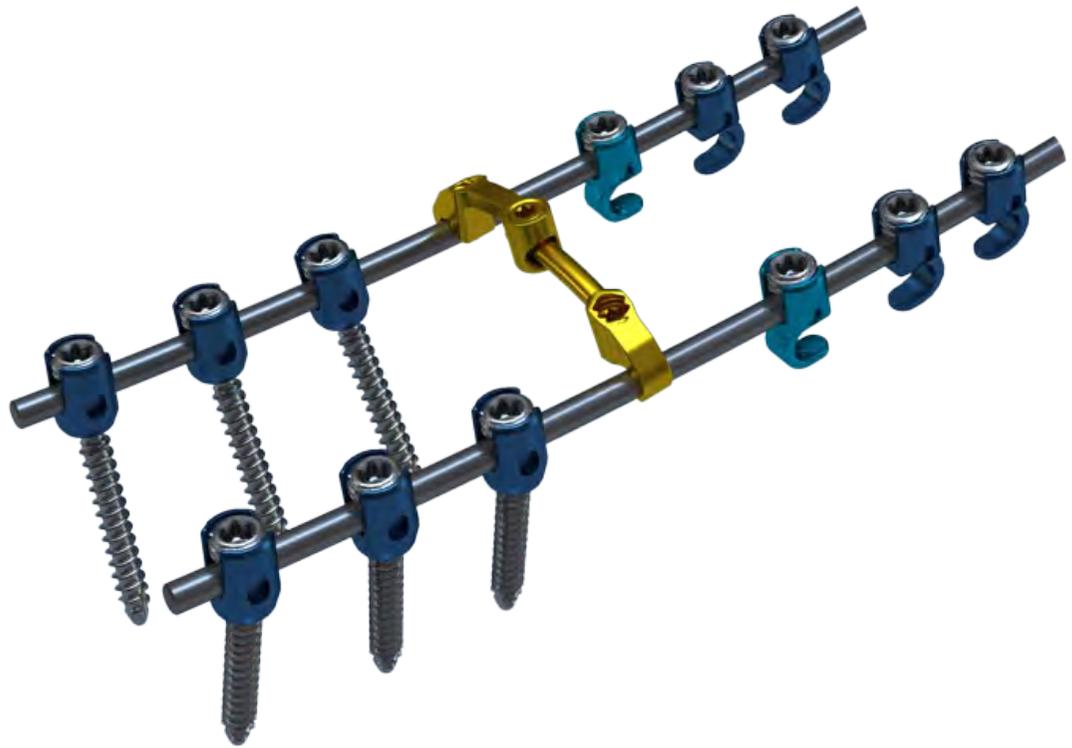


BLACKBIRD™ Surgical Technique
Posterior Cervical -Thoracic Fixation System



BLACKBIRD

CERVICAL-THORACIC SPINAL FIXATION SYSTEM

Table of Contents

System Features.....	4
Step 1 Positioning & Exposure.....	5
Step 2 Placement of Hooks.....	5
Step 3 Awl.....	5
Step 4 Drill.....	6
Step 5 Tap.....	6
Step 6 Screw Insertion.....	7
Step 7 Rod Insertion.....	7
Step 8 Set Screw Insertion.....	8
Step 9 Rod Reduction.....	8
Step 10 Compression/Distraction.....	9
Step 11 Set Screw Final Tightening.....	9
Step 12 Connector Placement.....	10
INDICATIONS FOR USE.....	11

The ChoiceSpine BLACKBIRD Cervical-Thoracic Spinal Fixation System is a comprehensive system for posterior fixation of the cervical and upper thoracic spine.



Description

The ChoiceSpine BLACKBIRD Spinal System is a posterior spinal fixation system. The system is composed of 3.5mm & 4.0mm polyaxial screws in 10-32mm lengths as well as 4.5mm polyaxial screws in 18-32mm lengths. 3.5mm smooth shank polyaxial screws are also available. Standard rod options are 3.5mm diameter straight, pre-bent, and transition. Connectors include rod to rod, lateral offset, and rod transition connectors. Multiple hook sizes are included.

