*Breakthrough Thinking™*

Fusion | Motion Preservation | Biologics

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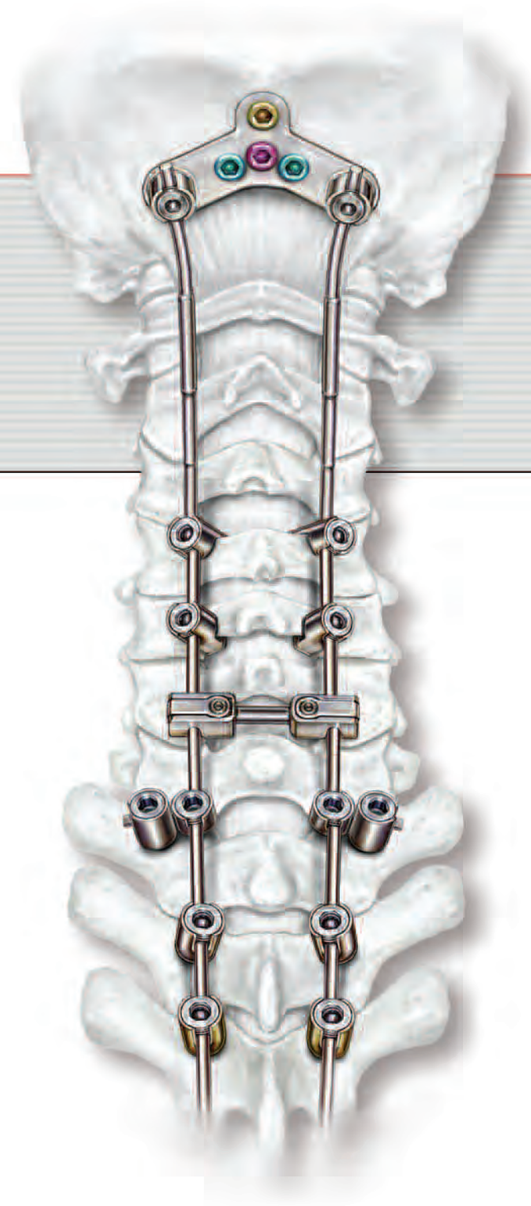
10-2158, 08/07

BLACKSTONE MEDICAL INC

*Breakthrough Thinking™*

an Orthofix Company

# Surgical Technique



# Ascent™

## Posterior Occipital Cervico-Thoracic (POCT) System

BLACKSTONE MEDICAL INC

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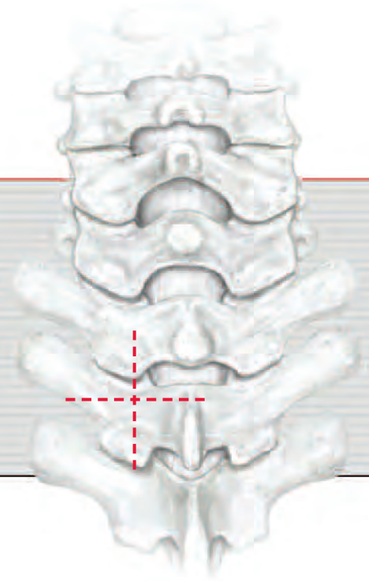
# Surgical Technique

1.

2.



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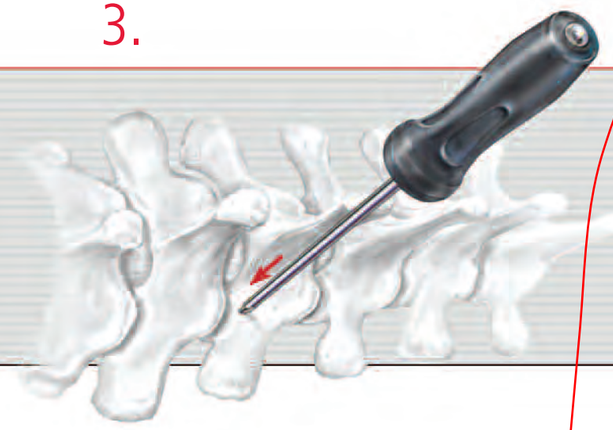


Fig. 3a

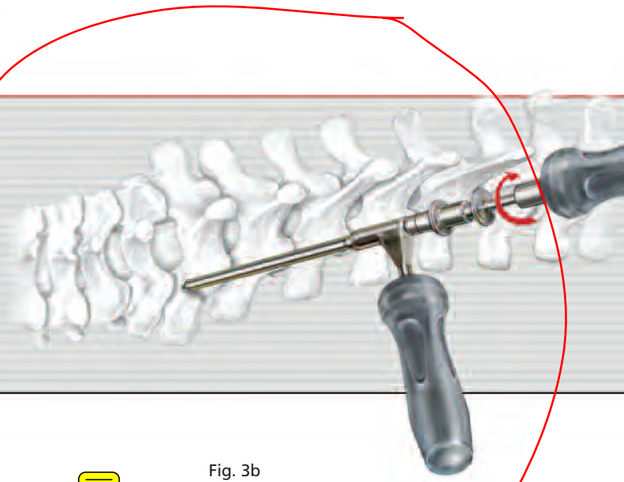


Fig. 3b

### Preoperative Planning and Patient Positioning

*Preoperative planning is critical in the preparation for spinal surgery.*

*A complete radiographic evaluation (A/P and lateral films) of the patient should be completed for proper diagnosis prior to surgery.*

