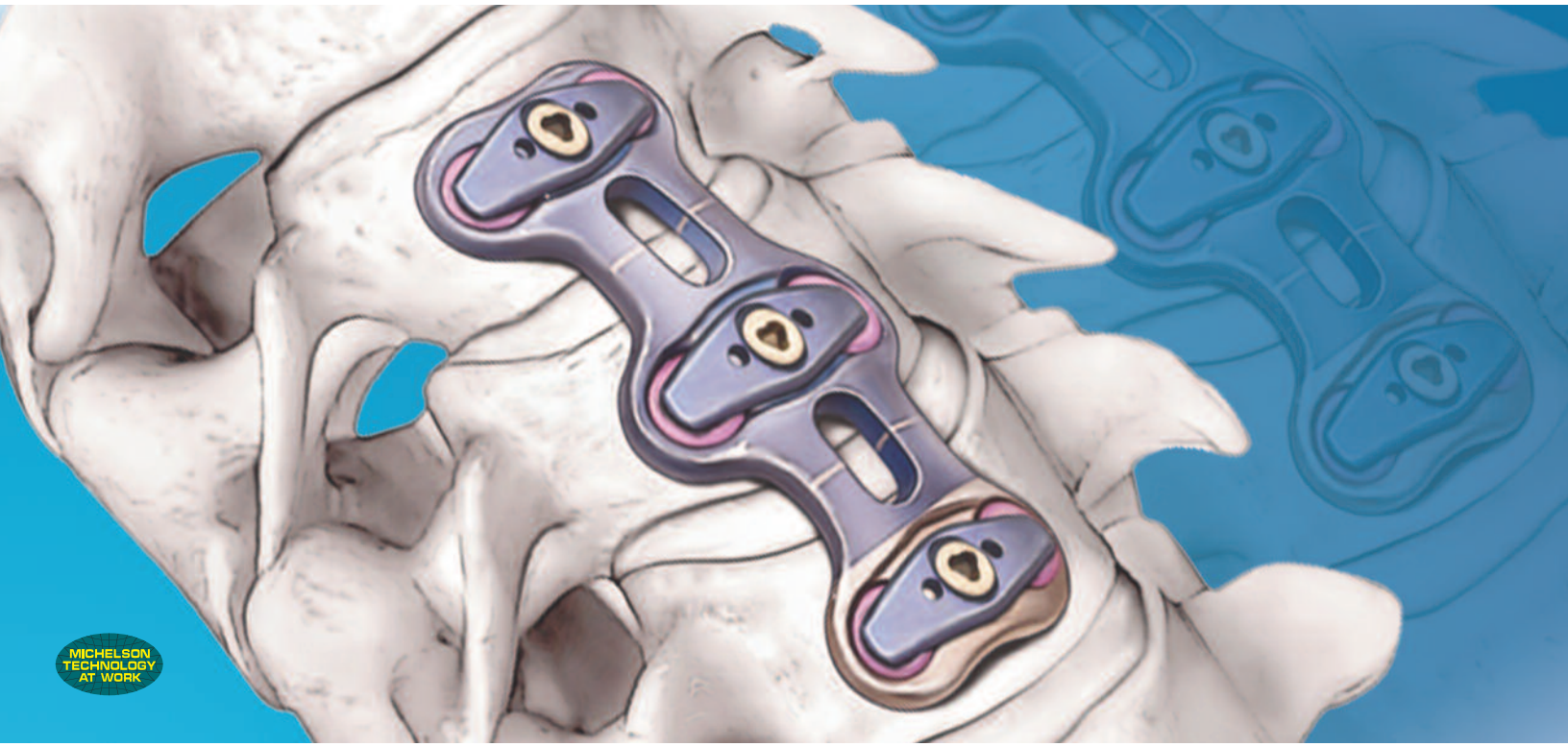
3° TM

ANTERIOR CERVICAL
PLATE SYSTEM



3° Operative Technique

U.S. EDITION

ORTHOFIX®

Orthofix Spinal Implants wishes to thank the following surgeon for his contribution to the development of the technique:

Howard Reichman, M.D.
Utah Neurological Clinic
Provo, UT

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

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.