The BLACKBIRD system is intended to be used in skeletally mature patients as an adjunct to fusion for stabilization of the cervical spine & thoracic spine (C1-T3) for the following conditions: degenerative disc disease, spondylolisthesis, trauma, fracture / dislocation, spinal stenosis, atlanto/axial fracture with instability, tumor, and revision of previous cervical spine surgery. The use of polyaxial screws is limited to the thoracic spine (T1-T3). This system can be linked to other systems using connectors & rods.

System Features

- Polyaxial head: non-biased 70° of conical angulation
- Multiple screw options: 3 diameters; fully threaded and smooth shank
- Dovetail set screw: minimizes head splaying and cross-threading
- Variety of connectors: allows for variations in anatomy and technique

Step 1 Positioning and Exposure

The patient should be positioned as appropriate for a posterior approach, taking care to preserve or improve sagittal alignment of the spine. Operative levels are verified clinically and/or radiographically. Ensure adequate exposure to perform the procedure.

WARNING: CARE MUST BE TAKEN TO AVOID VITAL STRUCTURES

Step 2 Placement of Hooks

Prepare the lamina. Select an appropriately sized hook based on anatomy. Insert the hook in desired location using the hook inserter (Fig 1). Repeat for the remaining hooks (Fig 2).



Figure 1



Figure 2

Step 3 Awl

Determine the entry point and trajectory of the screw. Create a pilot hole using the awl (Fig 3).



Figure 3

Step 4 Drill

Determine drill length and adjust the drill guide to match the corresponding length. Guide depth is adjusted by rotating the knob at the proximal end of the barrel (Fig 4). Each stop adjusts the depth by 2mm (Fig 5). Depth is visually confirmed by the gauge on side of the barrel. Attach the drill to a quick connect handle. Insert the drill into the drill guide and advance it until the stop on the drill makes contact with the drill guide (Fig 6). Confirm the integrity of the pedicle using a ball tip probe.

NOTE: Labeled drill length is equal to the screw length.



Figure 4



Figure 5



Figure 6

Step 5 Tap

The tap sleeve is designed for tissue protection during tapping. Select the appropriate diameter tap and attach it to the quick connect handle. Load the tap sleeve onto the tap by sliding tap sleeve over the distal tip of the tap and advance toward the handle until the sleeve clicks into place (Fig 7). Insert the tap into drilled hole and advance. The sleeve is spring loaded and will retract from the tip as the tap advances. Tap depth is indicated on the tap at the top of the tap sleeve (Fig 8).

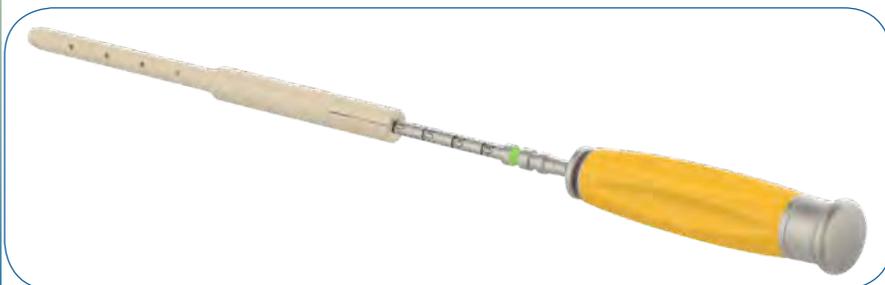


Figure 7



Figure 8

Step 6 Screw Insertion

Select appropriate screw size based on the prepared hole. To load the screw, attach the driver to the quick connect handle. Grasp the screw threaded area. Hold the driver vertical with the handle oriented down. Load the screw on to the tip of the driver to ensure the screw is fully engaged (Fig 9). Slide the outer sleeve until it reaches the tulip. Rotate the sleeve until it engages the threads of the tulip and hand tighten (Fig 10). Drive the screw into the pedicle to the desired depth.