*Carefully place the patient in the prone position following induction of anesthesia.*

### Exposure

*Incise the skin and subcutaneous tissue longer than the planned fusion. Once bleeding is controlled, deepen the exposure through the fascia level and dissect laterally to the transverse processes.*

### Pedicle Identification

*In general, the entrance of the pedicle is located at the intersection of a horizontal line parallel to the upper 1/3 of the transverse process and a vertical line through the middle of the superior facet.*

### Pedicle Preparation and Screw Length Selection

### Bone Awl

*Penetrate the cortex of the bone with the bone awl. (Fig. 3a)*

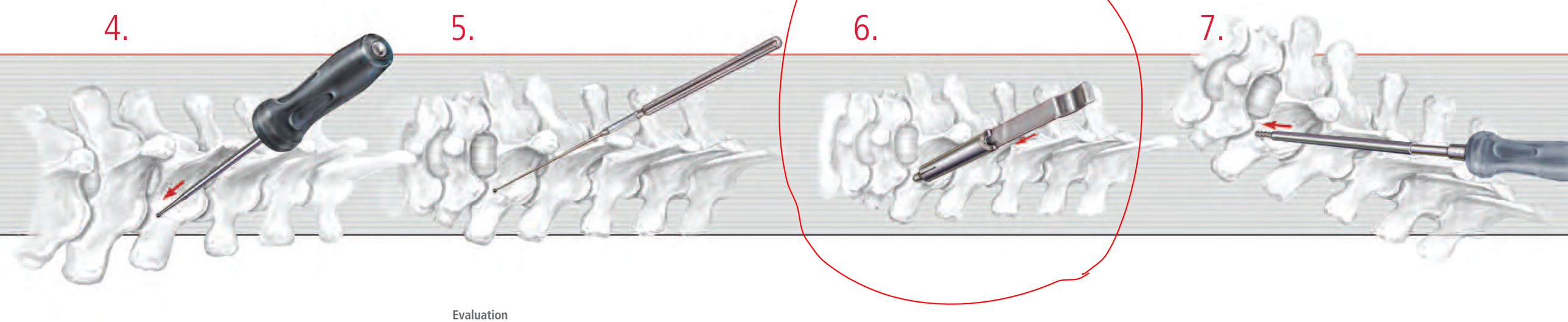
### Drill

*Slide the adjustable drill stop over the drill. Place the appropriate drill securely into the modular handle. Set the drill stop to the appropriate drilling depth (between 6-30mm in 2mm increments).*

*Insert the drill into the drill guide and drill to the appropriate depth. (Fig. 3b) A positive stop on the drill stop will prevent over-drilling.*

*X-rays may be helpful in the intraoperative assessment of appropriate pedicle depth and screw length.*

# Surgical Technique




**Bone Probe**

*Use the bone probe to elongate the hole to the desired depth in the pedicle canal.*

**Warning:**

*If resistance is felt while advancing the probe, the position in the pedicle canal should be evaluated via radiograph. When advancing the probe, a change in resistance is a warning that the wall of the pedicle is in danger of being perforated.*

*A laminectomy can be performed to visualize and feel the medial, cephalad and caudad aspect of the pedicle.*

**Evaluation**

**Sounders**

*Use the straight sounder or the curved sounder to evaluate the condition of the cortical wall of the pedicle. Apply the appropriate probe and externally or internally palpate the wall or canal of the pedicle to ensure the wall is not perforated.*

**Depth Gauge**

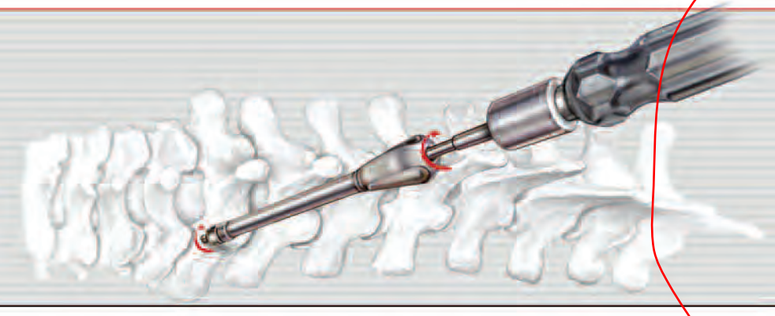
*Check the final screw position by placing a series of K-wires or X-ray markers in the pedicle canals and taking a lateral and A/P X-ray. Use the depth gauge to confirm the depth of the pilot hole.*

**Tap**

*Place the tap securely into the modular handle. Tap to the appropriate depth.*

# Surgical Technique

8.



