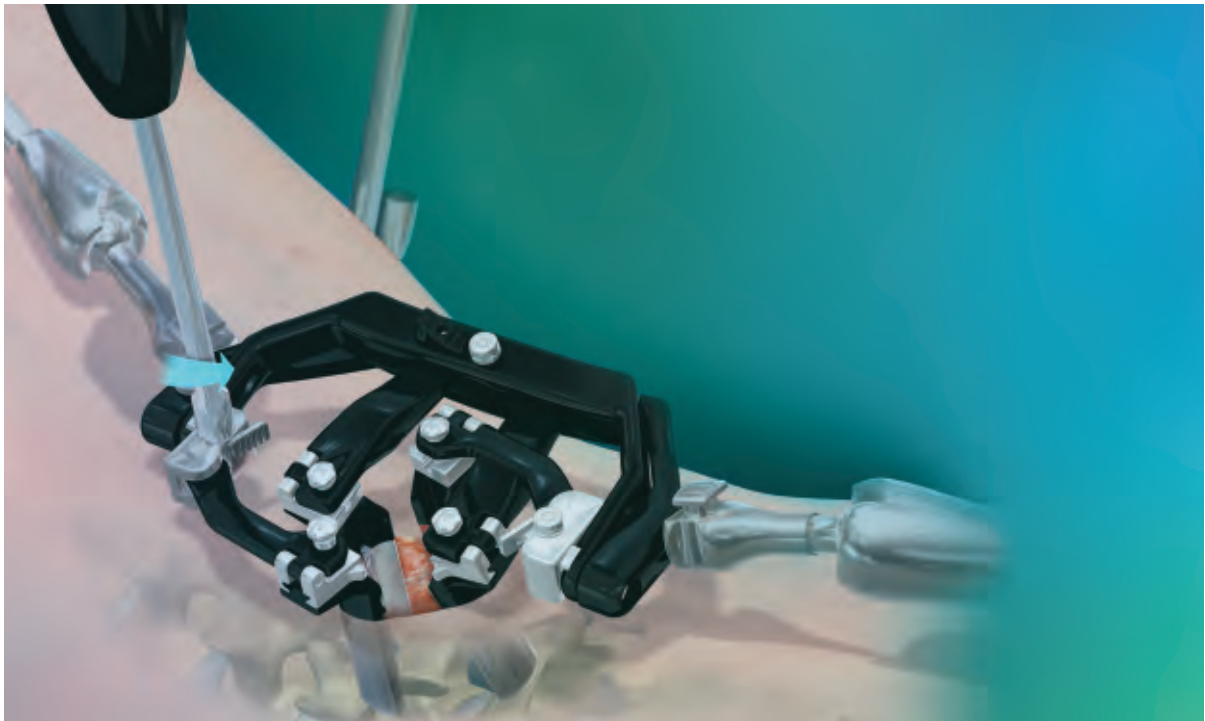


AccuVision[™]
*Minimally Invasive Spinal
Exposure System*

Surgical Technique



AccuVision[™]



Contents

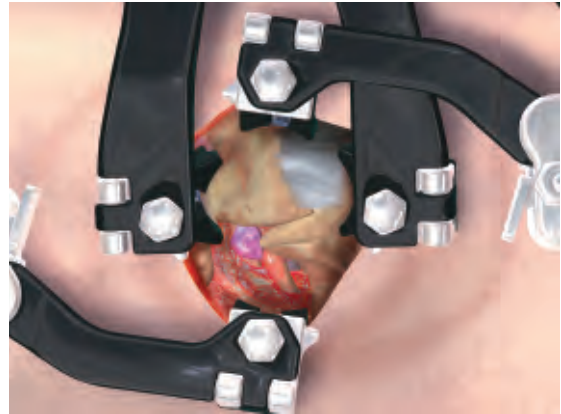
Introduction	Page 1
Features And Benefits	Page 2
Instruments	Page 3
Surgical Technique.....	Page 5
Posterior Fixation With Polaris™ 5.5 Pedicle Screws	Page 12
AccuVision Frame Removal And Closure	Page 18
Indications For Use.....	Page 19
Sterilization Recommendations	Page 20
Ordering Information	Page 21
Further Information.....	Page 22



