



ZIMMER BIOMET

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Polaris™ Spinal System

Domino Rod Connectors

Surgical Technique Guide

INTRODUCTION



The Polaris Dominos are part of the Polaris Spinal System. They are spinal fixation devices intended to connect spinal fusion rods with congruent or non-congruent diameters.

The dominos will allow the extension of a construct to higher or lower vertebral bodies from pre-existing spinal fusion rods. Dominos are available in three different styles: parallel wedding band, parallel and axial. The titanium Polaris dominos are compatible with 3.5 mm – 6.35 mm rods in either Ti alloy, CP Ti or CoCr. The stainless steel Polaris dominos are compatible with only stainless steel rods.

- Available in stainless steel and titanium
- Parallel Wedding Band, Parallel and Axial

TABLE OF CONTENTS

Introduction	2
Implants	4
Surgical Technique / Implant Procedure	6
Tray Layouts	8
Ordering Information	10
Important Information on the Polaris Spinal Fixation System	12

Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

IMPLANTS

1) PARALLEL WEDDING BAND DOMINO

The parallel wedding band domino has two thru holes to accept two different rods in a parallel construct. The rods are locked in place by inserting and tightening two set screws in the top of the domino. Different combinations of dominos are available to accept rods of varying diameters so various diameter rods can be connected. See Figure 1 for an example of a parallel wedding band domino demonstrating a 5.5 mm rod and a 6.35 mm rod combination.

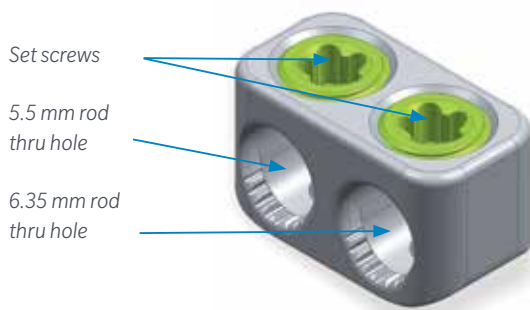


Figure 1
Parallel wedding band domino

2) PARALLEL DOMINO

The parallel domino and the parallel wedding band domino have the same basic design except the parallel domino has four set screws instead of two for additional stability and strength. The Polaris parallel domino has two thru holes to accept two rods in a parallel construct and the rods are locked in place by inserting and tightening four set screws in the top of the domino. See Figure 2 for an example of the parallel domino demonstrating a 5.5 mm rod and a 6.35 mm rod combination.



Figure 2
Parallel domino with four set screws

3) AXIAL DOMINO

The axial domino will have one thru hole to accept two different rods in an end-to-end construct. The rods are locked in place by inserting and tightening four set screws in the top of the domino. Different combinations of dominos are available to accept rods of varying diameters. See Figure 3 below for an example of an axial domino demonstrating a 5.5 mm rod and a 6.35 mm rod combination.

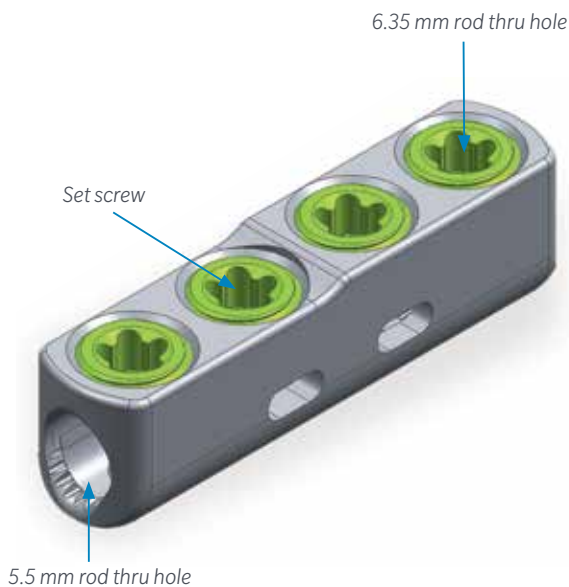


Figure 3
Axial domino with four set screws

4) SET SCREWS

All of the domino styles are locked using the set screw. It has a machine thread, which threads into the top of the domino. When it is tightened, it locks the rod in place. Dominos are available in titanium and stainless steel. The light green set (Figure 4) screws should only be utilized in conjunction with titanium dominos. The grey set screws (Figure 5) should only be utilized in conjunction with stainless steel dominos. Stainless steel dominos are laser marked with the letters SST.



