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Surgical technique

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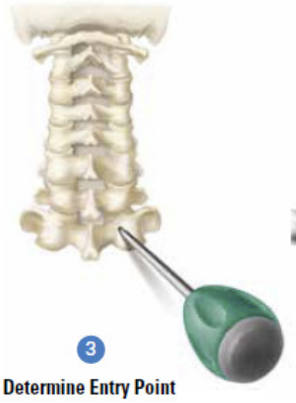
OPERATIVE TECHNIQUE OVERVIEW

Hook Placement

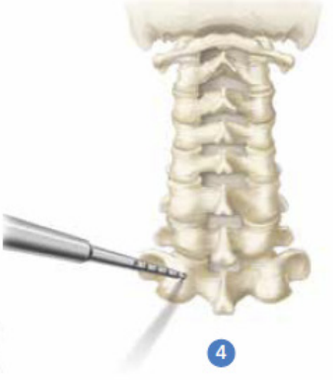
1 Place Hooks

2 Insert Set Screws

Screw Placement



3 Determine Entry Point



4 Cannulate the Pedicle

5 Test Pedicular Wall

6 Drill

7 Tap to Desired Depth

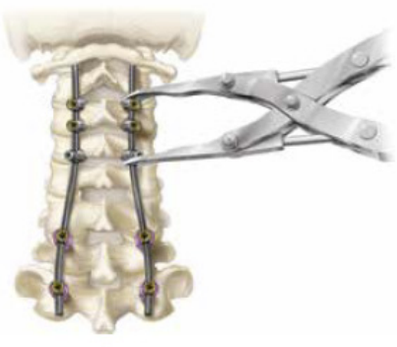
8 Insert Screw

9
Cut and Contour the Rod

10
Place Rod into Tulip Heads

11
Insert Set Screw

12
Tighten Set Screws



13
Compression/Distraction

14
Final Tightening

15
Additional Options – Cross Connectors
and Rod-to-Rod Connectors

DETAILED OPERATIVE TECHNIQUE

PLACEMENT OF LAMINAR HOOKS
Hooks are available for use in the cervical spine. Select the appropriate Hook size and configuration for the anatomy. There are five different types of Hooks available: Straight, Left and Right Offset and Left and Right Angle Hooks.

Clamp the desired Hook with the Hook Holder making sure that the prongs of the instrument interface with the indentations on the outside head of the Hook (Figure 1).

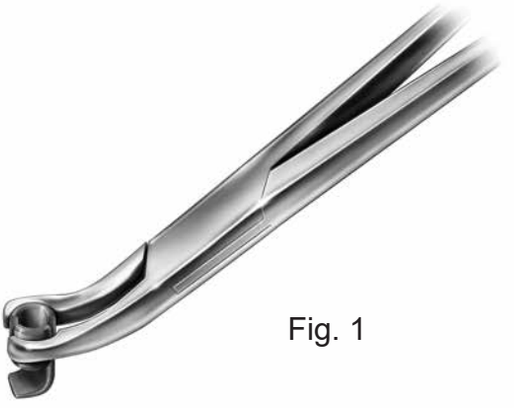


Fig. 1

Place Hooks as needed under the superior or inferior lamina (Figure 2).

The Hooks may be oriented either in a cranial or caudal position.

Fig. 2

Once the Hooks have been inserted, utilize the Set Screw Starter to insert the appropriate inner Set Screw and provisionally tighten in a clockwise motion (Figure 3).

Fig. 3

Fig. 4

PLACEMENT OF POLYAXIAL SCREWS
Determine the ideal entry point for the Polyaxial Screw and penetrate the cortical bone to initiate an entry point using the Awl (Figure 4).

The Probe can then be used to cannulate the pedicle (Figure 5).

Fig. 5

After the pedicle has been cannulated, it may be tested to ensure the integrity of the pedicular wall by using the Sounding Probe (Figure 6).

Determine the desired diameter and depth of the drill penetration. There are two drill options available, Fixed and Adjustable. Fixed drills are available in either a 12mm or 14mm depth. Adjustable Drill and Drill Guide Stop offer a drilling depth range from 14mm to 28mm in 2mm increments. The depth is determined by the position of the drill guide stop on the adjustable drill.

