stryker®

Spine

Reflex® Hybrid
Surgical Technique

Anterior Cervical Plating System

Table of Contents

Introduction

Anterior cervical discectomy and fusion remains one of the most successful surgical procedures, and the application of a plate to provide temporary postoperative stability has gained widespread acceptance as the "gold standard" of care. Anterior cervical plating systems continue to evolve and incorporate contemporary biomechanical understanding of the demands placed on these devices.

Currently available anterior cervical instrumentation includes constrained systems, in which the screws are rigidly locked to the plate, and semi-constrained systems, which allow motion of the screws with respect to the plate. Combining these two fixation philosophies allows the surgeon to use the most applicable technique when treating a variety of traumatic and non-traumatic cervical spine pathologies.

The Reflex Hybrid Anterior Cervical Plate system offers optimized versatility along with an easy, reproducible implantation technique. By accommodating both constrained and semi-constrained constructs, the system offers solutions for a wide variety of anterior cervical cases.

Acknowledgments

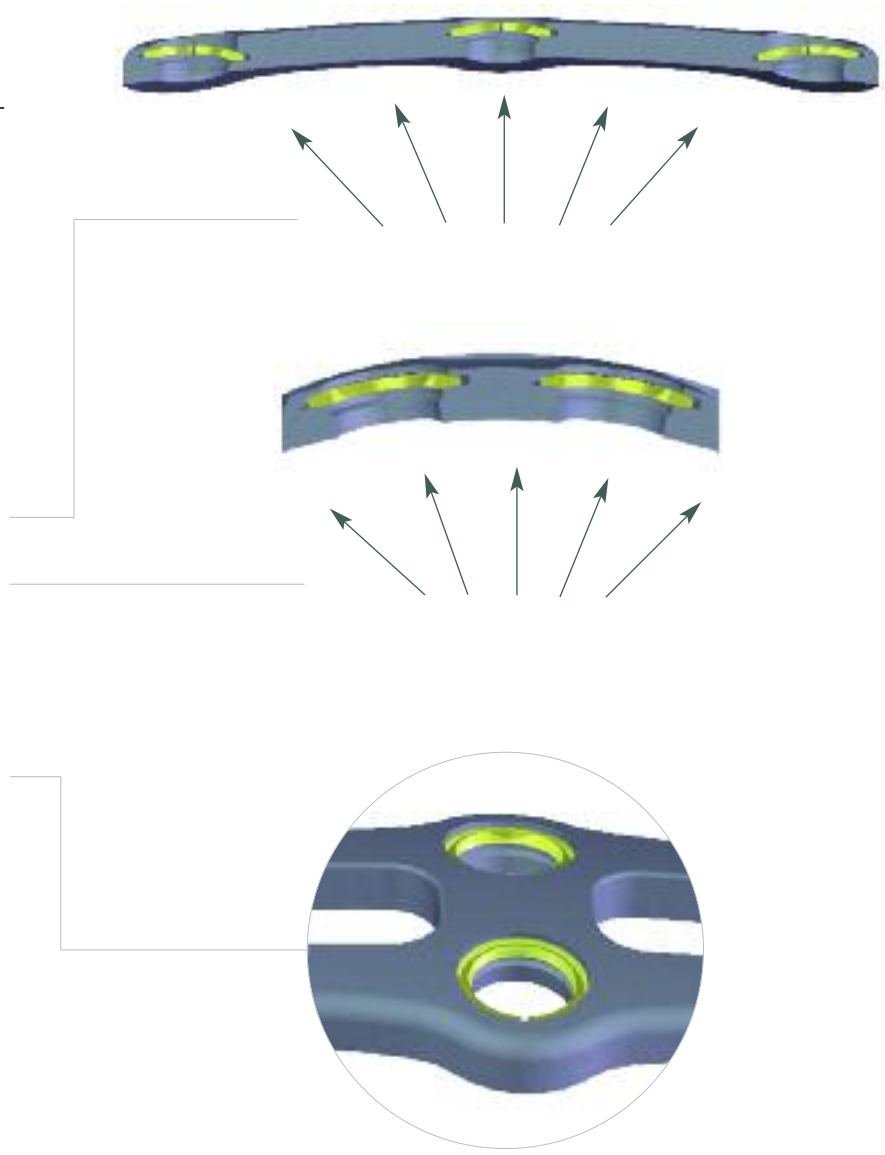
Stryker Spine would like to thank **Edward J. Goldberg, MD**, Chicago, IL, and **Rick Delamarter, MD**, Santa Monica, CA, for their contribution.

System Overview

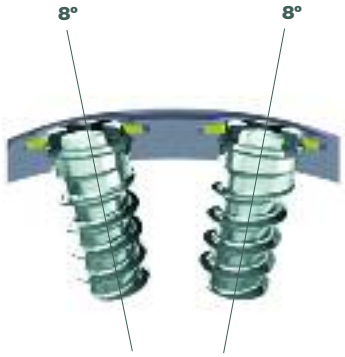
The Reflex Hybrid ACP System offers a low-profile anterior cervical plate along with a selection of bone screw types to allow for a wide variety of constructs. Depending on the component combination, the system can accommodate both semi-constrained and rigid bone screw fixation philosophies. Instrument options further enhance surgical technique versatility by matching surgeon preference regarding approach and screw pathway preparation.

The Reflex Hybrid plate, made from a Ti-6Al-4V alloy, is **2.1mm thick** to help reduce soft tissue irritation and may provide a suitable option for small stature patients. The **radius of curvature is 160mm in the sagittal plane** and **30mm in the axial plane** for optimal matching of the patient's anatomy. The large graft-viewing windows allow for visualization of the endplates to aid in graft positioning.

