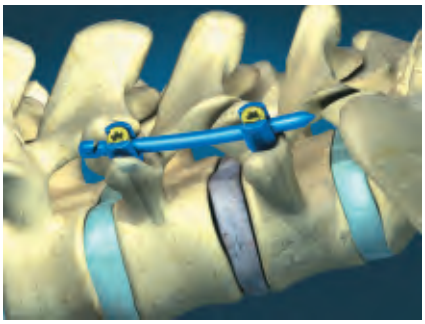
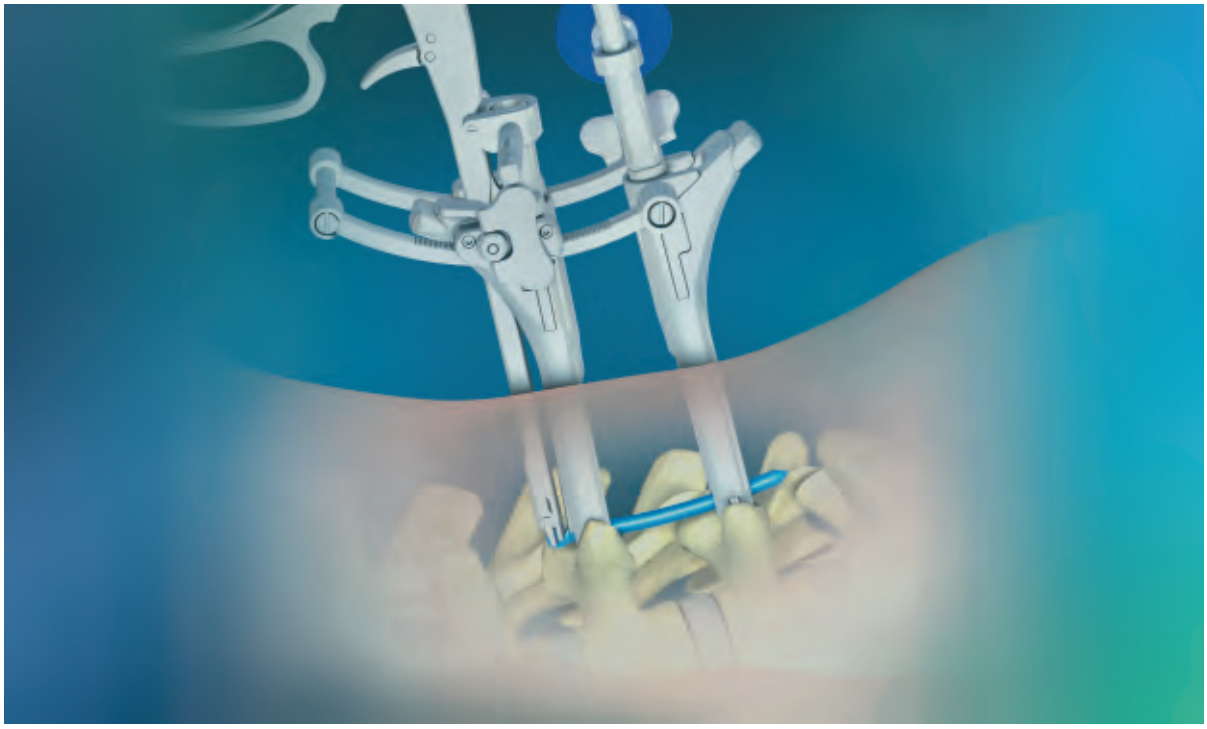
BIOMET SPINE

Ballista™ Percutaneous Screw Placement System

Surgical Technique



BALLISTA™



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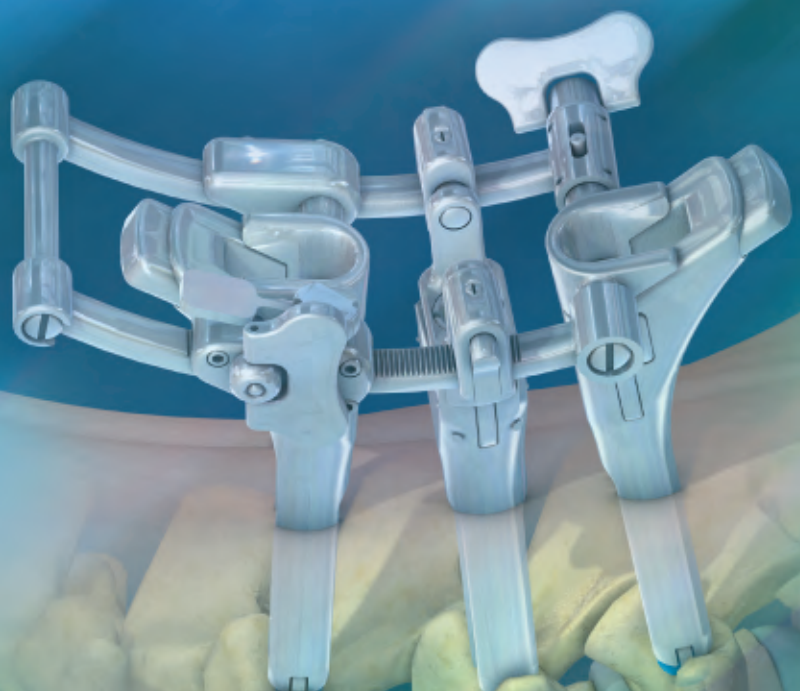
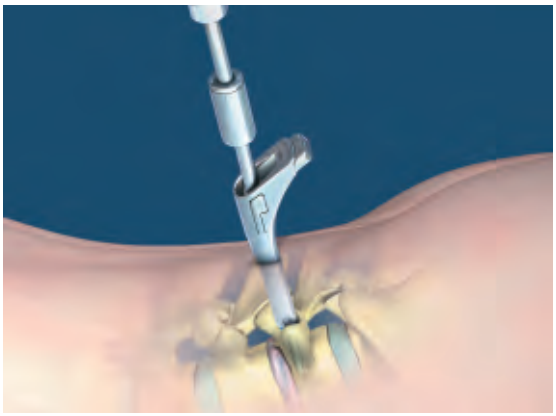