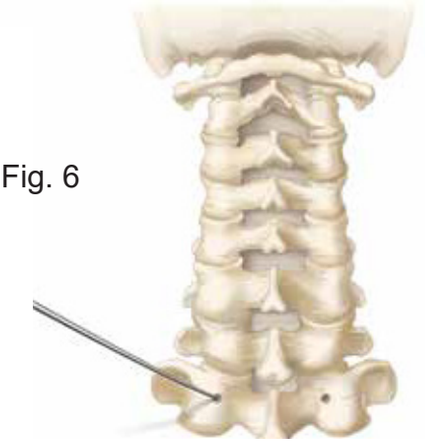


Fig. 6

Attach the Drill Bit to the desired handle. Align the Drill Guide with the appropriate screw trajectory. Insert the Drill Bit through the Drill Guide and proceed with drilling to the desired depth (Figure 7).

Confirm depth and containment within the pilot hole with the Depth Gauge or probe. Tap the pilot hole using the 3.5 or 4.0mm Tap while maintaining the appropriate trajectory (Figure 8). Note: The Taps are undersized by approximately 0.15mm. Continue to drill and tap the remaining pilot holes in the same manner.

Fig. 7

SCREW INSERTION

Connect the Polyaxial Screwdriver to the desired Handle. After selecting the appropriate screw size, insert the hexalobe tip of the Screwdriver into the screw. Rotate the outer knob of the Screwdriver clockwise until the head of the screw is secured on the Driver (Figure 9). Insert the screw into the prepared pilot hole to the desired depth (Figure 10).

To disengage the screw from the driver, turn the knob counterclockwise to and pull straight out of the internal hexalobe on the screw. The Removal Screwdriver was designed to back out the polyaxial screws if needed. To back out the screw, insert the hexalobe tip of the screwdriver in to the screw. Rotate the outer knob of the screwdriver clockwise until the screwdriver is secured to the screw. Once the screw is engaged, back out the screw by turning the handle counterclockwise. Continue to insert all remaining Polyaxial Screws in the same manner.

ROD PLACEMENT

The rods are provided in pre-contoured, precut lengths, however a Rod Cutter is provided if other sizes are needed. The final length of the rod should extend 2mm beyond the margin of the screw housing so the screw locking mechanism engages correctly (Figure 11). To contour the rods, secure the rod with the Rod Bender and contour to achieve the desired curvature (Figure 12).

Handheld Rod Benders are also available and can be used to provide additional leverage when contouring the rod. Utilize the removal screwdriver to adjust the A-P height of the screws as needed. Adjust the alignment of the Polyaxial Screws using the Head Turner so that the rod openings are in alignment. Once adjusted, they will easily stay in the correct alignment due to the unique EZ Set Tulip Design.

Fig. 8

Fig. 9

Fig. 10

Fig. 11

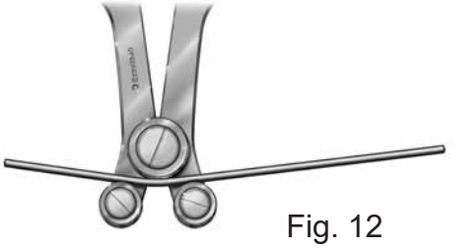


Fig. 12

Fig. 13

Place the contoured rod into Polyaxial Screw (Figure 13). If necessary, there are two options for reducing the rod into the Hook or screw heads.

1) The Rod Persuader can be placed over the head of the hook or screw and the handles compressed to reduce the rod (Figure 14).

2) There are also multiple Inline Rod Persuaders which fit over the individual screw heads. The Inline Rod Persuader Knob is inserted over the top of the Inline Rod Persuader and rotated clockwise to reduce the rod (Figure 15). The Rod Persuader Knob can then be removed and placed over the next Inline Rod Reducer to reduce the rod into the next screw head sequentially.

Fig. 14

SET SCREW INSERTION

Determine the appropriate inner set screw for each Polyaxial Screw or Hook, depending on whether a cross connector will be used at the indicated level. Utilizing the threaded Set Screw Starter, insert the appropriate inner set screw into the Hooks and Polyaxial Screws and provisionally tighten in a clockwise motion (Figure 16).