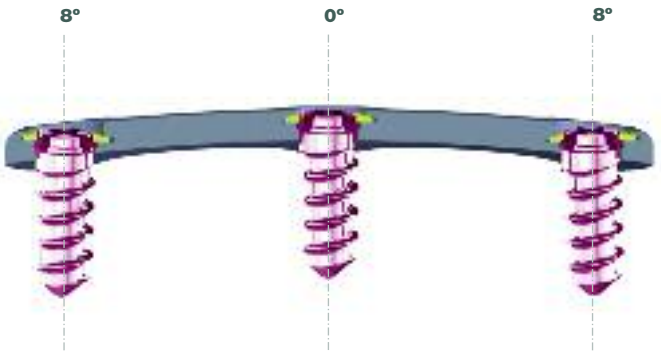
The **one-step locking ring** of the Reflex Hybrid system, which is integrated into every screw hole, is designed to expand upon screw insertion and then contract over the head to hold each screw securely in place. The screw hole geometry accommodates both fixed and variable angle screws at any plate level.



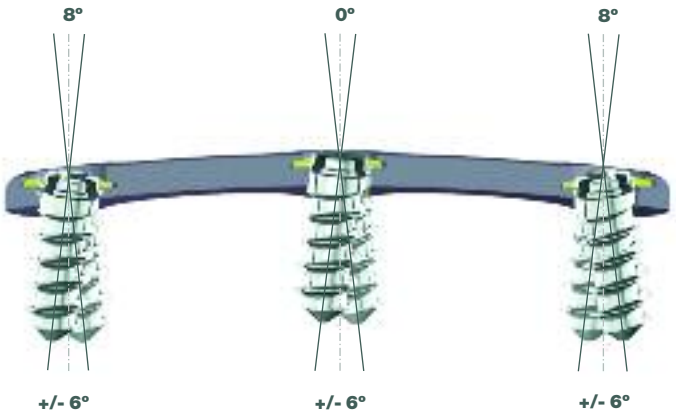
The neutral axis of the end-hole bone screws is defined as 8° cephalad or 8° caudal from perpendicular to the plate in the sagittal plane as well as **8° of medial convergence in the axial plane**. All types of screws have the same degree of medial convergence.



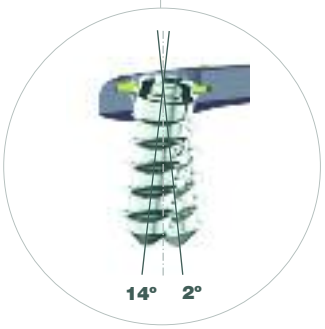
Fixed angle bone screws, which are used if a rigid construct is desired, are inserted into the plate in the neutral position as described above, and they remain in this position under loading. Fixed bone screws in the middle holes are inserted perpendicularly to the plate (at 0 degrees angulation).



Variable angle bone screws, which allow +/- 6 degrees of movement from the neutral axis in all directions, follow the philosophy of load sharing through the bone graft as a prerequisite for a successful fusion. In the sagittal plane, the end-hole variable angle screws can move +/- 6° from the neutral axis, **resulting in an actual range of angulation of 2 up to 14 degrees from perpendicular to the plate.** Middle-hole screws also allow for +/- 6 degrees of angulation.



If desired, both types of bone screws can be combined into a hybrid construct, which includes fixed angle bone screws at one level and variable angle bone screws at the remaining levels.

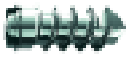


Both fixed and variable screws are offered as **self-tapping**, which feature a cutting flute and a less aggressive screw tip, and **self-drilling**, which have been designed with a sharp tip for insertion without prior drilling.

Self-tapping screw

Self-drilling screw

The individual screw families have been **color coded** for easy identification:

Screw Type	Variable Angle	Fixed Angle
4.0mm Self-Tapping		
4.0mm Self-Drilling		
4.5mm Self-Tapping		

The Reflex Hybrid plates and screws represent a complete system, which is separate and **not interchangeable with the original Reflex ACP system implants.**

Refer to the indications and limitations of the Reflex Hybrid ACP system provided in the back of this brochure and to the Packaging Insert/Instructions for Use.

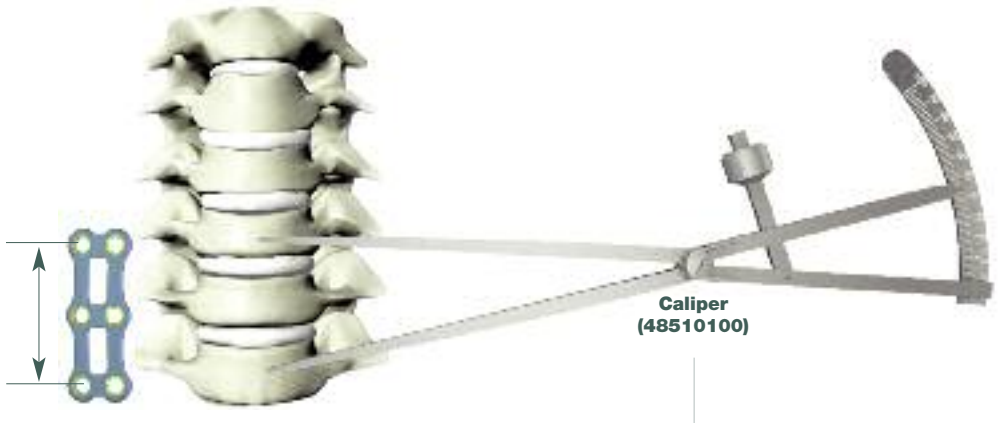
Patient Positioning and Exposure

Patient is placed in a supine position with the head turned slightly away from the side of the approach. For one- or two-level procedures, a transverse incision parallel to the skin creases of the neck is recommended. Longer level procedures usually require an oblique incision placed along the anterior border of the sternocleidomastoid. The left side is preferred, as the more constant course of the recurrent laryngeal nerve on this side potentially minimizes the risk of its injury. After blunt dissection through the various tissue layers, the anterior cervical spine is gently exposed.

The implantation of the anterior cervical plate follows a discectomy or a corpectomy, including an appropriate interbody/bone graft insertion.

Implant Selection and Preparation

The **sizing of the Reflex Hybrid plates** is measured from the center of the cephalad hole to the center of the caudal hole. Using the **caliper**, measure the distance between the center points of the appropriate vertebrae and select the corresponding plate. For cases in which the measured distance falls between two sizes, it is usually recommended that the smaller size be used, because a plate that is too long may interfere with the disc space above or below the implanted construct. Regardless of the plate size selected, the screws must be inserted with the correct amount of screw angulation. A **universal plate holder** is available to hold the plate next to the vertebral column to confirm size selection.



