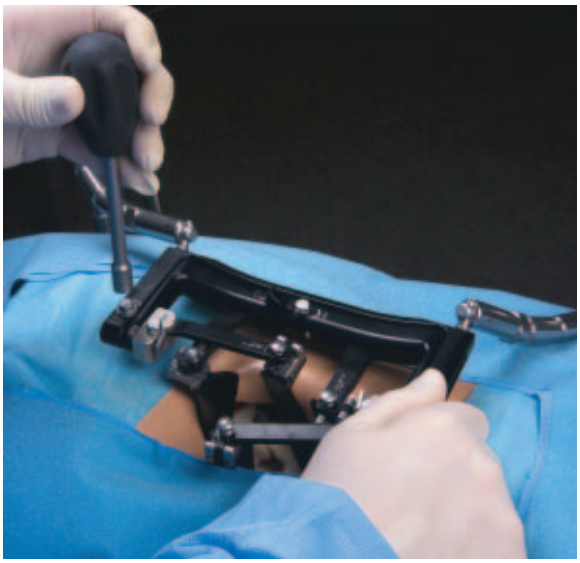
AccuVision™ Minimally Invasive Spinal Exposure System

Reference Guide
Clinical Evaluation

Contents

Clinical Evaluation

Introducing the **AccuVision** Minimally Invasive Spinal Exposure System, the newest addition to the Biomet Spine Minimally Invasive Product Line. The **AccuVision** System has been designed and developed in an effort to facilitate the ever-increasing demand for Minimally Invasive Surgical Options. The **AccuVision** System provides the surgeon with a greater visualization of the anatomy by utilizing up to four separate points of retraction. Each retraction point of the **AccuVision** System is able to articulate and be independent of one another allowing for the surgeon to "custom-fit" the surgical approach to each patient's individual anatomy.



The purpose of this clinical evaluation reference guide is to provide a comprehensive system overview and operating room tips to share with your O.R. staff. As part of the Clinical Evaluation team, you play a significant role in the future of the **AccuVision** System.

The enclosed questionnaire must be completed after each procedure to aid us in improving the system. Your feedback and participation in this evaluation is extremely valuable and greatly appreciated.

System Overview

The **AccuVision** Minimally Invasive Spinal Exposure System, when utilized with the Polaris™ 5.5 Helical Flange™ Spinal System implants, is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery. The indications for use are detailed in the US 510(k), and include: degenerative, trauma, and tumor pathologies. The **AccuVision** Retractor System includes the retractor frame, supplemental retractor modules, retractor blades, arms, and a series of instruments to help aid in the surgical exposure for the patient-specific pathology.

The **AccuVision** System is configured in a logical and comprehensive manner to create an ease of use and comfort level with the system. For a complete listing of products and instrumentation included with the **AccuVision** System, please see the "System Layout" Section located in this Evaluation Packet.

1. Design Criteria

- Provide a simple, easy-to-use retractor system for a minimally invasive approach to posterior spine surgery without compromising visualization or exposure
- Ergonomically designed frame to allow for versatile placement and contour of anatomy
- Independently operated lateral retractor modules and retraction points
- Unique, versatile retractor blade system on a stable platform with a minimal number of components
- Short learning curve
- Use with the **Polaris** 5.5 Spinal Systems utilizing **Helical Flange** Locking Technology

Helical Flange Technology

Helical Flange describes the interface between the seat and plug. It differs from the buttress or dove-tail thread used in comparable systems. The cross section of the seat has a flange facing down while the plug is machined with a flange facing up. When combined, the flanges on the seat/plug interlock, thus minimizing seat splay and cross threading.

System Overview (Continued)

2. The Frame

The **AccuVision** "Frame" houses the articulating arms and independent retractor blades to gain exposure to the surgical site. The frame, constructed from aluminum, is partially radiolucent and contains the ratcheting mechanism utilized for the initial cephalad/caudal retraction. Furthermore, it allows for the attachment of additional medial and/or lateral retractor modules via a quick connect mechanism, thus providing additional points of retraction. The built-in lordotic curve of the frame ensures proper positioning on the patient.

