stryker

Spine

DynaTran®
Surgical Technique

Dynamic Anterior Cervical Plating System

- Internally dynamized
- Low 2.5mm profile
- Graft and endplate visualization

Introduction

Introduction

DynaTran® is an **internally-dynamized** anterior cervical plating system that is designed to allow axial settling while reducing the risk of plate impingement on adjacent discs. With an integrated one-step screw locking mechanism, DynaTran® maintains a **low 2.5mm profile** across the entire surface of the plate. The **uniquely-shaped graft windows** enable both graft and end plate visualization to facilitate screw placement. The system offers **custom distraction pins** that allow DynaTran® plates to be positioned with the pins still in place to facilitate plate alignment and soft tissue retraction.

Philosophy of Dynamic Plating

Dynamic or translational plates are designed to allow axial settling so as to maintain load sharing on the graft. Such settling can occur due to graft resorption, graft subsidence into the end plate or imperfect graft and end-plate contact. A dynamic plate allows load to continue to be applied to the graft even after subsidence occurs to assist in obtaining a sound fusion.[1]

With internally-dynamized plates, the screws can remain fixed in the vertebral bodies, while the plate compresses. This is in contrast to the "slotted" dynamic plates in which the screws can move within the plate, which may allow the plate to potentially impinge on the adjacent disc.

Acknowledgements

Stryker Spine would like to thank the following surgeons for their participation in the development of the DynaTran® System:

- Paul A. Anderson, MD
- Bradford L. Currier, MD
- Harry N. Herkowitz, MD
- William C. Watters, III, MD

[1] "Dynamic Cervical Plates: Biomechanical Evaluation of Load Sharing and Stiffness." D. S. Brodke, et al. SPINE 2001. Volume 26, Number 12, pp 1324–1329.

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DynaTran® Surgical Technique

System Overview

Plates are implanted with clips in place

After screws are implanted, clips are removed

As settling occurs, the plate can compress

The DynaTran® ACP System offers a low profile, **internally dynamized** plate with a variety of screw options. The system is designed to provide up to 2mm of translation per level.

The plate is inserted with the plate clips in place. After the screws are implanted, the plate clips are removed to allow the plate to close, as graft settling occurs.

The plate can also be inserted with one or more of the clips removed, so that those levels are in the closed position (see picture). In this way, the plate acts as an adjustable plate, allowing the surgeon to size the implant intraoperatively.

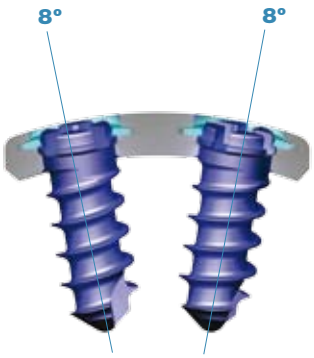
The one-step locking ring expands upon screw insertion, and then contracts over the screw head to hold each screw securely in place. The screw hole geometry accommodates both fixed and variable angle screws.

The rings are color-coded to indicate the different degrees of screw angulation permitted at the cephalad, middle and caudal holes:

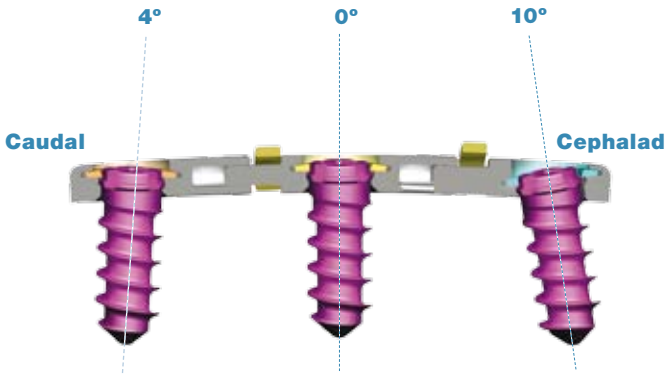
(green) 10° at cephalad screw hole
(gold) 0° in center screw holes
(pink) 4° in caudal screw hole

Note: The DynaTran® ACP System is intended to be used in conjunction with the Reflex® Hybrid bone screws and instrumentation.