The Reflex Hybrid plate has been designed with a slight sagittal and axial bend for optimal matching of a patient's anatomy. If additional plate contouring is necessary, use the **plate bender** as follows:

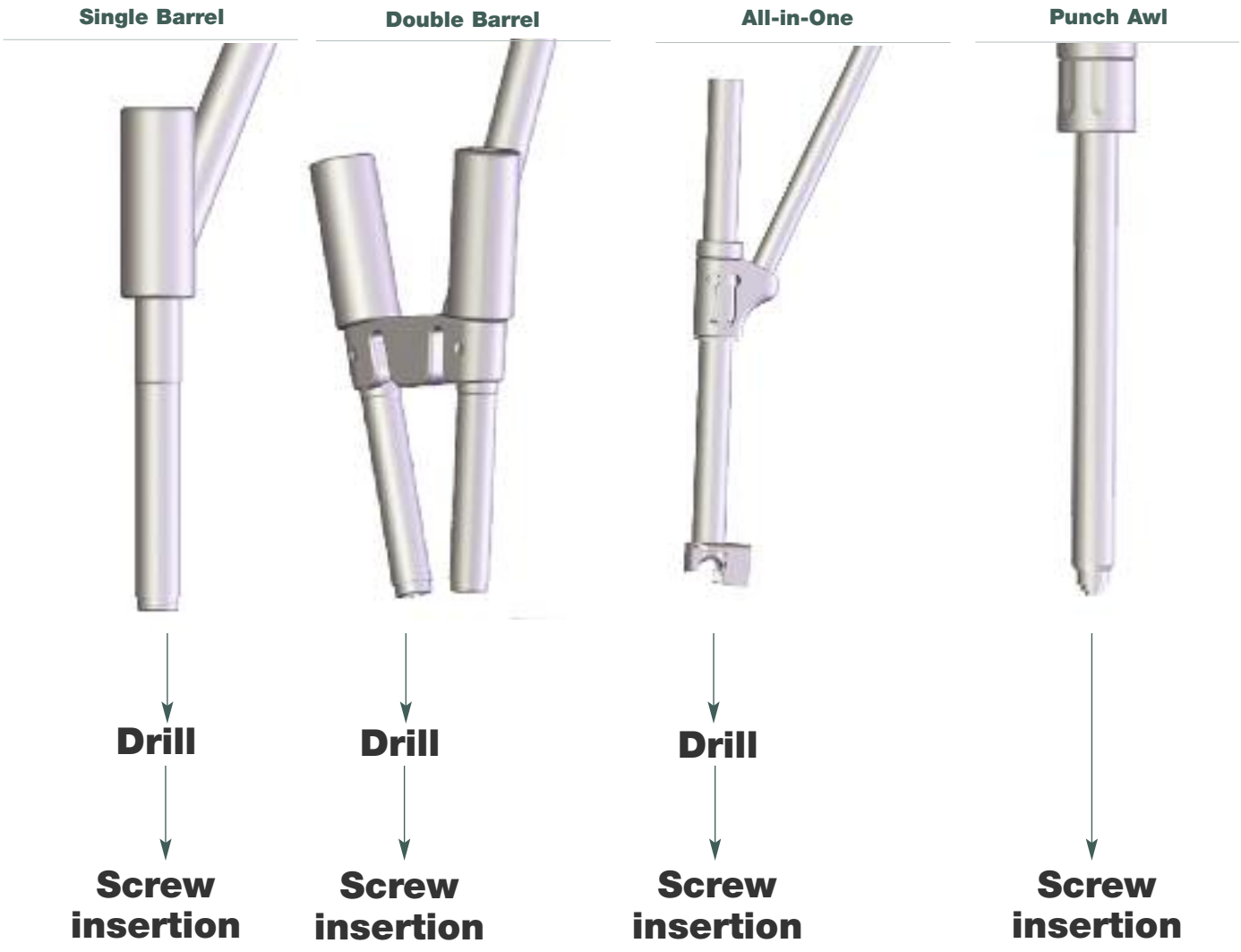
Depending on whether lordosis needs to be added or reduced, adjust the movable bending block to face up with the correct side (laser marking indicates + or – lordosis). Pull the block out, turn it to the desired position, and release it to let it lock in place. Slide the plate between the block and the top bending hammer in such a way that the plate is bent in the area between screw holes. **Bending the plate in a vicinity of a screw hole must be avoided as it may compromise the locking ring mechanism.** Due to the notch sensitivity of titanium, the plate should never be reverted to its original shape once it has been contoured.

Temporary fixation pins are available to hold the plate during screw hole preparation. The threaded pins – short or long – are loaded onto the quick-release pin inserter and threaded through one of the holes of the plate. Placement of two pins diagonally from each other is recommended for stabilization of the plate on the anterior vertebral column.

Note: Excessive pivoting or angulation on the pin inserter should be avoided, as it can cause fracturing of the fixation pins in vertebral body.

Screw Hole Preparation

Depending on the type of a screw selected for a particular procedure, the following options are available for screw hole preparation.



In all procedures above, optional tapping would precede screw insertion, if desired.

Note: To ensure proper locking of the bone screws, freehand insertion of the bone screws is not recommended and can result in backout of bone screws if not properly aligned.

While certain instruments – such as the awl, drills, tap, and the screwdriver – are used for all types of bone screws, **the drill guides and punch awl must correspond to whether fixed or variable angle bone screws will be implanted**. The variable and fixed angle guides can be identified by their blue and purple handles, respectively. The punch awl handle is not screw-specific; however, the fixed and variable angle awl sleeves can be identified by the appropriate laser marking.

Both the fixed and the variable angle guide instruments direct the screw trajectory within the range that ensures optimal functioning of the locking ring. The **fixed guides are rigidly attached to the plate at 8 degrees of sagittal angulation** in the end holes (neutral axis) and 0 degrees of sagittal angulation in the middle holes. The tip design of the **variable guides allows for a range of sagittal angulation from +/- 6 degrees** in all screw holes. Positioning the bone screws within the allowed range of angulation will ensure secure locking of the screws within the plate.