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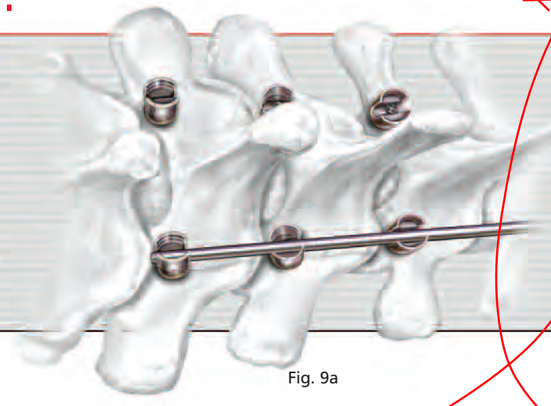


Fig. 9a

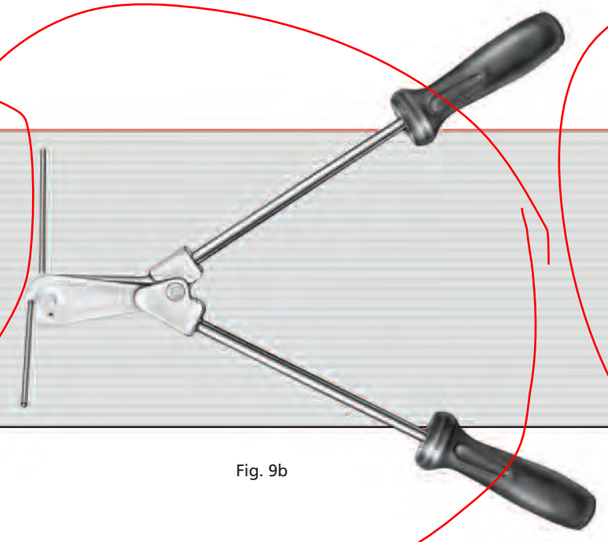
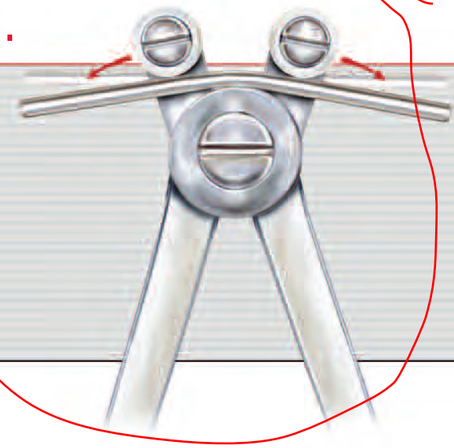


Fig. 9b

10.



### Screw Insertion

*Place the multi-axial screw driver securely into the modular handle. Attach the appropriate multi-axial screw to the multi-axial screw driver.*

*Insert multi-axial screw into the prepared pedicle until it is positioned to the correct level. The screw should extend approximately 50% to 80% into the vertebral body and should not create soft tissue impingement at closure.*

### Screw Adjusters

*Use the screw adjuster to adjust the sagittal height of the multi-axial screw and the screw head adjuster to align the saddles of the multi-axial screw.*

*At the cephalad aspect of the construct, the screws should not impinge upon the facet joint.*

### Rod Contouring and Cutting

*Determine the rod contour and length required with the rod template. (Fig. 9a)*

### Rod Cutter

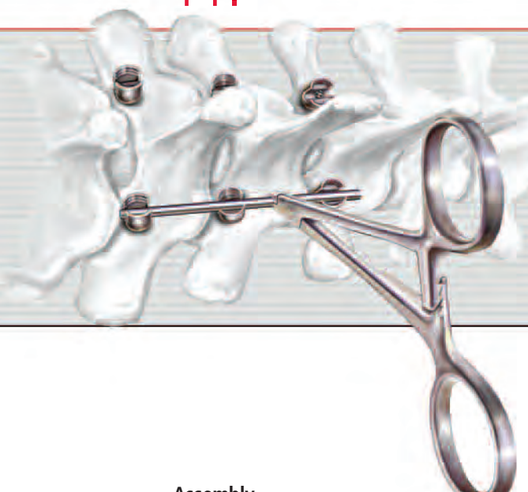
*Once the correct length is established, use the rod cutter to cut rod to the desired requirements. (Fig.9b)*

### Rod Bender

*Utilizing the rod bender, create the correct contour, referencing the rod template as a guide.*

# Surgical Technique

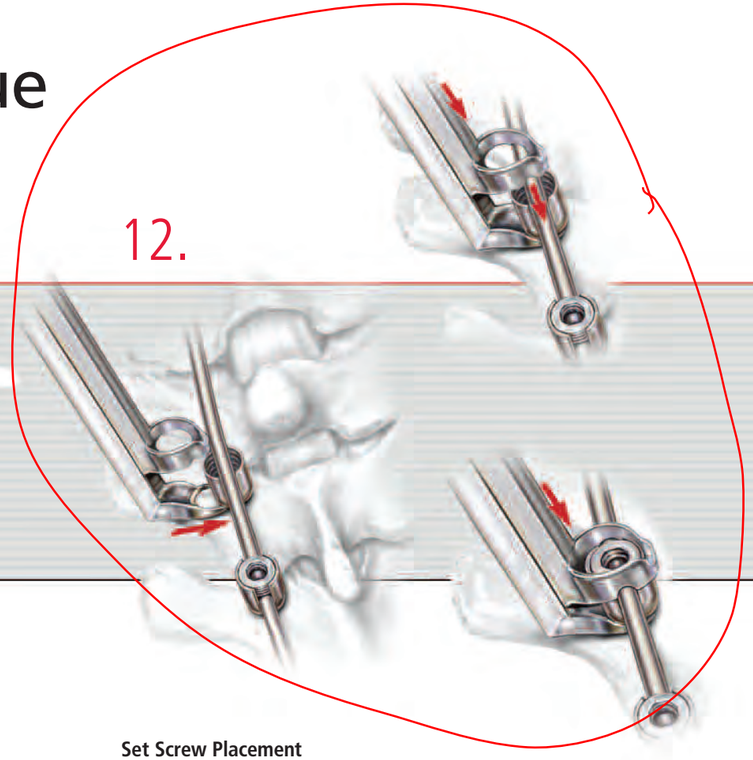
11.