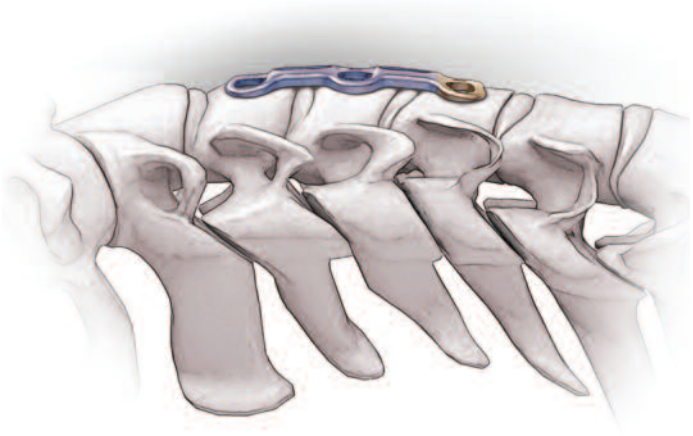


Fig. 2a

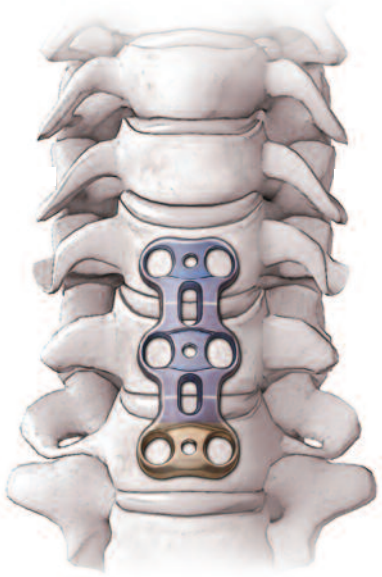


Fig. 2b

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.

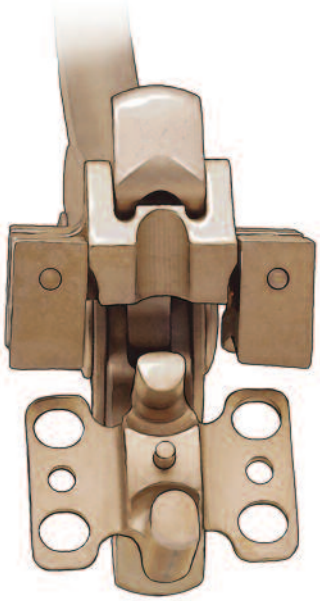


Fig. 3a

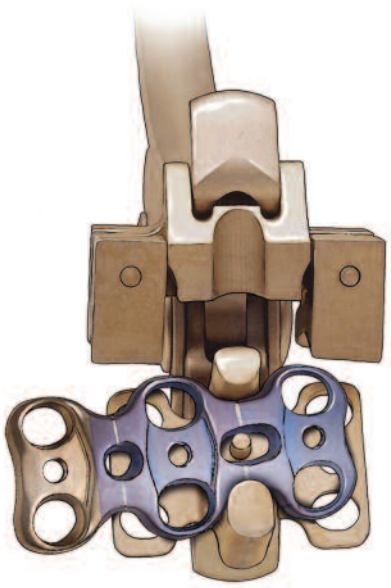


Fig. 3b

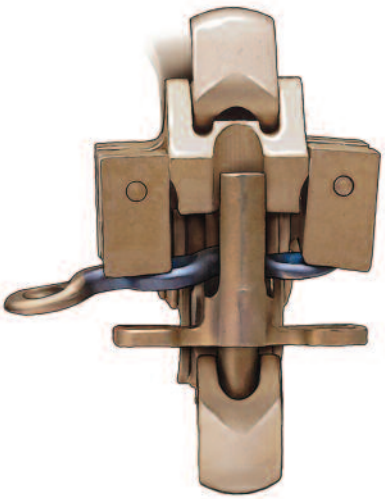


Fig. 3c

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.