Note: Both the fixed and variable guides must be engaged securely to the plate prior to screw hole preparation. Additionaly they will disengage from the plate if they are positioned outside the optimal range of angulation.

Drill bits, which are available in 2.5mm diameter and six sizes corresponding to the screw lengths (10, 12, 14, 16, 18, and 20mm), provide a positive stop for accurate drilling depth in combination with any of the guides. The tap, which can be used free-hand or through the all-in-one guide, is available in one pre-set depth (10mm).

Caution: Aviator drill bits are 10mm longer than the Reflex Hybrid drill bits and are not interchangeable. Using an Aviator drill bit in a Reflex Hybrid drill guide could lead to over-drilling by as much as 10mm. Prior to surgery check the drill bit length in each respective drill guide to ensure the correct length protrudes through the guide. Also check the part numbers: Reflex Hybrid part numbers start with "485," and Aviator part numbers start with "487."

Drill Guide Handle

Screw Type	Variable Angle	Fixed Angle
4.0mm Self-Tapping		
4.0mm Self-Drilling		
4.5mm Self-Tapping		

Bone Screw Insertion

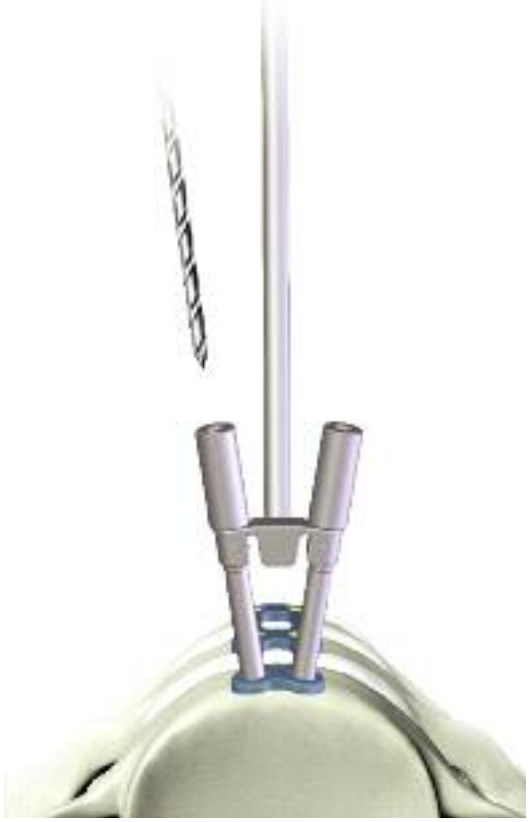
The **single-barrel drill guide** (fixed or variable) directs the drill bit to prepare the screw pathway. The guide provides a positive "lock" when inserted into the screw hole in the plate. The guide needs to be removed for tapping and/or screw insertion. A slight rocking motion facilitates assembly and disassembly; forcing the guide straight into or out of the screw hole should be avoided.

The fixed guide attaches rigidly to the plate when positioned in the neutral axis as described above (8 degrees of sagittal angulation on the end holes, and perpendicular to the plate in the center holes). Outside of this position, the fixed guide does not provide the optimal trajectory and may result in an inaccurate screw position.

Note: The proper angulation of the fixed guide can be confirmed by releasing the handle, as the instrument will "stand up" on its own in this location.

The **double-barrel drill guide** (fixed or variable) allows for both screw holes at a certain plate level to be prepared at the same time. The barrels are directed at 8 degrees of convergence for both screw types (fixed and variable); while the variable guide allows for sagittal angulation, the fixed guide is positioned rigidly in the neutral axis. Rocking the instrument from left to right facilitates assembly, i.e. attaching the left barrel first and then allowing the right barrel to come into position. Reversing the motion will ensure smooth disengagement of the guide. Similarly to the single-barrel drill guides, the double-barrel drill guide only allows for passage of the drill, but does not accommodate tapping and/or screw insertion.

Note: When correctly attached to the plate, the left barrel of the Double-Barrel Drill Guide will be "snapped" into the plate, while the right barrel will hover within the screw hole.



The **all-in-one guide** (fixed or variable) provides a secure cannula for drilling, tapping (if desired), and screw insertion. The two attachment tabs at the bottom of the guide fit between screw holes at any level of the plate. Attaching the tab within the plate window first and then positioning the tab on the outside of the plate facilitates assembly of the guide to the plate. The entire end-piece with the two tabs can be rotated 180 degrees for use on the contralateral side of the plate. **The all-in-one guide is strongly recommended when self-drilling screws are used, as it is designed to promote an optimal screw trajectory.**

As an alternative to a drill guide, the **punch awl** may be used to center and direct the pathway of the self-drilling screws. Interchangeable **fixed or variable sleeves** (identified by the approproate laser marking) are threaded onto the punch awl shaft, and are designed to lock into the screw hole in the plate. As with the single- and double-barrel drill guides, the punch awl should rigidly attach to the plate for the fixed screws, and should provide the correct range of angulation for the variable screws when the awl is properly locked to the plate.

Select the appropriate punch awl sleeve and thread it onto the punch awl shaft. The awl should be in the "closed" position before attaching it to the plate, so as to avoid prematurely engaging the awl tip into the bone. Once the awl is attached to the plate, the awl may then be turned to the "open" position, and the handle depressed so as to engage the awl tip into the bone. A slight rocking motion facilitates disassembly. **The punch awl is strongly recommended when self-drilling screws are used, as it is designed to promote an optimal screw trajectory.**

Note: Each screw hole should use the technique as described above. The punch awl should be returned to the "closed" position before engaging the next screw hole.

Following screw hole preparation, select the appropriate screw and confirm its length using the **screw depth gauge** in the screw tray. The screw size indicates the actual amount of screw purchase in the bone below the bottom surface of the plate (i.e. a 14mm screw is protruding 14mm below the plate, while the screw head is contained within the screw hole).