The most beneficial feature of the **AccuVision** Frame, however, is the built-in angulation in the transverse plane. The two-stage design of the **AccuVision** Frame allows the outer frame to stay fixed providing stability, while the inner frame allows for 45° of total angulation, for enhanced medial visualization.

3. Retractor Modules

In order to maximize visualization and exposure, the **AccuVision** System utilizes a series of Retractor Modules. These "modules," when used in conjunction with the retractor blades, provide the surgeon the opportunity to retract in up to four directions.

Integrated into the **AccuVision** Frame are the cephalad/caudal retractors. These modules will provide the surgeon with the initial exposure to the surgical site. The length of this exposure is variable dependant upon the procedure, and can be adjusted utilizing the retractor wrench. See the "Retractor Wrench" section for information on this instrument.

In addition to the cephalad/caudal retractor modules integrated into the frame, the operating surgeon can also add a series of supplemental lateral retractor modules to provide medial/lateral exposure to the surgical site. The retractors attach to the ends of the inner portion of the **AccuVision** Frame via a dovetail connection, and can be adjusted in a straight plane initially.

Additional exposure is achieved by "toeing out" the blades. The distal end of the retractor blades will provide additional exposure and visibility.

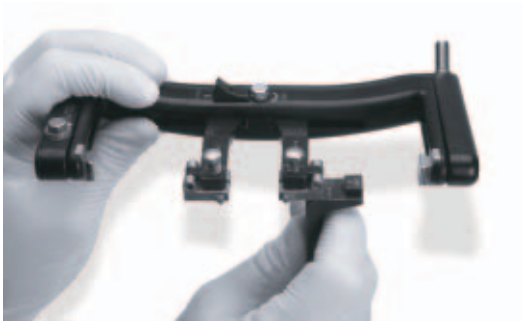
System Overview (Continued)

4. The Blades

The **AccuVision** System utilizes a series of blades in varied sizes and shapes to provide the exposure necessary for the surgical procedure. The blades vary in length from 40mm to 100mm. Each length blade is available in a Half Circle (marked as $\frac{1}{2}$), One-Third Circle (marked as $\frac{1}{3}$), or Flat Blade (marked as $\frac{1}{4}$) with minimal curvature. (Complete details of the blade lengths and forms can be found in the System Layout section)

Constructed of aluminum, the **AccuVision** blades are partially radiolucent, and connect to the retractor modules via a quick-connect mechanism. Simply slide the male T-Connect lip on the top of the blade into the female T-Slot opening until an audible click is heard. This verifies that the blade is locked in place.

The varying lengths and shapes of the blades can be mixed and matched intraoperatively to conform to individual patient anatomy.



5. Shim Extensions

The **AccuVision** System also allows for additional soft tissue retraction with the use of Shim Extensions. These shims, when used in conjunction with the blades will provide an additional 10mm of distal depth and exposure in the operating site.

The shims are introduced to the blades and advanced utilizing the Shim Advancing Tool.

System Overview (Continued)

6. Retractor Wrench

The **AccuVision** System requires only one instrument to modify the variability to all of the retractor points and mechanisms. The handle of the wrench is a teardrop shape and coated in silicone with a roughened finish to provide the surgeon with ample grip while adjusting the points of retraction. Please see the surgical technique guide for more information on adjusting the points on the **AccuVision** Frame.

7. Steinmann Pin And Dilation Tubes

To initiate the procedure of utilizing the **AccuVision** System, a series of sequential dilators is required, beginning with the Steinmann pin. A 2.8mm x 9" smooth wire with a trocar tip will identify access to the vertebral pedicle or transverse process.

Subsequent dilation is performed with the sequential dilators. The diameter of the dilators ranges from 7mm to 25mm, in five sequential steps in order to separate the soft tissue to a point where the retractor frame with blades can easily slide over the largest dilator, and soft tissue retraction can begin.