Figure 4
Titanium set screw



Figure 5
Stainless steel set screw

SURGICAL TECHNIQUE/IMPLANT PROCEDURE

1) DOMINO SELECTION

Select the proper domino configuration based on the diameters of the new and pre-existing rod diameters.

Note: Each configuration is available in all three styles.

2) LOOSEN SET SCREWS

Dominos are pre-loaded with the proper set screws. The set screws will need to be loosened prior to inserting the domino into the rod. Use the plug driver to loosen each of the set screws.

Note: Set screws are not captured in the domino. Take care not to overturn, allowing set screw to detach from the domino. A half turn should be sufficient.

3) DOMINO IMPLANTATION

Insert the domino over the rods ensuring that the proper diameter rods are placed in the correct domino thru hole. Each domino clearly identifies the proper diameter above each thru hole. Parallel and axial dominos have windows to confirm proper rod alignment.

4) PROVISIONAL TIGHTENING

Utilizing the plug driver tighten each set screw finger tight. This will secure the rods in place before final tightening.

5) FINAL LOCKING

Connect the torque-limiting T-handle to the plug driver. Place the domino torque stabilizer onto the rod as seen in Figure 6. A torque stabilizer may also be used on a neighboring screw to provide stability. A rod gripper can be used for extra stability. Insert the plug driver into the first set screw to begin final locking. The torque-limiting T-handle attaches to the plug driver. The torque-limiting T-handle is turned in a clockwise direction while the torque stabilizer is held with resistive force in a counter clockwise direction. The torque-limiting T-handle should be turned until an audible click is heard, applying 110 in-lbs of torque. All set screws are torque to 110 in-lbs for all rod sizes in both titanium and stainless steel dominos.



Figure 6
Domino torque stabilizer

CLOSURE

After implantation of the dominos is complete, the standard surgical technique should be followed.