Bone screws can be placed using one of three insertion drivers: the **quick-turn screwdriver**, the **collet screwdriver** or the **insertion driver**.

The **quick-turn screwdriver** features a draw rod to hold the screw head securely, reducing toggle during screw insertion. Prior to loading a bone screw, ensure the draw rod is inserted and fully seated in the screwdriver. Using the screw tray to load the screws, insert the draw rod into the cannulated head of the bone screw. Ensure that the tip of the screwdriver is aligned with the cruciform design of the bone screw. Once the screwdriver is **fully seated** into the bone screw, tighten the draw rod until resistance is felt and it captures the bone screw.

Note: Do not over-tighten the draw rod. Over-tightening the draw rod may cause screw disengagement difficulties.

Note: Insert the bone screws until they are just above the locking ring.

To avoid damage to the screwdriver, the final tightener MUST be used to lock the screws in the ring.

Quick-turn Screwdriver (48511820)

Quick-turn Screwdriver Inner-Shaft (48511820B)

Storage

The quick-turn screwdriver is a two piece design which must be taken apart (and placed in the auxiliary space) for sterilization and cleaning.

Bone screws can also be placed using the **collet screwdriver**, which features a self-centering pin and a sleeve to hold the screw head securely.

Ensure that the collet sleeve is in the open position by pulling it toward the driver handle. Utilizing the screw caddy as a base upon which to load the screws, insert the self-centering pin of the screwdriver into the cannulated head of the bone screw. Rotate the driver handle until the cruciform geometry seats itself over the cruciform design of the bone screw (Figure 1). When seated properly, the screwdriver collet is designed to be flush with the screw caddy.

Once the screwdriver is seated into the bone screw, lower the collet sleeve until it is fully depressed and captures the screwdriver collet (Figure 2). The harder the sleeve is depressed, the tighter the hold will be upon the bone screws. To disengage from the screw, retract the collet sleeve. Once all bone screws have been inserted, use the **Final Tightening Screwdriver** to drive the screws underneath the locking ring. **The collet screwdriver must not be used for final tightening**.

Note: Once the sleeve is fully depressed around the collet, remove the assembly from the screw caddy vertically. Any toggle while removing the assembly from the screw caddy may cause the bone screw to become disengaged.

Storage

The Collet Screwdriver is a three piece design which must be taken apart (and placed in the auxiliary space) forsterilization and cleaning. When assembled it is designed to fit in the upper level of the Reflex Hybrid System Container for storage.

Note: To maintain the retention of the screwdriver collet, ensure the screwdriver is stored with the collet sleeve in the open or retracted position.

Collet Screwdriver (48511815)

Fig. 1
Open Position

Fig. 2
Closed Position

Bone screws may also be placed using the **insertion screwdriver**, which features a tapered tip in combination with a small nitinol holding pin for a secure hold of the screw head

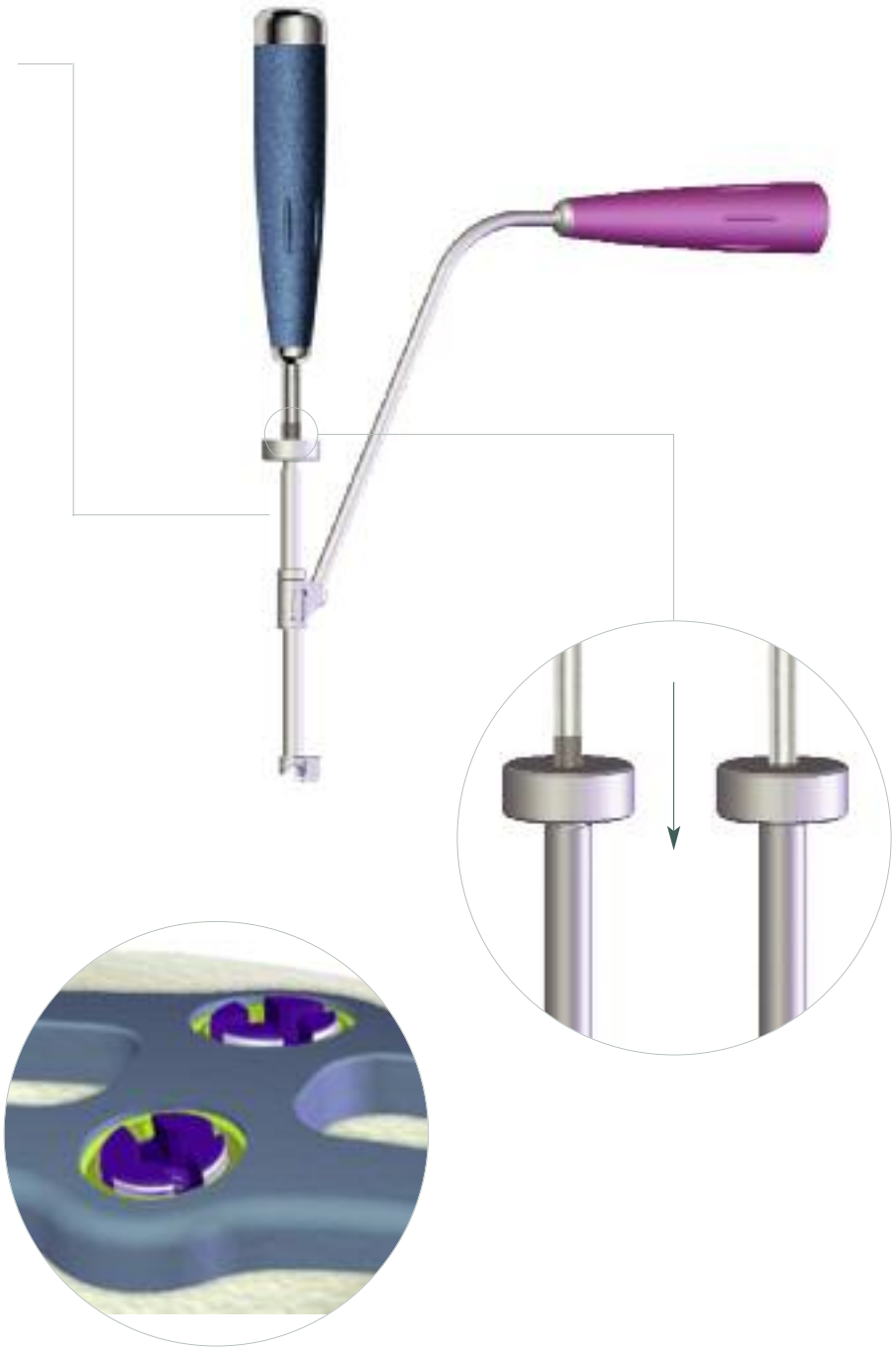
Screws should be inserted to the point where they are just above the ring. Inserting the screws sequentially at opposite corners of the plate – and working toward the center of the plate – helps keep the plate flat against the bone.

