

SlimLine[®]

Anterior Cervical Plate



Surgical Technique



Efficient Design. Proven Results. From the people of Zimmer Spine.

SlimLine is backed by an established history of thousands of successful patient results. This device offers surgeons a proven choice for efficient procedures and strong results. *SlimLine* has a narrow waist with variable-angle screw holes deliver a 15° conical range of motion for greater flexibility in screw placement.

Available in one to four levels, as well as a hybrid option, *SlimLine* provides surgeons a proven solution for your practice and your patients. From the people of Zimmer Spine.

Table of Contents

Indications/Contraindications	1
SC-AcuFix® Implants	3
<i>SC-AcuFix</i> Instruments	5
<i>SlimLine</i> Instruments	8
Surgical Technique	9
Kit Contents	20
Warnings and Precautions	26

Indications/Contraindications

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 proximate 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 which 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.

SlimLine Implants



One-Level Plate (20 - 34mm)

403-1120 to 403-1034

One-Level Spiked Plate (20 - 34mm)

403-1020 to 403-1034



One-Level Hybrid Plate (20 - 34mm)

10403-1120 to 11403-1134

One-Level Spiked Hybrid Plate (20 - 34mm)

10403-1020 to 10403-1034



Two-Level Plate (34 - 54mm)

403-2134 to 403-2154

Two-Level Spiked Plate (34 - 54mm)

403-2034 to 403-2054



Two-Level Hybrid Plate (34 - 54mm)

10403-2134 to 10403-2154

Two-Level Spiked Hybrid Plate (35 - 54mm)

10403-2034 to 10403-2054



Three-Level Plate (47 - 71mm)

403-3147 to 403-3171

Three-Level Spiked Plate (47 - 71mm)

403-3047 to 403-3071



Three-Level Hybrid Plate (47 - 71mm)

10403-3147 to 10403-3171

Three-Level Hybrid Spiked Plate (47 - 71mm)

10403-3047 to 10403-3071



Four-Level Plate (68 - 92mm)

403-4168 to 403-4192

Four-Level Spiked Plate (68 - 92mm)

403-4068 to 403-4092



Four-Level Hybrid Plate (68 - 92mm)

10403-4168 to 10403-4192

Four-Level Hybrid Spiked Plate (68 - 92mm)

10403-4068 to 10403-4092



Self-Tapping Wide Root Screw 4.0mm (12 - 15mm)

402-43112 to 402-43115



Rescue Screw 4.5mm (12 - 15mm)

402-45112 to 402-45115



Self-Drilling Wide Root Screw 4.0mm (12 - 15mm)

402-47112 to 402-47115

SC-AcuFix Instruments



Temporary Fixation Pins

457-1

Provides additional plate stability before screw insertion.



Temporary Fixation Pin Inserter

497-1

Places Temporary Fixation Pins.



Modular Drill Guide Handle

462-1

Secures to the Freehand Fixed Depth Drill Guides.



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.**



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.



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.**



Fixed Angle 2.5mm Hex Driver

493-11

Implants *SC-AcuFix* screws. When used with the Fixed Angled Drill Guide, it automatically disengages the implanted screw head 1 - 1.5mm proud of the *SecureRing* Screw Retention Mechanism, enabling easy removal and redirection of the screw, if necessary.



Rescue Driver

474-1

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



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.



Plate Bender

451-2

Used to increase the existing machined lordotic curve in the plate, if necessary (two to four level plates only).



Bone Compass

481-1

Used to measure the appropriate length to span the disc space.



Plate Holder

452-2

Used with the rotating handle to place the plate onto prepared surfaces. Attaches to the keyhole of the plate.



Plate Tamp

488-1

Used to set the posterior fixation spikes into the prepared surface.

SlimLine Instruments



2.0mm Cortical Spring Punch, 13mm

447-13

Punches holes for the screws; spares more bone than traditional tap.