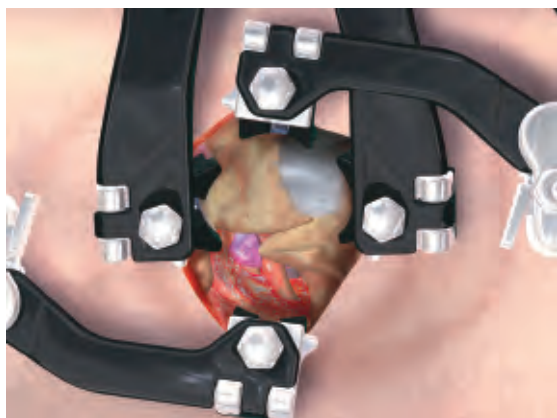
Introduction

Biomet Spine is proud to present the AccuVision™ Minimally Invasive Spinal Exposure System. The **AccuVision** System has been designed to offer a variable approach to lumbar fixation for the ever-growing Minimally Invasive approach to spine surgery. The **AccuVision** System features a Retractor frame with a series of blades, shims and retractor modules that provide exceptional exposure to the bony anatomy, while utilizing the widely accepted Modified-Wiltse, Paraspinous approach to Spinal Surgery.

The design goals for the **AccuVision** System were simple; provide a familiar modular, variable approach to minimally invasive spine surgery while maximizing the exposure to the anatomy. The ergonomically designed frame allows the surgeon to perform both non-fusion and fusion procedures with minimal change to the surgeon's individual technique.



Features And Benefits



Features	Benefits
Minimal Skin Incision	Less trauma to musculature around the spine
Mechanical Retraction System	Provides ample retraction up to four directions Steerable medial/lateral exposure without changing table/frame attachments Maximal exposure with minimal incision
Variable Blade Lengths	Custom fit system based on patient anatomy
Stable Platform	Provides the surgeon optimized work space without “fiddle factor” or floating of the frame in the surgical site

Instruments



Retractor Frame



Retractor Blades



Retractor Arms



Shim Advancer



Retractor Arms



Shim Retractor



Retractor Wrench

Instruments (Continued)



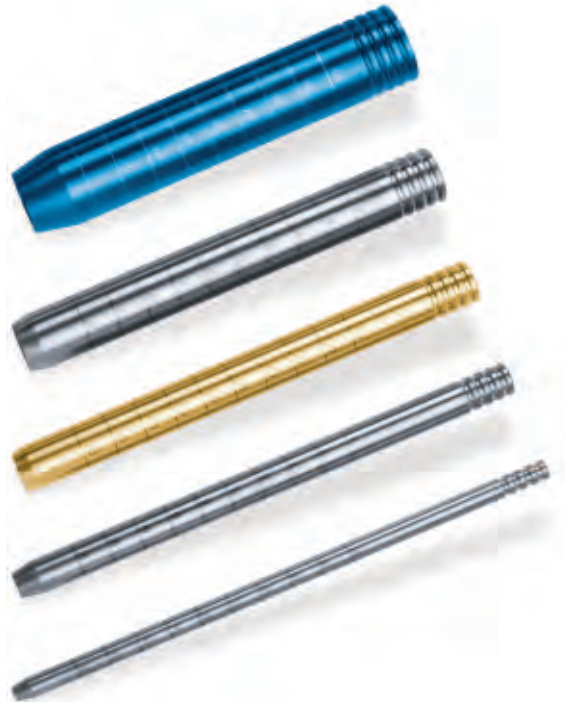
Disposable Blade Tips (Lighted and Non-Lighted)



Articulating Arm



Radial Setting Clamp



Dilators

Surgical Technique

Patient Positioning And Pre-Operative Planning

The patient is positioned prone in the surgeon preferred position for a posterior approach to spine surgery.