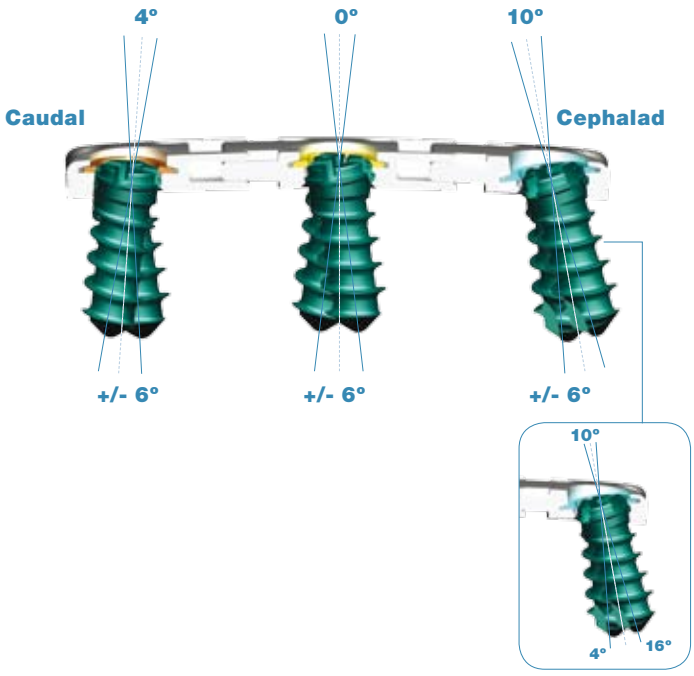
The system was optimized for usage with fixed screws and offers different neutral angles for the cephalad and caudal end screw holes. The neutral axis of the end-hole bone screws is defined as **10° cephalad and 4° caudal** from perpendicular to the plate in the sagittal plane. All screws have **8° of medial convergence in the axial plane**.



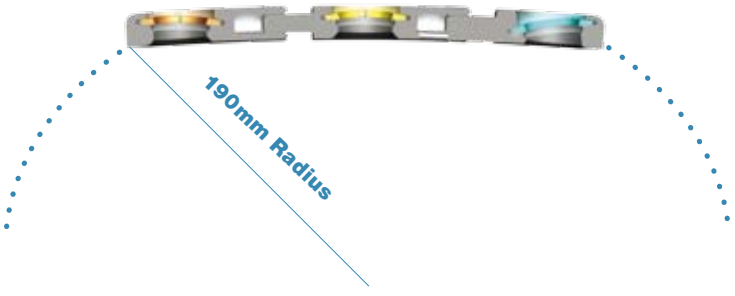
Reflex® Hybrid fixed angle bone screws are inserted into the plate in the neutral position as described above, and they remain in this position under loading. Fixed bone screws in the middle holes are inserted perpendicularly to the plate (at 0° angulation).



If additional screw angulation is required, **Reflex® Hybrid variable angle bone screws** may be used. These allow sagittal angulation of the screw within a certain range measured from the neutral axis. 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 4° up to 16° cephalad and -2° up to 10° caudal from perpendicular to the plate**. Middle-hole screws also allow for +/- 6 degrees of angulation.



The DynaTran® plate has been designed with a slight sagittal and axial bend to match patient anatomy. One- and two-level plates have a sagittal curve of 190mm. Three- and four-level plates have a sagittal curve of 390mm. All plates have an axial curve of 25mm.



Note: Do not attempt to create additional lordosis or kyphosis in these plates. The plates must not be bent so as not to affect the integrity of the locking ring or internal dynamization mechanism.

System Overview

Self-tapping screw

Self-drilling screw

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.

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

The individual screw families have been **color coded** for easy identification as indicated in the chart to the left.

The DynaTran® and Reflex® Hybrid 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 and the DynaTran® ACP System provided in the Packaging Insert / Instructions for Use.

Patient Positioning and Exposure

The 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. 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.

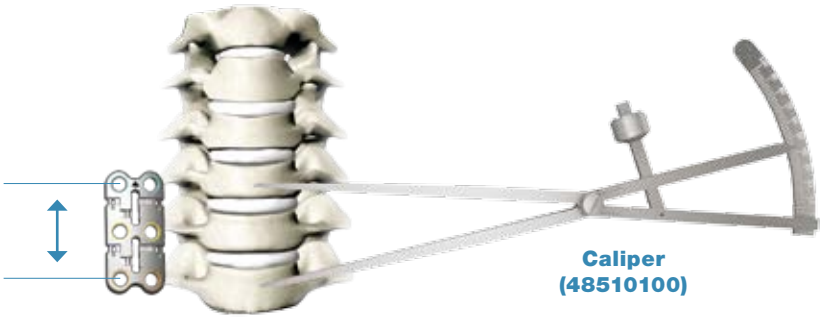
Anterior Cervical Discectomy and Fusion

The implantation of the anterior cervical plate follows discectomy and/or a corpectomy, and an appropriate bone graft insertion. Care should be taken to remove any soft tissue or osteophytes which would inhibit the DynaTran® plate from sitting flat against the bone.

The DynaTran® ACP system includes customized distraction pins that work in conjunction with the Reliance® C cervical instrumentation set. These distraction pins are designed to mate with the plate so that plates can be placed with distraction pins still in place.

Implant Selection and Preparation

The sizing of the **DynaTran® 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. In cases in which the measured distance falls between two sizes, it is usually recommended that the smaller size be used as 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.



Caliper (48510100)

Universal Plate Holder (48513010)

Hold the plate holder at the bend and attach to the narrow sides of the plate. Squeeze plate holder until it clicks one time to lock to the plate. Squeeze holder a second time to release plate from holder.