Short Freehand Fixed Depth Drill Guide (12-14mm)

458-12 to 458-14

Used with the 2.5mm Reduced Length Long Drill and Mini AO Fitting Handle to freehand drill for the 12mm, 13mm and 14mm screws.



Fixed Angle Drill Guide 6°/6°

485-1

Fixed Angle Drill Guide 6°/0°

469-1

Features single cannula for drilling and screw placement. Provides consistent screw angulation and screw to-plate trajectory. Predetermined 6° medial, 0° cephalad/caudal bias and 6° medial/6° cephalad/caudal bias options guarantees placement within (ROM).



Single Barrel Fixed Angle Drill Guide SlimLine 6°/6° Left / Right

496-1, 496-2

Features 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.

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 bending is necessary, use the Plate Bender. Do not bend at screw holes. Bending should be performed in small increments.

Note: Reverse bending should not be performed. DO NOT bend plate sizes 20mm-26mm.

Step 3



Plate Positioning

Attach the Plate Holder to your chosen plate. Press down on the end of the Plate Holder while inserting its tip into the plate's keyhole. Release thumb pressure and place the plate into the wound. If using a spiked plate, utilize the Plate Tamp to set the spikes.

Position the caudal and cephalad screw holes 3.0 - 3.5mm from the edge of the vertebral body, or as close as possible to the graft site without compromising the vertebral endplate.

Step 4



Temporary Fixation

Pull back on the center ring of the Temporary Fixation Pin Inserter to hold the long shaft of the Temporary Fixation Pin. Position the pin's tip in the center of any screw hole and at the same angle planned for the screw (ROM for screws is 15° and 0° for caudal end of Hybrid and four level *SlimLine* plates). Take care to maintain plate alignment and position.

Turn pin clockwise until seated in the screw hole; remove Temporary Fixation Pin Holder from the driver by pulling up on its outer sleeve.

Note: Use of Temporary Fixation Pins may affect the fixation of the screws. Be sure to remove the Fixation Pin prior to inserting screw and prior to closing the incision site.

Screw Placement - Fixed Angle Drill Option

Step 5 Option 1a



Prepare Drill Guide

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

The Fixed Angle Drill Guides provide consistent screw angulations and predictable screw to plate trajectory through use of a singular cannula for both drilling and screw placement.

The Fixed Angle Drill Guide fits directly into the keyhole on the end of each *SlimLine* plate (except for the 20mm, 22mm, 24mm and 26mm length single-level plate).

Note: Use the *Multi-Angle Drill Guide* for the intermediate holes of longer segment plates when using the *Fixed Angle Drill Guides*.

Step 5 Option 1b



Screw Preparation

Assemble the appropriate length Fixed Angle 2.5mm Stop Drill/Modular AO Handle.

Insert assembly into previously seated guide. Rotate clockwise, advancing into the bone until its hard stop makes contact with the top of the guide.

If using the Combo 2.5mm Drill/4.0mm Tap, observe the stop collar and stop rotation such that the drill/tap stops just short of seating on the top of the guide (to mitigate stripping). Instrument will not come to a hard stop.

Note: Use of power tapping is strongly discouraged with this tap.

Step 5 Option 1c**Screw Preparation**

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

Step 5 Option 1d**Prepare Driver**

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

Select a screw length consistent with your drill size. Secure the screw to the driver and insert into the Drill Guide cannula.

Note: Use of the Multi-Angle Drill Guide and Modular Hex Driver is strongly discouraged. Use may increase the risk of screw misalignment and/or alignment outside the ROM.

Step 5 Option 1e**Screw Placement**

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*.

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

Proceed to Final Tightening.

Screw Placement - Multi-Angle Fixed Drill Guide Option

Step 5 Option 2a



Prepare Drill Guide

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

Assemble the appropriate length Fixed Angle 2.5mm Stop Drill/Modular AO Handle.

Prior to drilling, set the tip of the modular tube assembly inside the *SecureRing* swivel. Ensure that the Drill Guide is placed perpendicular to the screw hole, then angle it to the desired location, taking care not to exceed (15°) ROM. For hybrid plates, recall that the caudal magenta swivel is constrained and has a 6°/0° bias.