NOTE: Final dilation can be either to 18mm or 25mm dependent upon individual surgeon preference for exposure and blade profile.

System Overview (Continued)

8. Access Arm

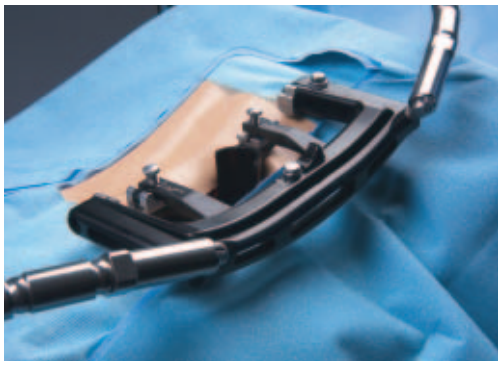
To allow stabilization and fixation to the specific O.R. table for the **AccuVision** Frame a combination of field posts and access arms are provided.

The access arms and field posts offer a sterile field set-up to adapt the retractor frame to the surgical site. These flexible arms provide the surgeon with the ability to reposition the retractor frame intra-operatively without compromising the sterile field or the surgical exposure. Once connected to the **AccuVision** Frame, via the corner posts, simply release the locking mechanism on the arm and adjust as necessary. When the modifications are complete, tighten the locking mechanism.

(See the O.R. Tips Section for information on adapting the **AccuVision** Frame to specific O.R. tables.)

NOTE: Surgeon preference will dictate single access arm or dual access arm stabilization to the frame.

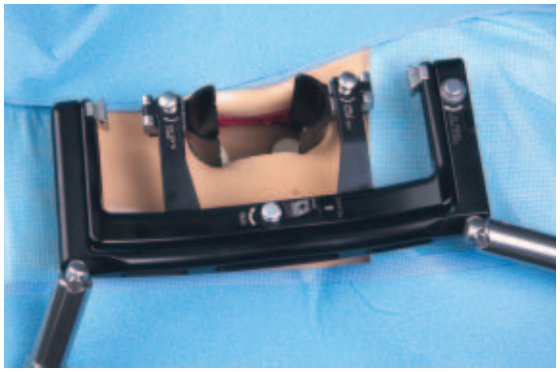
Features And Benefits

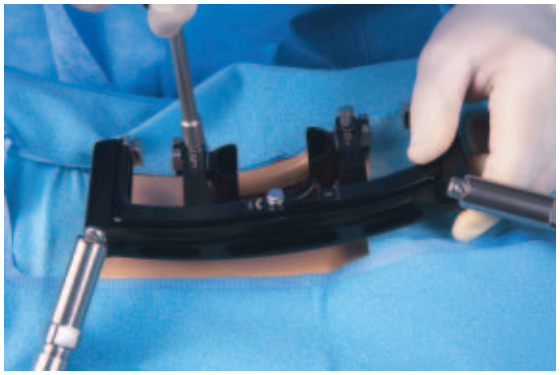


Features	Benefits
Minimal Skin Incision	Less trauma to musculature around the spine
Mechanical Retraction System	Provides ample retraction in up to four directions Maximal Exposure with Minimal Incision
Variable Blade Lengths	Custom fit the system based on patient anatomy
Stable Platform	Provides the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

O.R. Tips

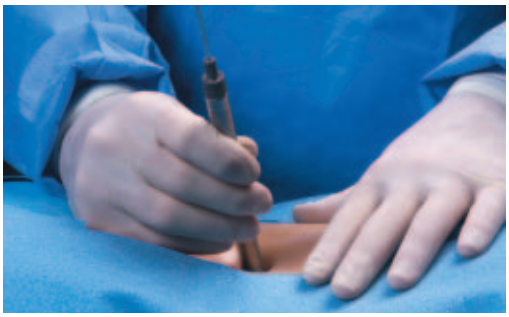
1. If using the carbon fiber frame configuration for the Jackson Table during surgery, order two Table Adapters (P/N 94166).