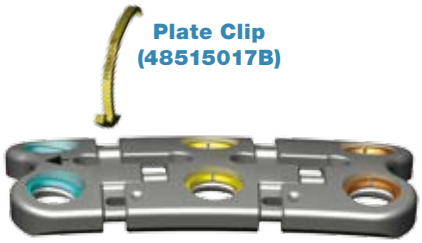
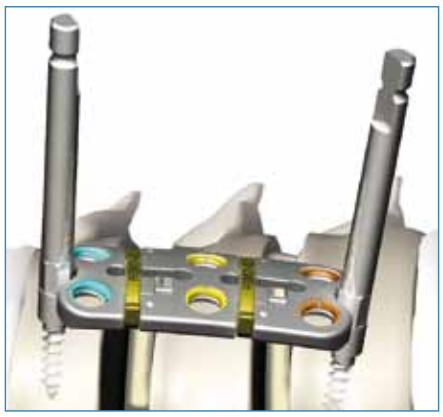


Plate Clip (48515017B)

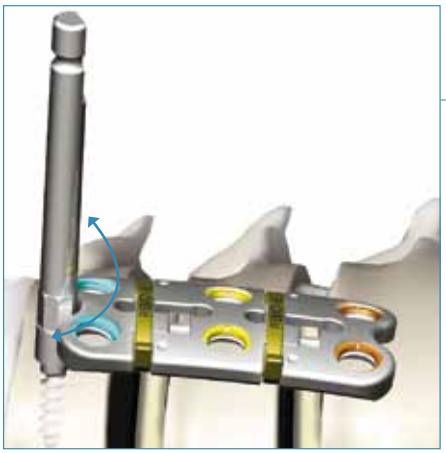
Each plate has been pre-assembled with one **plate clip** at each internal segment. These clips are designed to keep the plate in the extended position for easier screw insertion. The plate clips can be assembled with the hook facing either to the right or to the left to support the surgeon's surgical approach. If the hook is positioned to the right (to support a right-sided approach), the text "REMOVE" would be facing upsidedown.

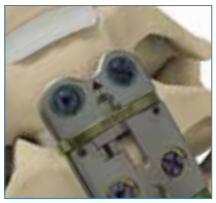
The plate clips should be removed after implantation of bone screws and prior to final tightening of the bone screws.



Distraction Pin (48515021)

The DynaTran® **distraction pin**, designed for use with the Reliance® C Cervical instrumentation set, can be used to facilitate plate placement. The distraction pins (12mm) are designed without a flange so that the plate can be positioned closer to the pins. In this way, the pins can be used as a soft tissue retractor, a visual cue to the midline, and to help stabilize the plate. To use the distraction pins to facilitate plate stabilization, place the distraction pins approximately 6.5mm to 8mm from the end plates. Remove one pin if necessary and rotate the plate around the pin to facilitate alignment.





The plate should be placed along the vertebral column so that the arrow is facing cephalad. **Proper positioning is required to accommodate the different angulation allowed at the superior and inferior ends**.

Temporary fixation pins pins are available to hold the plate during screw hole preparation. The DynaTran® temporary fixation pins are designed to fit within the graft window key hole. Alternatively, the Reflex® Hybrid temporary fixation pins are designed to fit within the screw holes. When fully inserted in the appropriate position, both pins can penetrate the bone up to 8mm. Load temporary fixation pin onto the quick-release pin inserter by pulling up the sleeve of the inserter. Position the pin in either the graft window key hole or in the center of the screw hole. Apply slight downward pressure while threading the pin into the bone. Placement of two pins diagonally from each other is recommended for stabilization of the plate on the anterior vertebral column.

Temporary Fixation Pin (48515020)

Note: Excessive pivoting or angulation on the pin inserter should be avoided, as it can cause fracturing of the fixation pins. As the point of the pins dull with repeated use, temporary fixation pins are recommended for single-use only.

* ***Plate clip material is a radio-opaque titanium alloy***

Screw Hole Preparation

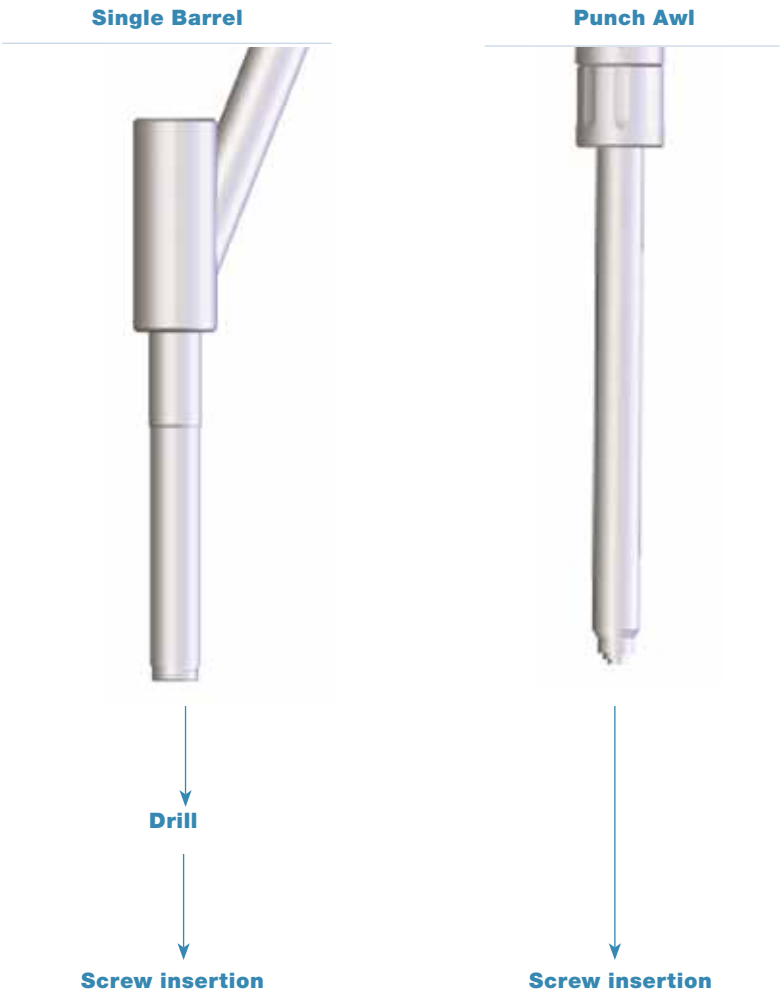
Note: The following instruments are found in the Reflex® Hybrid set.