### Assembly

*Orient the screws so that the screw saddles are in the longitudinal plane. Once positioning is achieved, place the rod in the screw saddles.*

12.



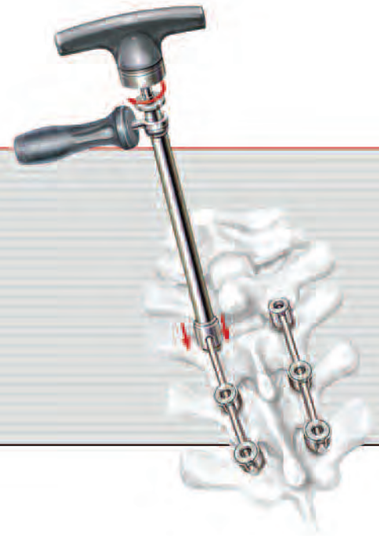
### Set Screw Placement

*Use the set screw holder to position and tighten the set screw on the multi-axial screw. Seat the rod fully in the screw saddle with the aid of the rod pusher.*

### Rod Reduction

*The rod reducer is used to seat the rod into the screw saddle for subsequent set screw placement.*

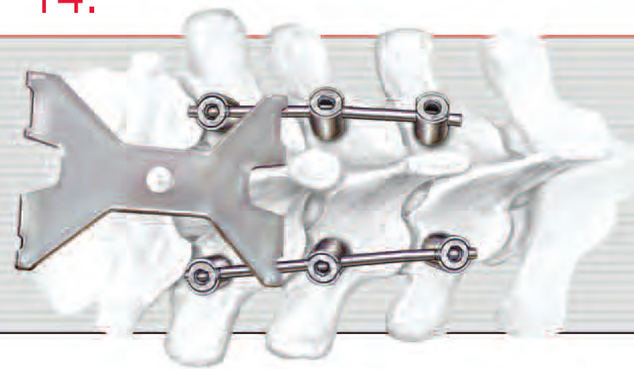
13.



### Final Tightening

*Position the counter torque wrench over the multi-axial screw. Place the torque limiting driver securely into the hex of the set screw. Turn the torque limiting driver clockwise to tighten the set screw to 22 in – lbs.*

14.



### Cross Connectors

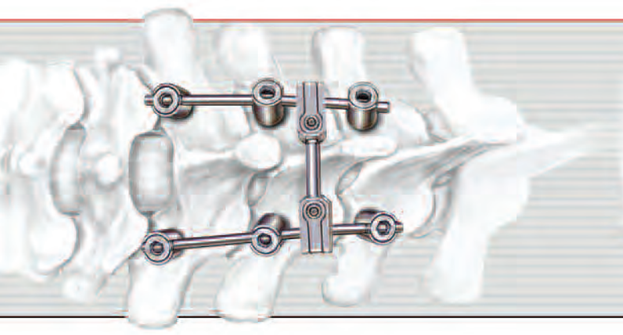
*Cross connectors provide additional torsional rigidity to the construct by bridging the parallel rods. Position the cross connector template directly over the rods and measure the distance across the rods.*

### Axial Rod Connector

*The Ascent POCT System can be linked to the Spinal Fixation System (SFS) using the 3.0mm to 5.5mm axial rod connector.*

*Instruments for implantation of the axial connector are located in the SFS Hook System.*

15.



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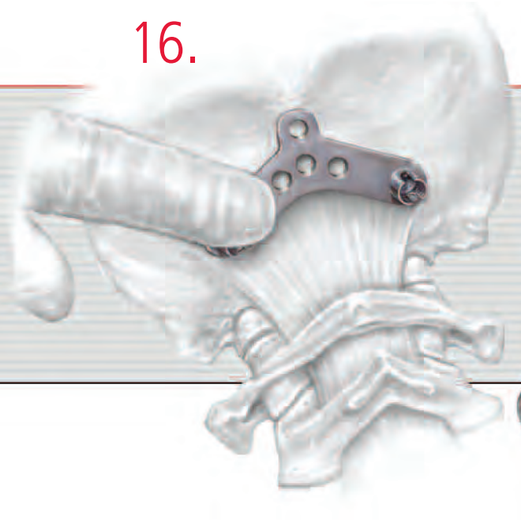