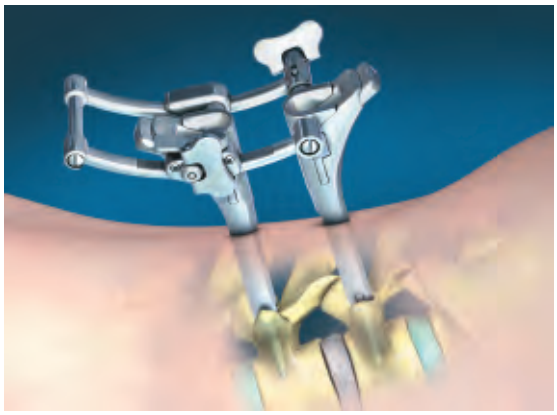
Introduction

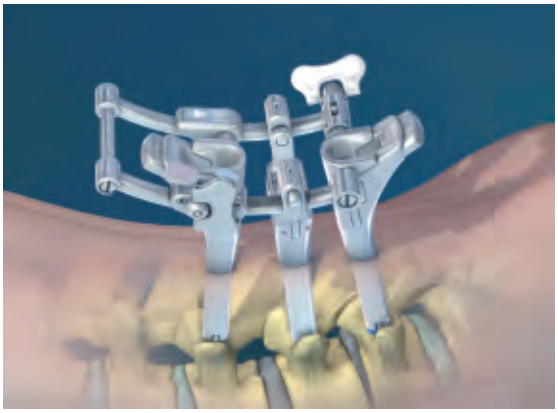
Biomet Spine is proud to introduce the Ballista™ Percutaneous Pedicle Screw Placement System. The **Ballista** System has been created to offer a novel approach to lumbar fixation for the ever-growing Minimally Invasive Fusion Market. The system utilizes a series of cannulated screws, uniquely designed rods and instrumentation intended specifically to introduce and complete a stabilization construct through a true Soft Tissue Fascial Sparing percutaneous approach.

The **Ballista** System also incorporates the innovative Helical Flange™ locking technology, a first in the industry for this type of fusion procedure. The **Helical Flange** technology minimizes cross threading and seat splay of the screws. The forces are concentrated inward which enables the seat and plug to create a reliable mechanical lock.



Features And Benefits





Features	**Benefits**
True Percutaneous System	A Muscle and Fascial Sparing Approach to Lumbar Fixation
Cannulated Screws	Allows for implantation of the Screws Over A Guide Wire
Helical Flange Technology	Starts Easily
	Minimizes Cross Threading and Seat Splay
	Forces are Concentrated Inward
Exclusive Rod Design	Permits the Insertion of the Rod Through the Screw Tower
	Accurately Seats the Rod Inside the Screw Head, Maintaining Sagittal Orientation of the Rod
	Allows the Rod to Pass Easily Through the Soft Tissue
Unique Screw Towers	Proprietary Design Allows for All Functions To Be Performed Through A True Percutaneous Approach
5.5mm Rod System	Low Profile
	Anatomical Fit

Implants

Helical Flange Plug

Cannulated Multi-axial Screws
Available In 5.5mm, 6.5mm And 7.5mm Diameters
In 30mm – 60mm Lengths

Percutaneous Rods
Pre-Formed Rods Available In 5.0mm Increments
25mm – 100mm Lengths

Instruments

Biopsy Needle

First Stage Dilator

Second Stage Dilator

Cannulated Taps

Percutaneous Screw Tower

Screw Inserter Shaft

Ratcheting Cannulated Tear Drop Handle

Fixed Tear Drop Handle

Compressor/Distractor Instrument

Middle Screw Tower

Middle Tower Cradle

Middle Tower Wrench

Instruments (Continued)

Variable Tissue Elevators

Fixed Tissue Elevators

Rod Inserter

Rod Inserter With Guide

Counter Torque

Plug Starter

Torque Wrench Handle

Open Counter Torque

Plug Driver Shaft

Tissue Elevator Handle

Dorsal Height Adjuster

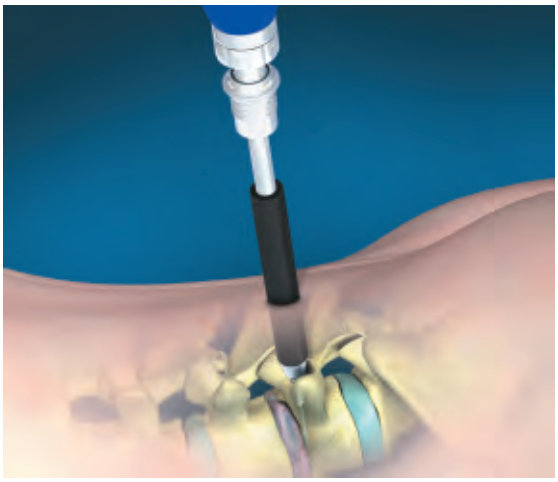
Guide Wire Driver

1. Patient Positioning And Pre-Operative Planning

The patient is positioned prone in the appropriate position for a posterior approach.

The patient is then prepared and draped in a conventional manner.

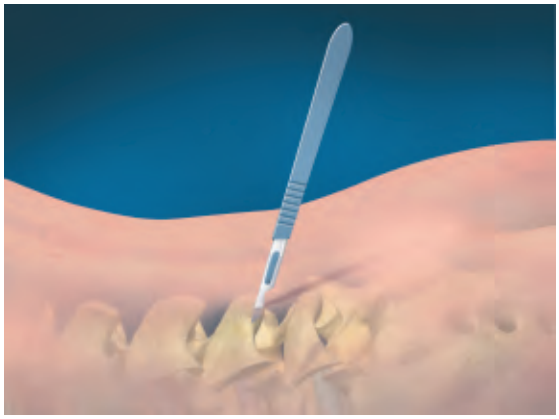
Utilizing anterior/posterior and lateral fluoroscopic imaging and palpation of the patient's appropriate vertebral landmarks, the targeted pedicles are located and marked on the patient's skin.



O.R. Tips

- The incision should be further lateral to the mid-line as the distance between the skin and posterior elements increases
- Use C-Arm prior to sterile preparation to check for satisfactory fluoroscopic visualization of planned surgical instrumental levels

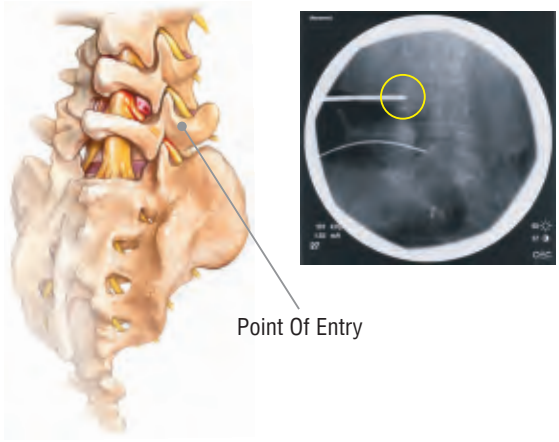
2. Incision And Exposure



A skin incision and a fascia release of about 1.5cm is made with a knife blade at the location marks on the patient skin and a biopsy needle is advanced through the skin incision. The needle is docked onto the targeted pedicle and verified with fluoroscopic imaging.