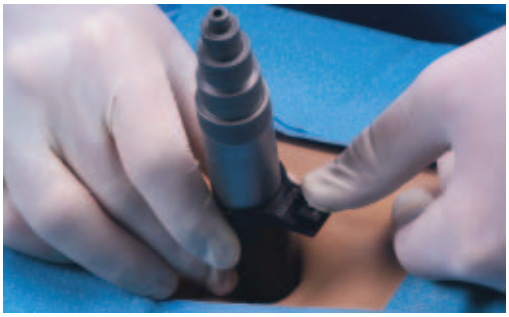


2. The ergonomically designed **AccuVision** Frame allows the surgeon to place the frame's longitudinal side either medially or laterally dependent upon individual surgeon preference.

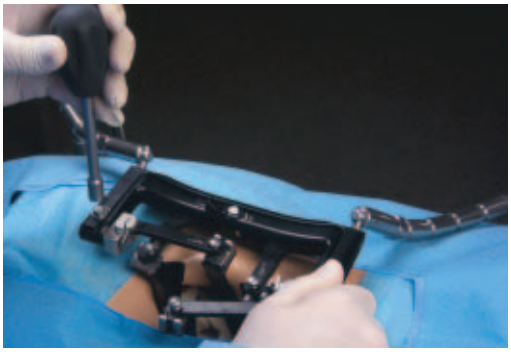
3. There are two options to facilitate measuring the correct blade depth for the **AccuVision** Blades:



a. In conjunction with fluoroscopic imaging utilize the depth markings on the 7mm sequential dilator.



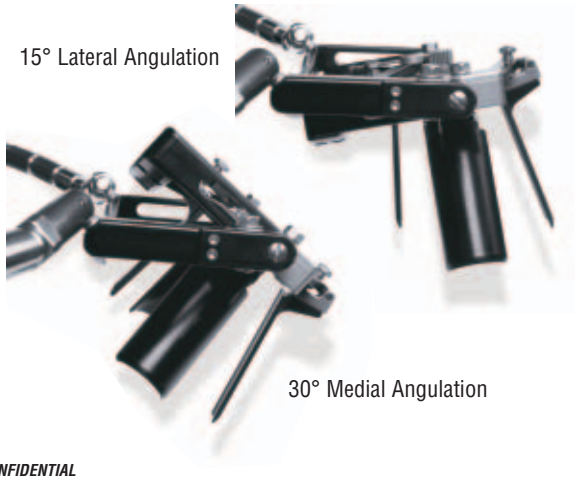
b. When sequential dilation is complete, trial individual blades to verify depth. This can be accomplished by inserting the blade in between the soft tissue dilators and the skin incision.



4. The **AccuVision** System provides the surgeon with additional medial visualization without modifying or compromising the surgical site. By utilizing the retractor wrench on the **AccuVision** Frame, the inner portion of the frame will "airplane" a total of 45° to provide the visualization necessary to complete the procedure or explore additional parts of the anatomy.

0° of Angulation

15° Lateral Angulation



30° Medial Angulation

5. Additional variation of the surgical site with the **AccuVision** System can be accomplished by utilizing the medial/lateral retractor modules. The system allows the surgeon to:

a. Place two "short" retractor modules medially

b. Place two "short" retractor modules laterally

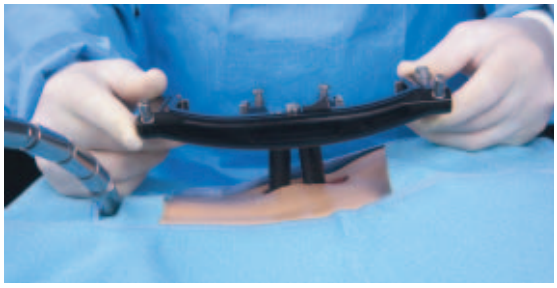
c. Place one "long" retractor module medially

d. Place one "long" retractor module laterally

O.R. Tips (Continued)

e. Place one “long” retractor module medially and one “long” retractor module laterally.