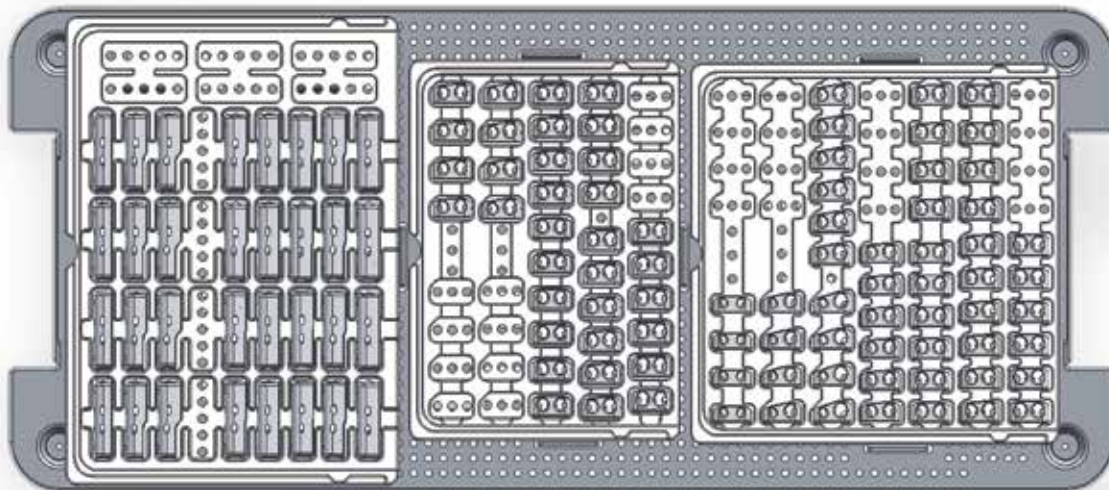
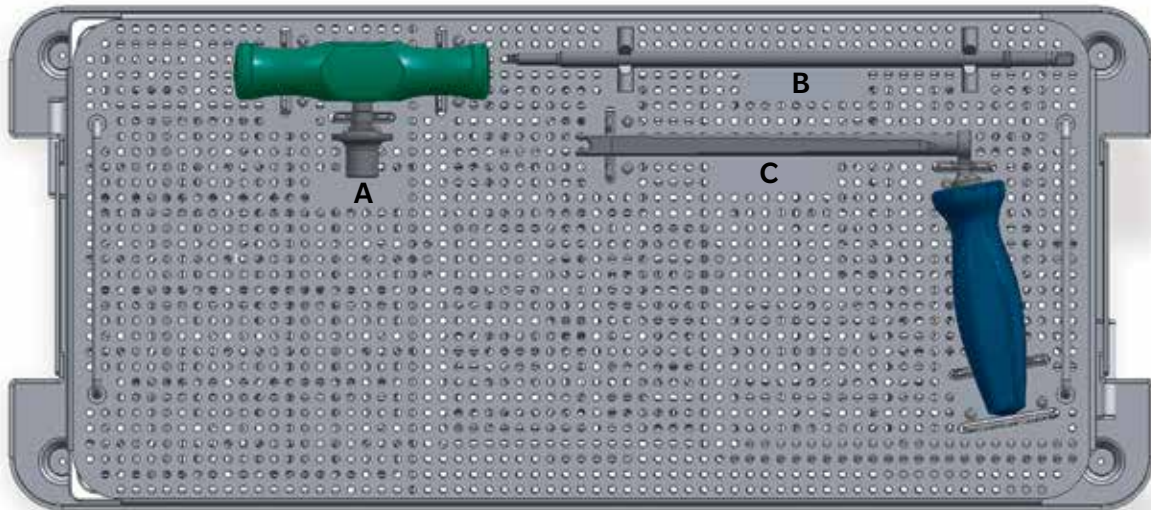
IMPLANT REMOVAL

Removal of the Polaris domino is performed by reversing the order of the implant procedure.