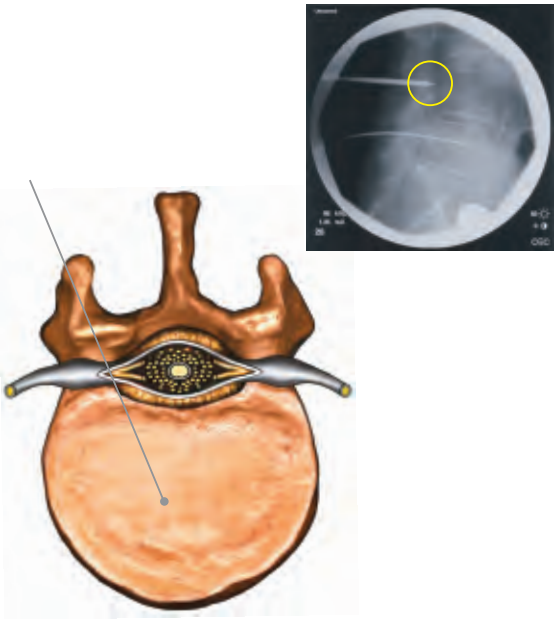
O.R. Tips

Ideal placement of the biopsy needle will be:



Lateral

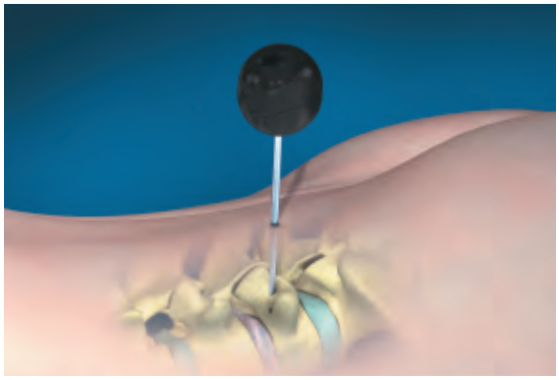
- The needle enters the vertebral body at the posterior wall of the pedicle



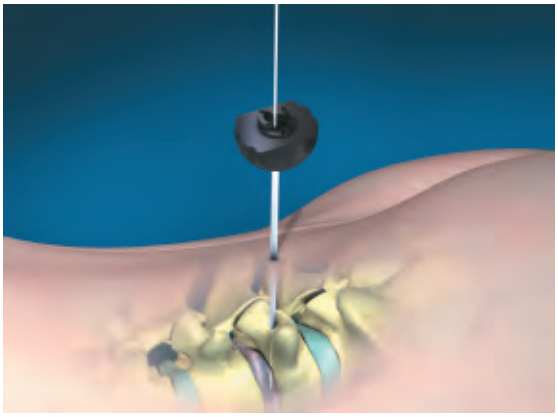
Posterior

- 5.0mm lateral to the medial wall of the pedicle

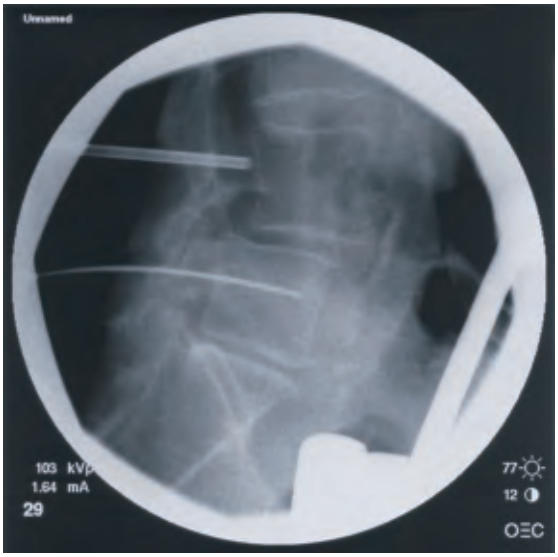
To aid in visualization of the pedicle, an en fasse fluoroscopic image may be helpful.



2. Incision And Exposure (Continued)

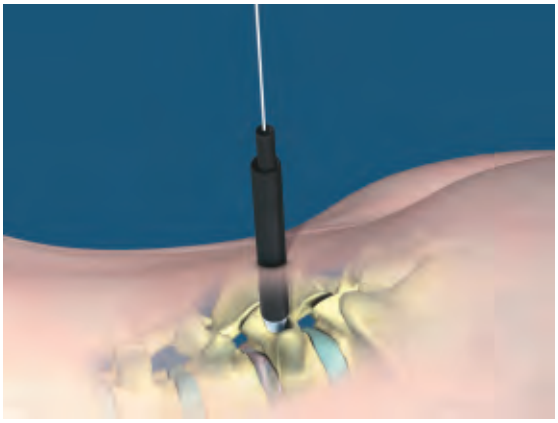


Once proper trajectory and docking of the biopsy needle is confirmed, the trocar needle is removed. The trocar needle is replaced by a guide wire.



With the guide wire in place, remove the needle cannula while ensuring that the guide wire maintains purchase in the pedicle.

The guide wire will remain in place to facilitate further steps in the procedure.



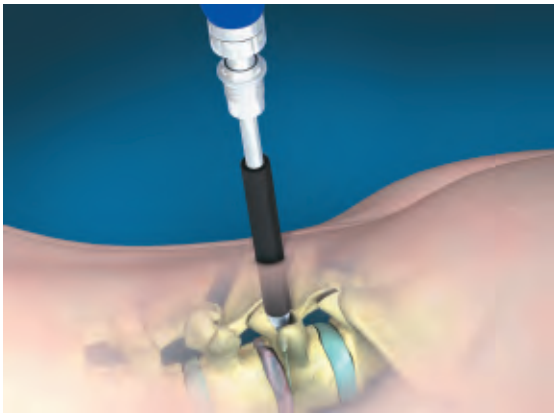
Dilation of the opening through the muscles is performed in a two-staged sequential manner over the guide wire.