Fig. 15

Fig. 16

COMPRESSION/DISTRACTION

After the construct has been properly assembled, segmental compression and/or distraction can be accomplished using the Compressor or Distractor while tightening the Set Screws sequentially (Figure 17).

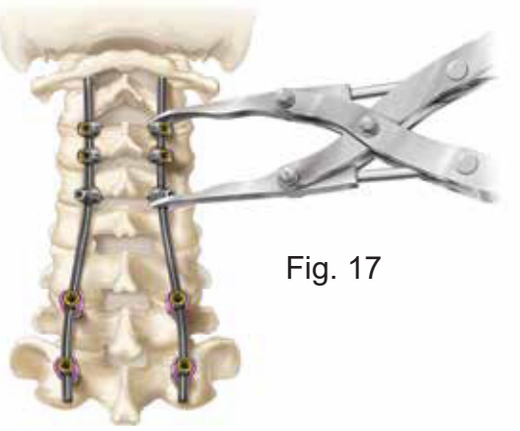


Fig. 17

FINAL TIGHTENING

To perform final tightening of the construct, insert the Set Screw Driver attached to the Torque Limiting Driver through the Counter Torque and turn the Torque Driver clockwise until the Torque Driver audibly clicks (Figure 18). Repeat in the same manner on all remaining components to secure the construct.

Fig. 18

ADDITIONAL OPTIONS

Rod to Rod Cross Connector Placement Choose the appropriate size Rod to Rod Cross Connector and contour as needed, using the Cross Connector Benders provided. Capture the Cross Connector Nut with the Cross Connector Nut Starter to hold the cross connector and place onto the rod (Figure 19). Insert the Set Screwdriver attached to the Torque Limiting Driver though the Torque Limiting Nut Driver over the rod to rod cross connector nut into the set screw. Rotate the Torque Limiting Nut Driver counter clockwise until the Torque handle breaks over (Figure 20). Repeat the procedure on the opposite side to final tighten the construct. Head to Head Cross Connector Placement Choose the appropriate size Cross Connector and contour as needed, using the Cross Connector Benders provided (Figure 21). Note: It is critical that the Cross Connector be contoured in most situations so that both rings of the cross connector are flush with the base of the tulip. If not contoured correctly, the application of torque to the Cross Connector Nut may cause issues with the inner set screw. Place the Hook Holder around the outside of the Polyaxial Screw where the Cross Connector will be inserted. Capture the retaining nut with the Cross Connector Nut Starter and turn clockwise to thread onto the extended Set Screw (Figure 22).

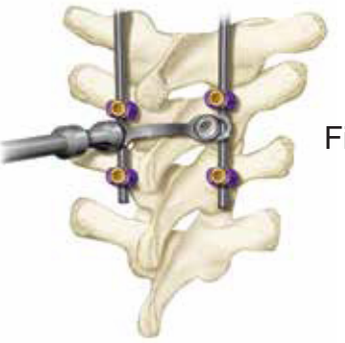


Fig. 19

Fig. 20

Fig. 21

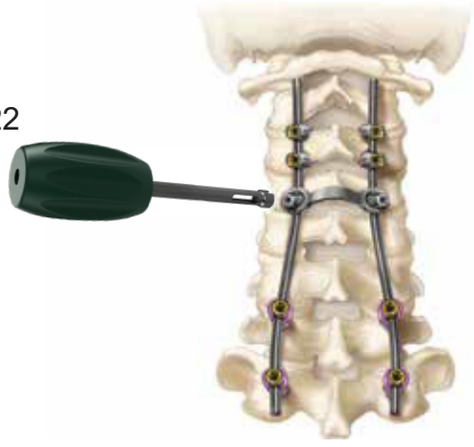


Fig. 22

Fig. 23

Fig. 24

Attach the cannulated palm torque nut driver on the cross connect nut, then put the Set Screw driver (T-15) with torque T-handle through cannulation palm torque handle to engage the T-15 set screw drive feature. Hold the Torque T-handle stationary, then rotate the cannulate palm torque handle clockwise until it audibly clicks to secure the Cross Connecter Retaining Nut (Figure 23).

