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AT WORK

**3°™**

ANTERIOR CERVICAL  
PLATING SYSTEM

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

## INTRODUCTION

The 3° low-profile Anterior Cervical Plating System was designed to allow the surgeon the versatility of controlling the dynamics of the plate.

The options consist of a:

- Constrained Construct
- Semi-Constrained Construct
- Unconstrained Construct

The 3° has one of the lowest plate profiles in the market. The profile is 2.1 mm with a leading edge of 1.2 mm.

The 4.4 mm and 4.75 mm self-tapping screws are color coded by length and are available in 10 mm through 18mm lengths in 2 mm increments.

The 3° is indicated for stabilizing the cervical spine from C2-C7.

- Degenerative Disc Disease
- Spondylolisthesis
- Spinal Stenosis
- Tumor
- Pseudarthrosis
- Deformities
- Trauma
- Revision of previous surgery

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PLATING SYSTEM**



### 1. PRE-OPERATIVE PLANNING AND PATIENT POSITIONING

As with any spine surgery, preoperative planning is essential to reduce the risk of intraoperative complications due to unrecognized anatomic aberrations. Measuring the vertebral body dimension in both A/P and lateral planes is recommended to determine the appropriate interbody device, cervical plate and bone screw sizes.

#### PATIENT POSITIONING

The patient is placed in a supine position with all bony prominences padded and the head in slight extension. The cervical spine is supported to maintain cervical lordosis.

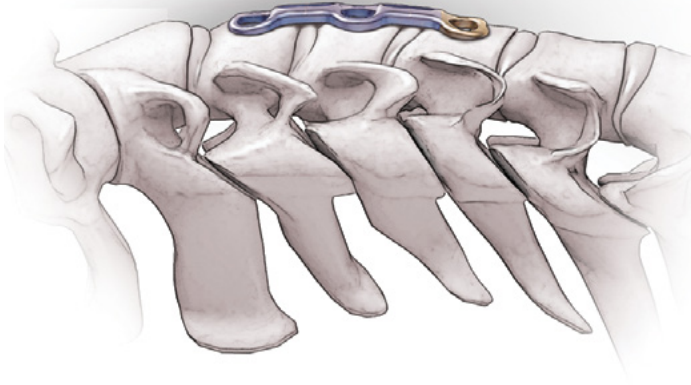


Fig. 2a

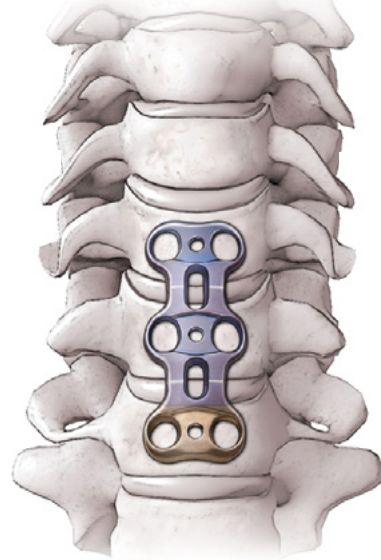


Fig. 2b

## 2. EXPOSURE

The approach to the anterior cervical spine makes use of natural anatomic planes that are relatively bloodless and safe.

Adequate visualization of the disc space or vertebrae to be considered for fusion should be obtained using standard surgical technique. After decompression and graft placement has been performed, a plate should be selected so that the superior and inferior screw holes extend approximately one third of the vertebral body above and below the disc space to be fused.

**NOTE:** Bone spurs should be removed from the end plates to create a smooth surface so the plate fits flush on the spine.