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

In all procedures, 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 allowed.

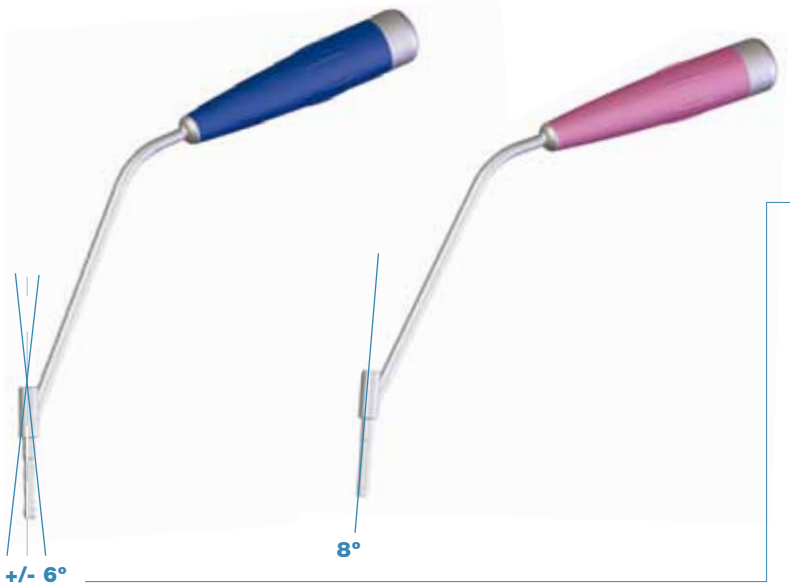
Note: The Reflex® Hybrid All-In-One Guide is NOT compatible with the DynaTran® plate.



Screw Hole Preparation

Drill Guide Handle

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



While certain instruments – such as the awl, drills, tap, and the screwdrivers – 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 appropriate range to help ensure optimal functioning of the locking ring. **The fixed guide is rigidly attached to the plate at 10° cephalad and 4° caudal angulation** in the end holes (neutral axis) and 0° of sagittal angulation in the middle holes. The tip design of the **variable guide allows for a range of sagittal angulation from +/- 6°** 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. Additionally, they will disengage from the plate if they are positioned outside the optimal range of angulation.

Drill bits (48510610 - 620)

Tap (48510700)

Drill bits, which are available in 2.5mm diameter and four sizes corresponding to the screw lengths (10, 12, 14, and 16mm), provide a positive stop for accurate drilling depth in combination with any of the guides. The **tap** is available in one pre-set depth (10mm).

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.

Single-Barrel Drill Guide - Variable (48511505)

The fixed guide attaches rigidly to the plate when positioned in the neutral axis as described above (10° cephalad and 4° caudal 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.

Single-Barrel Drill Guide - Fixed (48511500)

Bone Screw Insertion

Punch Awl Shaft (48511655)

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 appropriate laser marking) are threaded onto the punch awl shaft, and are designed to seat into the screw hole in the plate. As with the single-barrel drill guide, the punch awl will provide the correct range of angulation for both fixed and variable screws. **Do not use the punch awl without a sleeve.**

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.

With the sleeve assembled, the awl will snap into the screw hole. Position the awl for the desired screw trajectory. Turn the collar to the "open" position, and then apply downward pressure to penetrate the bone. When fully deployed, the awl can penetrate up to 8mm of bone. A slight rocking motion facilitates disassembly. Rotate the instrument while applying upward force to remove. Do not apply excessive cantilever loads.
A punch awl or drill guide must be used when self-drilling screws are used, as these instruments are designed to provide an optimal screw trajectory and help to position the screw in the center of the screw hole.

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.