O.R. Tips

- If a cannulated probe neurological monitor is to be performed, at the surgeon's discretion, remove the 1st stage dilator, leaving the guide wire and 2nd stage dilator in place
- Care must be taken that the guide wire is held in place during any transition of instruments. Failure to do so may result in the guide wire being inadvertently removed from the pedicle

3. Pedicle Preparation

Remove the 1st stage dilator only.

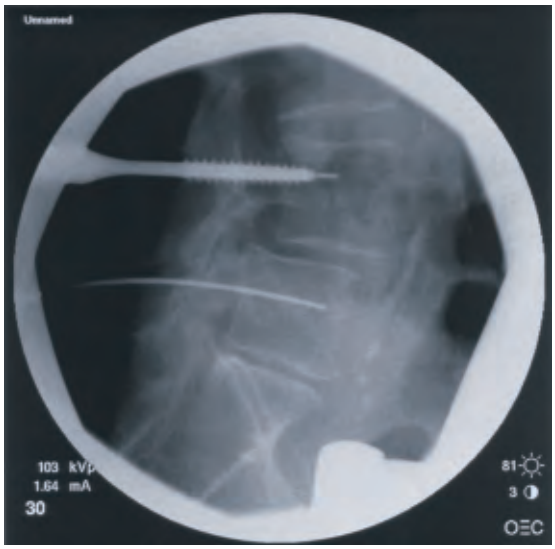


With the second stage dilator in place over the guide wire and acting as a soft tissue protector, the appropriate cannulated tap is advanced over the guide wire and the pedicle is prepared for a **Ballista** screw.

NOTE: During the tapping procedure, care must be taken to hold onto the guide wire to prevent it from advancing.

O.R. Tip

- The cannulated tap is calibrated and etched accordingly to provide the length of the required Ballista screw



O.R. Tip

- After the tip of the tap enters the tip of the vertebral body one can redirect the tap if necessary by pulling the guide wire tip back into the tap and redirecting the tap. The guide wire is then pushed back through the tap and into the vertebral body

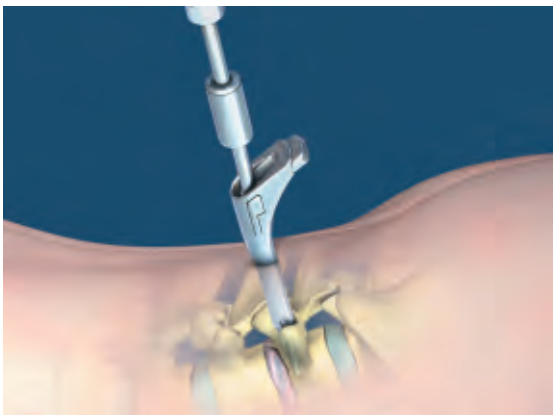
After completion of the tapping procedure the 2nd stage dilator is removed from the patient, leaving only the guide wire in place.

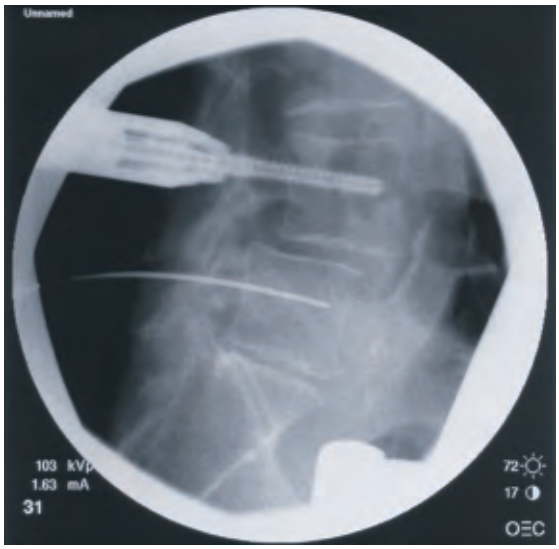
Repeat the process of pedicle preparation for subsequent vertebral bodies prior to moving forward to screw insertion.

4. Screw Placement

Load the appropriate **Ballista** screw onto the distal end of the screw tower. This is accomplished by first pressing the button on the rear of the screw tower and then pressing the buttons on the medial/lateral sides of the screw tower. This action will release the screw retainer mechanism. Simply align the features on the sides of the tulip into the retainer and push until an audible 'click' is heard. The screw is now locked onto the screw tower.

To implant the screw, first load the cannulated screw inserter through the screw tower guiding the pentalobe head into the female portion of the screw head. Next turn the knurled portion of the screw inserter in a clockwise motion threading the screw inserter into the **Helical Flange** thread at the inner portion of the tulip and finger tighten. While using fluoroscopic imaging, advance the screw tower assembly over the guide wire and implant the screw through the pedicle and into the vertebral body. **Take care that the guide wire is not being advanced while performing screw insertion.**





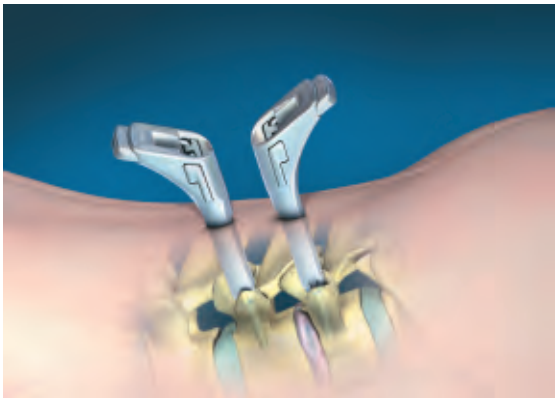
After confirming that the screw is in the proper position, remove the guide wire and cannulated pedicle screw inserter, leaving the screw tower in place.

O.R. Tips

- Do not bury the head of the screw into the facet joint
- At L5-S1 the medial border of the iliac crest may interfere with the polyaxial motion of the screw

NOTE: To aid in the removal of the guide wire, utilize the guide wire driver. Slide the guide wire through the cannulated portion of the instrument, and grasp the handle of the driver to act as a clamp securing the guide wire to the instrument. Pull back on the rounded handle of the driver to act as a slap hammer, or pull on the instrument while holding on to the handle of the driver, to pull the guide wire straight out of the pedicle. Hold firm pressure on the screw tower while using the slap hammer to remove the wire.