Utilize fluoroscopic imaging to confirm necessary visualization of surgical size.

The patient is then prepared and draped according to surgeon preference.

Utilizing anterior/posterior and lateral fluoroscopy imaging and palpation of the patient's appropriate vertebral landmarks, the incision line is identified 2 to 4cm lateral to the midline as directed by the surgeon for the indicated surgical procedure.

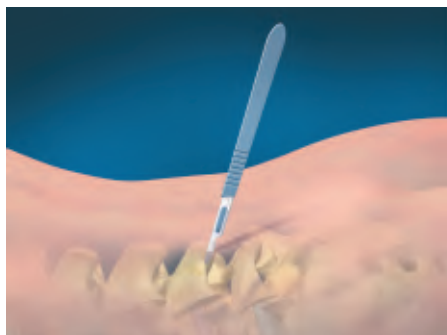


O.R. Tips

- As part of pre-operative planning, a spinal needle or guide wire can be used to confirm location and trajectory for targeting the pedicle entry point
 - Discectomy/Non-Fusion Procedures:
 - The target area is the lower aspect of the lamina overlying disc space to be accessed
 - Fusion Procedures:
 - The target area is midway between the cephalad and caudal pedicle at the level to be fused
- To perform a contralateral decompression through a single sided approach, the target area should be similar to the approach described above for a fusion procedure
- For a two-level decompression, target the middle vertebrae
 - E.G. L3 to L5 laminectomy, target over the middle of L4 vertebrae

Surgical Technique (Continued)

Incision And Exposure



Access to the bony aspect of the posterior spinal anatomy is initiated with a knife incision of the skin at the side and level of the spine requiring exposure for the prescribed procedure.

An incision of the fascia overlying the muscle groups is also performed to assist the exposure process. The length of the skin incision line will be dictated by the amount of anatomy needing exposure.

O.R. Tips

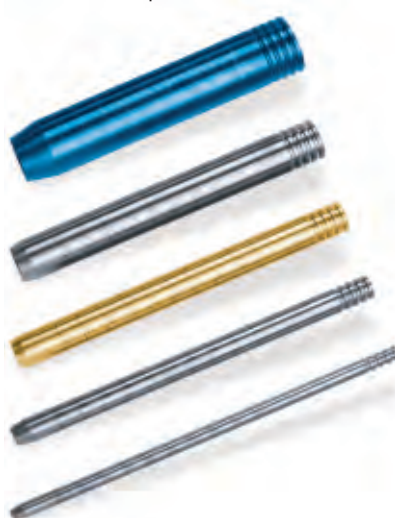
- The incision should be further lateral to the mid-line as the distance between the skin and posterior elements increases

NOTE: The length of the fascia release can extend beyond the length of the skin incision.



After the skin incision and fascia release have been completed, sequential dilation of the opening through the muscles is performed.

A Gentle sweeping of the first dilator (7mm diameter) should be performed to mobilize deep soft tissue off the bony anatomy and to achieve an accurate estimate of the tissue depth.



Subsequent sequential dilation can either be performed to the 18mm (yellow) dilator or the 25mm (blue) dilator dependent upon surgeon preference.

O.R. Tips

- Following the sequential dilation, remove the dilators and utilize a Cobb elevator to scrape the soft tissue off the posterior elements and re-dilate
- The correct blade length can be determined via the following method:



- Sound with the first sequential dilator (7mm diameter) into the operative site, using the depth markings to determine blade depth. If the depth is between two markings, utilize the shorter blade

Attachment Of Blade Tips:

Select the appropriate shape disposable blade and line up the channels of the blade to the posts of the reusable blade. Slide the shim retractor down the channel of the blade and align the "T" into the hole at the proximal end of the blade tip. Turn the handle of the shim retractor 90° and the spring-loaded instrument will pull the blade up.