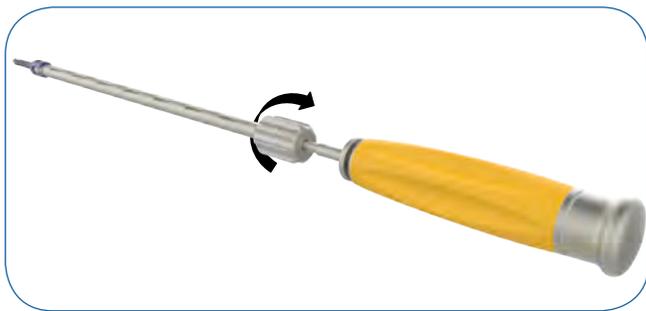


Figure 9



Figure 10

Step 7 Rod Insertion

The rod template may be used to measure the appropriate length and contour of the rods. Cut the rod to the determined length using the rod cutter (Fig 11). Note the designated cut line on the rod cutter. An option for measuring the cut length is to use the rod cutter ruler. Attach the rod cutter ruler to the rod cutter (Fig 12). To use the rod cutter, first rotate the dial to ensure the two arrows are aligned as shown. Pass the rod through the rod cutter. The end of the rod is to align to the desired length marked on the rod cutter ruler. Bending of the rod is done via the rod bender. Insert the rod into the hooks and screws (Fig 13).

NOTE: The rod cutter can only be used to cut the straight Ø3.5mm rods



Figure 11



Figure 12



Figure 13

Step 8 Set Screw Insertion

The set screw is provisionally tightened using a set screw starter. There are two versions of the set screw starter, a single end and a double ended (Fig 14). Load a set screw onto desired set screw starter and provisionally tighten (Fig 15). If the rod is not fully seated into the bottom of the screw tulip then rod reduction must be performed.

Note: Both starters will pass inside of the tower reducer and pistol reducer.



Figure 14



Figure 15

Step 9 Rod Reduction

The rods may be reduced using the tower reducer, pistol reducer, or rod rocker. Rotate the winged knob on the tower reducer counter clockwise to extend the inner sleeve. Connect the tower reducer to the screw tulip (Fig 16). Verify that the tower reducer is seated correctly on the screw tulip & rotate the winged knob clockwise and reduce the rod (Fig 17). Provisionally tighten the set screws once the rod has been reduced (Fig 18). The rocker will mate with the screw or hook on the outside of the tulip.

WARNING: The rod must be fully seated into the bottom of the screw tulip to avoid possible damage to the set screw and screw.

NOTE: Set screws may be inserted through the tower reducer or pistol reducer.



Figure 16



Figure 17



Figure 18

Step 10 Compression /Distraction

At least one set screw should be provisionally tightened prior to compression or distraction. To compress, place the compressor over the rod on the outside of the screw or hook. Squeeze the handle until the desired compression is achieved (Fig 19). To distract, place the distractor over the rod on the inside of the screw or hook. Squeeze the handle until the desired distraction is achieved (Fig 20). Provisionally tighten remaining set screws.

Step 11 Set Screw Final Tightening

Place the countertorque over the screw/hook/lateral connector. Assemble the final driver to the orange 30 in-lb T-handle. Pass the final driver down the inside of the countertorque and seat the driver into the set screw (Fig 21). Rotate the T-handle clockwise until the torque limiting value has been met. Repeat for all set screws. (Fig 22).