Note: Use of the Multi-Angle Drill Guide in the caudal holes with hybrid plates is strongly discouraged. Use may increase risk of screw misalignment outside the ROM.

Step 5 Option 2b



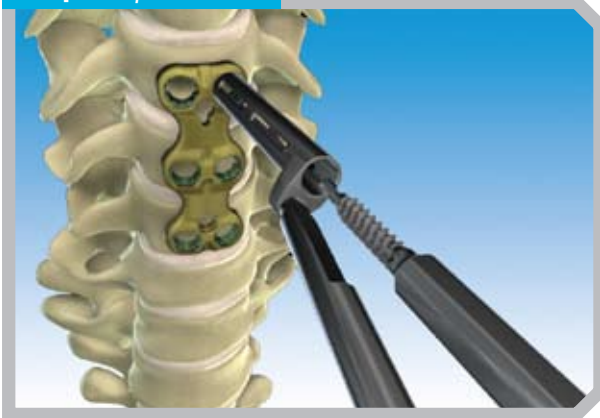
Screw Preparation

Assemble the Reduced Length 2.5mm Long Drill/Modular AO Handle.

Place the drill down by the previously oriented Multi-Angle Drill Guide assembly and rotate clockwise, advancing the drill into the bone until its hard stop makes contact with the back of the guide. To remove from the bone, turn it counterclockwise while pulling up.

If you prefer tapping, use the Fixed Angle Combo 2.5mm Drill/4.0mm Tap and observe the distance of the stop collar on the instrument and Drill Guide. Stop just short of setting the combo to mitigate stripping; it will not come to a hard stop.

Note: Power tapping is not recommended for use with this tap.

Step 5 Option 2c**Drill/Tap Removal**

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

Step 5 Option 2d**Prepare Driver**

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

Select a screw length consistent with the drill size. Secure the screw to the driver and insert a bone screw into the Drill Guide cannula.

Ensure that the Drill Guide is placed perpendicular to the screw hole, then angled to the desired location, taking care not to exceed (15°) ROM. For hybrid plates, recall that the caudal magenta swivel is constrained and has a 6°/0° bias.

Note: Use of the Multi-Angle Drill Guide in the caudal holes with hybrid plates is strongly discouraged. Use may increase risk of screw misalignment outside the ROM.

Step 5 Option 2e**Screw Placement**

Tighten 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 top of screw head 1 - 1.5mm proud of the *SecureRing*.

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

Proceed to Final Tightening.

Screw Placement - Freehand Fixed Depth Drill Option

Step 5 Option 3a



Prepare Drill Guide

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

Assemble the Reduced Length 2.5mm Drill, Mini AO Handle and appropriately sized Freehand Fixed Depth Drill Guides/Modular System Handle.

Prior to drilling, set the tip of the Drill Guide inside the *SecureRing* swivel. Ensure that the Drill Guide is placed perpendicular to the screw hole; then angle it to the desired location, taking care not to exceed (15°) ROM.

Step 5 Option 3b**Screw Preparation**

Place the drill down by the previously oriented Freehand Drill Guide assembly and rotate clockwise, advancing the drill into bone until its hard stop makes contact with the back of the guide. To remove from bone, turn counterclockwise while pulling up.

If you prefer tapping, use the Reduced Length Combo 2.5mm Drill/4.0mm Tap and observe the distance of the stop collar on instrument and Drill Guide. Stop just short of setting the combo to mitigate stripping; it will not come to a hard stop.

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

Note: *Power tapping is not recommended for use with this tap.*

Step 5 Option 3c**Screw Placement**

Assemble the Modular 2.5mm Hex Driver/Modular AO Handle.

Select a screw length consistent with the length of the Free Hand Fixed Depth Drill Guide. Secure the screw to the driver and insert it into the plate until screw is 1-2mm proud of the *SecureRing*. Angle the screw toward the desired location, taking care not to exceed 15° ROM. For hybrid plates recall that the caudal magenta *SecureRing* is constrained with a 6°/0° bias.