The blade assembly can now be loaded into the appropriate parts of the **AccuVision** Frame. The blade is loaded by aligning the Male "T" at the proximal portion of the blade to the Female "T" Slot on the appropriate blade arms. Simply slide the blade into the retaining feature of the arms until an audible 'click' is heard.



NOTE: the curved portion of the blade should always be facing towards the center of the frame.

To remove the blade from the individual arms, press on the tab of the retaining feature, and pull the blade straight back from the arm.

Articulating Arm Tips:

The **AccuVision** System comes with the option of attaching lighted or non-lighted blade tips to the individual retractor blades. With this in mind, pre-plan your retraction as necessary to determine where a lighted blade(s) would be necessary to aid in the visualization of the anatomy.



Light Source Information:

AccuVision Lighted Blade Tips are sterile packed with a standard ACMI Adapter. To connect to the O.R. supplied light source, a sterilized light cable needs to be supplied by the O.R. Do NOT connect the lighted blade tip directly to the light source.

Surgical Technique (Continued)

Articulating Arm And AccuVision Frame Configuration



Assembly Of Articulating Arm:

Determine whether the articulating arms will be situated on either the surgeon side or the assistant side. Following facility guidelines for aseptic technique, place the radial setting clamp over the surgical drapes to the track along the preferred side of the table, and fix to the track by turning the wing screws clockwise until tight.

Turn the blue double ended handle counterclockwise until the channel is open and guide the articulating arm through the opening until the desired height of the arm is achieved and turn the blue handle clockwise until tight.



O.R. Tip

- For maximum stabilization, one arm will be positioned cephalad to the operative site and one arm will be positioned caudal to the operative site. Spreading the table attachments will allow room for the surgical assistant and lateral fluoroscopic visualization

Position each articulating arm in the general area of the operative site and provisionally lock the arm in place until the **AccuVision** Frame is placed onto the surgical field.

Select retractor blades according to the length determined during the initial dilation and assemble them to the cephalad and caudal arms of the **AccuVision** Frame.

Set-Up Of The AccuVision Frame On The Surgical Field



Place the **AccuVision** Frame with the blades attached onto the surgical field. Position the device either medial or lateral to the patient's midline.

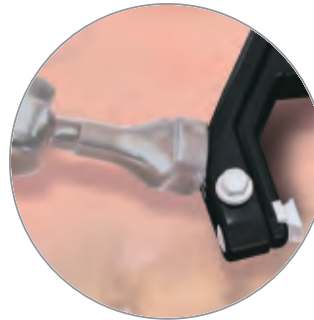


Ensure that there is no angulation or distraction of the retractor blades. Advance the retractor blades over the sequential dilators into the incision until the distal ends of the blades rest on the bony anatomy of the spine.

O.R. Tip

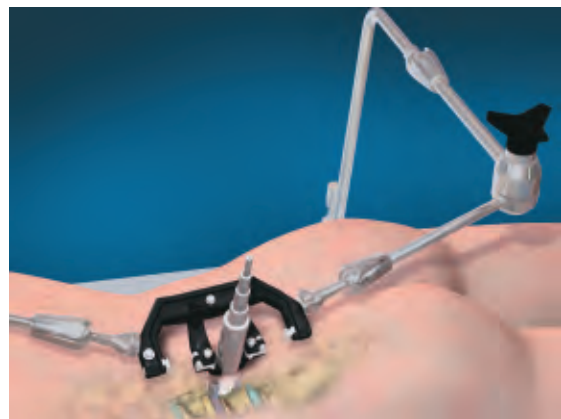
- If a bi-lateral approach is desired using two **AccuVision** Frames at once, the frame's longitudinal axis should be positioned lateral so that the patient's midline is uncovered

Unlock the articulating arm by turning the black star handle counter clockwise, note hold on to the distal portion of the arm as this will release the tension on the articulating arm. Guide the quick connect mechanism to the nearest corner post of the **AccuVision** Frame, align properly and push down until an audible click is heard. Turn the black star handle clockwise firmly to lock the arm in place. Repeat for the opposite side.