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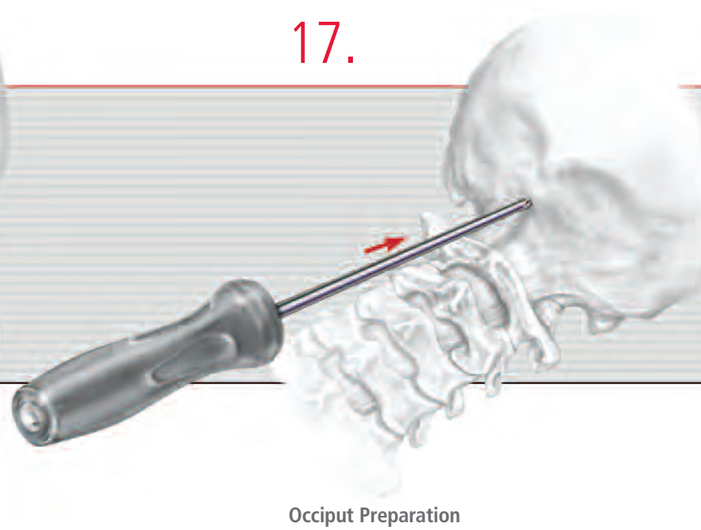

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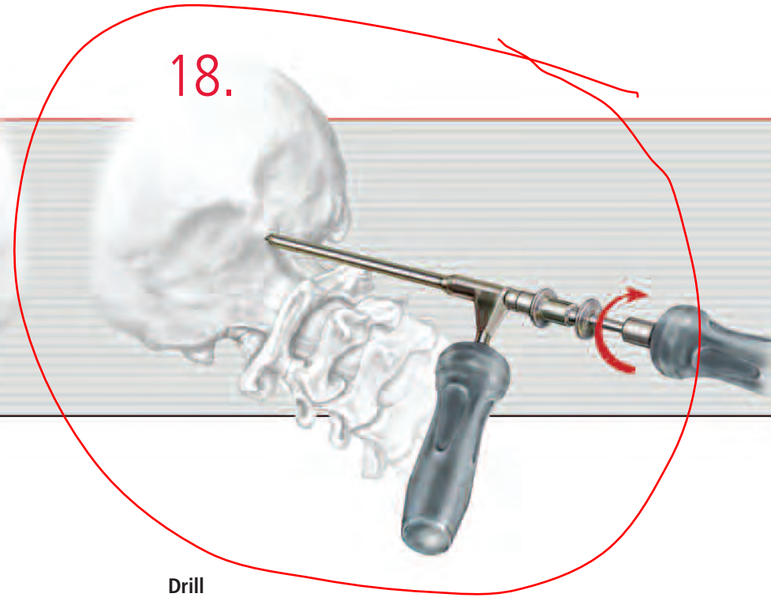


**Occipital Anchor Plate Positioning**

*Select the appropriate cross connector and position on the rods. Lock the cross connectors into position using the cross connector torque limiting driver.*

*An audible click will indicate when the final torque of 12 in – lb is achieved.*

**Occiput Preparation**

**Bone Awl**

*Penetrate the cortex of the occiput using the bone awl.*

**Drill**

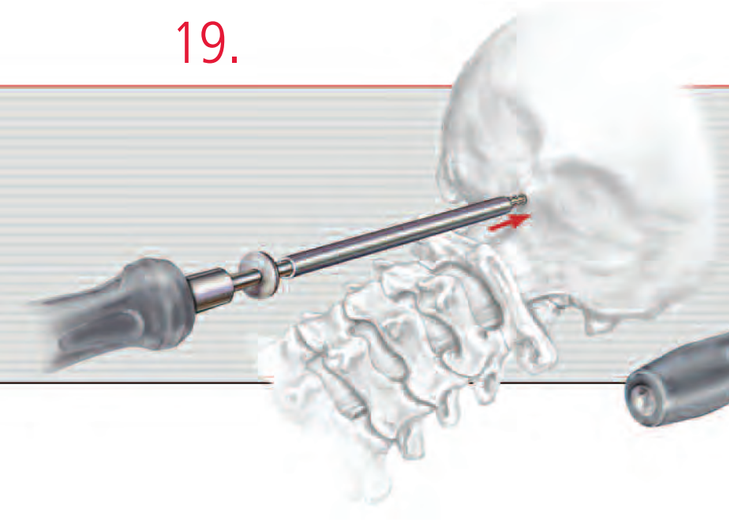
*Slide the adjustable drill stop over the drill. Place the appropriate drill securely into the modular handle. Set the drill stop to the appropriate drilling depth (between 6-14mm in 2mm increments).*

*Occipital screws should be placed bicortical to obtain adequate fixation.*

*The exterior occipital protuberance (EOP) and the nuchal line may be used as a guide for plate position and placement. Position the occipital plate below the EOP and the superior nuchal lines.*

# Surgical Technique

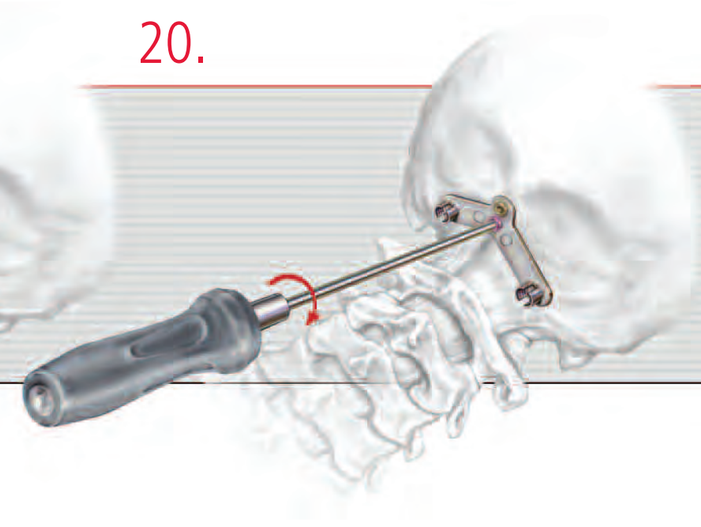
19.