5. Placement Of Cannulated Pedicle Screws At Adjacent Levels



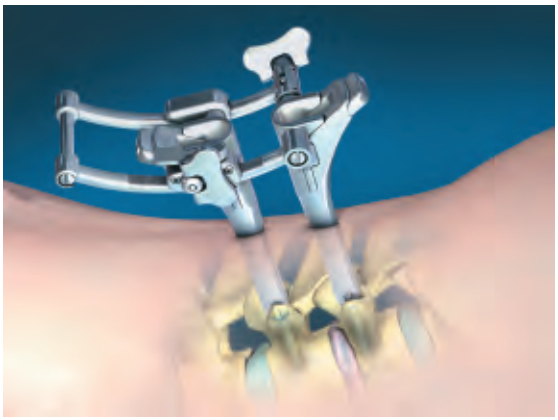
To implant **Ballista** cannulated bone screws into adjacent vertebral levels, repeat the procedural steps for planning, incision, exposure and pedicle preparation/screw placement as outlined in section three of this technique manual.

O.R. Tip

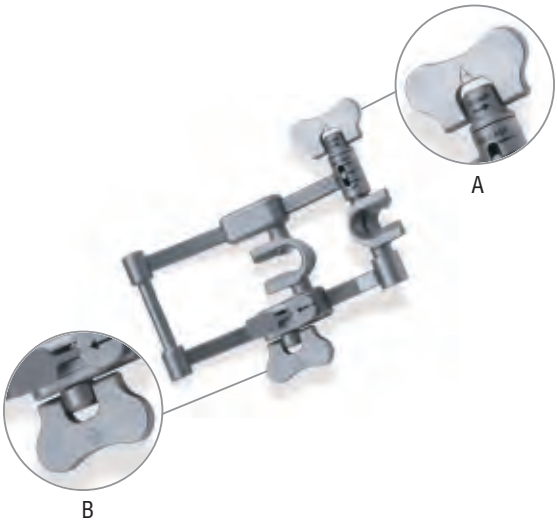
- Due to the unique design of the screw towers, when implanting a second screw tower ensure that the towers "face" each other, i.e. the ramped portion of the towers slope inward towards the center of the construct, to form a "V" shape

6. Intraoperative Compression/Distraction And Angulation Of Tower Assemblies

With screw towers and respective cannulated bone screws in place, attach the screw tower Compressor/Distractor (C/D) instrument to the screw towers and adjust as needed.



To attach the C/D instrument to the screw towers, ensure that the "A" Wing Key component is in the "release" position.



- This will allow the single cup to articulate in the plane of the instrument, allowing for easier placement of the C/D instrument into the screw towers

Press down on the lever over the “B” Wing Key and turn the thumb wheel until the arrow points to the side and release the lever. Line up the cups of the C/D instrument to the screw towers, when aligned properly push down until an audible ‘click’ is heard on both screw towers. This will verify that the instrument has seated properly into the towers.

NOTE: a visual check of the mating parts should be performed to ensure that full seating of the C/D instrument into the towers has been achieved.

O.R. Tips

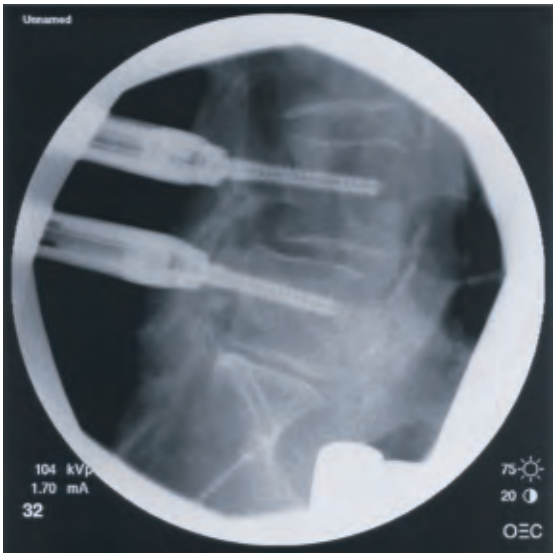
- The screw towers must be “movable” in order to connect the C/D Instrument, if the instrument does not connect to the towers, check to see if the screw head is buried too deep, and modify accordingly

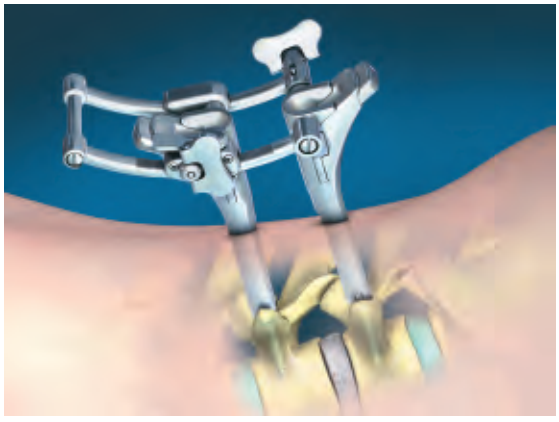
Upon full seating of the C/D instrument, turn the “A” Wing Key of the instrument in the direction of the arrow to the “Lock” position. This will stabilize the articulation of this component to allow the construct to perform compression and distraction accordingly.

- To distract the construct, press the lever arm and turn the thumb wheel so the arrow faces away from the center of the construct and release the lever arm. Turn the “B” Wing Key counterclockwise until the required amount of distraction has been accomplished
- To compress the construct, press the lever arm and turn the thumb wheel so the arrow faces towards the center of the construct and release the lever arm. Turn the “A” Wing Key clockwise until the required amount of compression has been accomplished

O.R. Tip

- If additional compression of the construct is required turn the “A” Wing Key in the direction of the arrow. You can gauge the amount of compression gained by watching the marker on the top of the C/D Instrument as it travels toward the “COMP’ line





7. Two-Level Construct Option

To implant additional **Ballista** Screws for a Two-Level Construct:

Load the **Ballista** screw onto the middle screw tower, by pressing the release tabs on the medial/lateral sides of the screw tower to release the retaining mechanism. Upon selection of the appropriate size **Ballista** screw align the features on the sides of the tulip into the retainer and push until an audible 'click' is heard. The screw is now locked onto the screw tower.