TRANSITIONAL RODS

Transitional Rods and Rod Connectors are available to link to other Exactech Spinal Systems. The Gibralt System offers two different types of transitional rods, which can be linked to thoracic components.

ROD-TO-ROD CONNECTORS

The Gibralt offers three different sizes of Rod-to-Rod Connectors for use with other ChoiceSpine Spinal Systems.

1) Axial Rod-to-Rod Connectors are available to connect 3.5mm to 5.5.mm and 3.5mm to 6mm rod sizes.
2) Wedding Band Connectors are available to connect 3.5mm to 5.5.mm and 3.5mm to 6mm rod sizes.
3) Inline Rod-to-Rod Connectors are available for 3.5mm to 3.5mm rods.

To utilize a Rod-to-Rod connector, select the appropriate type and size and insert the end of the 3.5mm rod into the 3.5mm opening of the connector. Use the Set Screw Starter to engage the appropriate set screw by turning clockwise in the locking hole to secure the rod provisionally.
Note: The open side of the wedding band connector utilizes the Rod to Rod Connector set screw. All other Rod to Rod Connectors utilize the Standard Set Screw. Next, insert the other rod (either 3.5mm, 5.5.mm or 6.0mm depending on the component used) into the remaining opening on the connector. Use the Set Screw Starter to engage the appropriate Set Screw by turning clockwise in the locking hole to secure the rod provisionally (Figure 24). Use the Set Screw Driver connected to the Torque Driver to tighten all Set Screws until the Torque Driver audibly clicks.

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IMPLANT LISTING

Catalog Number	Part Description
05-000-20-3510	Polyaxial Screw 3.5mm x 10mm
05-000-20-3512	Polyaxial Screw 3.5mm x 12mm
05-000-20-3514	Polyaxial Screw 3.5mm x 14mm
05-000-20-3516	Polyaxial Screw 3.5mm x 16mm
05-000-20-3518	Polyaxial Screw 3.5mm x 18mm
05-000-20-3520	Polyaxial Screw 3.5mm x 20mm
05-000-20-3522	Polyaxial Screw 3.5mm x 22mm
05-000-20-3524	Polyaxial Screw 3.5mm x 24mm
05-000-20-3526	Polyaxial Screw 3.5mm x 26mm
05-000-20-3528	Polyaxial Screw 3.5mm x 28mm
05-000-20-3530	Polyaxial Screw 3.5mm x 30mm *(Optional)*
05-000-20-3532	Polyaxial Screw 3.5mm x 32mm *(Optional)*
05-000-20-3534	Polyaxial Screw 3.5mm x 34mm *(Optional)*
05-000-20-3536	Polyaxial Screw 3.5mm x 36mm *(Optional)*
05-000-20-4010	Polyaxial Screw 4.0mm x 10mm
05-000-20-4012	Polyaxial Screw 4.0mm x 12mm
05-000-20-4014	Polyaxial Screw 4.0mm x 14mm
05-000-20-4016	Polyaxial Screw 4.0mm x 16mm
05-000-20-4018	Polyaxial Screw 4.0mm x 18mm
05-000-20-4020	Polyaxial Screw 4.0mm x 20mm
05-000-20-4022	Polyaxial Screw 4.0mm x 22mm
05-000-20-4024	Polyaxial Screw 4.0mm x 24mm
05-000-20-4026	Polyaxial Screw 4.0mm x 26mm
05-000-20-4028	Polyaxial Screw 4.0mm x 28mm
05-000-20-4030	Polyaxial Screw 4.0mm x 30mm *(Optional)*
05-000-20-4032	Polyaxial Screw 4.0mm x 32mm *(Optional)*
05-000-20-4034	Polyaxial Screw 4.0mm x 34mm *(Optional)*
05-000-20-4036	Polyaxial Screw 4.0mm x 36mm *(Optional)*
05-000-20-4520	Polyaxial Screw 4.5mm x 20mm
05-000-20-4525	Polyaxial Screw 4.5mm x 25mm
05-000-20-4530	Polyaxial Screw 4.5mm x 30mm
05-000-20-4535	Polyaxial Screw 4.5mm x 35mm
05-000-20-4540	Polyaxial Screw 4.5mm x 40mm
05-000-20-4545	Polyaxial Screw 4.5mm x 45mm
05-000-20-4550	Polyaxial Screw 4.5mm x 50mm
05-000-26-3520	Polyaxial Smooth Shank Screw 3.5mm x 20mm
05-000-26-3522	Polyaxial Smooth Shank Screw 3.5mm x 22mm
05-000-26-3524	Polyaxial Smooth Shank Screw 3.5mm x 24mm
05-000-26-3526	Polyaxial Smooth Shank Screw 3.5mm x 26mm
05-000-26-3528	Polyaxial Smooth Shank Screw 3.5mm x 28mm
05-000-26-3530	Polyaxial Smooth Shank Screw 3.5mm x 30mm
05-000-26-3532	Polyaxial Smooth Shank Screw 3.5mm x 32mm
05-000-26-3534	Polyaxial Smooth Shank Screw 3.5mm x 34mm *(Optional)*
05-000-26-3536	Polyaxial Smooth Shank Screw 3.5mm x 36mm *(Optional)*
05-000-26-3538	Polyaxial Smooth Shank Screw 3.5mm x 38mm *(Optional)*
05-000-26-4020	Polyaxial Smooth Shank Screw 4.0mm x 20mm
05-000-26-4022	Polyaxial Smooth Shank Screw 4.0mm x 22mm
05-000-26-4024	Polyaxial Smooth Shank Screw 4.0mm x 24mm
05-000-26-4026	Polyaxial Smooth Shank Screw 4.0mm x 26mm
05-000-26-4028	Polyaxial Smooth Shank Screw 4.0mm x 28mm
05-000-26-4030	Polyaxial Smooth Shank Screw 4.0mm x 30mm
05-000-26-4032	Polyaxial Smooth Shank Screw 4.0mm x 32mm
05-000-26-4034	Polyaxial Smooth Shank Screw 4.0mm x 34mm *(Optional)*
05-000-26-4036	Polyaxial Smooth Shank Screw 4.0mm x 36mm *(Optional)*
05-000-26-4038	Polyaxial Smooth Shank Screw 4.0mm x 38mm *(Optional)*