To prevent 'twisting' during screw insertion, insert a second screw contralateral to the first.

Proceed to Final Tightening.

Screw Placement - Cortical Spring Punch Option

Step 5 Option 4a



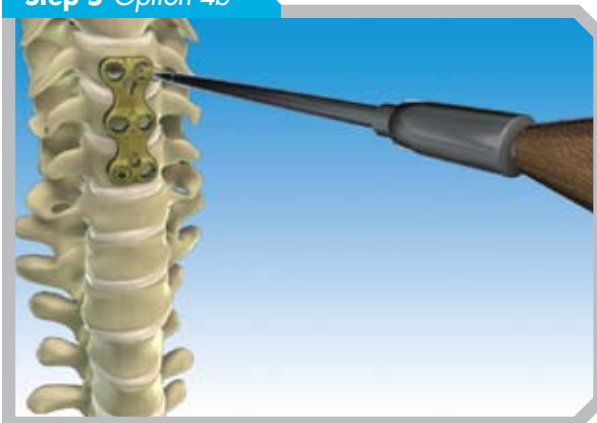
Screw Preparation

Screws should be placed in as many screw holes as possible. At a minimum, screws should be placed in all four cephalad/caudal holes.

Seat the Cortical Punch's tip inside the *SecureRing* mechanism. Position the punch perpendicular to the screw hole. Take care not to exceed 15° ROM. With hand pressure or a mallet, apply a downward force to the handle, causing the trocar tip to extend from the punch's distal end. You may twist or turn the trocar tip to penetrate the hard cortical bone prior to impacting the punch into the inner cancellous bone.

Note: *The punch can be placed through the Fixed Angle Drill Guide and the Multi-Angle Drill Guide.*

Step 5 Option 4b



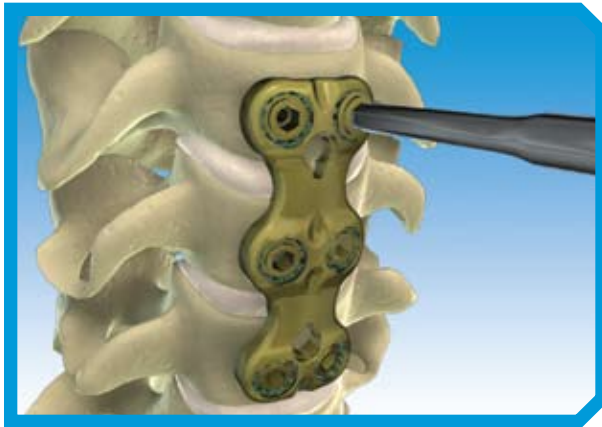
Screw Placement

Assemble the Modular 2.5mm Hex/Modular AO Handle. Select a screw length consistent with the depth of the punch. Secure the screw to the driver and insert it into the plate until head is 1-2mm proud of the *SecureRing*. To prevent 'twisting' during screw insertion, insert a second screw contralateral to the first.

Proceed to Final Tightening.

Final Tightening

Step 6

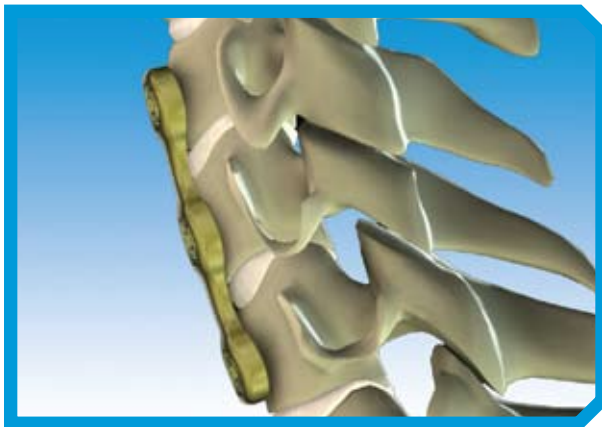


Securing the Plate

Assemble the 2.5mm Modular Hex Driver/Modular AO Handle.

