

## Surgical Technique

3°™

ANTERIOR CERVICAL  
PLATE SYSTEM



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 **ORTHOFIX SPINE**  
BLACKSTONE MEDICAL

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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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**Introduction**

The Blackstone 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
- Un-constrained Construct

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

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

1.



## Step 1

### Preoperative 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.

# Operative

2.



## Step 2

### Exposure

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

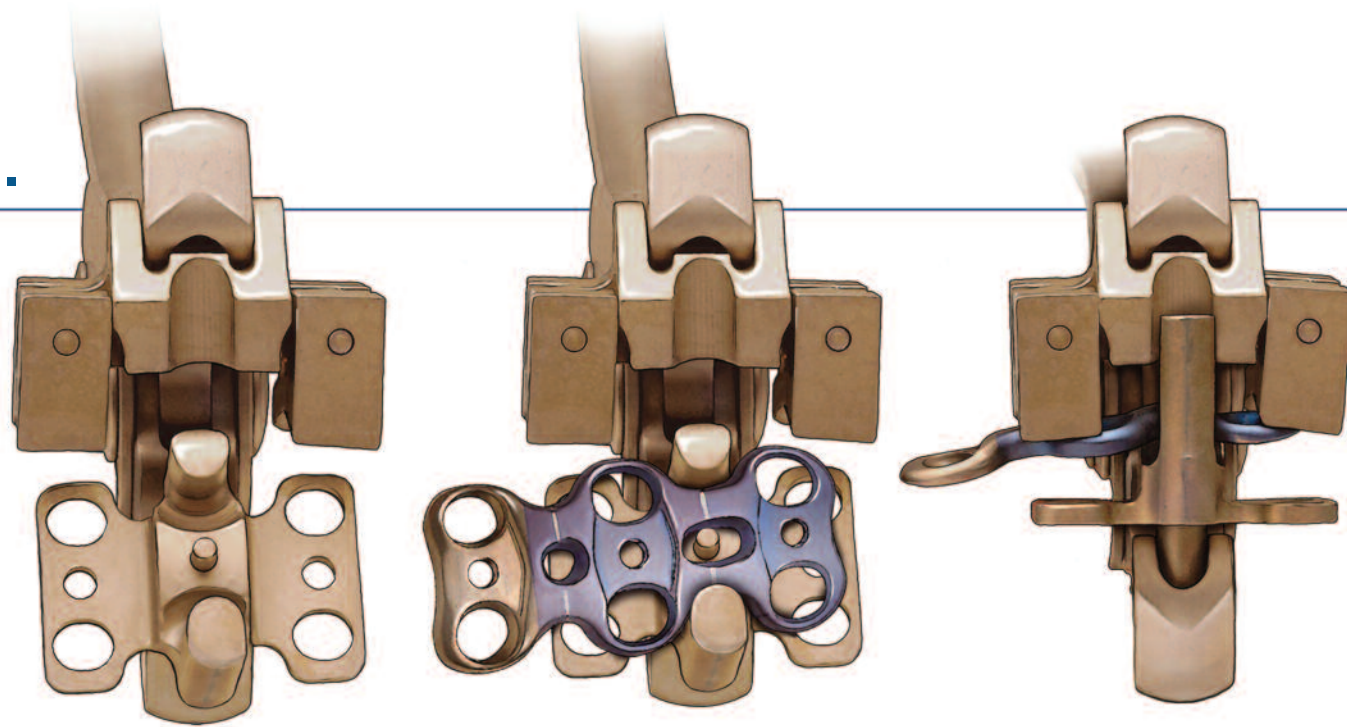
Adequate visualization of the disc space or vertebrae to be considered for fusion should be obtained using standard surgical technique. After decompression and graft placement has been performed, a plate should be selected so that the superior and inferior screw holes extend approximately one third of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

### DR. REICHMAN RECOMMENDS:

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



3.