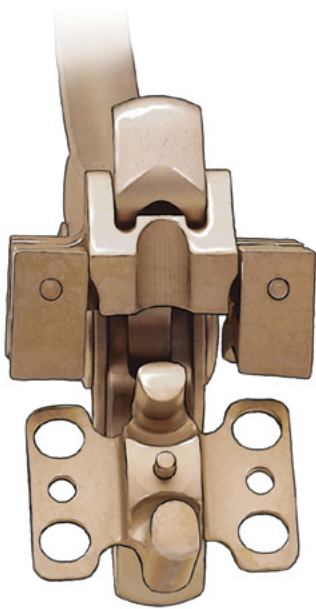


Fig. 3a

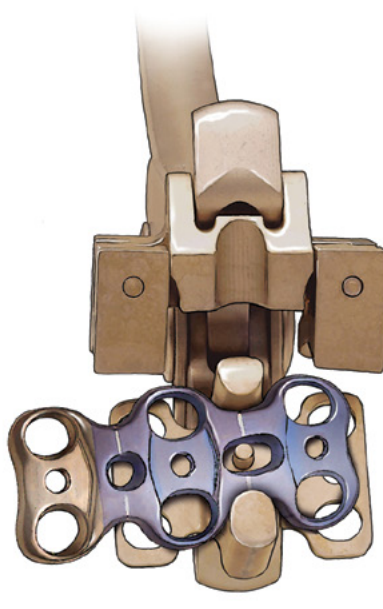


Fig. 3b

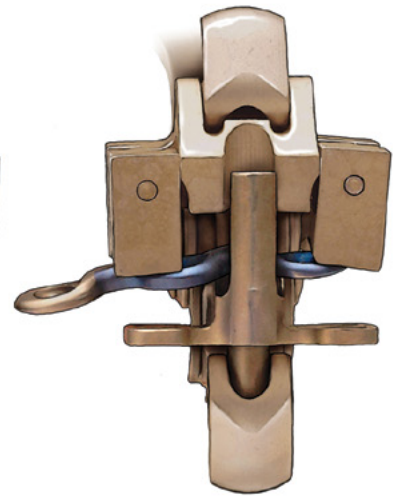


Fig. 3c

### 3. CONTOURING THE PLATE

The 3° Anterior Cervical Plate is pre-contoured. If additional contouring is required, the plates may be bent from 24 mm through 90 mm using the Orthofix Plate Bender.

To contour the plate:

- insert the plate into the plate bender
- align the “bend zones” on the plate with the bending template and post
- Upon positioning the plate correctly apply moderate pressure to the handles

NOTE: Due to the notch sensitivity of titanium, Orthofix does not recommend decreasing the contour if the plate has been overly bent.

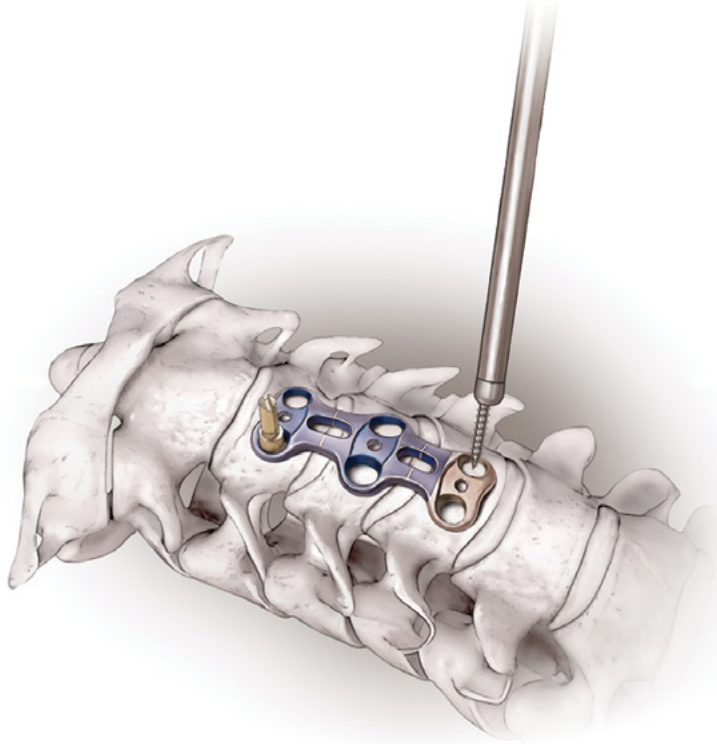


Fig. 4

#### 4. POSITIONING THE PLATE

After the plate is properly positioned, a temporary tack may be inserted into the cephalad or caudal screw hole to facilitate alignment.