Bone Screw Insertion

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 protrudes 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 Screw Insertion

Collet Screwdriver (48511815)

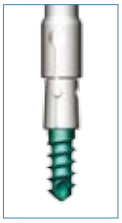


Fig. 1 Open Position

Fig. 2 Closed Position

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) for sterilization 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.

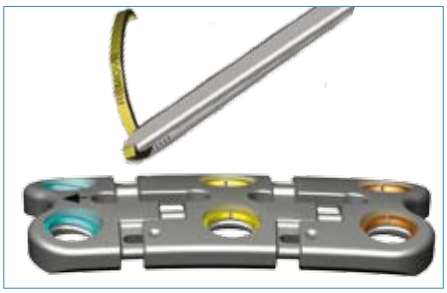
Bone Screw Insertion

The third option for screw insertion is 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.

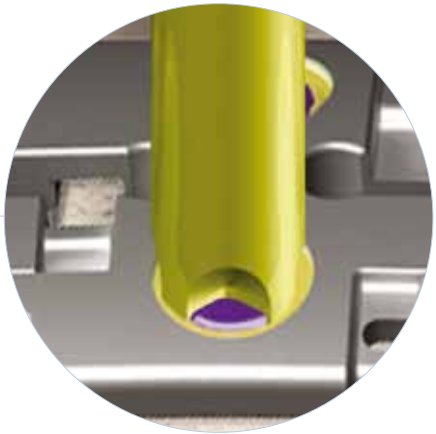
Plate Clip Removal

Once all screws have been implanted, remove each plate clip using general instruments such as a hemostat, needle driver or kocher. The plate clips are a one-time-use instrument and must be disposed.



Final Tightening

Once all bone screws have been inserted and the plate clips have been removed, 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 to minimize the risk of stripping. To facilitate identification, the shaft of the final tightening screwdriver has been anodized gold.



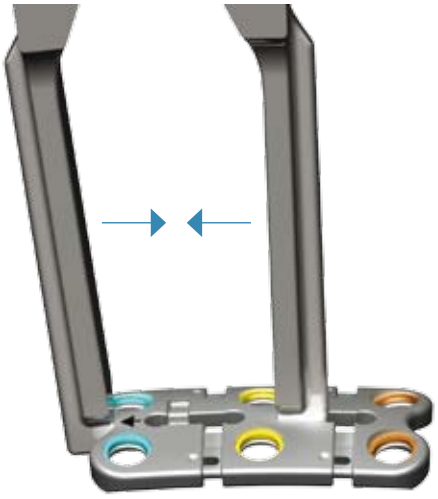
Note: The amount of torque required to complete final tightening can be done with a single hand, and must not exceed one quarter turn once the screw is underneath the ring.

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.

Compression

The compressor is designed to facilitate pre-compression of the graft. After removing distraction pins, place one arm of the **compressor** in a key hole of one segment, and the second arm of the compressor against the opposite end of the plate for 1 and 2-level plates. For 3 and 4- level plates, the opposite end of the instrument can also be placed in between key holes of other levels. The compressor is designed to allow one segment to be compressed at a time. **Compress instrument until you feel resistance. Avoid excessive compression.**

Note: This device is not to be used to take the place of proper graft fit.



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**.

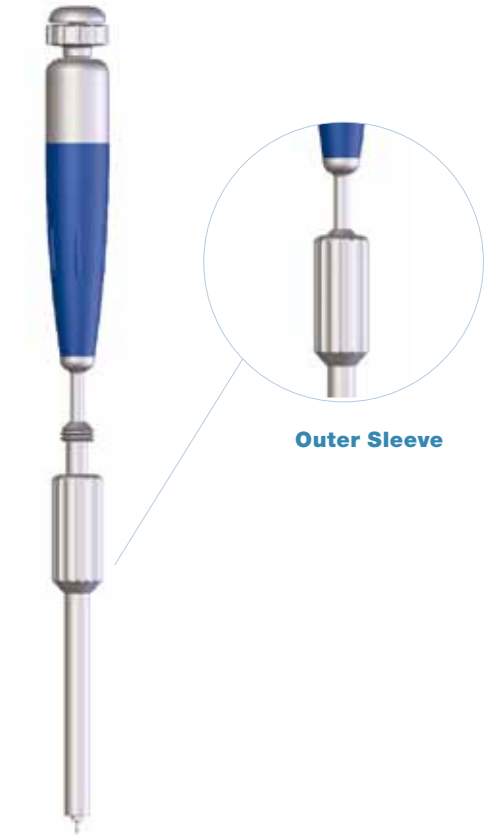
To begin removal of the screw, the outer sleeve should be pulled up and threaded onto the upper ring of threads just below the handle, so as to keep the sleeve from impeding visibility when seating the driver.

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 ¼ turn and hold stationary. **While holding the outer sleeve stationary, unthread the bone screw from the plate**.

The locking mechanism of the DynaTran® ACP System has been tested to ensure that a screw inserted into a previously used screw hole can be securely locked*. The locking ring can be reused 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.

Capture screw head



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

Bone Screw Removal

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**.