6. Prior to inserting and removing the **AccuVision** Frame and its components, care must be taken that all retractor points are “Zeroed-Out” i.e., there is no additional retraction and the distal ends of the retractor blades are not “toed out.”



System Layout

Retractor Frame Instrument Case

(Catalog #14-509600)

Catalog #	Description	Qty/Kit
2000-6500	Retractor Frame	1
2000-6502	Lateral Retractor Module A - Long	2
2000-6503	Lateral Retractor Module B - Long	2
2000-6504	Lateral Retractor Module A - Short	1
2000-6505	Lateral Retractor Module B - Short	1
2000-6506	Retractor Wrench	2
2000-6509	Shim Inserter	1
594146	25mm Dia. Dilation Tube	1
594147	22mm Dia. Dilation Tube	1
594148	18mm Dia. Dilation Tube	1
594149	12mm Dia. Dilation Tube	1
594150	7mm Dia. Dilation Tube	1
594152	2.8mm Dia. x 9" Smooth Steinmann Pin	1

Access Arm Instrument Case

(Catalog #14-509601)

Catalog #	Description	Qty/Kit
594122	Articulating Arm	2
594153	Field Post	2

System Layout (Continued)

Retractor Blades Case

(Catalog #14-509602)

Catalog #	Description	Qty/Kit
2000-6340	Half Blade 40mm x 25mm Dia.	2
2000-6341	Half Blade 50mm x 25mm Dia.	2
2000-6342	Half Blade 60mm x 25mm Dia.	2
2000-6343	Half Blade 70mm x 25mm Dia.	2
2000-6344	Half Blade 80mm x 25mm Dia.	2
2000-6345	Half Blade 90mm x 25mm Dia.	2
2000-6346	Half Blade 100mm x 25mm Dia.	2
2000-6350	Third Blade 40mm x 25mm Dia.	3
2000-6351	Third Blade 50mm x 25mm Dia.	3
2000-6352	Third Blade 60mm x 25mm Dia.	3
2000-6353	Third Blade 70mm x 25mm Dia.	3
2000-6354	Third Blade 80mm x 25mm Dia.	3
2000-6355	Third Blade 90mm x 25mm Dia.	3
2000-6356	Third Blade 100mm x 25mm Dia.	3
2000-6370	Third Blade 40mm x 18mm Dia.	3
2000-6371	Third Blade 50mm x 18mm Dia.	3
2000-6372	Third Blade 60mm x 18mm Dia.	3
2000-6373	Third Blade 70mm x 18mm Dia.	3
2000-6374	Third Blade 80mm x 18mm Dia.	3
2000-6375	Third Blade 90mm x 18mm Dia.	3
2000-6376	Third Blade 100mm x 18mm Dia.	3

(Continued)

Catalog #	Description	Qty/Kit
2000-6360	Flat Blade 40mm	2
2000-6361	Flat Blade 50mm	2
2000-6362	Flat Blade 60mm	2
2000-6363	Flat Blade 70mm	2
2000-6364	Flat Blade 80mm	2
2000-6365	Flat Blade 90mm	2
2000-6366	Flat Blade 100mm	2
2000-6367	Flat Blade 110mm	2
2000-6570	Standard Shim Half 25mm Dia.	2
2000-6571	Standard Shim Third 25mm Dia.	3
2000-6572	Standard Shim Flat	2
2000-6581	Standard Shim Third 18mm Dia.	3

Package Insert

Description

The **Polaris 5.5** Spinal System is a spinal fixation device made from titanium alloy (Ti 6Al 4V) and unalloyed titanium. The system includes self-tapping screws, various types and sizes of rods, locking nuts, hooks, and cross connectors. Various instruments are also available as part of the **Polaris 5.5** Spinal System for use by the surgeon to facilitate implantation of the device.

Indications For Use

The **Polaris 5.5** Spinal System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all the following indications, regardless of the 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., scoliosis, kyphosis, and lordosis), tumor, stenosis, pseudarthrosis, and failed previous fusion.