This will secure the plate to the cervical column to help prevent plate movement during the initial screw placement.

##### Dr. Reichman Recommends:

"When doing a single level, I use the temporary tack to stabilize the plate. With multilevel procedures the central screws are placed first. This anchors the plate and establishes the location for the upper and lower screws."

Fig. 5



#### 5. SELECTING THE DRILL GUIDES

The 3° Anterior Cervical Plating System contains 3 Free Hand Drill Guides and the "all-in-one" 0° and 10° Fixed Guides to facilitate intra-operative flexibility.

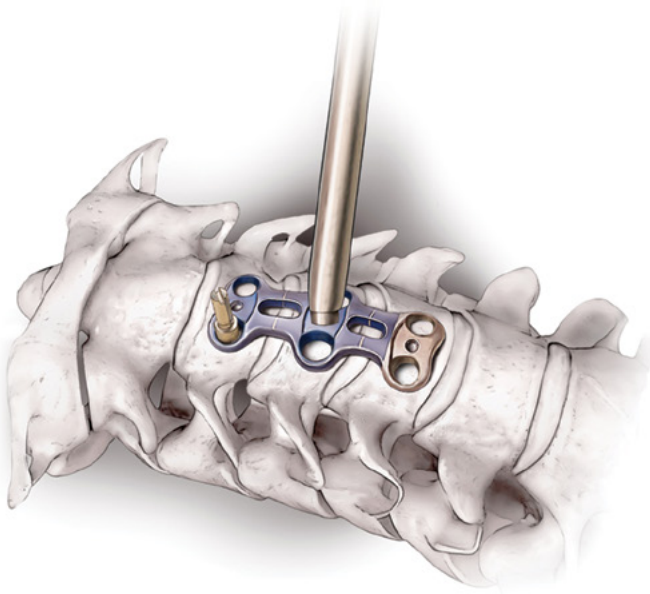


Fig. 6a

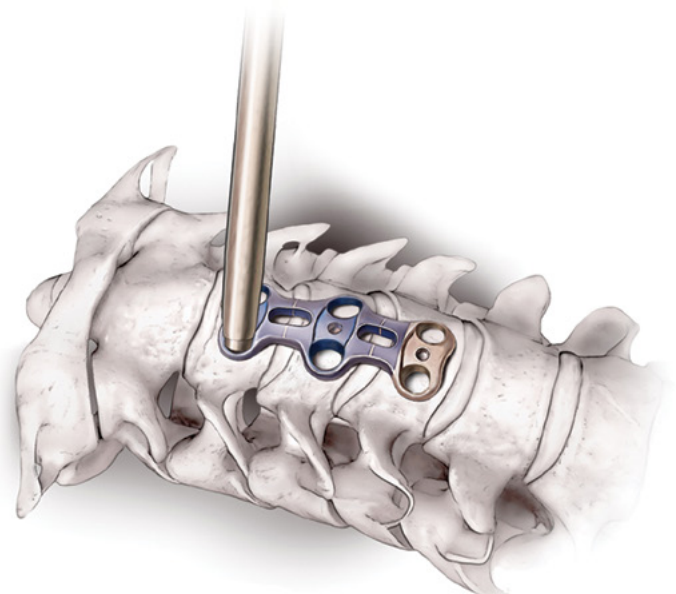


Fig. 6b

## 6. FREE HAND DRILL GUIDES

### 0° Free Hand Drill Guide

The 0° Free Hand Drill Guide allows the surgeon to drill and tap (if necessary) the bone screw holes at 0° perpendicular to the plate's lordosis with a convergent screw angle of 6°.