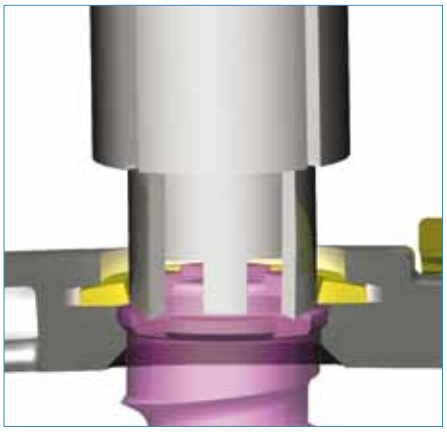
Note: The revision driver must be axially aligned with the screw trajectory and fully seated in the screw head before inserting or tightening the inner shaft.

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.

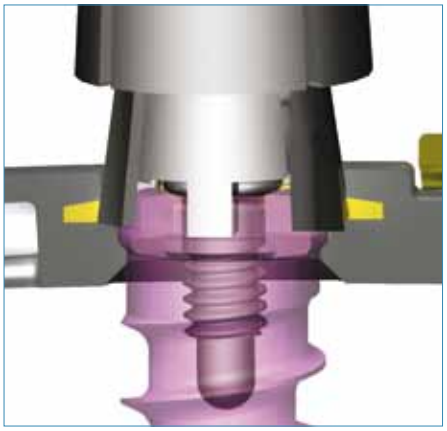
Tip: Check the tip of the Inner Shaft/Draw Rod regularly to ensure that the threaded tip hasn't stripped.

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.

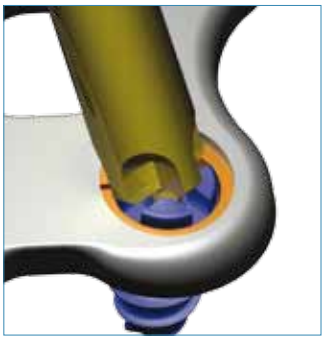
Ensure the screw extractor maintains proper alignment with the bone screw's trajectory. Apply and maintain downward pressure so that the screwdriver shaft stays seated within the screw head.

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.

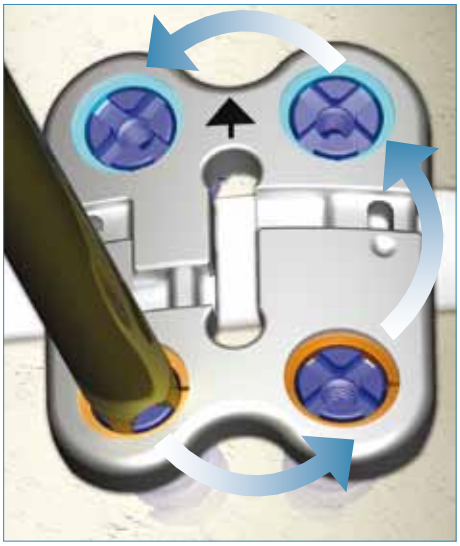
Technique: If necessary, the entire construct (plates with screws) may be removed by using your **final tightening screwdriver**.

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.

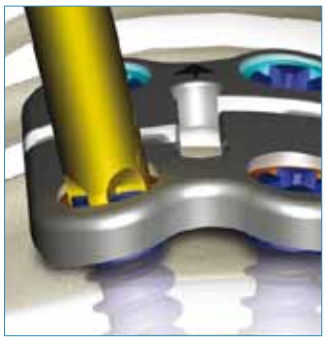


Improper

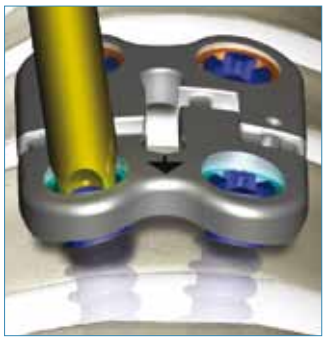
Proper



2nd Rotation



3rd Rotation



Implants

DynaTran® Implants

One-Level Plates - DynaTran® ACP

Part #	Description
48670114	Size 14mm
48670116	Size 16mm
48670118	Size 18mm
48670120	Size 20mm
48670122	Size 22mm
48670124	Size 24mm
48670126	Size 26mm

Two-Level Plates - DynaTran® ACP

Part #	Description
48670228	Size 28mm
48670230	Size 30mm
48670232	Size 32mm
48670234	Size 34mm
48670237	Size 37mm
48670240	Size 40mm
48670243	Size 43mm
48670246	Size 46mm

Three-Level Plates - DynaTran® ACP

Part #	Description
48670342	Size 42mm
48670345	Size 45mm
48670348	Size 48mm
48670351	Size 51mm
48670354	Size 54mm
48670357	Size 57mm
48670360	Size 60mm
48670363	Size 63mm
48670366	Size 66mm
48670369	Size 69mm

Four-Level Plates - DynaTran® ACP

Part #	Description
48670460	Size 60mm
48670464	Size 64mm
48670468	Size 68mm
48670472	Size 72mm
48670476	Size 76mm
48670480	Size 80mm
48670484	Size 84mm
48670488	Size 88mm
48670492	Size 92mm
48670496	Size 96mm