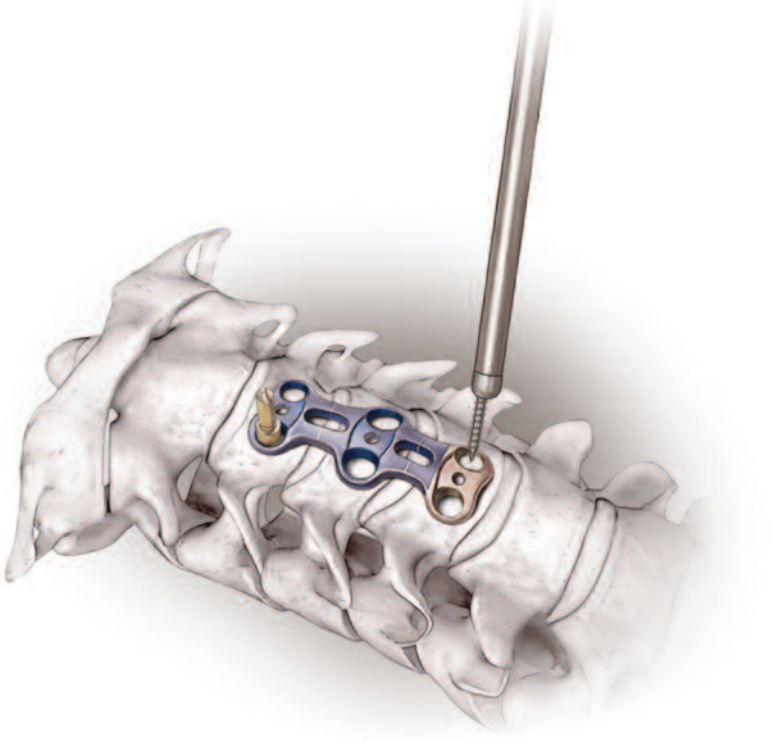


Fig. 4

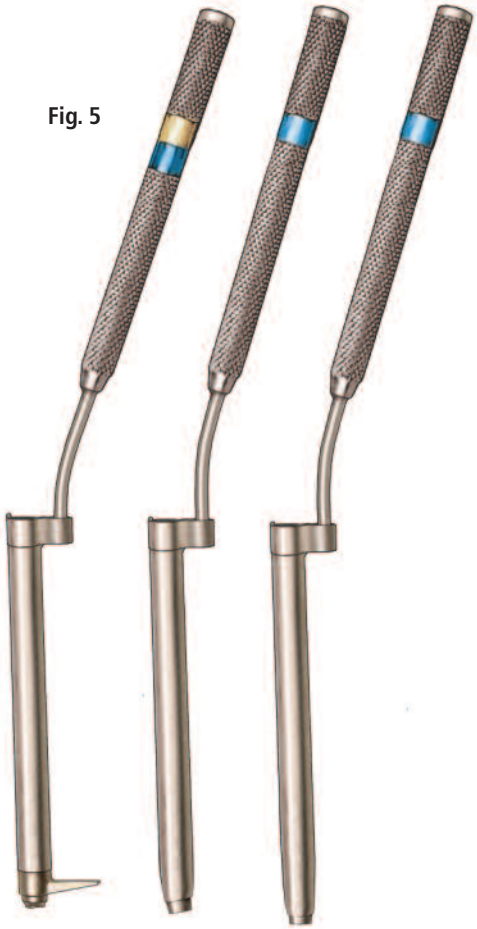


Fig. 5

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."

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.