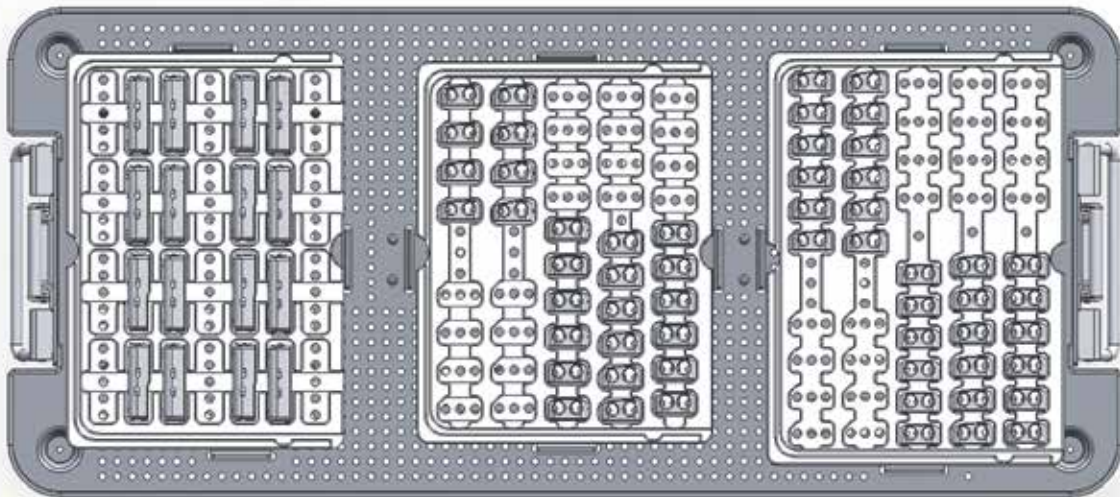
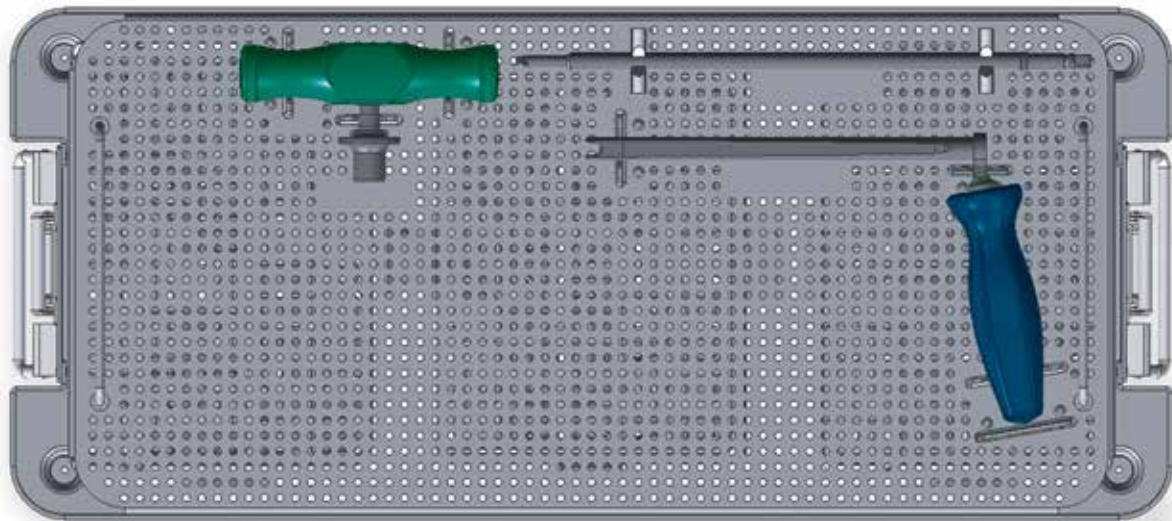
TRAY LAYOUTS

Titanium Tray Layout

- ✓ (A) Torque-limiting T-handle
- ✓ (B) Plug Driver
- ✓ (C) Torque Stabilizer



Stainless Steel Tray Layout



ORDERING INFORMATION

TITANIUM DOMINO STANDARD IMPLANT AND INSTRUMENT KIT

Kit Number: 14-509661

DESCRIPTION	QTY	PART NUMBER
4.75 mm x 5.5 mm Parallel Ti Domino	4	14-500812
4.75 mm x 6.35 mm Parallel Ti Domino	4	14-500814
5.5 mm x 5.5 mm Parallel Ti Domino	6	14-500815
5.5 mm x 6.0 mm Parallel Ti Domino	4	14-500816
5.5 mm x 6.35 mm Parallel Ti Domino	6	14-500817
6.0 mm x 6.35 mm Parallel Ti Domino	4	14-500819
6.35 mm x 6.35 mm Parallel Ti Domino	6	14-500820
3.5 mm x 3.5 mm Parallel Ti Wedding Band Domino	4	14-500836
3.5 mm x 5.5 mm Parallel Ti Wedding Band Domino	4	14-500839
3.5 mm x 6.35 mm Parallel Ti Wedding Band Domino	4	14-500841
4.75 mm x 5.5 mm Parallel Ti Wedding Band Domino	6	14-500848
4.75 mm x 6.35 mm Parallel Ti Wedding Band Domino	6	14-500850
5.5 mm x 5.5 mm Parallel Ti Wedding Band Domino	6	14-500851
5.5 mm x 6.0 mm Parallel Ti Wedding Band Domino	4	14-500852
5.5 mm x 6.35 mm Parallel Ti Wedding Band Domino	4	14-500853
6.0 mm x 6.35 mm Parallel Ti Wedding Band Domino	4	14-500855
6.35 mm x 6.35 mm Parallel Ti Wedding Band Domino	6	14-500856
3.5 mm x 3.5 mm Axial Ti Domino	4	14-500750
3.5 mm x 4.75 mm Axial Ti Domino	4	14-500752
3.5 mm x 6.35 mm Axial Ti Domino	4	14-500755
4.75 mm x 5.5 mm Axial Ti Domino	2	14-500762
4.75 mm x 6.35 mm Axial Ti Domino	2	14-500764
5.5 mm x 5.5 mm Axial Ti Domino	4	14-500765
5.5 mm x 6.0 mm Axial Ti Domino	2	14-500766
5.5 mm x 6.35 mm Axial Ti Domino	4	14-500767
6.0 mm x 6.35 mm Axial Ti Domino	2	14-500769
6.35 mm x 6.35 mm Axial Ti Domino	4	14-500770
Domino Torque Stabilizer	1	14-500899
Plug Driver	1	2000-9061
Torque-limiting T-handle	1	94522