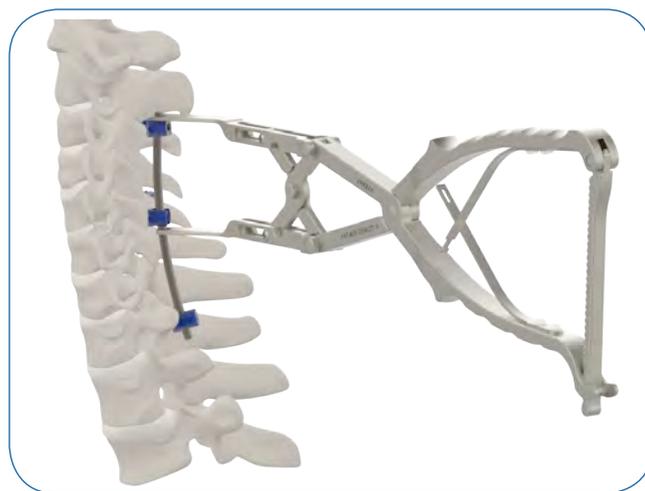


Figure 19

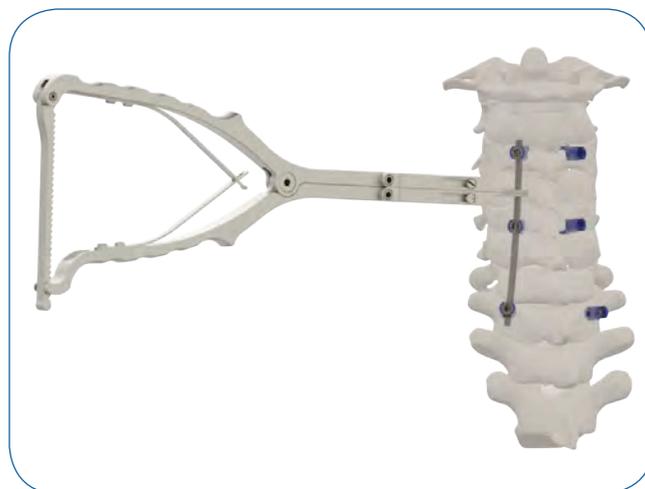


Figure 20

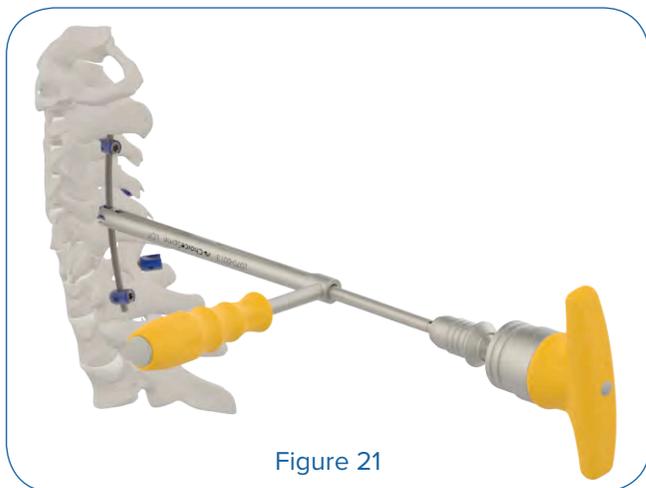


Figure 21



Figure 22

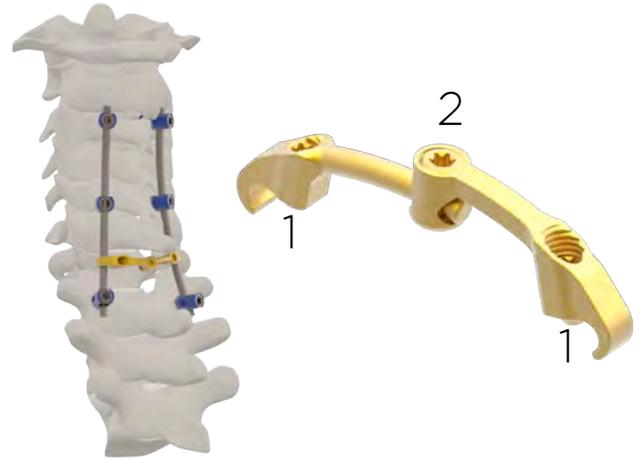
Step 12 Connector Placement

There are a variety of connectors available in the BLACKBIRD system.

WARNING: BEFORE INSERTING ANY CONNECTORS VERIFY THE POSITION OF THE SETS SCREWS TO ENSURE THEY DO NOT RESTRICT SEATING.