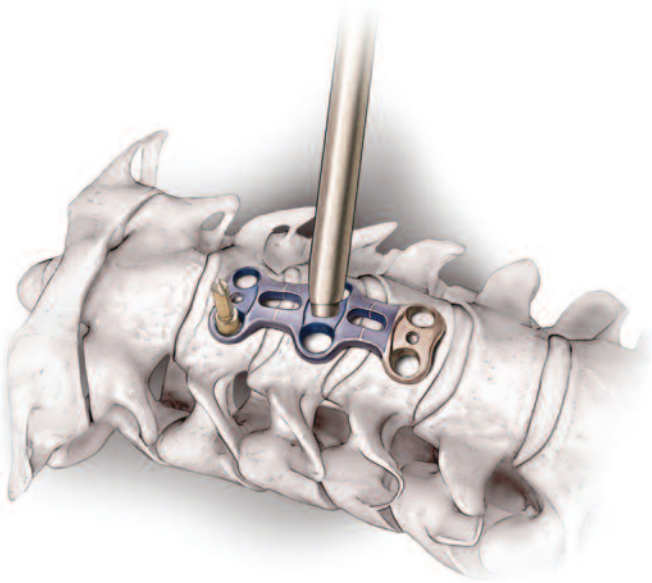


Fig. 6a

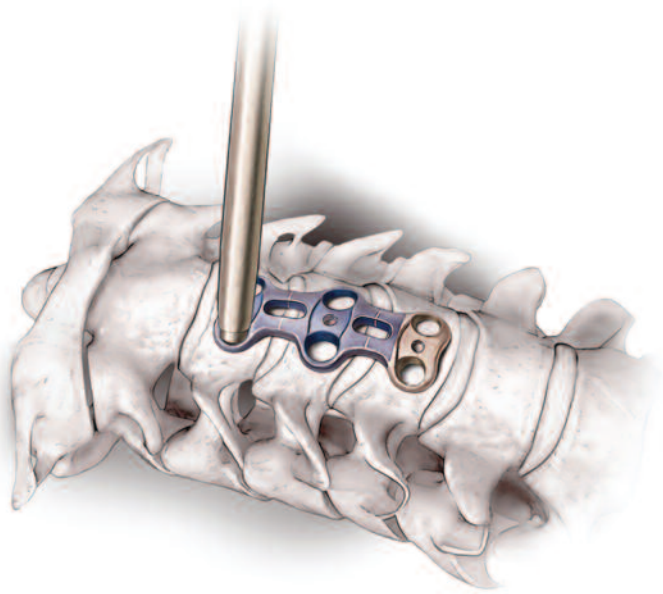


Fig. 6b

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.