STAINLESS STEEL DOMINO STANDARD IMPLANT AND INSTRUMENT KIT

Kit Number: 14-509662

DESCRIPTION	QTY	PART NUMBER
4.75 mm x 5.5 mm Parallel SST Domino	4	14-500827
4.75 mm x 6.35 mm Parallel SST Domino	4	14-500829
5.5 mm x 5.5 mm Parallel SST Domino	6	14-500830
5.5 mm x 6.35 mm Parallel SST Domino	6	14-500832
6.35 mm x 6.35 mm Parallel SST Domino	6	14-500835
4.75 mm x 5.5 mm Parallel SST Wedding Band Domino	6	14-500863
4.75 mm x 6.35 mm Parallel SST Wedding Band Domino	6	14-500865
5.5 mm x 5.5 mm Parallel SST Wedding Band Domino	6	14-500866
5.5 mm x 6.35 mm Parallel SST Wedding Band Domino	6	14-500868
6.35 mm x 6.35 mm Parallel SST Wedding Band Domino	6	14-500871
4.75 mm x 5.5 mm Axial SST Domino	2	14-500777
4.75 mm x 6.35 mm Axial SST Domino	2	14-500779
5.5 mm x 5.5 mm Axial SST Domino	4	14-500780
5.5 mm x 6.35 mm Axial SST Domino	4	14-500782
6.35 mm x 6.35 mm Axial Ti Domino	4	14-500785
Domino Torque Stabilizer	1	14-500899
Plug Driver	1	2000-9061
Torque-limiting T-handle	1	94522