O.R. Tip

- While attaching the articulating arms to the **AccuVision** Frame, hold firm downward pressure on the frame as to not lose the targeted position and trajectory of the setup



Remove the sequential dilators from the patient.

O.R. Tip

- Use of A/P and lateral fluoroscopic imaging to confirm placement of the device onto the bony anatomy of the spine is recommended

Surgical Technique (Continued)

Intra-Operative Repositioning Of The AccuVision Frame And Addition Of Supplemental Retractor Blades



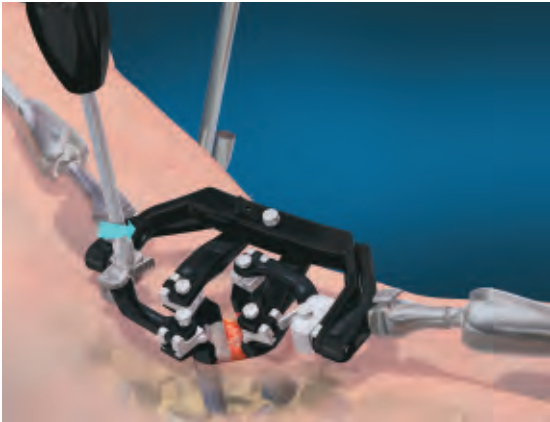
To extend the exposure of the spine longitudinally within the operative site, use the provided hex wrench to turn the ratchet control point on the long side of the **AccuVision** Frame to retract the cephalad and caudal retractor blades.



To angle the distal end of a retractor blade out, use the hex wrench and turn the setscrew on the arm attached to that blade in a clockwise rotation.



To provide additional medial or lateral exposure of the operative site, select the appropriate blade and attach it to the supplemental retractor module. Attach the module to the appropriate dovetail connector on the arm of the **AccuVision** Frame.



Independent articulation of the lateral retractor module and angulation of the retractor blade is achieved by using the hex wrench and turning the setscrew for the desired motion in the correct rotation.

NOTE: The primary retractor modules require counter clockwise rotation.



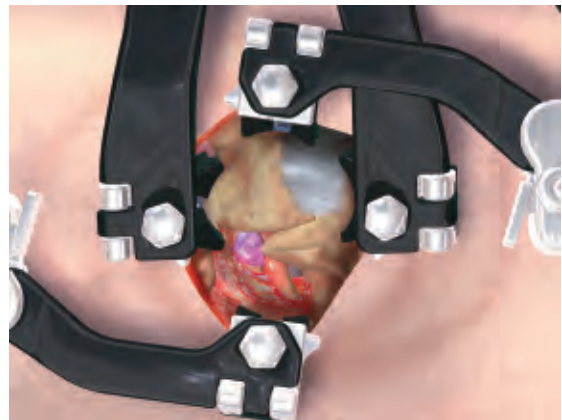
While the alternate (etched as "A") retractor module require clockwise rotation.



Utilization of the primary or alternate lateral retractors is based on surgeon preference.



Intraoperative medial/lateral angulation of the entire **AccuVision** Frame is achieved by using the hex wrench to adjust the setscrew on the side of the frame. This angulation will "air-plane" the entire inner portion of the frame to allow for additional medial or lateral exposure.



View of anatomy with **AccuVision** Frame in place.

Posterior Fixation With Polaris 5.5 Pedicle Screws

Pedicle Preparation

After adequate exposure is achieved, the appropriate pedicle entry point is selected and the entrance to the pedicle is opened with an awl, burr, or curette. The appropriate diameter Reamer Probe is used to prepare the pedicle using a slow circular motion, allowing the Reamer Probe to center itself along the longitudinal axis of the pedicle. Each Reamer Probe is marked with the major diameter of the screw with which it is to be used. The Reamer Probe is initially advanced to a depth of approximately 30mm using the depth markings as a guide.