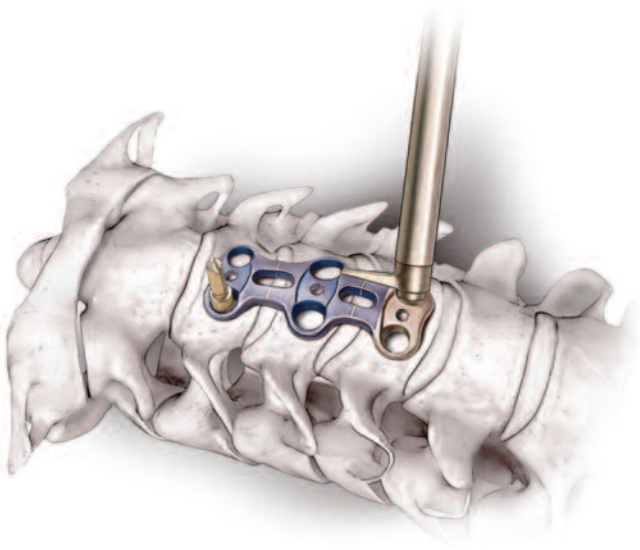


Fig. 7

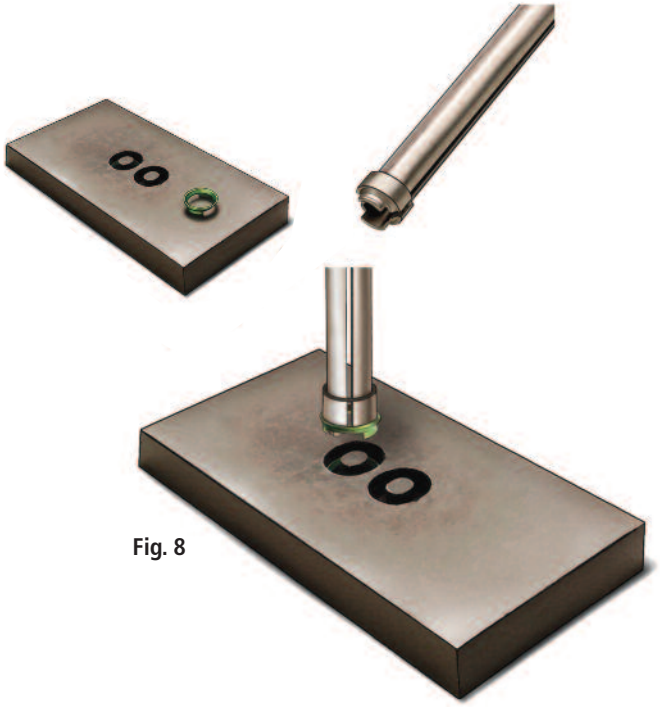


Fig. 8

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.

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

Fig. 12

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.

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.

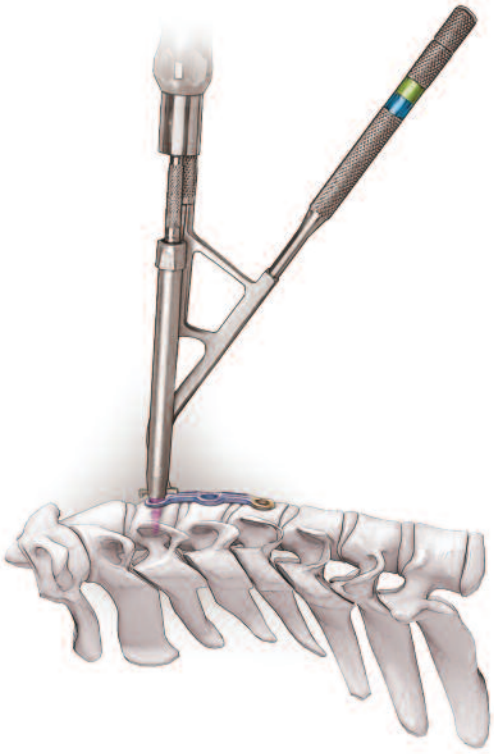


Fig. 13

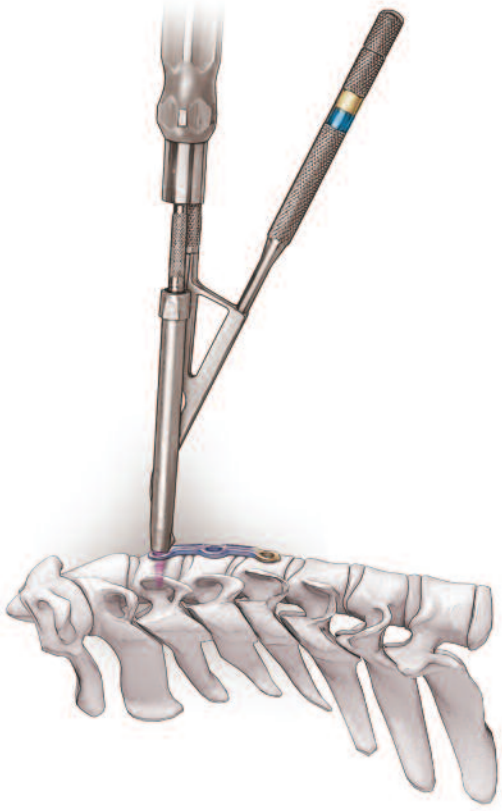


Fig. 14

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.