### Tap

*Place the tap securely into the modular handle. Tap to the appropriate depth.*

20.

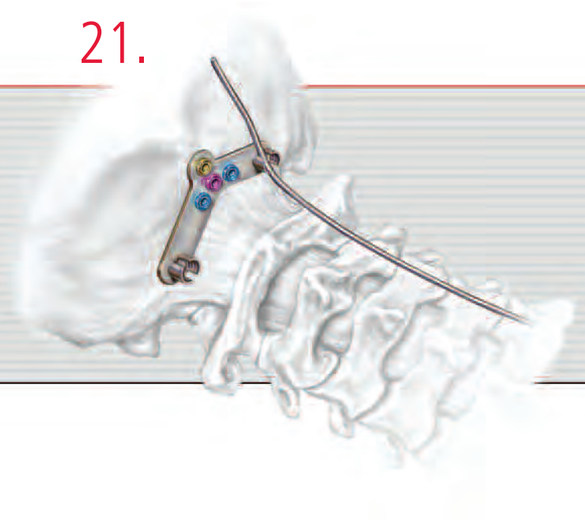


### Occipital Bone Screw Insertion

*Place the occipital anchor plate into its previously determined position. Attach the appropriate length occipital bone screw to the occipital bone screw driver. Insert the occipital bone screw into the prepared hole locking the occipital anchor plate into position.*

*Place remaining screws using the same technique.*

21.



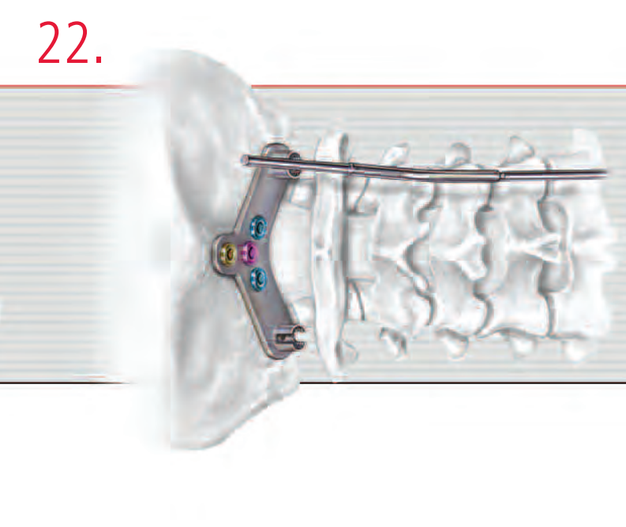
### Occipito-Cervical Rod

*Determine the appropriate occipito-cervical lordotic length with the rod template.*

### Rod Cutter

*Once the correct length is established, use the rod cutter to cut the rod to the desired requirements.*

22.



### Construct Assembly

*Once positioning is achieved, place the rod in the saddle of the occipital anchor plate.*

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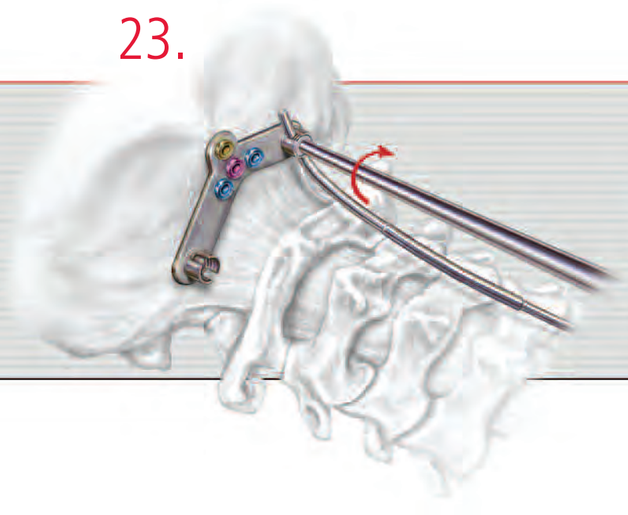
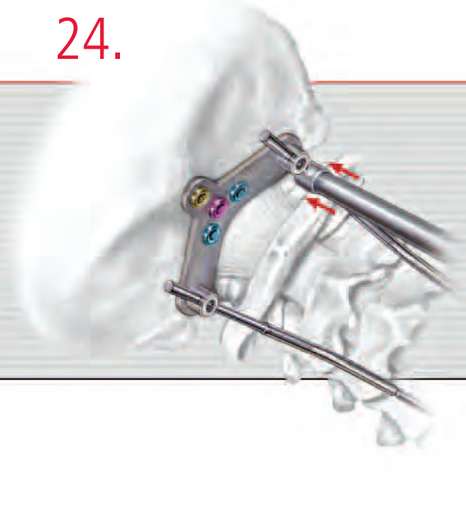


**Final Tightening**

*Use the set screw holder to position the set screw on the occipital anchor plate.*

24.