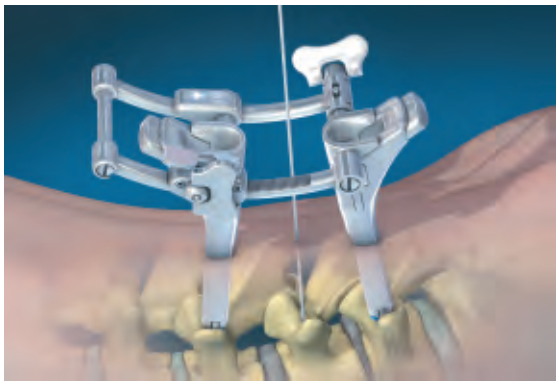
Assemble the middle tower cradle to the proximal end of the middle screw tower. Align the 'thread' of the cradle into the hole at the proximal end of the screw tower, and ensure that the tabs are on the medial/lateral walls of the screw tower, overlapping the release buttons of the screw tower. Utilize the middle tower wrench to secure the cradle to the screw tower by turning the wrench clockwise until tight.

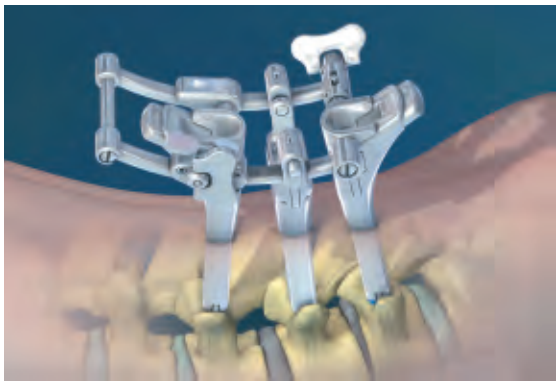
NOTE: It is necessary to insert the most cephalad and caudal screw towers prior to placement of middle screw tower.

O.R. Tip

- To aid in proper alignment of all screw heads, during pedicle preparation draw a line between the most cephalad and caudal screw towers. The entry point for the middle screw should be along this line

To implant the middle screw, first load the cannulated screw inserter through the middle screw tower guiding the pentalobe head into the female portion of the screw head. Next, turn the knurled portion of the screw inserter in a clockwise motion threading the screw inserter into the **Helical Flange** thread at the inner portion of the tulip and finger tighten. The entire construct will be inserted over the guide wire as one complete assembly. While using fluoroscopic imaging, advance the screw tower assembly over the guide wire and implant the screw through the pedicle and into the vertebral body.





O.R. Tip

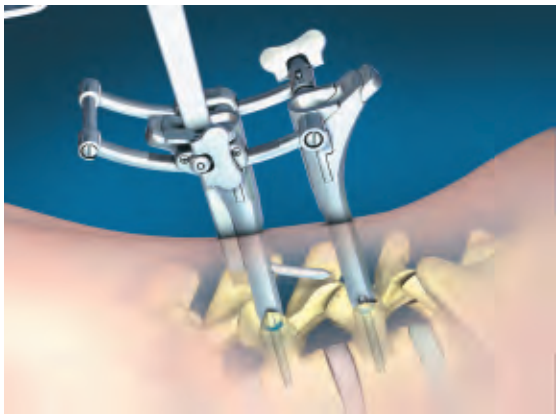
- The screw will be fully docked to the C/D Instrument when the tabs at the medial/lateral sides of the cradle lock onto the racks of the C/D Instrument. Care must be taken that orientation of the middle tower assembly is in line to allow the tabs to be in line with the racks of the instrument

8. Placement Of Ballista Rod

With the C/D instrument attached, tissue elevators are advanced from screw head to screw head through the screw towers to initiate a path through the soft tissue.

O.R. Tip

- To aid in the placement of the rod, introduce the tissue elevators in a cephalad to caudal and caudal to cephalad motion



O.R. Tip

- Confirm tissue elevators are passing through both towers using A/P and lateral fluoroscopy

Select the appropriate length percutaneous rod as indicated by the C/D instrument and load it onto the rod introducer. To load the percutaneous rod onto the rod introducer, adhere to the following steps:

O.R. Tip

- To confirm rod size the variable tissue elevators can act as a guide for verification. The blade on the tissue elevators are sized to 40mm, 65mm and 90mm in length

8. Placement Of Ballista Rod (Continued)

Holding the preformed **Ballista** rod in one hand, take the rod introducer and slide the mouth of the rod onto the pushing mechanism of the rod introducer.

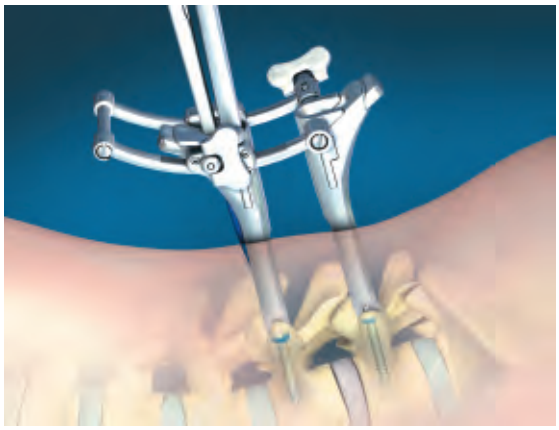
Pull the trigger of the rod introducer and the jaws will open and allow the pivot hole of the **Ballista** rod to be accessed by the jaws.

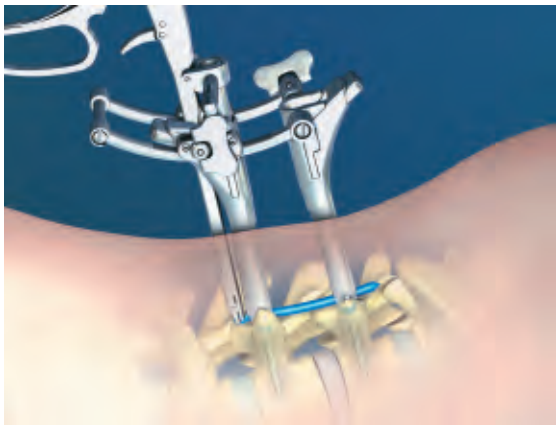
Line up the jaws of the rod introducer to the pivot hole and release the trigger.

Press the lock button on the rod introducer, the **Ballista** rod is now securely attached to the rod introducer.

Contained within the set you will find two distinct rod inserters for the **Ballista**. One has a barrel or “guide” and the other does not have the guide. Both rod inserters; when utilized in conjunction with the **Ballista** rod provide an exclusive design that allows for ease of rod insertion through the **Ballista** towers. The inserter attaches to the ballista rod at the distal end of the instrument via two mechanisms, there are jaws that attach to the pivot point mechanism, as well as a slider bar to articulate the rod in conjunction with the pivot mechanism. The ultimate goal of both instruments is to provide one function, placement of the rod within all of the screw seats.