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Catalog Number	Part Description
05-002-03-3530	Gibralt Curved Rod 30mm
05-002-03-3540	Gibralt Curved Rod 40mm
05-002-03-3550	Gibralt Curved Rod 50mm
05-002-03-3560	Gibralt Curved Rod 60mm
05-002-03-3570	Gibralt Curved Rod 70mm
05-002-03-3580	Gibralt Curved Rod 80mm
05-002-03-3590	Gibralt Curved Rod 90mm
05-000-24-0275	Set Screw
05-000-24-0925	Cross Connector Set Screw
05-000-25-0001	Cross Connector Retaining Nut
05-002-00-3512	Rod 3.5mm x 120mm
05-002-00-3524	Rod 3.5mm x 240mm
05-002-01-0001	Transitional Rod, 3.5mm to 5.5mm x 420mm
05-002-01-0002	Transitional Rod, 3.5mm to 6.0mm x 420mm
05-002-01-0003	Transitional Rod, 3.5mm to 5.5mm x 600mm
05-002-01-0004	Transitional Rod, 3.5mm to 6.0mm x 600mm
05-004-10-2230	Cross Connector, 22mm to 30mm
05-004-10-2636	Cross Connector, 26mm to 36mm
05-004-10-3242	Cross Connector, 32mm to 42mm
05-004-10-3848	Cross Connector, 38mm to 48mm
05-004-10-4452	Cross Connector, 44mm to 52mm
05-004-00-2230	Rod to Rod Cross Connector, 22mm to 30mm
05-004-00-2636	Rod to Rod Cross Connector, 26mm to 36mm
05-004-00-3242	Rod to Rod Cross Connector, 32mm to 42mm
05-004-00-3848	Rod to Rod Cross Connector, 38mm to 48mm
05-004-00-4452	Rod to Rod Cross Connector, 44mm to 52mm
05-000-24-0002	Set Screw for Rod to Rod Connectors
05-004-05-3535	Rod-to-Rod Connector, Inline, 3.5mm to 3.5mm
05-004-06-3555	Rod-to-Rod Connector, Combination, 3.5mm to 5.5mm
05-004-06-3560	Rod-to-Rod Connector, Combination, 3.5mm to 6.0mm
05-004-07-3555	Rod-to-Rod Connector, Wedding Band, 3.5mm to 5.5mm
05-004-07-3560	Rod-to-Rod Connector, Wedding Band, 3.5mm to 6.0mm
05-006-01-3501	Straight Hook