Once all bone screws have been inserted, the **final tightening screwdriver** should be used to lock the screws into the ring. The final tightening screwdriver, which features a protruding center pin to facilitate placement into the screw head, has been designed for optimal strength as to minimize the risk of stripping. To facilitate identification, the shaft of the final tightening screwdriver has been anodized gold.

Note: The amount of torque required to complete final tightening can be done with a single hand, and should not exceed one quarter turn once the screw is underneath the ring.

In addition to the tactile sensation of the locking ring closing over the bone screw head, final screw locking should also be confirmed visually with the **ring being clearly visible over the bone screw head**. It is possible that the entire ring may not be visible if the screws have been implanted at their extreme angulation; however, two-thirds of the ring provides sufficient coverage for safe locking of the bone screw to the plate.

When using the insertion screwdriver through the all-in-one-guide, the screw should be inserted just to the point where the finger flange on the screwdriver sleeve hits the guide tube. At this point, the screw is still above the ring. If the laser-marked band on the screwdriver disappears, the screw has been locked beneath the ring. It is recommended that all bone screws be seated in this manner prior to proceeding with the final tightening.



Bone Screw Removal

The **screw extractor** is the primary instrument used to remove bone screws that have been locked into the plate. While the larger tip of the screwdriver spreads the locking ring, the threaded inner shaft allows for rigid attachment of the screw to the screwdriver. In addition, the instrument utilizes an outer sleeve to provide counter force against the plate during screw removal. **Do not pull the screw out with only the draw rod**.

To begin removal of the screw, the outer sleeve should be pulled up and threaded onto the upper ring of threads just below the handle, so as to keep the sleeve from impeding visibility when seating the driver.

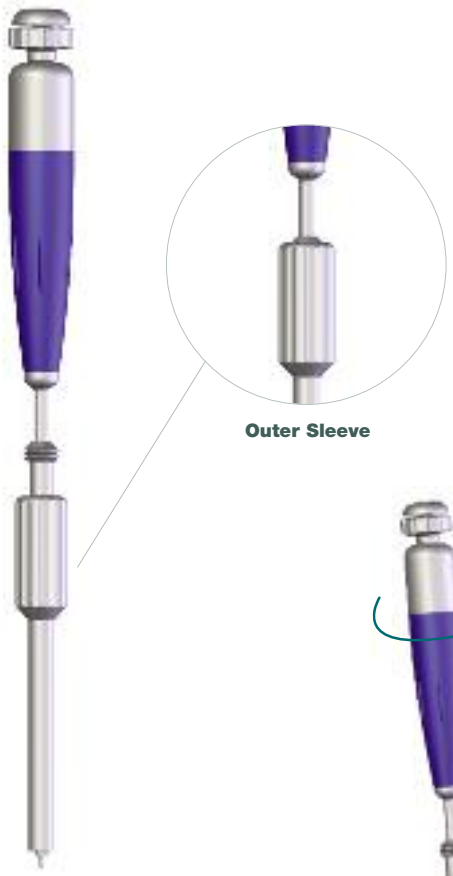
Fully seat the screwdriver into the cruciform of the bone screw. Insert and tighten the inner shaft until the knob will no longer turn (approximately 10-12 rotations).

Before removing the screw, release the outer sleeve from the upper ring of threads, and allow it to drop on to the plate. Back the sleeve off of the plate one quarter turn and hold stationary. **While holding the outer sleeve stationary, unthread the bone screw from the plate**.

The locking mechanism of the Reflex Hybrid ACP System has been tested to ensure that a screw inserted into a previously used screw hole will be securely locked*. The locking ring can be re-used for the implantation of a rescue screw. However, repeated screw insertion through the locking ring should be avoided as its function may have been compromised. A maximum of two bone screw insertions is recommended for any screw hole within a plate.

*Data on file at Stryker Spine.
Ref. GTmemo cib 310309-02.

Capture screw head



Outer Sleeve

Keep sleeve stationary

The **revision driver** may also be used to remove bone screws that have been locked to the plate. The revision driver has a narrow tip that helps to bypass the locking ring and engage the bone screw.

The **draw rod** allows for rigid attachment of the screw to the revision driver. Do not pull the screw out with only the inner shaft/draw rod.

Note: Do not utilize the revision driver as an insertion driver.

To begin removal of the screw, insert the draw rod into the inner cannula of the bone screw. Fully seat the cruciform head of the revision driver into the cruciform of the bone screw. Maintain alignment with the bone screw and its trajectory. Insert and tighten the threaded inner shaft until the knob will no longer turn (approximately 10-12 rotations).

Turning the blue handle, rotate the entire instrument counterclockwise to extract the bone screw. The draw rod knob may provide spring back or feel like a hard stop when fully engaged.

Note: Ensure that the tip is fully expanded (draw rod tightened finger-tight) prior to attempting to remove the screw.

Note: The distal tip of the revision driver is designed to bypass the locking ring. No downward pressure is required for the use of the revision driver.

The handle is designed to give you an ability to use the driver with just your fingers. Avoid pulling upward on the revision driver, or placing a palm on top of the draw rod to minimize risk of disengaging driver from the cruciform.