ROD TO ROD CONNECTORS

Measure the distance between the rods using the cross connector caliper and select the appropriate sized connector. Place the connector on the rods at the appropriate spinal location and provisionally tighten the lateral set screws followed by the central set screw. Final tighten the lateral set screws first followed by the medial set screw using the connector driver and the yellow 25 in-lb T-Handle.



LATERAL OFFSET CONNECTORS

Lateral connectors may be used when an offset is warranted or anatomy necessitates medial-lateral flexibility. Determine the amount of the offset and select the appropriate sized lateral connector. The lateral connectors accept the same set screw as the polyaxial screws and are final tightened using the orange 30 in-lb T-handle.



INLINE & DOMINO CONNECTORS

There are multiple styles of connectors to connect the BLACKBIRD system with other ChoiceSpine spinal systems. These connectors should be carefully selected to match the correct existing rod diameters. The set screws are final tightened using the connector driver and the orange 30 in-lb T-handle. Use the inline countertorque to aid in final tightening of the inline transition connector.



Removal

To remove the device components, first remove all connectors using a cross connector driver attached to a quick connect handle. Lateral connectors are loosened using a set screw starter attached to a quick connect handle. Remove the rods. To remove polyaxial screws, mate a driver to the base of the screw. Back the screw. To remove the hook, carefully manipulate the hook to remove it from its location.

General Description:

The ChoiceSpine BLACKBIRD™ Spinal System is a comprehensive system for posterior fixation of the cervical and upper thoracic spine. It is to be implanted posteriorly. The system is composed of polyaxial screws and smooth shaft polyaxial screws in various sizes, set screws, straight rods, pre-bent rods, transition rods, cross connectors, lateral offset connectors, rod transition connectors, and hooks. All implant components will be made from Ti 6Al 4V-ELI alloy or Cobalt-28 Chromium-6 Molybdenum Alloy per ASTM F1537. Associated instrumentation will accompany the implant components. Instruments will be made from biocompatible materials.

Indications for Use:

The Choice Spine BLACKBIRD Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion for stabilization of the cervical spine & thoracic spine (C1-T3) for the following conditions:

- degenerative disc disease (DDD; defined as neck pain of discogenic origin with degeneration of the disk as confirmed by history & radiographic studies)
- spondylolisthesis
- trauma
- fracture / dislocation
- spinal stenosis
- atlanto/axial fracture with instability
- tumor
- revision of previous cervical spine surgery

The use of polyaxial screws is limited to the thoracic spine (T1-T3) “ for anchoring the construct only” and not intended to be placed in the cervical spine. The use of the rods and hooks are intended to provide stabilization and promote fusion in the cervical / upper thoracic (C1-T3) spine. This system can be linked to a Ø6.0 mm rod system such as the Choice Spine Starfire™ Pedicle Screw System.

Contraindications:

Contraindications include, but are not limited to:

- infection, systemic or localized
- signs of local inflammation
- morbid obesity
- fever or leukocytosis
- mental illness
- alcoholism or drug abuse
- pregnancy
- severe osteopenia
- suspected or documented sensitivity or allergies to the implant materials
- presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
- any condition having inadequate tissue coverage over the operative site
- any circumstances not described under Indications for Use
- patients unwilling or unable to follow post-operative instructions

Cautions, Precautions, Warnings, Possible Adverse Effects**Cautions:**

- Mixing of dissimilar metals can accelerate the corrosion Process. Stainless steel and titanium components must NOT be used together.

- Do not use components of the Blackbird™ Spinal System with components from any other manufacturer.
- As with all orthopedic implants, none of the Blackbird Spinal System components should ever be reused under any circumstances.

Precautions:

- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Patients who smoke have been shown to have an increased incidence of non- union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Warnings:

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

This device system is not intended to be the sole means of spinal support. It's use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

The implantation of Choice Spine BLACKBIRD spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain,function, or fusion is not always achieved in every surgical case. The BLACKBIRD™ Spinal System has not been evaluated for safety and compatibility in the MR environment. The BLACKBIRD™ Spinal System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the BLACKBIRD™ Spinal System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.



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