**Step 3**

**Contouring the Plate**

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

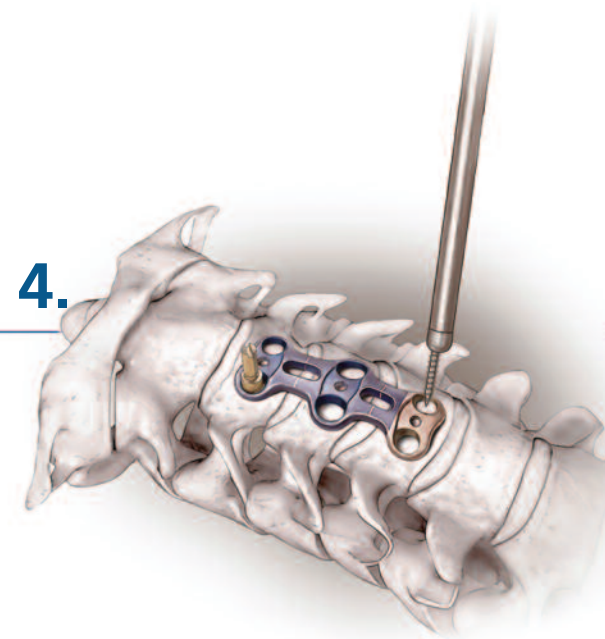
Upon positioning the plate correctly

- apply moderate pressure to the handles

**NOTE:**

Due to titanium’s notch sensitivity, Blackstone Medical does not recommend decreasing the contour if the plate has been over bent.

4.



**Step 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.

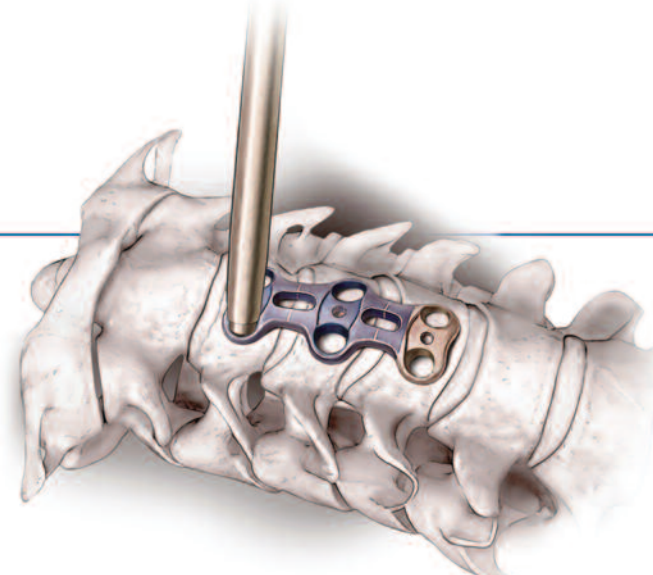
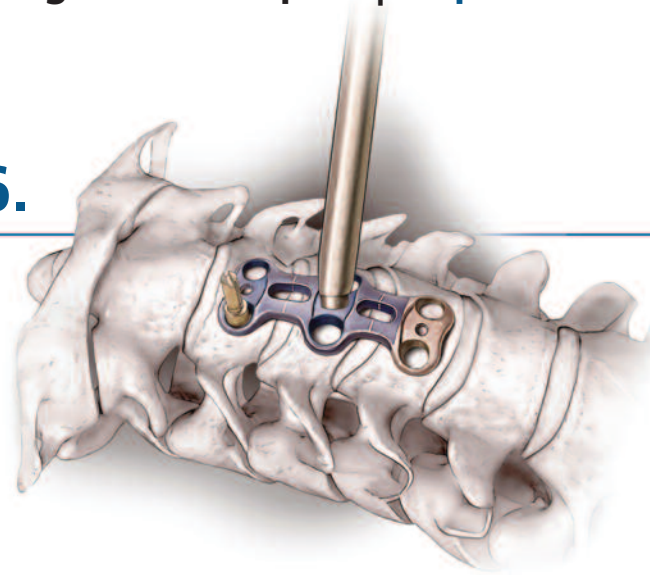