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IMPLANT LISTING

Catalog Number	Part Description	
05-006-01-3502	Left Angle Hook	
05-006-01-3503	Right Angle Hook	
05-006-01-3504	Offset Right Hook	
05-006-01-3505	Offset Left Hook	
05-004-08-3512 05-004-08-3515	Offset Connector 12mm Lg. Offset Connector 15mm Lg.	

INSTRUMENT LISTING

Catalog Number	Part Description	
05-009-02-0000	Awl	
05-009-03-0000	Probe	
05-009-04-0000	Sounding Probe	
05-009-05-0000 05-009-07-0000	3.5mm Tap 4.0mm Tap	
05-009-10-0000	Depth Gauge	

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Catalog Number	Part Description
05-009-94-0020	2.0mm Adjustable Drill
05-009-10-2010	2.0mm x 10mm Fixed Drill Bit
05-009-10-2012	2.0mm x 12mm Fixed Drill Bit
05-009-10-2014	2.0mm x 14mm Fixed Drill Bit
Optional Drill Bits	
05-009-11-2412	2.4mm x 12mm fixed drill bit
05-009-11-2414	2.4mm x 14mm fixed drill bit
05-009-10-2016	2.0mm x 16mm Fixed Drill Bit
05-009-11-2410	2.4mm x 10mm Fixed Drill Bit
05-009-11-2412	2.4mm x 12mm Fixed Drill Bit
05-009-11-2414	2.4mm x 14mm Fixed Drill Bit
05-009-11-2416	2.4mm x 16mm Fixed Drill Bit
05-009-12-2710	2.7mm x 10mm Fixed Drill Bit
05-009-12-2712	2.7mm x 12mm Fixed Drill Bit
05-009-12-2714	2.7mm x 14mm Fixed Drill Bit
05-009-12-2716	2.7mm x 16mm Fixed Drill Bit
05-009-13-3010	3.0mm x 10mm Fixed Drill Bit
05-009-13-3012	3.0mm x 12mm Fixed Drill Bit
05-009-13-3014	3.0mm x 14mm Fixed Drill Bit
05-009-13-3016	3.0mm x 16mm Fixed Drill Bit
05-009-93-0000	Adjustable Drill Stop
05-009-15-0000	Drill Guide
05-069-11-0000	AO Handle
05-009-61-0000	Polyaxial Screwdriver
05-009-85-0000	Fixed Handle Polyaxial Screwdriver
05-009-86-0000	Gibralt Screwdriver Sleeve
05-009-20-0000	Double End Set Screw Starter
05-009-19-0000	Set Screwdriver








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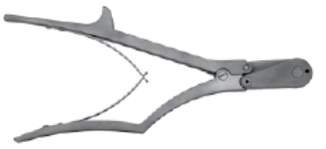
INSTRUMENT LISTING

Catalog Number	Part Description	
05-009-95-0000	Inline Counter Torque	
05-009-51-0000	Counter Torque Cross Connectors	
05-009-53-0000	Cross Connector Nut Starter	
05-009-88-0000	Gibralt Cross Connector Torque Handle	
05-009-22-0000	Rod Bender	
05-009-23-0001 05-009-23-0002	In-Situ Rod Bender In-Situ Rod Bender	
05-009-31-0000	Rod Cutter	

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Catalog Number	Part Description	
05-009-26-0000	Rod Holder	
05-009-40-0000	Hook Holder	
05-009-41-0000	Cross Connector Bender	
05-009-28-0000	Compressor	
05-009-29-0000	Distractor	
05-009-33-0000	Rod Persuader	
05-009-78-0000	Torque, Short T-Handle	
05-009-64-0000	Axial Ratchet Handle, Square Drive	
05-009-79-0000	Ratchet T-Handle, Square Drive	