The drill guide is color-coded with a blue band. It is only used with the "slotted holes" and centers the screw head in the slotted bone screw hole.

#### Dr. Reichman Recommends:

"On multi-levels I always use the 0 degree freehand guide and place the middle screws first. Holding the plate with my finger, I put the 0 degree freehand guide in the bone screw hole and insert the first screw. Do not tighten the initial screw because the plate will ride up. After the second middle screw is placed, tighten both completely and place the locking plate over the two screws."

### 10° Free Hand Drill Guide

The 10° Free Hand Drill Guide allows the surgeon to drill and tap (if necessary) the bone screw holes 10° perpendicular to the plate's lordosis with a convergent angle of 6°.

The drill guide is color-coded with a blue band and is only used with the "slotted" holes.



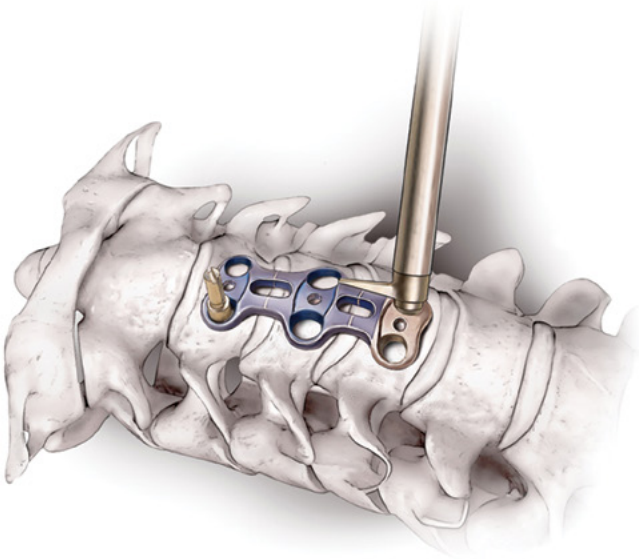


Fig. 7

### 7. FIXED FREE HAND GUIDE

The Fixed Free Hand Guide will allow the surgeon to insert the screws at 10° on the gray 0° portion of the plate and 0° when a screw is inserted in a washer. The drill guide is color coded with a gray and green band.

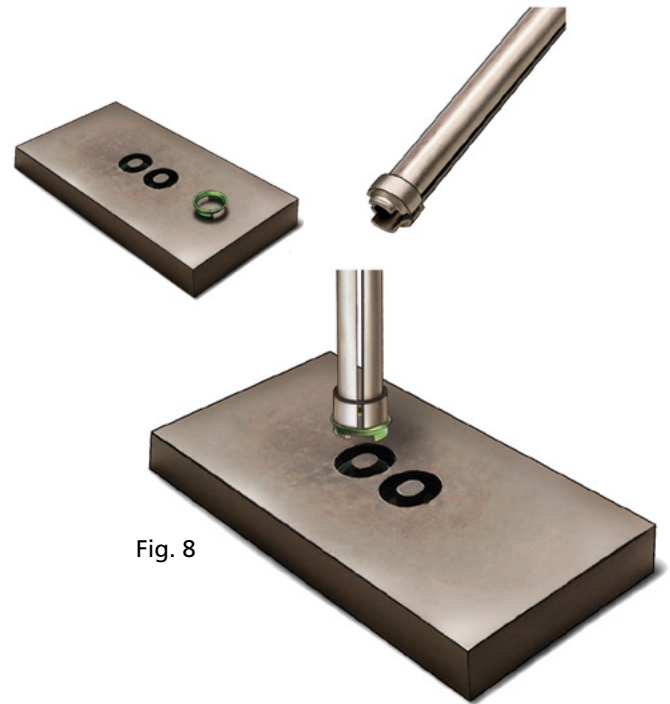


Fig. 8

### 8. WASHER INSERTION

Pick up the washer by inserting the Fixed Washer Inserter into the Fixed Washer Nest with the slot in line with the two steam-port holes. The oval feature on the top of the inserter will align with the oval shaped nest.