Tighten all screws finger-tight and position the plate flush to the anterior cortex of the cervical spine; screws should be locked in the *SecureRing* mechanism, flush or below the proximal surface of the plate.

Step 7



SecureRing Verification

Proper *SecureRing* 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



Rescue Driver (If Necessary)

Insert the driver's tip into the screw. Rest the driver's handle in your palm while applying downward pressure; rotate the driver's head in a 2-inch circle, ensuring that its head stays seated within the screw. Remove the screw, maintaining downward pressure.

Step 8 Option 2



Threaded Driver (If Necessary)

Secure the driver's threaded post into the central internal thread of the bone screws. Tighten 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.

SlimLine Kit Contents

Module Number 400-0005-PL

SC-AcuFix Core Instruments

Part Number	Description	Standard Kit Quantity
450-2	2.5mm Modular Hex Driver	2
451-2	Plate Bender	1
452-2	Plate Holder With Rotating Handle	1
453-31	2.5mm Reduced Length Long Drill	1
457-1	Screw Hole Temporary Fixation Pin	3
462-1	Modular Drill Guide Handle	2
474-1	Hex Rescue Driver Assembly	1
479-1	Threaded Screw Removal Driver	1
480-312	FA ShrtCmbo Stp 2.5mmDril/4mmTap 12	1
480-313	FA ShrtCmbo Stp 2.5mmDril/4mmTap 13	1
480-314	FA ShrtCmbo Stp 2.5mmDril/4mmTap 14	1
481-1	Bone Compass	1
482-312	ACP FA 2.5mm Dia Shrt Stp Dril,12mm	1
482-313	ACP FA 2.5mm Dia Shrt Stp Dril,13mm	1
482-314	ACP FA 2.5mm Dia Shrt Stp Dril,14mm	1
488-1	Plate Tamp	1
489-31	Rdcd Lgth Combo 2.5mm Drill/4mm Tap	1
491-1	Multi-Angle Fixed Drill Guide	1
493-11	FA 2.5mm Hex Driver, Short	1
497-1	SC-AcuFix Temp Fixation Pin Insrter	1
561-2	D Cnct Finger Tip Handle AO Capture	2

Module Number 430-0022-PL

SlimLine Specific Instruments

Part Number	Description	Standard Kit Quantity
447-13	2.0mm Spring Punch - 13mm	1
458-12	Shrt Frhnd Fxd Depth Drill Guide 12	1
458-13	Shrt Frhnd Fxd Depth Drill Guide 13	1
458-14	Shrt Frhnd Fxd Depth Drill Guide 14	1
469-1	Fixed Angle Drill Guide, 6°/0°	1
485-1	Fixed Angle Drill Guide 6°/6°	1
496-1	Sngl Brl FA Drill Gde, Slim 6/6 Left	1
496-2	Sngl Brl FA Drill Gde, Slim 6/6 Rite	1

Module Number 430-0014-PL

SlimLine Top Level Module Screws

Part Number	Description	Standard Kit Quantity
402-43112	Self Tap 4mm WideRt Scrw IntThrd 12	10
402-43113	Self Tap 4mm WideRt Scrw IntThrd 13	10
402-43114	Self Tap 4mm WideRt Scrw IntThrd 14	10
402-43115	Self Tap 4mm WideRt Scrw IntThrd 15	6
402-45112	4.5mm Rescue Screw Int Thread 12mm	6
402-45113	4.5mm Rescue Screw Int Thread 13mm	6
402-45114	4.5mm Rescue Screw Int Thread 14mm	6
402-45115	4.5mm Rescue Screw Int Thread 15mm	6