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INSTRUMENT LISTING

Catalog Number	Part Description	
05-009-35-0000	Contour Rod Template	
05-009-56-0000	Polyaxial Screw Driver	
05-009-59-0000	Polyaxial Head Breaker	
05-009-60-0000	Polyaxial Screw Countersink	
05-009-65-0000	Inline Rod Persuader	
05-009-66-0000	Inline Rod Persuader Knob	
05-009-87-0000	Gibralt Rod Rocker	

Catalog Number	Description	Material
05-002-10-3508	Cobalt Chrome Rod, Straight, Ø3.5mm x 80mmL	Co-28Cr-6Mo per ASTM F1537
05-002-10-3512	Cobalt Chrome Rod, Straight, Ø3.5mm x 120mmL	
05-002-10-3524	Cobalt Chrome Rod, Straight, Ø3.5mm x 240mmL	
05-002-10-3536	Cobalt Chrome Rod, Curved, Ø3.5mm x 360mmL	
05-002-13-3530	Cobalt Chrome Rod, Curved, Ø3.5mm x 30mmL	
05-002-13-3540	Cobalt Chrome Rod, Curved, Ø3.5mm x 40mmL	Co-28Cr-6Mo per ASTM F1537
05-002-13-3550	Cobalt Chrome Rod, Curved, Ø3.5mm x 50mmL	
05-002-13-3560	Cobalt Chrome Rod, Curved, Ø3.5mm x 60mmL	
05-002-13-3570	Cobalt Chrome Rod, Curved, Ø3.5mm x 70mmL	
05-002-13-3580	Cobalt Chrome Rod, Curved, Ø3.5mm x 80mmL	
05-002-13-3590	Cobalt Chrome Rod, Curved, Ø3.5mm x 90mmL	

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INDICATIONS FOR USE

GENERAL DESCRIPTION

The Gibralt® Spine System is a posterior system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the cervical, and/or upper thoracic spine. The system consists of a variety of sizes of rods, hooks, poly-axial screws and connecting components, which can be rigidly locked to the rod in various configurations. The Gibralt Spine System components are manufactured from titanium alloy per ASTM F136.

This system can be used independently or in conjunction with Exactech 5.5mm or 6.0mm rod-based Thoraco-Lumbar Pedicle Screw Systems. The 5.5mm or 6.0mm rod-based Pedicle Screw systems are not covered by these instructions for use. Reference the instructions for use accompanying the Pedicle Screw System components for complete instructions for use.

INDICATIONS FOR USE

When intended to promote fusion of the cervical spine, and the thoracic spine, (C3-T3), the Gibralt Spine System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C3-T3) spine.

The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Polyaxial screws are not intended to be placed in the cervical spine.

This system can be used independently or in conjunction with Exactech 5.5mm or 6.0mm rod-based Thoraco-Lumbar Pedicle Screw Systems.

CONTRAINDICATIONS FOR USE

Contraindications include, but are not limited to:

- Presence of overt infectious process or significant risk of infection (immunocompromise)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Grossly distorted anatomy caused by congenital abnormalities
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count, or a marked left shift in the white blood count differential count
- Suspected or documented metal allergy or intolerance
- Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation
- Any patient unwilling to follow postoperative instructions
- Any case not needing a bone graft and fusion
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Presence of any neural or vascular deficit or other compromising pathology, which may be further injured by device intervention
- Any case not described in the indications

WARNINGS AND PRECAUTIONS

The Gibralt Spine System should only be implanted by experienced spine surgeons with specific training in the use of this spine system because this is a technically demanding procedure presenting a risk of serious injury to the patient. In addition, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions (e.g., smoking, occupation), which may impact on the performance of the system.

The Gibralt Spine System has not been evaluated for safety and compatibility in the MR environment. The Gibralt Spine System has not been tested for heating or migration in the MR environment.

Notes

ChoiceSpine™
Propelling Spinal Surgery

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