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°.

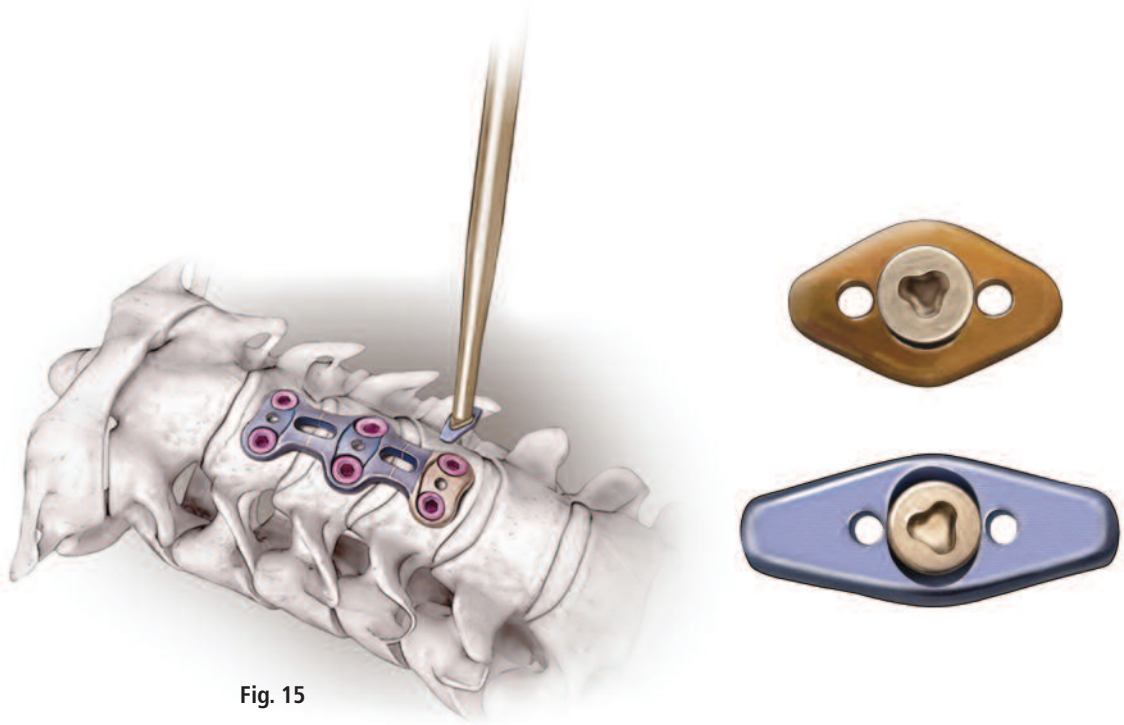


Fig. 15

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."

Device System Name

Orthofix 3°™ Anterior Cervical Plating System

Description

The 3° Anterior Cervical Plating System consists of an assortment of implantable titanium alloy plates, screws, and locking plate that are sold non-sterile.

Indications

The Hallmark (ACP) System is a temporary implant, 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 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, 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 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, bone 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 microdiscectomy 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.

Cleaning

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization

The 3° Anterior Cervical System should be sterilized by the hospital using the recommended cycle:

Method: Steam	Or:	Method: Steam
Cycle: Gravity		Cycle: Prevac
Temperature: 250° F (121° C)		Temperature: 270° F (132° C)
Exposure time: 30 minutes		Exposure time: 8 minutes

Physician's Manual

Patient Selection
Patient selection is an extremely important factor in the success of implant procedures. It is important that the candidates be carefully screened and the optimal therapy selected.

Preoperative
1. Carefully screen the patient, choosing only those that fit the indications described above.
2. Care should be exercised in the handling and storage of the implant components; the implants should not be scratched or otherwise damaged; store away from corrosive environments.
3. An adequate inventory should be available at surgery than those expected to be used.
4. All components and instruments should be cleaned and sterilized prior to each use; additional sterile components should be available in case of an unexpected need.