**Step 5**

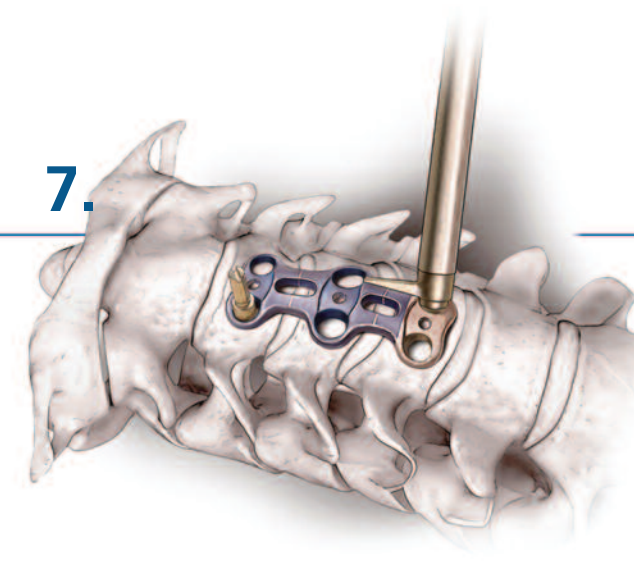
**Selecting the Drill Guides**

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.

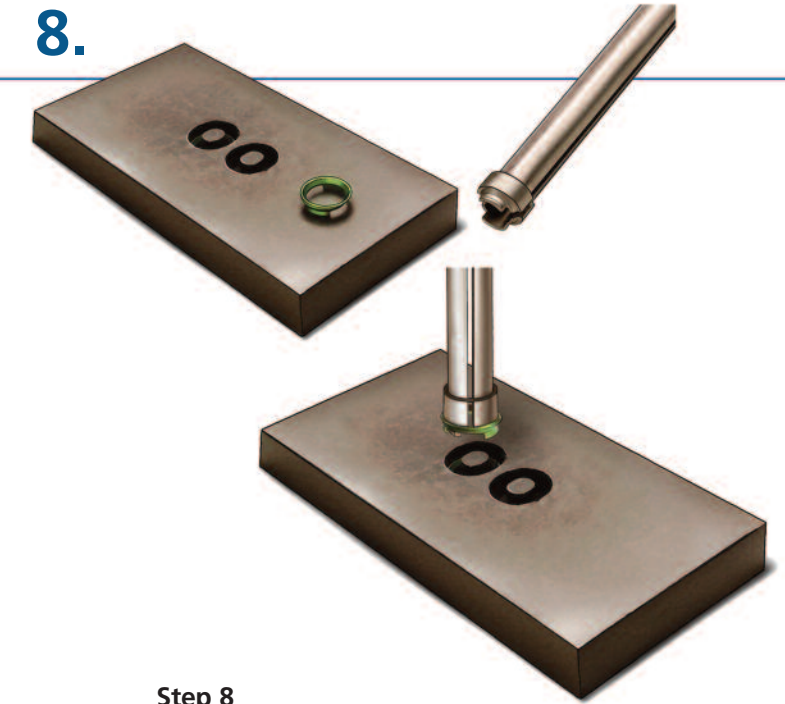
6.



7.



8.



**Step 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.

**Step 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.

**Step 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.

Make sure flange is aligned with slot on insertion instrument!



9.



**Step 9**

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.



**Step 10**

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

11.



**Step 11**

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.