*Position the counter torque wrench over the set screw and rod. Place the torque limiting driver securely into the hex of the set screw. Turn the torque limiting driver clockwise to tighten the set screw to 22 in – lb.*

### Songer Spinal Cable System

*The Songer Spinal Cable System, to be used with the Ascent POCT System, allows for wire/cable attachment to the posterior spine.*

# Part Numbers



Ascent Posterior Occipital Cervico-Thoracic System

| IMPLANTS | |
|---|---|
| | *Multi-Axial Screws* |
| **65-3310** | 3.5mm x 10mm Multi-Axial Screw |
| **65-3312** | 3.5mm x 12mm Multi-Axial Screw |
| **65-3314** | 3.5mm x 14mm Multi-Axial Screw |
| **65-3316** | 3.5mm x 16mm Multi-Axial Screw |
| **65-3318** | 3.5mm x 18mm Multi-Axial Screw |
| **65-3320** | 3.5mm x 20mm Multi-Axial Screw |
| **65-3322** | 3.5mm x 22mm Multi-Axial Screw |
| **65-3324** | 3.5mm x 24mm Multi-Axial Screw |
| **65-3326** | 3.5mm x 26mm Multi-Axial Screw |
| **65-3328** | 3.5mm x 28mm Multi-Axial Screw |
| **65-3330** | 3.5mm x 30mm Multi-Axial Screw |
| **65-3410** | 4.0mm x 10mm Multi-Axial Screw |
| **65-3412** | 4.0mm x 12mm Multi-Axial Screw |
| **65-3414** | 4.0mm x 14mm Multi-Axial Screw |
| **65-3416** | 4.0mm x 16mm Multi-Axial Screw |
| **65-3418** | 4.0mm x 18mm Multi-Axial Screw |
| **65-3420** | 4.0mm x 20mm Multi-Axial Screw |
| **65-3422** | 4.0mm x 22mm Multi-Axial Screw |
| **65-3424** | 4.0mm x 24mm Multi-Axial Screw |
| **65-3426** | 4.0mm x 26mm Multi-Axial Screw |
| **65-3428** | 4.0mm x 28mm Multi-Axial Screw |
| **65-3430** | 4.0mm x 30mm Multi-Axial Screw |
| | *3.0mm Diameter Rods/Set Screw* |
| **65-2002** | Domed Set Screw |
| **65-2060** | Occipital Rod |
| **65-2070** | 70mm Rod |
| **65-2120** | 120mm Rod |
| **65-2200** | 200mm Rod |
| | *Lateral Offset and Axial Rod Connector* |
| **65-6310** | 10mm Lateral Offset Connector |
| **65-6425** | 3.0mm to 5.5mm Axial Rod Connector |

| IMPLANTS | |
|---|---|
| | *Hook Implants* |
| **67-3010** | 4.5mm Laminar Hook |
| **67-3011** | 6.0mm Laminar Hook |
| | *Occipital Bone Screws and Anchors* |
| **65-2006** | 6mm Occipital Bone Screw |
| **65-2008** | 8mm Occipital Bone Screw |
| **65-2010** | 10mm Occipital Bone Screw |
| **65-2012** | 12mm Occipital Bone Screw |
| **65-2014** | 14mm Occipital Bone Screw |
| **65-2040** | 31mm Occipital Anchor |
| **65-2041** | 37mm Occipital Anchor |
| **65-2042** | 45mm Occipital Anchor |
| **65-2043** | 50mm Occipital Anchor |
| | *Cross Connectors* |
| **65-5320** | 20mm Cross Connector Assembly |
| **65-5325** | 25mm Cross Connector Assembly |
| **65-5330** | 30mm Cross Connector Assembly |
| **65-5335** | 35mm Cross Connector Assembly |
| **65-5340** | 40mm Cross Connector Assembly |
| **65-5345** | 45mm Cross Connector Assembly |
| **65-5350** | 50mm Cross Connector Assembly |
| | *Cables* |
| **65-2050** | Double Loop Cable w/Four (4) Crimps |
| **65-2053** | Single Loop Cable w/Two (2) Crimps |
| **65-2056** | Crimp Two (2) Pack |

Ascent POCT System

| INSTRUMENTATION | |
|---|---|
| | *Disposable Instrumentation* |
| **65-1015** | 3.5mm Drill Bit |
| **65-1016** | 4.0mm Drill Bit |
| **65-1055** | 70mm Trial Rod |
| **65-1056** | 120mm Trial Rod |
| **65-1057** | 200mm Trial Rod |
| | |
| **55-1072** | Cross Connector Bender Left |
| **55-1073** | Cross Connector Bender Right |
| **57-0027** | Set Screw Driver, (Spline Drive) |
| **57-0047** | Set Screw Torque Handle |
| **65-1001** | Bone Awl |
| **65-1002** | Bone Probe |
| **65-1004** | Straight Sounder |
| **65-1005** | Curved Sounder |
| **65-1006** | Depth Gauge |
| **65-1010** | Drill Guide |
| **65-1011** | Drill Stop |
| **65-1025** | 3.5mm Tap |
| **65-1026** | 4.0mm Tap |
| **65-1030** | Modular Handle |
| **65-1037** | Multi-Axial Screw Driver |
| **65-1041** | Rod Cutter |
| **65-1042** | Rod Bender |
| **65-1043** | Rod Holder |
| **65-1045** | Screw Head Adjuster |
| **65-1048** | Compressor |
| **65-1049** | Cannulated Rod Pusher |
| **65-1060** | Domed Set Screw Holder |
| **65-1062** | Screw Adjuster |
| **65-1063** | Occipital Screw Driver |
| **65-1064** | Domed Set Screw Driver (used w/65-2002) |
| **65-1065** | Torque Limiting Driver |