Intraoperative
1. Instructions should be carefully followed.
2. Extreme caution should be used around the spinal cord and nerve roots.
3. The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct.
4. Bone grafts must be placed in the area to be fused such that the graft fits snugly against the upper and lower vertebral bodies.
5. Bone cement should not be used as it will make removal of the components difficult or impossible.
6. Before closing soft tissue, check each screw to make sure that none have loosened.

Postoperative
1. Detailed instructions should be given to the patient regarding care and limitations, if any.
2. To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations; the patient should not smoke or consume alcohol during the healing process.
3. The patient should be advised of their limitations and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs; failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant; it is important that immobilization of the spinal segment be maintained until fusion has occurred.
5. The implants are temporary internal fixation devices; internal fixation devices are designed to stabilize the spine during the normal healing process; after the spine is fused, the devices serve no functional purpose and should be removed.

Patient Information

The temporary internal fixation device used in your recent spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts. These implants have been shown to be valuable aids to surgeons in the treatment of bony fusions. These devices do not have the capabilities of living bone. Intact living bone is self repairing, flexible and occasionally breaks and/or degrades. The anatomy of the human body places a size limitation on any artificial fixation device used in surgery. This maximum size limitation increases the chances of the mechanical complication of loosening, bending, or breaking of the devices. Any of these complications could result in the need for additional surgery. Accordingly, it is very important that you follow the recommendations of your physician. Use braces as instructed. By following these instructions, you can increase your chances of a successful result and reduce your risk of injury and/or additional surgery.

Product Complaints

Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify:

Orthofix Spinal Implants
1720 Bray Central Drive
McKinney, TX 75069
Telephone: 1.888.298.5700
Email: complaints@orthofix.com

1–LEVEL PLATES

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

2-LEVEL PLATES

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

3-LEVEL PLATES

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

GRAFT SCREW

60-1080	8mm Graft Screw

4.4MM PRIMARY SELF-TAPPING SCREWS

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

4.75MM RESCUE SELF-TAPPING SCREWS

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

4.4MM PRIMARY SELF-DRILLING/SELF-TAPPING SCREWS

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

LOCKING PLATES

60-3000	Dynamic Locking Plate	**60-5000**	Fixed Locking System Washer
60-4000	Compliant Locking Plate		

CERVICAL TACK

60-0021	Cervical Tack — Threaded Tip 180	**60-0022**	Cervical Tack — Trocar Tip

DISPOSABLE INSTRUMENTATION

60-0034	10mm Drill Bit	**60-0044**	10mm Tap
60-0035	12mm Drill Bit	**60-0045**	12mm Tap
60-0036	14mm Drill Bit	**60-0046**	14mm Tap
60-0037	16mm Drill Bit	**60-0047**	16mm Tap
60-0038	18mm Drill Bit	**60-0048**	18mm Tap

INSTRUMENTATION

60-0010	Cannula Assembly	**60-0050**	Bone Screw Driver
60-0011	0º Freehand Drill Guide	**60-0055**	Tri-Lobe Driver
60-0012	10º Freehand Drill Guide	**60-0060**	Top Locking Plate Torque Driver
60-0013	Fixed Freehand Guide	**60-0061**	Top Locking Plate Holder
60-0014	0º Plate Holding Guide	**60-0062**	Fixed Washer Inserter
60-0017	10º Plate Holding Guide	**60-0070**	Plate Bender
60-0020	Tack Holder	**60-0090**	System Case
60-0025	Modular Handle		

Orthofix Spinal Implants
1720 Bray Central Drive
McKinney, TX 75069

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
⚠ Refer to the instructions for use supplied with product for specific information on indications for use, contraindications, warnings, precautions, adverse reaction information, and sterilization.

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1.888.298.5700
www.orthofix.com

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