The **Polaris 5.5** Spinal System Percutaneous Instruments, when used with the **Polaris 5.5** Spinal System cannulated screws and percutaneous rods, are indicated to provide the surgeon with a percutaneous 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), stenosis, pseudarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

The **Polaris 5.5** Spinal System Mini-Open Instruments, 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, pseudarthrosis, and failed previous fusion that warrant a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

Contraindications

A. Spinal infection or inflammation
B. Morbid obesity
C. Mental illness, alcoholism or drug abuse
D. Pregnancy
E. Metal sensitivity/foreign body sensitivity
F. Patients with inadequate tissue coverage over the operative site
G. Open wounds local to the operative area
H. Any case not described in the specific indications

Warnings

A. 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 failed previous 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 fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

B. Implant Strength and Loading. The **Polaris 5.5** Spinal System is intended to assist healing and is not intended to replace normal bony structures. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Therefore, it is important that immobilization of the operative site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The surgeon must be thoroughly knowledgeable in the medical, surgical, mechanical and metallurgical aspects of the **Polaris 5.5** Spinal System. Postoperative care is extremely important. The patient should be warned that noncompliance with postoperative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the implant.

C. Selection of Implants. Selection of the proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants.

D. Corrosion. Contact of dissimilar metals accelerates the corrosion process, which could increase the possibility of fatigue fracture of the implants. Therefore, only use like or compatible metals for implants that are in contact with each other.

E. Sterile Packaging. The **Polaris 5.5** Spinal System Mini-Open plastic components are packaged sterile as a single use device. Do not re-sterilize for reuse.

Limits Of System Compatibility

When used with the 5.5 **Helical Flange** Percutaneous Instruments, the use of the **Polaris 5.5** Spinal System cannulated screws and percutaneous rods is limited to the implantation of rod lengths of 100mm or less, and excludes the use of system cross connectors or hooks.

When used with the **Polaris 5.5** Spinal System Mini-Open Instruments, the use of the **Polaris 5.5** Spinal System is limited to the implantation of rod lengths of 100mm or less, and excludes the use of system cross connectors or hooks.

Precautions

A. Single Use Only. Never reimplant an explanted metal device, under any circumstances. Although the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage.

B. Handling of Implants. If contouring of the rod is required, avoid sharp bends and reverse bends. Avoid notching or scratching of the device, which could increase internal stresses and lead to early breakage.

C. Implant Removal After Healing. After healing is complete, the implant is intended to be removed since it is no longer necessary. Implants that are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone, particularly in young, active patients. Implant removal should be followed by adequate postoperative management.

D. Adequate Patient Instructions. A patient must be instructed on the limitations of the metallic implant, and should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.

E. Surgical Techniques. 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. Please refer to the specific surgical technique for this device for more information.

Possible Adverse Effects

A. Nonunion (pseudarthrosis) or delayed union
B. Bending, fracture, loosening or migration of the implant
C. Metal sensitivity or foreign body reaction
D. Decrease in bone density due to stress shielding
E. Pain, discomfort, or abnormal sensations due to presence of the implant
F. Nerve, soft tissue, or blood vessel damage due to surgical trauma
G. Fracture of bony structures nerve root or spinal cord impingement
H. Dural leak
I. Bursitis
K. Necrosis of bone
L. Hemorrhage
M. Infection
N. Death

Sterilization

The **Polaris 5.5** Spinal 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

Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

Package Insert (Continued)

The **Polaris 5.5** Spinal System Mini-Open sterile packaged plastic components are sterilized by exposure to a minimum dose of 25-kGy gamma radiation. Plastic components are for single use only and cannot be re-sterilized. Do not use if package has been compromised.

Care And Handling Instructions

Sterile packaged, single use components should be inspected prior to use for damage or contamination. If components appear damaged, Do Not Use.