Instead of a Reamer Probe, a Pedicle Probe may be utilized. The Pedicle Probe is used to create the pedicle hole by advancing the Probe to a depth of approximately 30-40mm using the depth markings as a guide. The Pedicle Sound is then used to confirm bony containment of the pedicle hole by palpating all four walls as well as the bottom of the hole through the pedicle and into the vertebral body.

Although the screws are self-tapping, Taps are available with the System and may be utilized to prepare the pedicle hole. Select the corresponding Tap for the chosen screw diameter and advance the Tap into the pedicle hole using the Quick Connect Handle.

The Trial Pins may be utilized to confirm proper orientation and trajectory.



Open the entrance to the pedicle with the Pedicle Awl



Prepare the pedicle hole with the Reamer Probe



Prepare the pedicle hole with the chosen Tap



Confirm containment of the pedicle with the Pedicle Sound



Use the Trial Pins to ensure proper orientation and trajectory

Screw Selection And Insertion

Self-tapping screws are available in several diameters and lengths. The appropriate screw length is determined by using the depth markings on the Pedicle Probe or Reamer Probe. The Multi-axial Screws may be loaded freehand or while seated within the surgical tray. Attach the Multi-axial Screw Driver to the Quick Connect Handle by pulling back on the plunger at the base of the quick connect mechanism, inserting the shaft, and releasing the plunger to lock the shaft in place. Hold the screw by the screw shaft and load the screw onto the tip of the Multi-axial Screw Driver. Ensure that the male pentalobe at the distal tip of the Multi-axial Driver is fully seated within the female pentalobe located at the top of the screw shaft. Turn the knurled-T in a clockwise direction to thread the outer shaft into the seat. Confirm that the screw is straight and secure in the Driver. The screw is advanced into the pedicle to the desired depth. During insertion, guide the Driver by holding the blue sleeve on the shaft of the instrument. The Driver is disengaged from the screw by rotating the knurled-T in a counter-clockwise direction and then lifting the Driver from the screw.

NOTE: The Multi-axial Screw must not be driven into the pedicle hole so tightly that variable angulation of the seat is prevented.



Select the appropriate screw size



Load the screw onto Multi-axial Screw Driver



Turn the knurled T at the top of the Driver to thread the outer shaft into the seat



Insert the screw into the pedicle

Posterior Fixation With Polaris 5.5 Pedicle Screws (Continued)

Rod Application

Once all screws have been inserted, the appropriate length rod should be chosen according to the construct. The Rod Template may be used to aid in rod selection. The rod should project at least 2mm beyond the screw seats at the end of the construct. Be sure to account for large curves and distractions when choosing rod length. If necessary, the selected rod may be contoured with the Rod Bender.



Measure length of the rod using the Rod Template



Select appropriate length rod



Insert rod using the Rod Holder



Set the dial on the Rod Bender to achieve the desired curvature

Helical Flange Plug Application

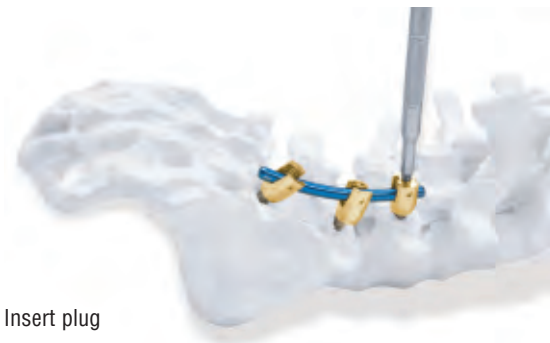
When all screws have been inserted and the rods have been placed in the screw seats, the construct is then secured using **Helical Flange** Plugs. One plug is firmly pressed onto each end of the Double End Plug Starter. All plugs should be placed and then provisionally tightened.