Additionally available through special order only

DESCRIPTION	PART NUMBER	DESCRIPTION	PART NUMBER
3.5 mm x 3.5 mm Parallel Ti Domino	14-500800	4.5 mm x 4.5 mm Parallel SST Domino	14-500821
3.5 mm x 4.5 mm Parallel Ti Domino	14-500801	4.5 mm x 4.75 mm Parallel SST Domino	14-500822
3.5 mm x 4.75 mm Parallel Ti Domino	14-500802	4.5 mm x 5.5 mm Parallel SST Domino	14-500823
3.5 mm x 5.5 mm Parallel Ti Domino	14-500803	4.5 mm x 6.0 mm Parallel SST Domino	14-500824
3.5 mm x 6.0 mm Parallel Ti Domino	14-500804	4.5 mm x 6.35 mm Parallel SST Domino	14-500825
3.5 mm x 6.35 mm Parallel Ti Domino	14-500805	4.75 mm x 4.75 mm Parallel SST Domino	14-500826
4.5 mm x 4.5 mm Parallel Ti Domino	14-500806	6.0 mm x 6.0 mm Parallel SST Domino	14-500833
4.5 mm x 4.75 mm Parallel Ti Domino	14-500807	6.0 mm x 6.35 mm Parallel SST Domino	14-500834
4.5 mm x 5.5 mm Parallel Ti Domino	14-500808	4.5 mm x 4.5 mm Parallel SST Wedding Band Domino	14-500857
4.5 mm x 6.0 mm Parallel Ti Domino	14-500809	4.5 mm x 4.75 mm Parallel SST Wedding Band Domino	14-500858
4.5 mm x 6.35 mm Parallel Ti Domino	14-500810	4.5 mm x 5.5 mm Parallel SST Wedding Band Domino	14-500859
4.75 mm x 4.75 mm Parallel Ti Domino	14-500811	4.5 mm x 6.0 mm Parallel SST Wedding Band Domino	14-500860
4.75 mm x 6.0 mm Parallel Ti Domino	14-500813	4.5 mm x 6.35 mm Parallel SST Wedding Band Domino	14-500861
6.0 mm x 6.0 mm Parallel Ti Domino	14-500818	4.75 mm x 4.75 mm Parallel SST Wedding Band Domino	14-500862
3.5 mm x 4.5 mm Parallel Ti Wedding Band Domino	14-500837	4.75 mm x 6.0 mm Parallel SST Wedding Band Domino	14-500864
3.5 mm x 4.75 mm Parallel Ti Wedding Band Domino	14-500838	5.5 mm x 6.0 mm Parallel SST Wedding Band Domino	14-500867
3.5 mm x 6.0 mm Parallel Ti Wedding Band Domino	14-500840	4.5 mm x 5.5 mm Axial SST Domino	14-500773
4.5 mm x 4.5 mm Parallel Ti Wedding Band Domino	14-500842	4.5 mm x 6.0 mm Axial SST Domino	14-500774
4.5 mm x 4.75 mm Parallel Ti Wedding Band Domino	14-500843	4.5 mm x 6.35 mm Axial SST Domino	14-500775
4.5 mm x 5.5 mm Parallel Ti Wedding Band Domino	14-500844	4.75 mm x 4.75 mm Axial SST Domino	14-500776
4.5 mm x 6.0 mm Parallel Ti Wedding Band Domino	14-500845	4.75 mm x 6.0 mm Axial SST Domino	14-500778
4.75 mm x 6.0 mm Parallel Ti Wedding Band Domino	14-500849	5.5 mm x 6.0 mm Axial SST Domino	14-500781
6.0 mm x 6.0 mm Parallel Ti Wedding Band Domino	14-500854	6.0 mm x 6.0 mm Axial SST Domino	14-500783
3.5 mm x 4.5 mm Axial Ti Domino	14-500751	6.0 mm x 6.35 mm Axial SST Domino	14-500784
3.5 mm x 5.5 mm Axial Ti Domino	14-500753		
3.5 mm x 6.0 mm Axial Ti Domino	14-500754		
4.5 mm x 4.5 mm Axial Ti Domino	14-500756		
4.5 mm x 4.75 mm Axial Ti Domino	14-500757		
4.5 mm x 5.5 mm Axial Ti Domino	14-500758		
4.5 mm x 6.0 mm Axial Ti Domino	14-500759		
4.5 mm x 6.35 mm Axial Ti Domino	14-500760		
4.75 mm x 6.0 mm Axial Ti Domino	14-500763		
6.0 mm x 6.0 mm Axial Ti Domino	14-500768		

IMPORTANT INFORMATION ON THE POLARIS SPINAL SYSTEM

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 5.5 Polaris 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 and/or allograft.

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 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 Illuminated Blade Tip is intended for the illumination of surgical procedures and exclusively for use with the AccuVision retractor frame.

The Dominos in the Polaris™ Spinal System can be used to connect the Polaris™ Spinal System to the Altius™ Spinal System, The Array® Spinal System, the Biomet® Omega21™ Spinal System, or the Synergy™ Spinal System to achieve additional levels of fixation. Please refer to the individual system's Package Insert for a list of indications for use.

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, non-union, 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 3 mm fiber optic cable. Do not use light sources rated higher than 300 watts, or cables with fiber optic bundles of more than 3 mm 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.
7. The Polaris Spinal System has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

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 100 mm or less, and excludes the use of system cross connectors or hooks. When used with the AccuVision Instruments, it is limited to the implantation of rod lengths of 100 mm or less, and excludes the use of system cross connectors or hooks.

Precautions

1. Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.
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 pedicle screw spinal systems 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.

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.



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