The inserter with the guide will align all facets of the mechanism in parallel so that the “olive” on the proximal portion of the rod will set into the minor diameter of the screw head upon full insertion. Secondarily, the “guide” also acts as a rod pusher to help seat the rod properly. While this is a more constrained insertion method, it allows for a greater ease of insertion over the inserter without the guide. Conversely, the inserter without the guide allows the surgeon greater freedom in placing the rod.





- Advance the **Ballista** rod through the appropriate tower, using fluoroscopic imaging as a guide; slowly pull on the handle of the rod introducer to articulate the angle of the **Ballista** rod while pushing downward (CoAxial to the screw tower) until the rod is seated within both screw heads

Upon full seating of the **Ballista** rod, the rod introducer will stay connected to the rod, acting as a rod holder to allow for the placement of the **Helical Flange** Plugs.

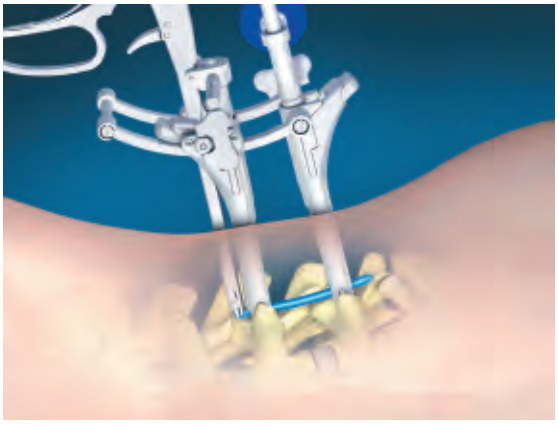
O.R. Tips

- To aid in full seating of the rod within the screw heads, introduce the tissue cutters into the cephalad and caudal screw towers to split the fascia accordingly
- Verify with A/P fluoro that the percutaneous rod is aligned through both screw seats
- At L5-S1, it may be easier to pass the rod caudal to cephalad due to the angle of the sacrum
- Verify full seating of the rod with A/P and Lateral Fluoroscopy, a final visual check at the distal screw tower is recommended in order to verify positioning prior to placing set screws

9. Placement Of Helical Flange Plug

To introduce the **Helical Flange** plugs onto the percutaneous screws, adhere to the following steps:

- Load the plug starter with a **Helical Flange** Plug



- Introduce the Counter Torque through the proximal or distal screw towers, which will perform three functions:
  - Act as a rod pusher, fully seating the rod into the screw seats
  - Provide a sleeve to guide the **Helical Flange** Plug into the screw seats
  - Perform as a counter torque during the final tightening process
- Introduce the Plug through the proximal screw tower (whichever tower is holding the rod) and provisionally tighten. Repeat for the opposite screw tower

O.R. Tip

- To remove the rod inserter, release the safety button to the "unlock" position. Pull the finger trigger on the rod inserter and pull up

10. Final Compression/Distraction Of The Tower Assembly And Torque Of The Percutaneous System Construct

Per the surgeon's discretion, make the final compression, distraction and angulation of the construct with the C/D instrument.

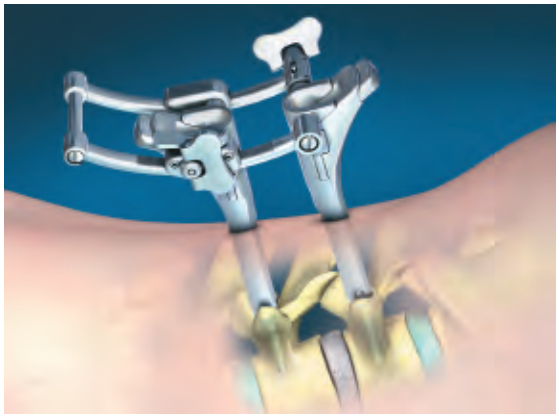
The set screws are tightened with the torque wrench in conjunction with the counter torque. Insert the torque device through the center of the counter torque and through one of the screw towers. Position the tip of the torque wrench into the plug. Seat the distal end of the counter torque over the screw seat and confirm that the counter torque fits firmly on the rod. The rod will be positioned within the slots of the stabilizer.

The torque-limiting wrench is turned in a clockwise direction while the counter torque is held with resistive force in a counterclockwise direction. Upon reaching the intended final torque, 110in-lbs, an audible "Click" will be heard, thus verifying the final torque.

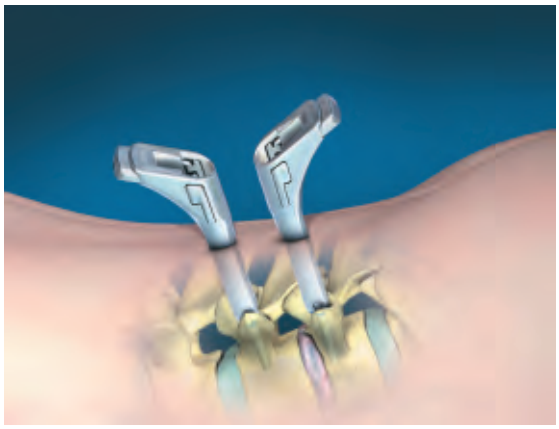
Repeat the above steps for the subsequent set screws.

11. Removal Of The Percutaneous Screw Towers And Closure

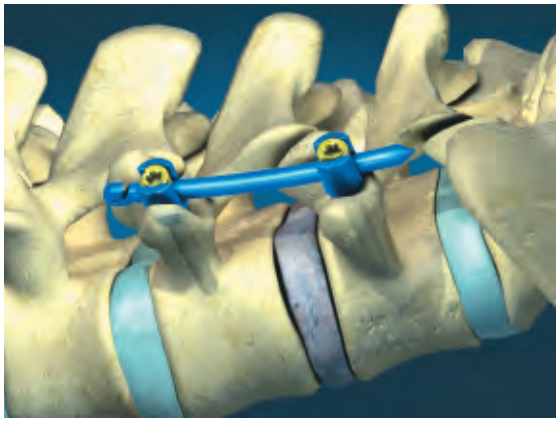
Remove the Counter Torque Instruments from the construct.



Remove the C/D Instrument by pressing the button on the rear of the **Ballista** Towers while lifting the instrument from each tower.



Remove each screw tower by first pressing the button on the rear of the screw tower and then pressing the button on the Medial/Lateral sides of the screw tower. This will disengage the tower from the **Ballista** screws and allow the screw towers to be removed from the surgical site.