NOTE: Make sure flange is aligned with slot on insertion instrument.



Fig. 9



Fig. 10

### 9. FIXED WASHER INSERTER

The two "foot" snap features of the Fixed Washer should be centered in line with the slot on the Fixed Washer Inserter. Make sure that the washer feet are always facing down.

### 10. FIXED WASHER

The oval feature on the top of the Fixed Washer Inserter should be in the bone screw hole. The washer will "snap" into place.



Fig. 11

### 11. FIXED WASHER PLACEMENT

The Fixed Washer is now in place. It will only fit into the bone screw holes in the blue portion of the cervical plate. The gray region is already fixed. The Fixed Washer is only to be used with the 0 Degree Fixed and the Fixed Freehand Guides.

The Washer is seated with the “snaps” positioned in the long axis of the plate.

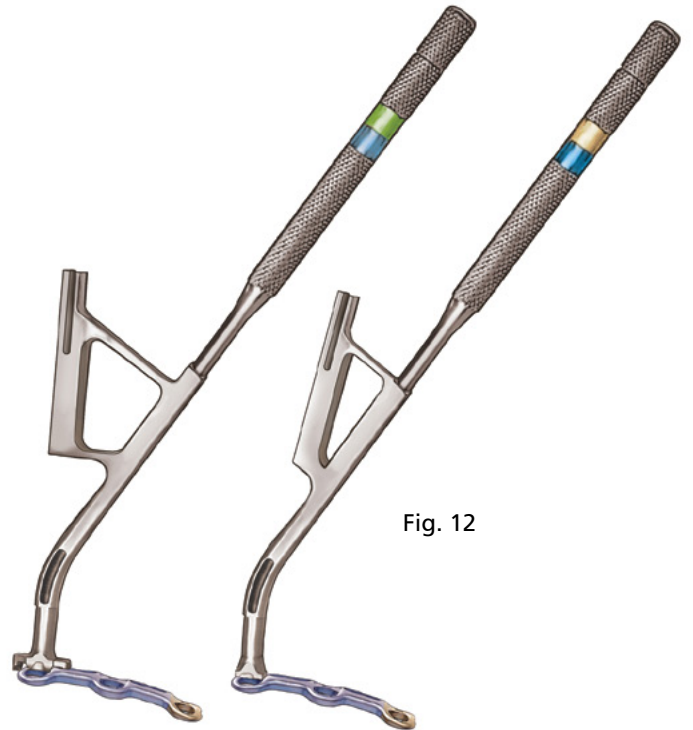


Fig. 12

### 12. “ALL IN ONE” FIXED GUIDES

The “all-in-one” Fixed Guides were designed at 0 and 10 degrees with the ability to easily lock into the plate.

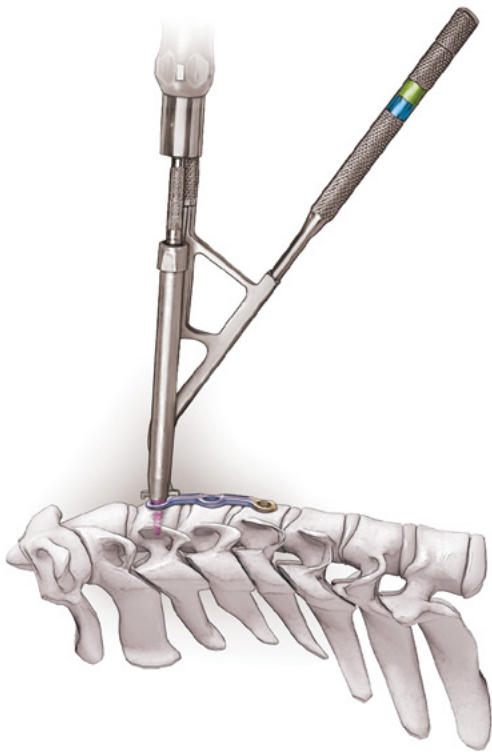


Fig. 13

### 13. 0° "ALL IN ONE" FIXED GUIDE

The 0° "all-in-one" Fixed Guide is color coded with a blue and green band on the handle.