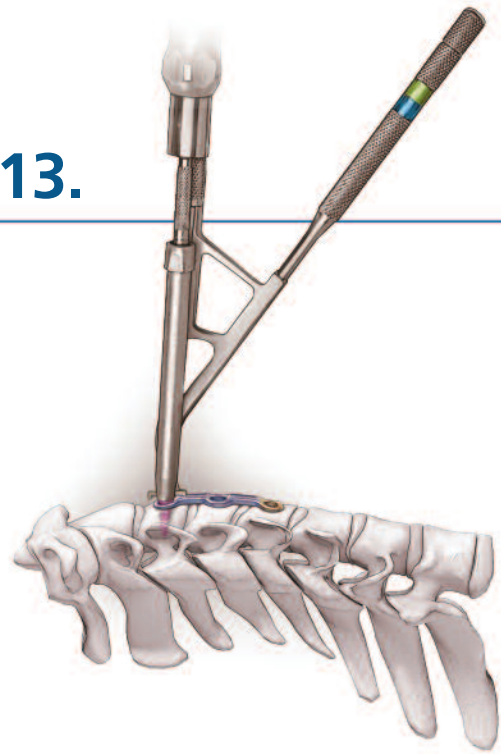


**Step 13**

**“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.

13.



**Step 13**

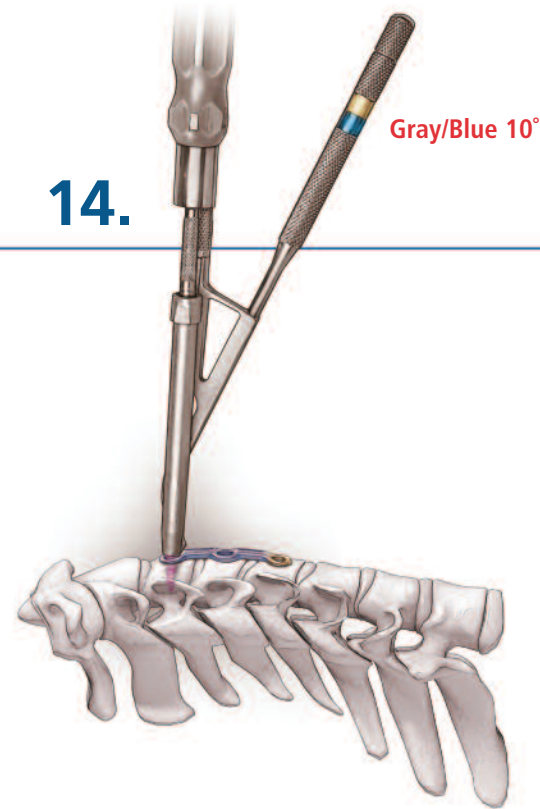
**0° "All-in-One" Fixed Guide**

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.



**Step 14**

**10° "All-in-One" Fixed Guide**

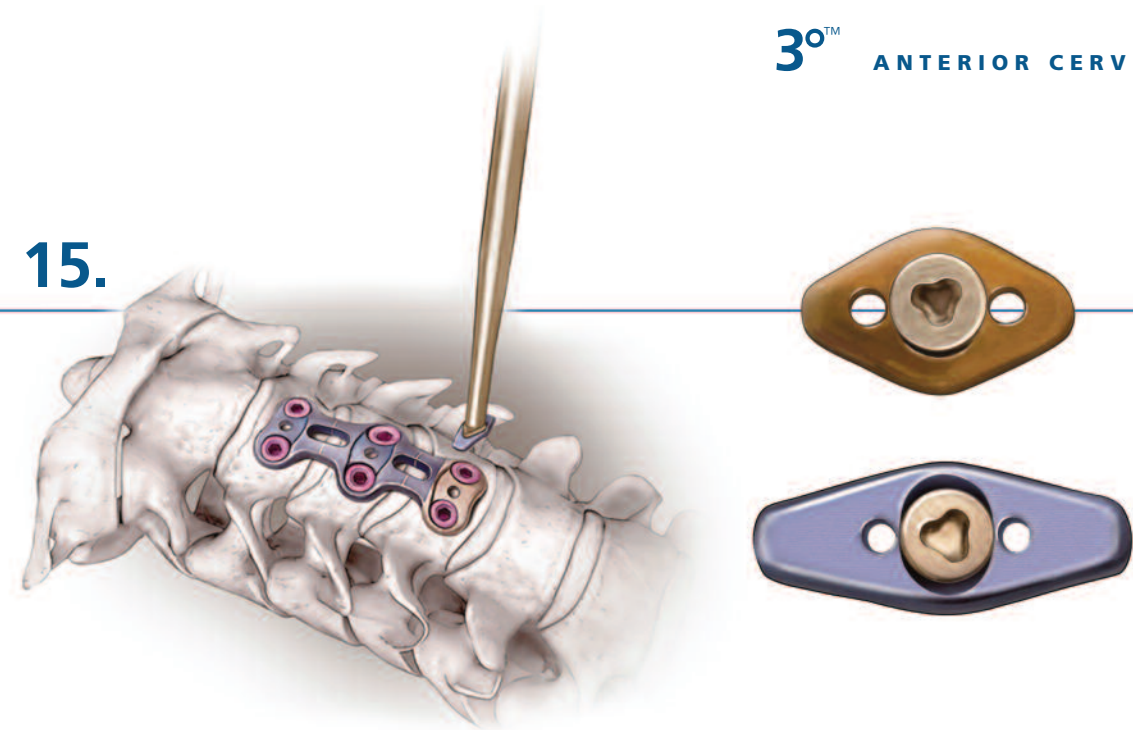
The 10° "all-in-one" Fixed Angle Guide is color coded with blue and gray bands on the handle.