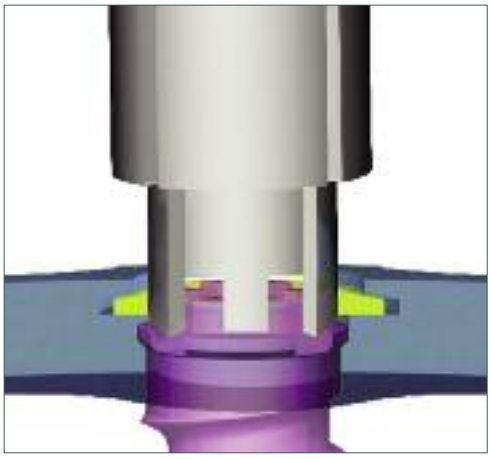
Note: The revision driver must be axially aligned with the screw trajectory and fully seated in the screw head before inserting or tightening the inner shaft.

Note: While the revision driver is attached to the screw, pivoting or angulation of the instrument must be avoided, as it can cause bending or breakage of the inner shaft.

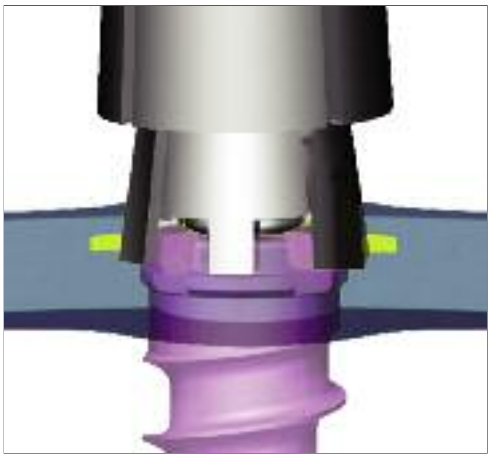
Tip: Check the tip of the inner shaft/draw rod regularly to ensure that the threaded tip hasn't stripped.

Inner Shaft/Draw Rod (48511906B)

Revision Driver (48511906)



Bypass locking ring to seat driver



Thread draw rod to capture screw head and expand ring

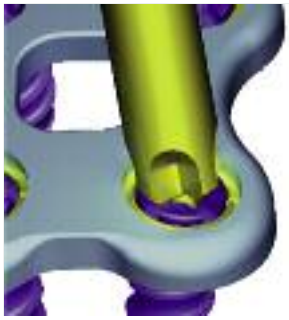
Bone Screw Removal

Tips and Techniques

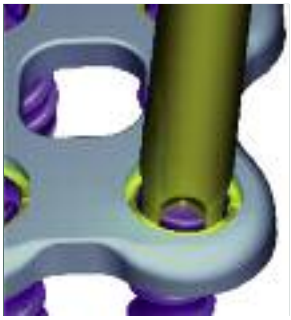
Tip: Use the gold final tightening driver to loosen all bone screws ¼ turn or until they touch the undersurface of the ring.

Technique: The **screw extractor** may also be used without the inner shaft. To do so, remove the outer sleeve from the screw extractor. Seat the screw extractor into the head of the bone screw, ensuring there are no gaps between the instrument and the implant.

Ensure the screw extractor maintains proper alignment with the bone screw's trajectory. Apply and maintain downward pressure so that the screwdriver shaft stays seated within the screw head.



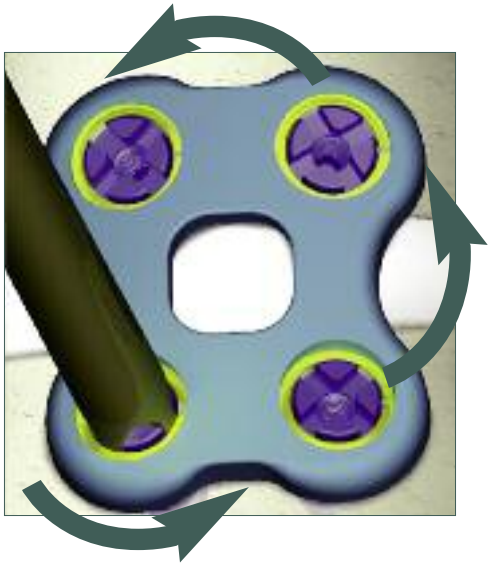
Improper



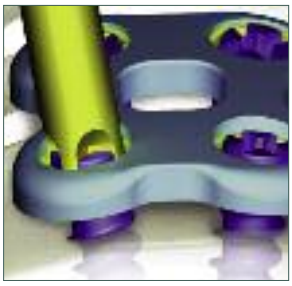
Proper

Note: Proper alignment and downward pressure will ensure the locking ring is expanded and will allow the bone screw to pass through the locking ring.

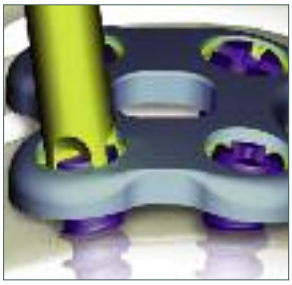
Keeping downward pressure, rotate the instrument counter-clockwise until the bone screw is released from the locking ring. No additional downward pressure is required after the bone screw bypasses the locking ring. Remove the bone screw from the plate.



2nd Rotation



3rd Rotation



Technique: If necessary, the entire construct (plates with screws) may be removed by using your **final tightening screwdriver**.

Starting in a corner screw hole, sequentially back out each screw 1 - 2 turns. Continue in one direction (clockwise or counter-clockwise) until the entire construct with plate and screws attached is backed out of the vertebral bodies.