This guide will allow the surgeon to drill, tap (if necessary) and insert the bone screw via a cannula at 0° perpendicular to the plate's lordosis with a 6° convergent angle.

The surgeon may use this drill guide in the blue holes or in the blue holes that have had green washers inserted to make the construct constrained.

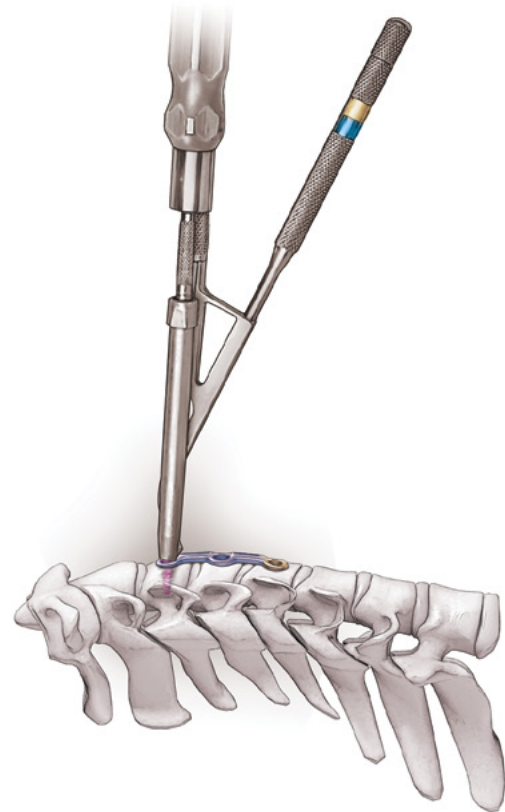


Fig. 14

### 14. 10° "ALL IN ONE" FIXED GUIDE

The 10° "all-in-one" Fixed Angle Guide is color coded with blue and gray bands on the handle.

NOTE: A perpendicular approach must be employed when tightening the bone graft screw using the non-torque driver.

This guide will allow the surgeon to drill, tap (if necessary) and insert bone screws at 10° perpendicular to the plate's lordosis with a convergent angle of 6°.