Module Number 430-0021-PL

SlimLine Spiked Plates

Part Number	Description	Standard Kit Quantity
10403-4068	ACP 4 Lvl Spiked Hybrid Plate 68mm	1
10403-4072	ACP 4 Lvl Spiked Hybrid Plate 72mm	1
10403-4076	ACP 4 Lvl Spiked Hybrid Plate 76mm	1
10403-4080	ACP 4 Lvl Spiked Hybrid Plate 80mm	1
10403-4084	ACP 4 Lvl Spiked Hybrid Plate 84mm	1
10403-4088	ACP 4 Lvl Spiked Hybrid Plate 88mm	1
10403-4092	ACP 4 Lvl Spiked Hybrid Plate 92mm	1
403-1020	ACP 1 Lvl Spiked Plate 20mm	1
403-1022	ACP 1 Lvl Spiked Plate 22mm	1
403-1024	ACP 1 Lvl Spiked Plate 24mm	2
403-1026	ACP 1 Lvl Spiked Plate 26mm	2
403-1028	ACP 1 Lvl Spiked Plate 28mm	2
403-1030	ACP 1 Lvl Spiked Plate 30mm	1
403-1032	ACP 1 Lvl Spiked Plate 32mm	1
403-1034	ACP 1 Lvl Spiked Plate 34mm	1
403-2034	ACP 2 Lvl Spiked Plate 34mm	1
403-2036	ACP 2 Lvl Spiked Plate 36mm	1
403-2038	ACP 2 Lvl Spiked Plate 38mm	1
403-2040	ACP 2 Lvl Spiked Plate 40mm	2
403-2042	ACP 2 Lvl Spiked Plate 42mm	2
403-2044	ACP 2 Lvl Spiked Plate 44mm	2
403-2046	ACP 2 Lvl Spiked Plate 46mm	1
403-2048	ACP 2 Lvl Spiked Plate 48mm	1
403-2050	ACP 2 Lvl Spiked Plate 50mm	1
403-2052	ACP 2 Lvl Spiked Plate 52mm	1
403-2054	ACP 2 Lvl Spiked Plate 54mm	1
403-3047	ACP 3 Lvl Spiked Plate 47mm	1
403-3050	ACP 3 Lvl Spiked Plate 50mm	1
403-3053	ACP 3 Lvl Spiked Plate 53mm	1
403-3056	ACP 3 Lvl Spiked Plate 56mm	1
403-3059	ACP 3 Lvl Spiked Plate 59mm	1
403-3062	ACP 3 Lvl Spiked Plate 62mm	1
403-3065	ACP 3 Lvl Spiked Plate 65mm	1
403-3068	ACP 3 Lvl Spiked Plate 68mm	1
403-3071	ACP 3 Lvl Spiked Plate 71mm	1