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

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510(k) Summary

EBI, L.P.'s 5.5 Helical Flange Spinal System

JUL 25 2006

SUBMITTER:	EBI, L.P.
ADDRESS:	100 Interpace Parkway Parsippany, NJ 07054
PHONE:	(973) 299-9300
FAX:	(973) 257-0232
CONTACT PERSON:	Jennifer P. Harakal
DATE PREPARED:	May 22, 2006
TRADE NAME:	EBI® 5.5 Helical Flange Spinal System
COMMON NAME:	Spinal Fixation Device
CLASSIFICATION NAMES:	Spondylolisthesis Spinal Fixation Device System Spinal Intervertebral Body Fixation Orthosis Spinal Interlaminal Fixation Orthosis
REGULATION NUMBERS:	21 CFR 888.3050, 21 CFR 888.3070, 21 CFR 888.3060
PRODUCT CODES:	NKB, MNH, MNI, KWQ, KWP
PREDICATE DEVICES:	-EBI® Array Spinal Fixation System/EBI® SpineLink II Spinal Fixation system with the VuePASS™ Portal Access Surgical System -EBI® Array Spinal Fixation System -EBI® Webb Morley Spine System -Interpore Cross International Synergy™ Spinal System (Posterior) -Interpore Cross International Synergy Spinal System (Anterior) -Medtronic Sofamor Danek CD HORIZON® Spinal System

INTENDED/INDICATIONS FOR USE:

The 5.5 Helical Flange Spinal System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the 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., scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

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PG 2 OF 2

The 5.5 Helical Flange Spinal System Percutaneous Instruments, when used with the 5.5 Helical Flange Spinal System cannulated screws and percutaneous rods, are indicated to provide the surgeon with a percutaneous 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), stenosis, pseudoarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

The 5.5 Helical Flange Spinal System Mini-Open Instruments, when used with the 5.5 Helical Flange 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 use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

TECHNOLOGICAL CHARACTERISTICS:

Performance Testing

Mechanical testing of the EBI® 5.5 Helical Flange Spinal System was conducted and demonstrates that the proposed system conforms to its design specifications. The design requirements were established based on those of the previously cleared predicate devices. The results of testing conducted demonstrate that the proposed system adequately meets the requirements established in design specifications for its mechanical performance.

Substantial Equivalence

The EBI® 5.5 Helical Flange Spinal System is substantially equivalent to other legally marketed spinal fixation devices with respect to intended use and indications, technological characteristics, and basic principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2006

EBI, LP
% Ms. Jennifer P. Harakal
Regulatory Affairs Specialist
100 Interspace Parkway
Parsippany, New Jersey 07054

Re: K061441
Trade/Device Name: EBI® 5.5 Helical Flange Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Orthosis, Spinal pedicle fixation, for degenerative disc disease
Regulatory Class: III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: May 22, 2006
Received: May 24, 2006

Dear Ms. Harakal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: EBI® 5.5 Helical Flange Spinal System

Indications for Use:

The 5.5 Helical Flange Spinal System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the 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., scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

The 5.5 Helical Flange Spinal System Percutaneous Instruments, when used with the 5.5 Helical Flange Spinal System cannulated screws and percutaneous rods, are indicated to provide the surgeon with a percutaneous 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), stenosis, pseudoarthrosis, and failed previous fusion that warrant the use of a non-cervical spinal fixation device intended for use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

The 5.5 Helical Flange Spinal System Mini-Open Instruments, when used with the 5.5 Helical Flange 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 use as a pedicle screw fixation system or sacral/iliac screw fixation system. Pedicle screw fixation is limited to skeletally mature patients.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bordnick for

(Division Sign-Off)
Division of General, Res...
and Neurological Devices

510(k) Number K061441

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Further Information

The **AccuVision** Minimally Invasive Spinal Exposure System is covered by numerous pending U.S. and International patent applications belonging to EBI/Biomet.

The **Polaris** 5.5 Spinal Implant System is covered by numerous pending US and International patents. US 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:

Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299-9300 - (800) 526-2579
www.biometspine.com

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