If necessary, the Plug Starter may be used in combination with the Rod Persuader, Reduction Fork, or Rod Pusher.

When using the Rod Persuader, place the Persuader over the top of the screw seat. The internal stop of the Persuader will ensure the instrument is in the correct position on the seat to facilitate manipulation. Squeeze the handle of the Rod Persuader to fully seat the rod in the screw seat. The Plug Starter will fit through the cannulated portion of the Persuader, allowing for plug application with the Rod Persuader in place. To release the Persuader, press the trigger located underneath the handle. Once released, the Persuader may then be removed from the screw seat.



Load plug onto the Double End Plug Starter



Insert plug



The Persuader may be used to fully seat the rod in the screw seat

Posterior Fixation With Polaris 5.5 Pedicle Screws (Continued)

Helical Flange Plug Application (Continued)

When using the Reduction Fork, position the fork section underneath screw seat. Tilt the Reduction Fork to persuade the rod into the screw seat.

When using the Rod Pusher, place the distal tip onto the rod and push the rod down to persuade the rod into the screw seat.

The Torque Stabilizer may be used to reposition the axis of the screw seat while simultaneously acting as a guide for the Plug Starter.

NOTE: If soft tissue is interfering with proper plug placement, the Soft Tissue Retractor may be utilized to retract the soft tissue away from the screw by placing the bifid tip of the retractor under the screw seat.



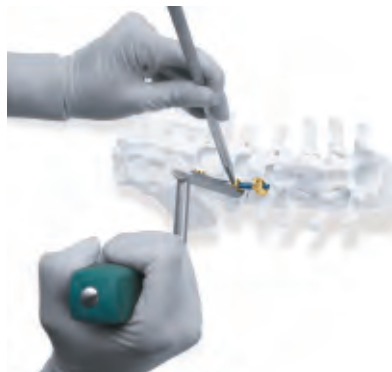
Reduction Fork



Push the rod down to persuade rod into the seat and insert the plug



Torque Stabilizer may be used to guide the Plug Starter



The Soft Tissue Retractor aids retraction of the soft tissue away from the screw seat

Final Locking

After provisional tightening, proper implant placement should be confirmed with radiographs. The plugs are then tightened with either the Torque Indicating Wrench or the Torque Limiting Wrench in combination with the Torque Stabilizer. Insert the chosen torquing device through the center of the Torque Stabilizer. Position the tip of the Torque Wrench into the plug. Seat the distal end of the Torque Stabilizer over the screw seat and confirm that the Stabilizer fits firmly on the rod. The rod will be positioned within the slots of the Stabilizer.

The Torque Indicating Wrench is turned in a clockwise direction while the Torque Stabilizer is held with resistive force in a counter-clockwise direction. Two etched arrows indicate when the appropriate torque is obtained. The first set of arrows line up showing the start position at zero. Upon reaching the intended final torque, two arrows will line up at 110in-lbs.

THERE IS NO AUDIBLE CLICK with the Torque Indicating Wrench. Over torquing with the Torque Indicating Wrench (turning beyond the point where the arrows line up) may damage the wrench. Always ensure the wrench indicates 0in-lbs. of torque prior to use.

The Torque Limiting Handle attaches to the Plug Driver. The Torque Limiting Wrench is turned in a clockwise direction while the Torque Stabilizer is held with resistive force in a counter-clockwise direction. The Torque Limiting Wrench should be turned until an audible click is heard, applying 110in-lbs of torque.



Arrows of the Torque Indicating Wrench line up at 0, signifying the start position. When the torque level is achieved, the arrow will line up at 110in-lbs.

THERE IS NO AUDIBLE CLICK



Turn the Torque Limiting Wrench clockwise until an audible click is heard at 110in-lbs of torque

NOTE: Use the chosen torque instrument in combination with the Torque Stabilizer.

AccuVision Frame Removal And Closure



After completion of the selected spine procedure(s) utilizing the **AccuVision** System, first reduce the distraction and angulation from any auxiliary blades and remove all lateral retractor modules.