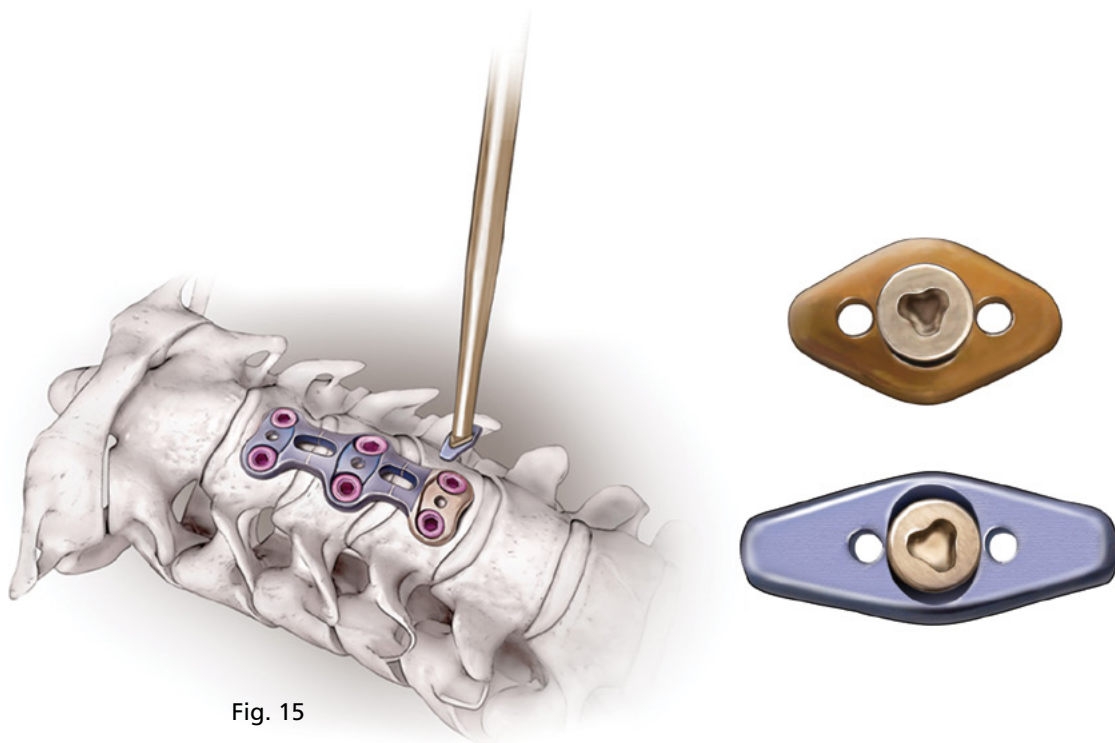


Fig. 15

## 15. TOP LOCKING PLATE

### Controlled Linear Translation

The "Bronze" Top Locking Plate is to be used when constructing a "constrained" or "unconstrained" plate construct.

The "Blue" Top Locking Plate is to be used when constructing a "semi-constrained plate construct."

**Description:**

The 3° Anterior Cervical Plating System is a temporary titanium alloy (Ti6Al-4V ELI, per ASTM F136) system comprised of a variety of non-sterile, single use components that allow the surgeon to build an anterior cervical implant construct. The system's design is intended to stabilize the cervical spinal operative site during the fusion process of a bone graft in the disc space. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation which assist in the surgical implantation of the devices. The system is provided non-sterile and requires sterilization prior to use.

**Indications for Use:**

The 3° Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies).
2. Spondylolisthesis.
3. Fracture.
4. Spinal stenosis.
5. Deformities (i.e., scoliosis, kyphosis, and/or lordosis).
6. Tumor.
7. Pseudoarthrosis.
8. Revision of previous surgery.

**Contraindications:**

The 3° Anterior Cervical Plating System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies. Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

**Potential Adverse Events:**

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products and graft material, including metallosis, straining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Vertebral body fracture at, above, or below the level of surgery.
8. Loss of neurological function, including paralysis (complete or incomplete).
9. Non-union, delayed union.
10. Pain, discomfort, or abnormal sensations due to the presence of the device.
11. Hemorrhage.
12. Cessation of any potential growth of the operated portion of the spine.
13. Death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

**Warnings and Precautions:**

1. Single use only.
2. The 3° Anterior Cervical Plating System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
3. Nonsterile; the plates, screws and instruments are sold nonsterile, and therefore, must be sterilized before each use.
4. Always orient the plate along the midline of the spine.
5. To optimize bony union, perform an anterior microdissectomy or corpectomy as indicated.
6. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
7. Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
8. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
9. Do not reuse implants; discard used, damaged, or otherwise suspect implants.
10. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not re-sterilize single-use implants that come in contact with body fluids.

**MRI Compatibility Information:**

The 3° Anterior Cervical Plating System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. This system has not been tested for heating or migration in the MR environment.

