

## (English) Polaris™ 5.5 Spinal System

### DESCRIPTION

The **Polaris** Spinal System is a spinal fixation device made from titanium alloy (Ti-6Al-4V), unalloyed titanium, and Cobalt Chrome Alloy (Co-28Cr-Mo) 5.5mm diameter Rods. The system includes screws, various types and sizes of rods, locking nuts, hooks, lateral connectors, plugs, fixation washers, dominoes and various cross connectors. Various instruments are also available as part of the **Polaris** Spinal System for use by the surgeon to facilitate implantation of the device.

### INDICATIONS FOR USE

The **Polaris** Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion 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 and for use with autograft. The device is indicated for all the following indications: 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 **Ballista**™ instruments are intended to be used with the **Polaris** 5.5 implants. The **Ballista** Instruments, when used with the **Ballista** cannulated screws and percutaneous rods, are indicated to provide the surgeon with a percutaneous approach for posterior spinal surgery for the following indications: 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 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 and for use with autograft.

The **AccuVision**™ Instruments, when used with the **Polaris** Spinal System, are indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery for the following indications: 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 that warrant a noncervical 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 and for use with autograft. The **AccuVision** Illuminated Blade Tip is intended for the illumination of surgical procedures and exclusively for use with the **AccuVision** retractor frame.

The **AccuVision** Illuminated Blade Tip is a sterile, single use, latex free, plastic fiber optic device intended to bring cool area lighting into spinal surgeries. The **AccuVision** Illuminated Blade Tip is intended for use with a 300 watt xenon illuminator, using a 3mm fiber optic cable with a female ACMI connector.

### CONTRAINDICATIONS

1. Spinal infection or inflammation
2. Morbid obesity
3. Mental illness, alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/foreign body sensitivity
6. Patients with inadequate tissue coverage over the operative site
7. Open wounds local to the operative area
8. Any case not described in the specific indications

The **AccuVision** Blade Tips present no additional contraindications. The user should be familiar with the use of light sources and cables and should take precautions accordingly.

## **WARNINGS**

1. 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, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.
2. **Implant Strength and Loading.** The **Polaris** 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** 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.
3. **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.
4. **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. **Never use stainless steel and titanium implant components in the same construct.**  
**Cobalt Chrome Alloy rods should not be used with Stainless Steel Components.**  
**Cobalt Chrome Alloy rods are to be used ONLY with titanium implant components in the same construct.**
5. **Sterile Packaging.** The **AccuVision** plastic components are packaged sterile as a single use device. Do not re-sterilize for reuse.
6. **Light Source.** The **AccuVision** Illuminated Blade Tip is designed for use with 300 watt xenon illuminators, using a 3mm fiber optic cable. Do not use light sources rated higher than 300 watts, or cables with fiber optic bundles of more than 3mm diameter. Use of higher watt sources or larger diameter cables could result in overheating; causing product failure and patient injury. Should the blade assembly become cut, collect fluid inside, appear broken or damaged in any manner, it should be replaced to minimize risk to the patient.

Do not operate the light source and cable without the light strip attached. Without the **AccuVision** Illuminated Blade Tip, the output from the fiberoptic cable is extremely bright, hot and may cause burns, ignite drapes/gowns, or temporarily blind vision.

## **LIMITS OF SYSTEM COMPATIBILITY**

When used with the **Ballista** Instruments, the use of the **Ballista** cannulated 5.5 screws and percutaneous 5.5 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 **AccuVision** Instruments, is limited to the implantation of rod lengths of 100mm or less, and excludes the use of system cross connectors or hooks.

## PRECAUTIONS

1. **Single Use Only.** Never re-implant an explanted device, under any circumstances. Although the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage.
2. **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.
3. **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.
4. **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.
5. **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.
6. **Illuminated Blades.** Light sources vary widely in emission of visible and infrared energy. As a precautionary measure, when using **AccuVision** Illuminated Blade Tips we recommend occasionally monitoring connector temperature during first time use with a new light source or lamp; thereafter if needed. As is common with fiber optic equipment, metal portion of connector can become hot to the touch. Use plastic grip as handle. Do not place the metal ring portion of connector directly on the patient's skin. After use, the **AccuVision** Blade Tips may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

## POSSIBLE ADVERSE EFFECTS

1. Nonunion (pseudarthrosis) or delayed union
2. Bending, fracture, loosening or migration of the implant
3. Metal sensitivity or foreign body reaction
4. Decrease in bone density due to stress shielding
5. Pain, discomfort, or abnormal sensations due to presence of the implant
6. Nerve, soft tissue, or blood vessel damage due to surgical trauma
7. Fracture of bony structures
8. Nerve root or spinal cord impingement
9. Dural leak
10. Bursitis
11. Necrosis of bone
12. Hemorrhage
13. Infection
14. Death

## DIRECTIONS FOR USE – ILLUMINATED BLADES

See the **AccuVision** surgical technique for instructions on attaching the **AccuVision** Illuminated Blade Tip to the retractor system. The **AccuVision** Illuminated Blade Tip should be used in accordance with all instructions for the **AccuVision** retractor frame. The **AccuVision** Illuminated Blade Tip connects to a light source used for head lamps or endoscopes. A 3mm fiber optic cable with an ACMI fitting attaches the light source and **AccuVision** Illuminated Blade Tip. Make sure the Lighted Blade connector is securely attached to the cable. The cable should be in good repair with clean optics. Dirty optics or cables in need of repair can cause excessive heat at the connectors.

Turning down overhead lighting may improve visualization within the surgical site.

Sterile unless package is opened or damaged. Do not use if package is opened or damaged.

## STERILIZATION

The **Polaris** 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
<b>Note:</b>	<b>Allow for cooling</b>

Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard. The **AccuVision** sterile packaged plastic components are sterilized by exposure to a minimum dose of 25-kGy gamma radiation or by EtO, according to individual component labeling. These 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 and 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.

## INFORMATION

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

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U.S. Patent No. 5466237, 5474555, and Patents Pending

### For AccuVision Blade Tip only:

Manufactured for:  
Biomet  
Parsippany, NJ 07054, USA



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Biomet UK Ltd.  
Waterton Industrial Estate  
Bridgend  
CF31 3XA UK



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