Reduce distraction of the cephalad and caudal blades by engaging the release mechanism and using the hex wrench to turn the ratchet control screw.



Once all distraction and angulation is adequately reduced, remove the frame and articulating arms from the surgical field.

Closure of the operative site is performed in layers according to standard protocols and facility guidelines.

NOTE: Ensure that all **AccuVision** components have been removed via visual check prior to closure.

Indications For Use

Indications For Use

The **AccuVision** Minimally Invasive Spinal Exposure System, when used with the **Polaris** 5.5 Spinal System implants are indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery for the following indications, regardless of intended use: 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., kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for the use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

Contraindications

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

See the package insert for warnings, precautions, adverse events and other product information.

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 with 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 the 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.

Sterilization Recommendations

The **AccuVision** Minimally Invasive Spinal Exposure System is provided nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

Cycle: High Vacuum
Temperature: 270°F (132°C)
Time: 8 Minutes
Note: Allow for cooling

Ordering Information

AccuVision Disposable Blade Tip Case

(Catalog # 14-509625)

Catalog #	Description	Qty/Tray
14-500550	Blade Tip 1/3 - 18mm Dia.	4
14-500551	Blade Tip 1/4 - 25mm Dia.	4
14-500552	Blade Tip 1/3 - 25mm Dia.	4
14-500555	Illuminated Blade Tip 1/3 - 18mm Dia.	2
14-500556	Illuminated Blade Tip 1/4 - 25mm Dia.	2
14-500557	Illuminated Blade Tip 1/3 - 25mm Dia.	2

AccuVision Blade Mount Case

(Catalog # 14-509622)

Catalog #	Description	Qty/Tray
14-500504	18mm Blade 40mm Long	3
14-500505	18mm Blade 50mm Long	3
14-500506	18mm Blade 60mm Long	3
14-500507	18mm Blade 70mm Long	3
14-500508	18mm Blade 80mm Long	3
14-500509	18mm Blade 90mm Long	3
14-500510	18mm Blade 100mm Long	3
14-500511	18mm Blade 110mm Long	3
14-500514	Flat Blade 40mm Long	2
14-500515	Flat Blade 50mm Long	2
14-500516	Flat Blade 60mm Long	2
14-500517	Flat Blade 70mm Long	2
14-500518	Flat Blade 80mm Long	2
14-500519	Flat Blade 90mm Long	2
14-500520	Flat Blade 100mm Long	2
14-500521	Flat Blade 110mm Long	2
14-500524	25mm Blade 40mm Long	3
14-500525	25mm Blade 50mm Long	3
14-500526	25mm Blade 60mm Long	3
14-500527	25mm Blade 70mm Long	3
14-500528	25mm Blade 80mm Long	3
14-500529	25mm Blade 90mm Long	3
14-500530	25mm Blade 100mm Long	3
14-500531	25mm Blade 110mm Long	3

AccuVision Access Arm Case

(Catalog # 14-509621)

Catalog #	Description	Qty/Tray
2000-6455	AccuVision Articulating Arm	2
2000-6452	AccuVision Radial Setting Clamp	2

AccuVision Retractor Frame Case

(Catalog # 14-509620)

Catalog #	Description	Qty/Tray
2000-6510	AccuVision Retractor Frame - Small	1
2000-6512	AccuVision Lateral Retractor Module A	2
2000-6513	AccuVision Lateral Retractor	2
2000-6506	Retractor Wrench	2
14-500545	Shim Advancer	1
14-500546	Shim Retractor	1
2000-6405	25mm Dilation Tube - Blue	1
2000-6404	22mm Dilation Tube	1
2000-6403	18mm Dilation Tube - Yellow	1
2000-6402	12mm Dilation Tube	1
2000-6401	7.0mm Dilation Tube	1
594152	2.8mm Trocar Steinmann Pin	1

Further Information

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.

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