Reflex® Hybrid Implants

Variable Angle Bone Screws, Self-Tapping

Part #	Description
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

Part #	Description
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

Part #	Description
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

Part #	Description
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

Part #	Description
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

Part #	Description
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

Instruments

DynaTran® Instruments

Part #	Description	
48510005	Container	
48513010	Universal Plate Holder	
48515017B	Plate Clip	
48515019	Compressor	
48515020	Temporary Fixation Pin	
48515021	Distraction Pin	

Reflex® Hybrid Instruments

Part #	Description	
48510100	Caliper	
48510400	Fixation Pin Inserter	
48511500	Single-Barrel Drill-Guide - Fixed	
48511505	Single-Barrel Drill-Guide - Variable	
48510600	Quick-Release Handle	
48510610 48510612 48510614 48510616 48510618 48510620	Drill - 10 mm Drill - 12 mm Drill - 14 mm Drill - 16 mm Drill - 18 mm Drill - 20 mm	
48511655	Punch Awl Shaft	
48511655V	Variable Awl Sleeve	
48511655F	Fixed Awl Sleeve	
48510410	Temporary Fixation Pin, Standard	
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 DYNATRAN® ANTERIOR CERVICAL PLATING SYSTEM

NON STERILE PRODUCT

DESCRIPTION

The Stryker Spine DynaTran® Anterior Cervical Plating (ACP) System consists of bone plates that are available in a variety of sizes in order to accommodate individual patient physiology and pathology and to facilitate anterior stabilization of the cervical spine. The DynaTran® plates are intended to be used with the Reflex Hybrid bone screws. The DynaTran® ACP System is intended for unilateral fixation.

MATERIAL

The components of the DynaTran® ACP System are manufactured out of Titanium alloy as defined in the ISO 5832-3 and ASTM F136 standards.

INDICATIONS

The DynaTran® Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is 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)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

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

CAUTION

Based on the fatigue testing results, the physician/ surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

GENERAL CONDITIONS OF USE

Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal device. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Consult the medical literature for information regarding proper surgical techniques, precautions, and potential adverse effects associated with spinal fixation surgery

Do not substitute another manufacturer's device for any component of the DynaTran® ACP System. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting mixed component implant.

Do not mix metals (i.e. Titanium based devices with stainless steel items). Some corrosion occurs on all implanted metals and alloys. Contact of dissimilar metals, however, may accelerate corrosion. Corrosion may accelerate fatigue fracture of implants, and cause metal compounds to be released into the body.

ANATOMICAL LIMITATIONS

- The DynaTran® ACP System is intended for use in the cervical spine only. However, as with any orthopaedic implant, even when an implant's design does not expressly contraindicate its placement in a particular area, the surgeon may encounter certain patient physiologies which impose their own unique anatomic limitations.
- Anterior cervical plates are for use in the cervical region of the spine only and must not be used below T1.

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 weightbearing, 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. Such patients should be advised 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 f or failure of the fusion and/or the device.
- Surgeons should 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 surgeons should counsel patient to 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 should be made prior to material implantation.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised 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.

THE CHOICE OF IMPLANTS

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INTRA-OPERATIVE PRECAUTIONS

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Stryker Spine.
- Discard all damaged or mishandled implants.
- Stryker Spine implants must not be reshaped, unless otherwise indicated in the surgical technique instructions. When implants need to be bent, the bending must be carried out gradually using the appropriate instruments, provided by Stryker Spine. The use of inappropriate instruments may result in scratches, notches, and sharp bending, causing the breakage of the implants. Improper seating of the implant may result in implant failure.
- Never reuse an implant, even though it may appear undamaged.
- Do not mix metals.

POST-OPERATIVE PRECAUTIONS

Physician instructions regarding full weight-bearing activities must be complied with until maturation of the fusion mass is confirmed. Failure to comply with physician instructions may result in failure of the implant, the fusion, or both.

SIDE EFFECTS

Include but are not limited to:

- Late bone fusion or no visible fusion mass and pseudarthrosis;
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis;
- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reactions to the implanted materials although uncommon can occur;
- Metal sensitivity of allergic reactions to a foreign body have been reported, possibly leading to tumor formation;
- Decrease in bone density due to stress shielding;
- Neurological and spinal dura mater lesions from surgical trauma;
- Dural leak requiring surgical repair;
- Asymptomatic presence of microparticles may be observed around the implants as a result of interaction between the components as well as between the component and bone (i.e. wear).
- Cessation of growth of the fused portion of the spine;
- Loss of proper spinal curvature, correction, height and/or reduction;
- Pain, discomfort, or abnormal sensations due to the presence of the device;
- Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
- Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation.