| INSTRUMENTATION | |
|---|---|
| **65-1066** | Counter Torque Wrench |
| **65-1068** | Tensioner and Crimper |
| **65-1070** | Distractor |
| **65-1071** | Rod Reducer |
| **65-1072** | Crimp Inserter |
| **65-1074** | Cable Cutter |
| **65-1076** | Cable Torque Driver |
| **65-1078** | Nerve Hook |
| **65-1082** | Cross Connector Set Screw Driver |
| **65-1083** | Cross Connector Torque Limiting Driver |
| **65-1086** | Cross Connector Template 20mm |
| **65-1087** | Cross Connector Template 25-30mm |
| **65-1088** | Cross Connector Template 35-40mm |
| **65-1089** | Cross Connector Template 45-50mm |
| **65-1090** | System Case #1 |
| **65-1091** | System Case #2 |
| **65-1092** | Cable System Instrument Case #3 |
| **67-0001** | Hook Holder, Straight |
| **67-0003** | Hook Holder, Angled |
| **67-0040** | Laminar Elevator |

# Instructions For Use



## Device System Name: Blackstone Medical, Inc.
## Ascent Posterior Occipital Cervical Thoracic System

**Description:**

The Blackstone Ascent Posterior Occipital Cervical Thoracic System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The Ascent Posterior Occipital Cervical Thoracic System consists of an assortment of rods, set screws, cross connectors, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws, and Songer Cables.

The Blackstone Ascent Posterior Occipital Cervical Thoracic System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial Connector.

**Levels of Use:**

When used in the occipito-cervico-thoracic spine, the Blackstone Posterior Cervical System may be used from the occiput to T3.

**Indications:**

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Blackstone Ascent Posterior Occipital Cervical Thoracic System is indicated for:

a) Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
b) Spondylolisthesis
c) Fracture/dislocation
d) Spinal stenosis
e) Atlanto-axial fracture with instability
f) Occipito-cervical dislocation
g) Tumors
h) Revision of previous cervical spine surgery

The occipital bone screws are limited to occipital fixation only. The use of the multi-axial screws is limited to placement in the upper thoracic spine (T1-T3) for the treatment of thoracic conditions only. They are not intended to be placed in the cervical spine. The lateral offset adapter is indicated for use in the upper thoracic spine (T1-T3). The hooks are intended to be placed from C1 to T3. The Songer Cable (titanium) System to be used with the Blackstone Ascent Posterior Occipital Cervical Thoracic System allows for wire/cable attachment to the posterior cervical spine.

The Blackstone Ascent Posterior Occipital Cervical Thoracic System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial Connector.

**Contraindications:**

1) Morbid obesity
2) Mental illness
3) Alcoholism or drug abuse
4) Pregnancy
5) Metal sensitivity/allergies
6) Severe osteopenia
7) Patients unwilling or unable to follow post-operative care instructions
8) Any circumstances not listed under the heading Indications

**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) Device component fracture
2) Loss of fixation
3) Non-union
4) Fracture of the vertebra
5) Neurological injury
6) Vascular or visceral injury
7) Early or late loosening of any or all of the components
8) Disassembly and/or bending of any or all of the components
9) Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
10) Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation and/or pain
11) Post-operative change in spinal curvature, loss of correction, height and/or reduction
12) Infection
13) Pain, discomfort or abnormal sensations due to the presence of the device
14) Hemorrhage
15) Cessation of any potential growth of the operated portion of the spine
16) Death

Note: Potential risks identified with the use of the device system may require additional surgery.

**Warnings and Precautions:**

1) Single use only
2) Nonsterile: the screws, plates, rods, connectors, adapters, and instruments are sold nonsterile and therefore must be sterilized before use
3) 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 Blackstone Ascent Posterior Occipital Cervical Thoracic System should be sterilized by the hospital using the recommended cycle:

Method: Steam
Cycle: Gravity
Temperature: 250° F (121° C)
Exposure time: 30 minutes

**Or:**

Method: Steam
Cycle: Prevac
Temperature: 270° F (132° C)
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) The construct should be assembled prior to surgery. An adequate inventory should be available at surgery other than those expected to be used.
4) All components and instruments should be cleaned and sterilized prior to 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 cement should not be used, as it will make removal of the components difficult or impossible.
5) 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 vibration. 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 injury is 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 Health Care 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 Blackstone Medical, Inc., 90 Brookdale Drive, Springfield, MA 01104, USA, Telephone: (413) 731- 8711.

**Further Information:**

Recommended surgical techniques for the use of this system are available upon request.
Blackstone Medical, Inc., 90 Brookdale Drive, Springfield, MA 01104, USA, Telephone: (413) 731-8711, Fax: (413) 731-8712.

**Authorized European Representative:**

Medical Device Safety Service (MDSS)
Burckhardtstrasse 1
D-30163 Hannover
Germany

CE 0044

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