Module Number 430-0019-PL

SlimLine Spikeless Plates

Part Number	Description	Standard Kit Quantity
10403-4168	ACP 4 Lvl Spkless Hybrid Plate 68mm	1
10403-4172	ACP 4 Lvl Spkless Hybrid Plate 72mm	1
10403-4176	ACP 4 Lvl Spkless Hybrid Plate 76mm	1
10403-4180	ACP 4 Lvl Spkless Hybrid Plate 80mm	1
10403-4184	ACP 4 Lvl Spkless Hybrid Plate 84mm	1
10403-4188	ACP 4 Lvl Spkless Hybrid Plate 88mm	1
10403-4192	ACP 4 Lvl Spkless Hybrid Plate 92mm	1
403-1120	ACP 1 Lvl Spikeless Plate 20mm	1
403-1122	ACP 1 Lvl Spikeless Plate 22mm	1
403-1124	ACP 1 Lvl Spikeless Plate 24mm	2
403-1126	ACP 1 Lvl Spikeless Plate 26mm	2
403-1128	ACP 1 Lvl Spikeless Plate 28mm	2
403-1130	ACP 1 Lvl Spikeless Plate 30mm	1
403-1132	ACP 1 Lvl Spikeless Plate 32mm	1
403-1134	ACP 1 Lvl Spikeless Plate 34mm	1
403-2134	ACP 2 Lvl Spikeless Plate 34mm	1
403-2136	ACP 2 Lvl Spikeless Plate 36mm	1
403-2138	ACP 2 Lvl Spikeless Plate 38mm	1
403-2140	ACP 2 Lvl Spikeless Plate 40mm	2
403-2142	ACP 2 Lvl Spikeless Plate 42mm	2
403-2144	ACP 2 Lvl Spikeless Plate 44mm	2
403-2146	ACP 2 Lvl Spikeless Plate 46mm	1
403-2148	ACP 2 Lvl Spikeless Plate 48mm	1
403-2150	ACP 2 Lvl Spikeless Plate 50mm	1
403-2152	ACP 2 Lvl Spikeless Plate 52mm	1
403-2154	ACP 2 Lvl Spikeless Plate 54mm	1
403-3147	ACP 3 Lvl Spikeless Plate 47mm	1
403-3150	ACP 3 Lvl Spikeless Plate 50mm	1
403-3153	ACP 3 Lvl Spikeless Plate 53mm	1
403-3156	ACP 3 Lvl Spikeless Plate 56mm	1
403-3159	ACP 3 Lvl Spikeless Plate 59mm	1
403-3162	ACP 3 Lvl Spikeless Plate 62mm	1
403-3165	ACP 3 Lvl Spikeless Plate 65mm	1
403-3168	ACP 3 Lvl Spikeless Plate 68mm	1
403-3171	ACP 3 Lvl Spikeless Plate 71mm	1

Module Number 430-0018-PL

SlimLine Hybrid Spiked Plates

Part Number	Description	Standard Kit Quantity
10403-1020	ACP 1 Lvl Spiked Hybrid Plate 20mm	1
10403-1022	ACP 1 Lvl Spiked Hybrid Plate 22mm	1
10403-1024	ACP 1 Lvl Spiked Hybrid Plate 24mm	2
10403-1026	ACP 1 Lvl Spiked Hybrid Plate 26mm	2
10403-1028	ACP 1 Lvl Spiked Hybrid Plate 28mm	2
10403-1030	ACP 1 Lvl Spiked Hybrid Plate 30mm	1
10403-1032	ACP 1 Lvl Spiked Hybrid Plate 32mm	1
10403-1034	ACP 1 Lvl Spiked Hybrid Plate 34mm	1
10403-2034	ACP 2 Lvl Spiked Hybrid Plate 34mm	1
10403-2036	ACP 2 Lvl Spiked Hybrid Plate 36mm	1
10403-2038	ACP 2 Lvl Spiked Hybrid Plate 38mm	1
10403-2040	ACP 2 Lvl Spiked Hybrid Plate 40mm	2
10403-2042	ACP 2 Lvl Spiked Hybrid Plate 42mm	2
10403-2044	ACP 2 Lvl Spiked Hybrid Plate 44mm	2
10403-2046	ACP 2 Lvl Spiked Hybrid Plate 46mm	1
10403-2048	ACP 2 Lvl Spiked Hybrid Plate 48mm	1
10403-2050	ACP 2 Lvl Spiked Hybrid Plate 50mm	1
10403-2052	ACP 2 Lvl Spiked Hybrid Plate 52mm	1
10403-2054	ACP 2 Lvl Spiked Hybrid Plate 54mm	1
10403-3047	ACP 3 Lvl Spiked Hybrid Plate 47mm	1
10403-3050	ACP 3 Lvl Spiked Hybrid Plate 50mm	1
10403-3053	ACP 3 Lvl Spiked Hybrid Plate 53mm	1
10403-3056	ACP 3 Lvl Spiked Hybrid Plate 56mm	1
10403-3059	ACP 3 Lvl Spiked Hybrid Plate 59mm	1
10403-3062	ACP 3 Lvl Spiked Hybrid Plate 62mm	1
10403-3065	ACP 3 Lvl Spiked Hybrid Plate 65mm	1
10403-3068	ACP 3 Lvl Spiked Hybrid Plate 68mm	1
10403-3071	ACP 3 Lvl Spiked Hybrid Plate 71mm	1
10403-4068	ACP 4 Lvl Spiked Hybrid Plate 68mm	1
10403-4072	ACP 4 Lvl Spiked Hybrid Plate 72mm	1
10403-4076	ACP 4 Lvl Spiked Hybrid Plate 76mm	1
10403-4080	ACP 4 Lvl Spiked Hybrid Plate 80mm	1
10403-4084	ACP 4 Lvl Spiked Hybrid Plate 84mm	1
10403-4088	ACP 4 Lvl Spiked Hybrid Plate 88mm	1
10403-4092	ACP 4 Lvl Spiked Hybrid Plate 92mm	1