REMOVAL

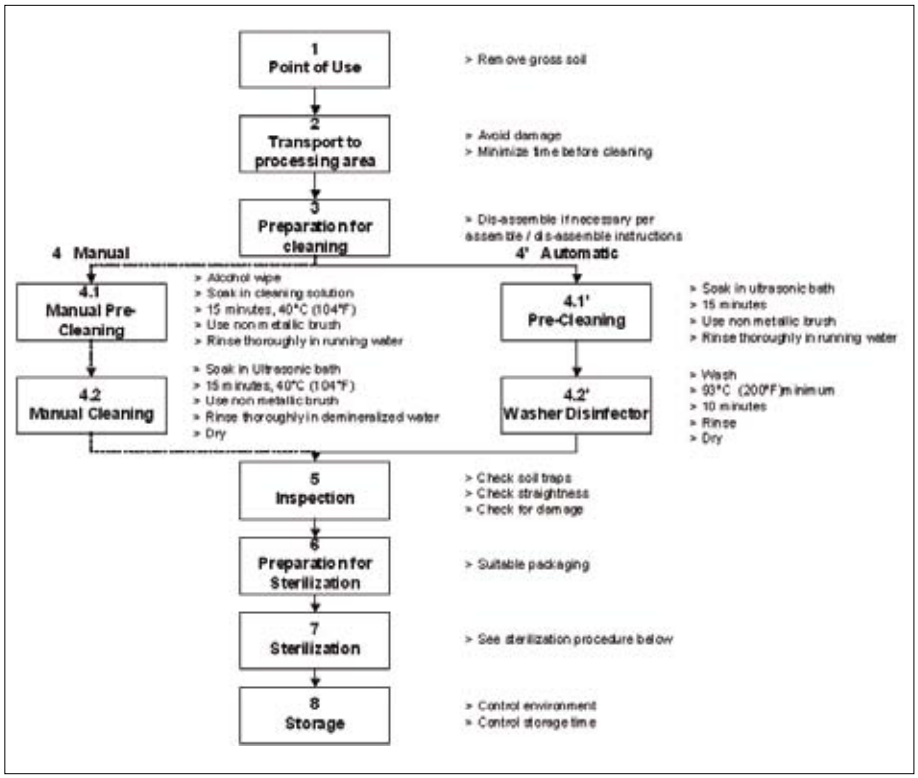
- Stryker Spine devices are indicated for treatment of fracture or stabilization of a surgical site during the normal bone consolidation process. After this period, the presence of the device is no longer strictly required and its removal can be planned. Removal may also be necessary as a result of the 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 should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

PACKAGING

- The implants are delivered in packages; these must be intact at the time of receipt.
- The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

PRE-CLEANING / CLEANING AND STERILIZATION PROCEDURE RECOMMENDED FOR NON STERILE MEDICAL DEVICE

For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following chart.



WARNING: SPECIAL DECONTAMINATION PROCEDURE FOR NCTA (CREUTZFELDT-JAKOB DISEASE) FOLLOWING FRENCH GUIDELINE DGS/DHOS N°138:
If, for any reason, a device is suspected to have been contaminated with NCTA (Creutzfeldt-Jakob disease), the following procedure must be followed depending on the device material:
1- If the device is made of titanium or titanium alloy, immerse totally in a 2% sodium hypochlorite solution for 1 hour.
If the device is made of stainless steel, immerse totally in a 1M NaOH solution for 1 hour.
If the device is made of aluminium you can use either of the two aforementioned agents for decontamination but instruments will have to be discarded.
2- The device must be autoclaved at 137°C (278°F) for 18 minutes in a porous-load autoclave.
After this process, devices are considered decontaminated against NCTA and sterile (a Sterility Assurance Level (SAL) of 10-6 is obtained).

Devices made of titanium or titanium alloy are identified by a T laser marking.
Devices made of stainless steel are identified by an S laser marking.
Plastic materials used by STRYKER Spine withstand both treatments described above.
If the device material is not identified, please contact your local STRYKER Spine representative.
A list of instruments potentially used - or intended to be used - in high contamination risk procedures can be obtained by contacting a STRYKER Spine representative.

STERILIZATION PROCEDURE RECOMMENDED FOR NON-STERILE MEDICAL DEVICES INCLUDING IMPLANTS
Medical Devices should be sterilized in their container with water vapor in an autoclave in accordance with standard hospital procedure. The sterilization method suggested has been validated according to the AAMI TIR 12 in order to obtain a Sterility Assurance Level (SAL) of 10-6.

STERILIZATION CONDITIONS: 2 sets of low parameters have been validated on wrapped items:
- Prevacuum steam sterilization (Porous load autoclave): TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 4 minutes, DRY TIME: 45min.
- Gravity-displacement steam sterilization: TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 10 minutes, PRESSURE: 2.5 Bars/36-PSIG, DRY TIME: 45min.

STRYKER Spine recommends for either prevacuum sterilization or gravity-displacement steam sterilization using higher parameters: TEMPERATURE: 137°C (278°F), EXPOSURE TIME: 18 minutes, PRESSURE: 2.5 Bars/36-PSIG, DRY TIME: 45min.
All intermediary sets of parameters can be used.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.
If sterilization containers with paper filters are used, it is advisable to use a new filter for each sterilization.
If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated.

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.

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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