 8 Option 2**

**Threaded Driver (If Necessary)**
Secure the driver’s threaded post into the central, internal thread of the bone screws. The internal threads can be engaged by twisting the knob on top of the handle clockwise. Once the driver and the screw have been secured, twist the handle counterclockwise until the screw has been removed.
## ThinLine Kit Contents

### SC-AcuFix Core Instruments

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>450-2</td>
<td>2.5mm Modular Hex Driver</td>
<td>2</td>
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<tr>
<td>451-2</td>
<td>Plate Bender</td>
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<tr>
<td>452-2</td>
<td>Plate Holder With Rotating Handle</td>
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<tr>
<td>462-1</td>
<td>Modular Drill Guide Handle</td>
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<tr>
<td>474-1</td>
<td>Hex Rescue Driver Assembly</td>
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<td>479-1</td>
<td>Threaded Screw Removal Driver</td>
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<tr>
<td>481-1</td>
<td>Bone Compass</td>
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<tr>
<td>488-1</td>
<td>Plate Tamp</td>
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<tr>
<td>491-1</td>
<td>Multi-Angle Fixed Drill Guide</td>
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<tr>
<td>493-11</td>
<td>FA 2.5mm Hex Driver, Short</td>
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<td>497-1</td>
<td>SC-AcuFix Temp Fixation Pin Insrter</td>
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<td>561-2</td>
<td>D Cnct Finger Tip Handle AO Capture</td>
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<tr>
<td>1091-0003</td>
<td>Full Size Mod IIH 2&quot; Deep Insert</td>
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<td>490-14</td>
<td>Core Instrument Insert</td>
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<td>490-37</td>
<td>Small Instrument Block</td>
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<td>490-38</td>
<td>Small Instrument Block Lid</td>
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<td>AcuFix Drill &amp; Hex Driver Insert Plt</td>
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<td>490-40</td>
<td>Core Instrument Insert Tray Lid</td>
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### SC-AcuFix Core Consumables

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<tr>
<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
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<tbody>
<tr>
<td>453-31</td>
<td>2.5mm Reduced Length Long Drill</td>
<td>1</td>
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<td>457-1</td>
<td>Screw Hole Temporary Fixation Pin</td>
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<td>480-312</td>
<td>FA ShrtCmbo Stp 2.5mmDril/4mmTap 12</td>
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<tr>
<td>480-313</td>
<td>FA ShrtCmbo Stp 2.5mmDril/4mmTap 13</td>
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<td>480-314</td>
<td>FA ShrtCmbo Stp 2.5mmDril/4mmTap 14</td>
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<tr>
<td>482-312</td>
<td>ACP FA 2.5mm Dia Shrt Stp Dril,12mm</td>
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<td>482-313</td>
<td>ACP FA 2.5mm Dia Shrt Stp Dril,13mm</td>
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<td>482-314</td>
<td>ACP FA 2.5mm Dia Shrt Stp Dril,14mm</td>
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<tr>
<td>489-31</td>
<td>Rdcd Lgth Combo 2.5mm Drill/4mm Tap</td>
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## ThinLine Specific Instruments

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<th>Part Number</th>
<th>Description</th>
<th>Standard Kit Quantity</th>
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<tbody>
<tr>
<td>440-13</td>
<td>2.50mm Spring Punch, 13mm</td>
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<td>444-1</td>
<td>Plate Bender</td>
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<tr>
<td>446-60</td>
<td>FADG Caudal Version</td>
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<td>446-66</td>
<td>FADG Cephalad Version</td>
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<tr>
<td>473-12-FA</td>
<td>Restricted Angle Drill Tube, Mod 12</td>
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<tr>
<td>473-13-FA</td>
<td>Restricted Angle Drill Tube, Mod 13</td>
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<td>473-14-FA</td>
<td>Restricted Angle Drill Tube, Mod 14</td>
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<tr>
<td>1091-0001</td>
<td>Mod II 4” Deep Insert Case Base</td>
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<td>1091-0002</td>
<td>Full Size Modultainer II Case Lid</td>
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<td>1091-0004</td>
<td>Full Size Mod II Insert Tray Lid</td>
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<tr>
<td>1091-0005</td>
<td>Case Mat (1 pair)</td>
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<tr>
<td>490-12</td>
<td>System Tray II</td>
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## ThinLine Screws

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<tr>
<td>402-44012</td>
<td>Low Profile Primary Screw, 12mm</td>
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<tr>
<td>402-44013</td>
<td>Low Profile Primary Screw, 13mm</td>
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<td>402-44014</td>
<td>Low Profile Primary Screw, 14mm</td>
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<td>402-46012</td>
<td>Low Profile Rescue Screw, 12mm</td>
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<tr>
<td>402-46013</td>
<td>Low Profile Rescue Screw, 13mm</td>
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<td>402-46014</td>
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### ThinLine Self Drilling Screws

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<tr>
<td>402-46012</td>
<td>Low Profile Rescue Screw, 12mm</td>
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<tr>
<td>402-46013</td>
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<td>Low Profile Rescue Screw, 14mm</td>
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<td>402-48112</td>
<td>Low Prof Self Drill Screw 12</td>
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<td>402-48114</td>
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### ThinLine Spiked Plates

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## ThinLine Spikeless Plates

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Warnings

Following are specific warnings, precautions, and adverse effects, which should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects, which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. In the U.S.A., this product has labeling limitations.

2. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

3. Potential risks identified with the use of this device system, which may require additional surgery, include:
   a) Device component fracture.
   b) Loss of fixation.
   c) Non-union.
   d) Fracture of the vertebra.
   e) Neurological injury.
   f) Vascular or visceral injury.

Precautions

1. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of the metal implants should only be done with proper equipment. It is recommended that contouring be gradual and that great care be used to avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

2. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
3. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient’s ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and follow the post-operative care regimen as instructed by his or her physician.

4. DO NOT ALTER OR MODIFY ANY SC-AcuFix SYSTEM INSTRUMENT. Repairs should only be accomplished by the manufacturer. The SC-AcuFix System is only a temporary implant used for the correction and stabilization of the cervical spine. A successful result is not achieved in every surgical case. Bone grafting must be part of the spinal fusion procedure in which the SC-AcuFix System is used.

5. All implants and some instruments are intended for single use only; refer to the product label to determine if the instrument is single use only. Single use devices should not be re-used. Possible risks associated with re-use of single-use devices include:
   • Mechanical malfunction
   • Transmission of infectious agents

Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur. These complications may include but not be limited to:

1. Device corrosion with localized tissue reaction and pain.
2. Device migration which may result in injury to soft tissue, visceral organs or joints.
3. Loosening or disassembly of implant resulting in additional injury.
4. Bending, loosening or breaking of the implant making removal difficult, impractical or impossible.
5. Abnormal sensations, discomfort or pain.
6. Increased risk of infection.
7. Bone loss due to stress shielding.

Preoperative and operating procedures including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the SC-AcuFix System by the surgeon.

Proper patient selection and the patient’s ability to comply with physician instructions and follow prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations. If a surgical candidate exhibits any contraindication or is predisposed to any contraindication, DO NOT USE the SC-AcuFix System.

Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Patients with poor bone quality are also poor candidates for surgery.
Disclaimer:
This documentation is intended exclusively for physicians and is not intended for laypersons.
Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.
Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.