**1-Level Plates**

Part #	Description
60-6200	20mm Plate
60-6220	22mm Plate
60-6240	24mm Plate
60-6260	26mm Plate
60-6280	28mm Plate
60-6300	30mm Plate
60-6320	32mm Plate
60-6340	34mm Plate
60-6360	36mm Plate

**2-Level Plates**

Part #	Description
60-6380	38mm Plate
60-6400	40mm Plate
60-6420	42mm Plate
60-6440	44mm Plate
60-6460	46mm Plate
60-6480	48mm Plate
60-6500	50mm Plate
60-6520	52mm Plate
60-6540	54mm Plate

**3-Level Plates**

Part #	Description
60-6560	56mm Plate
60-6580	58mm Plate
60-6600	60mm Plate
60-6620	62mm Plate
60-6640	64mm Plate
60-6660	66mm Plate
60-6680	68mm Plate
60-6700	70mm Plate
60-6740	74mm Plate
60-6780	78mm Plate
60-6820	82mm Plate
60-6860	86mm Plate
60-6900	90mm Plate

**Graft Screw**

Part #	Description
60-1080	8mm Graft Screw

**4.4mm Primary Self-Tapping Screws**

Part #	Description
60-1100	4.4mm x 10mm Primary Screw
60-1120	4.4mm x 12mm Primary Screw
60-1140	4.4mm x 14mm Primary Screw
60-1160	4.4mm x 16mm Primary Screw
60-1180	4.4mm x 18mm Primary Screw

**4.75mm Rescue Self-Tapping Screws**

Part #	Description
60-2100	4.75mm x 10mm Rescue Screw
60-2120	4.75mm x 12mm Rescue Screw
60-2140	4.75mm x 14mm Rescue Screw
60-2160	4.75mm x 16mm Rescue Screw
60-2180	4.75mm x 18mm Rescue Screw



## 4.4mm Primary Self-Drilling/Self-Tapping Screws

Part #	Description
60-3100	4.4mm x 10mm Primary Screw
60-3120	4.4mm x 12mm Primary Screw
60-3140	4.4mm x 14mm Primary Screw
60-3160	4.4mm x 16mm Primary Screw
60-3180	4.4mm x 18mm Primary Screw

## Locking Plates

Part #	Description
60-3000	Dynamic Locking Plate
60-4000	Compliant Locking Plate
60-5000	Fixed Locking System Washer

## Cervical Tack


Part #	Description
60-0021	Cervical Tack – Threaded Tip 180
60-0022	Cervical Tack — Trocar Tip

## Disposable Instrumentation

Part #	Description
60-0034	10mm Drill Bit
60-0035	12mm Drill Bit
60-0036	14mm Drill Bit
60-0037	16mm Drill Bit
60-0038	18mm Drill Bit

## Instrumentation

Part #	Description
60-0010	Cannula Assembly
60-0011	0° Freehand Drill Guide
60-0012	10° Freehand Drill Guide
60-0013	Fixed Freehand Guide
60-0014	0° Plate Holding Guide
60-0017	10° Plate Holding Guide
60-0020	Tack Holder
60-0025	Modular Handle
60-0044	10mm Tap
60-0045	12mm Tap
60-0046	14mm Tap
60-0047	16mm Tap
60-0048	18mm Tap
60-0050	Bone Screw Driver
60-0055	Tri-Lobe Driver
60-0060	Top Locking Plate Torque Driver
60-0061	Top Locking Plate Holder
60-0062	Fixed Washer Inserter
60-0070	Plate Bender
60-0090	System Case

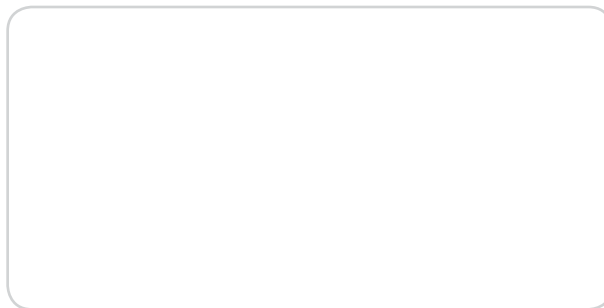
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