Perform closure of the percutaneous operative site in layers according to standard protocols and facility guidelines.

Indications For Use

The **Ballista** System is a non-cervical spinal fixation system intended for use as a pedicle screw fixation system or as an anterolateral spinal fixation system. Pedicle screw fixation is limited to skeletally mature patients. The use of the device is indicated for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformity, or curvature (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and previous failed fusion. See the package insert for warnings, precautions, adverse events and other product information.

Contraindications

The **Ballista** System is contraindicated in patients with spinal infection or inflammation, morbid obesity, mental illness, alcoholism or drug abuse, pregnancy, metal sensitivity/foreign body sensitivity, patients with inadequate tissue coverage over the operative site or open wounds local to the operative area, to the operative area, or any case not described in this specific indication.

Sterilization Recommendations

High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following cycles have been laboratory validated:

Method:	Steam	Steam
Cycle:	Gravity	Prevac
Temperature:	250°F (121°C)	270°F (132°C)
Exposure Time:	60 minutes	8 minutes
Drying:	20 minutes	

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 (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and previous failed fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Potential risks identified with the use of this device, which may require additional surgery, include device component failure, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury. See package insert for additional information.

Ordering Information

Ballista Implant Case

(Catalog #14-509624)

Catalog #	Description	Qty/Kit
2000-1005	HF PLUG – 5.5mm	12
2000-6905	1.6mm Guide Wire	12
2000-3330	5.5mm x 30mm **Ballista** Cannulated Screw	2
2000-3335	5.5mm x 35mm **Ballista** Cannulated Screw	4
2000-3340	5.5mm x 40mm **Ballista** Cannulated Screw	4
2000-3345	5.5mm x 45mm **Ballista** Cannulated Screw	4
2000-3350	5.5mm x 50mm **Ballista** Cannulated Screw	4
2000-3355	5.5mm x 55mm **Ballista** Cannulated Screw	4
2000-3430	6.5mm x 30mm **Ballista** Cannulated Screw	4
2000-3435	6.5mm x 35mm **Ballista** Cannulated Screw	8
2000-3440	6.5mm x 40mm **Ballista** Cannulated Screw	8
2000-3445	6.5mm x 45mm **Ballista** Cannulated Screw	8
2000-3450	6.5mm x 50mm **Ballista** Cannulated Screw	8
2000-3455	6.5mm x 55mm **Ballista** Cannulated Screw	8
2000-3460	6.5mm x 60mm **Ballista** Cannulated Screw	6
2000-3530	7.5mm x 30mm **Ballista** Cannulated Screw	4
2000-3535	7.5mm x 35mm **Ballista** Cannulated Screw	4
2000-3540	7.5mm x 40mm **Ballista** Cannulated Screw	6
2000-3545	7.5mm x 45mm **Ballista** Cannulated Screw	6
2000-3550	7.5mm x 50mm **Ballista** Cannulated Screw	6
2000-3555	7.5mm x 55mm **Ballista** Cannulated Screw	4
2000-3560	7.5mm x 60mm **Ballista** Cannulated Screw	2

Catalog #	Description	Qty/Kit
14-500425	25mm **Ballista** Curved Rod	4
14-500430	30mm **Ballista** Curved Rod	4
14-500435	35mm **Ballista** Curved Rod	4
14-500440	40mm **Ballista** Curved Rod	4
14-500445	45mm **Ballista** Curved Rod	4
14-500450	50mm **Ballista** Curved Rod	4
14-500455	55mm **Ballista** Curved Rod	4
14-500460	60mm **Ballista** Curved Rod	4
14-500465	65mm **Ballista** Curved Rod	4
14-500470	70mm **Ballista** Curved Rod	4
14-500475	75mm **Ballista** Curved Rod	4
14-500480	80mm **Ballista** Curved Rod	4
14-500490	90mm **Ballista** Curved Rod	2
14-500499	100mm **Ballista** Curved Rod	2

Ballista Screw Instrument Case

(Catalog #14-509623)

Catalog #	Description	Qty/Kit
2000-6900	Twist/Lock Biopsy Needle	4
2000-6408	1st Stage Dilator	1
2000-6409	2nd Stage Dilator	1
2000-6906	Guidewire Driver/Clamp	1
2000-6104	4.75mm Cannulated Tap	1
2000-6105	5.5mm Cannulated Tap	1
2000-6106	6.5mm Cannulated Tap	1
2000-6107	7.5mm Cannulated Tap	1
2000-6203	**Ballista** Screw Inserter	2
2000-6100	Screw Tower	4
2000-6272	Compression/Distraction Instrument	2
2000-6002	Intermediate Screw Tower	1
2000-6003	Middle Tower Cradle	1
2000-6005	Cradle Wrench	1
2000-6004	Radiolucent Targeter	1
2000-6481	Ratcheting Teardrop Handle	2
2000-9006	Fixed Teardrop Handle	1
2000-6008	Tower Alignment Tool	2

Ballista Rod Instrument Case

(Catalog #14-509626)

Catalog #	Description	Qty/Kit
2000-6275	Screw Tower Counter Torque	2
2000-6239	Fixed Tissue Elevator, 50°	1
2000-6240	Fixed Tissue Elevator, 70°	1
2000-6482	Tissue Elevator Handle	2
2000-6228	Variable Tissue Elevator, Small (40mm)	1
2000-6229	Variable Tissue Elevator, Medium (65mm)	1
2000-6230	Variable Tissue Elevator, Large (90mm)	1
2000-6248	Rod Inserter With Guide	1
2000-6249	Rod Inserter Without Guide	1
2000-6260	Screw Tower Plug Starter	2
2000-9061	Plug Driver Shaft – QC Shaft	2
594522	QC Set Screw Torque Wrench	1
2000-9075	Counter Torque – Open	1
2000-9072	Dorsal Height Adjuster	1
2000-6007	Tower Retriever	1
14-500570	Tissue Cutter – Small	1
14-500571	Tissue Cutter – Large	1

Further Information

This brochure describes the surgical technique used by Dan S. Cohen, M.D. Biomet Spine, as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

The **Polaris 5.5** Spinal System is covered by numerous U.S. and International patents. U.S. Patent Numbers: 5,360,431; 5,466,237; 5,474,555 and Patents Pending.

Helical Flange is a trademark of The Jackson Group.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

For further information, please contact the Customer Service Department at:

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Notes:

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