**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°.

15.



**Step 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:**

**Blackstone™ 3° Anterior Cervical Plating System**

Description: The Blackstone Medical Inc. 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 Blackstone Medical Inc. 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 Blackstone Medical Inc. 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 Hallmark (ACP) 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 Spine-Blackstone Medical Inc., 1211 Hamburg Turnpike, Suite 300, Wayne, NJ 07470. Telephone: 877-BMI-9494, (877-264-9494). Email: [complaints@blackstonemedical.com](mailto:complaints@blackstonemedical.com)

**Further Information:**

A recommended surgical technique for the use of this system is available upon request from Orthofix Spine-Blackstone Medical, 1211 Hamburg Turnpike, Suite 300, Wayne, NJ 07470 USA, Telephone: 888-298-5400.

**Authorized European Representative:**

Medical Device Safety Service (MDSS)  
Schiffgraben 41  
30175 Hanover, Germany

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

**1-LEVEL PLATES**

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

**2-LEVEL PLATES**

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

**3-LEVEL PLATES**

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

**GRAFT SCREW**

<b>60-1080</b>	8mm Graft Screw
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**4.4MM PRIMARY SELF-TAPPING SCREWS**

<b>60-1100</b>	4.4mm x 10mm Primary Screw	<b>60-1160</b>	4.4mm x 16mm Primary Screw
<b>60-1120</b>	4.4mm x 12mm Primary Screw	<b>60-1180</b>	4.4mm x 18mm Primary Screw
<b>60-1140</b>	4.4mm x 14mm Primary Screw		

**4.75MM RESCUE SELF-TAPPING SCREWS**

<b>60-2100</b>	4.75mm x 10mm Rescue Screw	<b>60-2160</b>	4.75mm x 16mm Rescue Screw
<b>60-2120</b>	4.75mm x 12mm Rescue Screw	<b>60-2180</b>	4.75mm x 18mm Rescue Screw
<b>60-2140</b>	4.75mm x 14mm Rescue Screw		

**4.4MM PRIMARY SELF-DRILLING/SELF-TAPPING SCREWS**

<b>60-3100</b>	4.4mm x 10mm Primary Screw	<b>60-3160</b>	4.4mm x 16mm Primary Screw
<b>60-3120</b>	4.4mm x 12mm Primary Screw	<b>60-3180</b>	4.4mm x 18mm Primary Screw
<b>60-3140</b>	4.4mm x 14mm Primary Screw		

**LOCKING PLATES**

<b>60-3000</b>	Dynamic Locking Plate	<b>60-5000</b>	Fixed Locking System Washer
<b>60-4000</b>	Compliant Locking Plate		

**CERVICAL TACK**

<b>60-0021</b>	Cervical Tack — Threaded Tip 180	<b>60-0022</b>	Cervical Tack — Trocar Tip
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**DISPOSABLE INSTRUMENTATION**

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

**INSTRUMENTATION**

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