Implants

Part #	Description	Screw Color

Variable Angle Bone Screws, Self-Tapping

48694010	Ø 4.0 x 10mm
48694012	Ø 4.0 x 12mm
48694014	Ø 4.0 x 14mm
48694016	Ø 4.0 x 16mm
48694018	Ø 4.0 x 18mm
48694020	Ø 4.0 x 20mm

48694512	Ø 4.5 x 12mm
48694514	Ø 4.5 x 14mm
48694516	Ø 4.5 x 16mm
48694518	Ø 4.5 x 18mm
48694520	Ø 4.5 x 20mm

Variable Angle Bone Screws, Self-Drilling

48644010	Ø 4.0 x 10mm
48644012	Ø 4.0 x 12mm
48644014	Ø 4.0 x 14mm
48644016	Ø 4.0 x 16mm
48644018	Ø 4.0 x 18mm

Fixed Angle Bone Screws, Self-Tapping

48674010	Ø 4.0 x 10mm
48674012	Ø 4.0 x 12mm
48674014	Ø 4.0 x 14mm
48674016	Ø 4.0 x 16mm
48674018	Ø 4.0 x 18mm
48674020	Ø 4.0 x 20mm

48674512	Ø 4.5 x 12mm
48674514	Ø 4.5 x 14mm
48674516	Ø 4.5 x 16mm
48674518	Ø 4.5 x 18mm
48674520	Ø 4.5 x 20mm

Fixed Angle Bone Screws, Self-Drilling

48654010	Ø 4.0 x 10mm
48654012	Ø 4.0 x 12mm
48654014	Ø 4.0 x 14mm
48654016	Ø 4.0 x 16mm
48654018	Ø 4.0 x 18mm

Part #	Description	Plate

One-Level Anterior Cervical Plate

48651112	Size 12mm
48651114	Size 14mm
48651116	Size 16mm
48651118	Size 18mm
48651120	Size 20mm
48651122	Size 22mm

Two-Level Anterior Cervical Plate

48651224	Size 24mm
48651226	Size 26mm
48651228	Size 28mm
48651230	Size 30mm
48651232	Size 32mm
48651234	Size 34mm
48651237	Size 37mm
48651240	Size 40mm
48651243	Size 43mm
48651246	Size 46mm

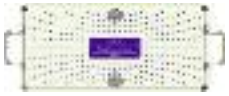
Three-Level Anterior Cervical Plate

48651339	Size 39mm
48651342	Size 42mm
48651345	Size 45mm
48651348	Size 48mm
48651351	Size 51mm
48651354	Size 54mm
48651357	Size 57mm
48651360	Size 60mm
48651363	Size 63mm
48651366	Size 66mm
48651369	Size 69mm

Four-Level Anterior Cervical Plate

48651460	Size 60mm
48651464	Size 64mm
48651468	Size 68mm
48651472	Size 72mm
48651476	Size 76mm
48651480	Size 80mm
48651484	Size 84mm
48651488	Size 88mm
48651492	Size 92mm
48651496	Size 96mm

Instruments

Part #	Description	
48510005	Container	
48510100	Caliper	
48510200	Plate Bender	
48513010	Universal Plate Holder	
48510300	Plate Holder	
48510400	Fixation Pin Inserter	
48510410	Temporary Fixation Pin, Standard	
48510420	Temporary Fixation Pin, Long	
48511500	Single-Barrel Drill-Guide - Fixed	
48511505	Single-Barrel Drill-Guide - Variable	
48511510	Double-Barrel Drill-Guide - Fixed	
48511515	Double-Barrel Drill-Guide - Variable	
48510520	All-in-one Guide - Fixed	
48510525	All-in-one Guide - Variable	

Part #	Description	
48510600	Quick-Release Handle	
48510610	Drill - 10 mm	
48510612	Drill - 12 mm	
48510614	Drill - 14 mm	
48510616	Drill - 16 mm	
48510618	Drill - 18 mm	
48510620	Drill - 20 mm	
48511655	Punch Awl Shaft	
48511655F	Fixed Awl Sleeve	
48511655V	Variable Awl Sleeve	
48510700	Tap	
48510800	Screwdriver	
48511815	Retaining Collet Screwdriver	
48511820	Quick Turn Screwdriver	
48511820B	Quick-Turn Screwdriver Inner Shaft	
48510810	Final-Tightening Screwdriver	
48511905	Screw Extractor	
48511905R	Screw Extractor Inner Shaft	
48511906	Revision Screwdriver	
48511906B	Revision Driver Inner Shaft	

IMPORTANT PRODUCT INFORMATION FOR STRYKER SPINE ANTERIOR CERVICAL PLATING SYSTEMS

NON STERILE PRODUCT

INDICATIONS
The ACP Systems are intended for anterior intervertebral screw fixation of the cervical spine from C2 – T1. These systems are indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:
- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lodosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusions
- Spondylolisthesis
- Spinal stenosis

WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

CONTRA-INDICATIONS
- Marked local inflammation.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Bony abnormalities preventing safe screw fixation.
- Open wounds.
- Rapid joint disease, bone absorption, osteopenia, osteomalacia, and/or osteoporosis. Osteoporosis or osteopenia are relative contraindications, since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Metal sensitivity, documented or suspected.
- Pregnancy.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Inadequate tissue coverage over the operative site.

Other medical or surgical conditions which would preclude the potential benefit of surgery, such as congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count. These contra-indications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

INFORMATION FOR PATIENT
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight-bearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise of this fact and warned of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

PRE-OPERATIVE PRECAUTIONS
The surgical indication and the choice of implants must take into account certain important criteria such as:
- Patients involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests must be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

REMOVAL
- Stryker Spine devices are designed for treatment of fracture or stabilisation of a surgical site during the normal bone consolidation process. After this period, the presence of the device is no longer strictly required and its removal can be planned. Removal may also be necessary as a result of the above mentioned adverse effects.
- Removal of an ACP System may require special instruments to disengage the implant from the vertebrae. Appropriate recommendations are provided in the Surgical Technique brochure.
- Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

FURTHER INFORMATION
A surgical technique brochure is available on request through your Stryker agent or directly from Stryker Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

The STRYKER Spine Reflex ACP (Anterior Plate System) and Reflex Hybrid ACP System has not been evaluated for safety and compatibility in the MR environment. STRYKER Spine Reflex ACP (Anterior Plate System) and Reflex Hybrid ACP System has not been tested for heating or migration in the MR environment.

COMPLAINTS
Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and / or its performance, should notify STRYKER Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, STRYKER Spine or its representative must be advised immediately.

If a STRYKER Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or STRYKER Spine must be informed as soon as possible by telephone, fax or in writing.
For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and an exhaustive description of the event to help STRYKER Spine understand the causes of the complaint.

For further information or complaints, please contact:

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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