Module Number 430-0015-PL

SlimLine Hybrid Spikeless Plates

Part Number	Description	Standard Kit Quantity
10403-1120	ACP 1 Lvl Spkless Hybrid Plate 20mm	1
10403-1122	ACP 1 Lvl Spkless Hybrid Plate 22mm	1
10403-1124	ACP 1 Lvl Spkless Hybrid Plate 24mm	2
10403-1126	ACP 1 Lvl Spkless Hybrid Plate 26mm	2
10403-1128	ACP 1 Lvl Spkless Hybrid Plate 28mm	2
10403-1130	ACP 1 Lvl Spkless Hybrid Plate 30mm	1
10403-1132	ACP 1 Lvl Spkless Hybrid Plate 32mm	1
10403-1134	ACP 1 Lvl Spkless Hybrid Plate 34mm	1
10403-2134	ACP 2 Lvl Spkless Hybrid Plate 34mm	1
10403-2136	ACP 2 Lvl Spkless Hybrid Plate 36mm	1
10403-2138	ACP 2 Lvl Spkless Hybrid Plate 38mm	1
10403-2140	ACP 2 Lvl Spkless Hybrid Plate 40mm	2
10403-2142	ACP 2 Lvl Spkless Hybrid Plate 42mm	2
10403-2144	ACP 2 Lvl Spkless Hybrid Plate 44mm	2
10403-2146	ACP 2 Lvl Spkless Hybrid Plate 46mm	1
10403-2148	ACP 2 Lvl Spkless Hybrid Plate 48mm	1
10403-2150	ACP 2 Lvl Spkless Hybrid Plate 50mm	1
10403-2152	ACP 2 Lvl Spkless Hybrid Plate 52mm	1
10403-2154	ACP 2 Lvl Spkless Hybrid Plate 54mm	1
10403-3147	ACP 3 Lvl Spkless Hybrid Plate 47mm	1
10403-3150	ACP 3 Lvl Spkless Hybrid Plate 50mm	1
10403-3153	ACP 3 Lvl Spkless Hybrid Plate 53mm	1
10403-3156	ACP 3 Lvl Spkless Hybrid Plate 56mm	1
10403-3159	ACP 3 Lvl Spkless Hybrid Plate 59mm	1
10403-3162	ACP 3 Lvl Spkless Hybrid Plate 62mm	1
10403-3165	ACP 3 Lvl Spkless Hybrid Plate 65mm	1
10403-3168	ACP 3 Lvl Spkless Hybrid Plate 68mm	1
10403-3171	ACP 3 Lvl Spkless Hybrid Plate 71mm	1
10403-4168	ACP 4 Lvl Spkless Hybrid Plate 68mm	1
10403-4172	ACP 4 Lvl Spkless Hybrid Plate 72mm	1
10403-4176	ACP 4 Lvl Spkless Hybrid Plate 76mm	1
10403-4180	ACP 4 Lvl Spkless Hybrid Plate 80mm	1
10403-4184	ACP 4 Lvl Spkless Hybrid Plate 84mm	1
10403-4188	ACP 4 Lvl Spkless Hybrid Plate 88mm	1
10403-4192	ACP 4 Lvl Spkless Hybrid Plate 92mm	1

Warnings and Precautions

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.

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.



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