

# *Solitaire*<sup>™</sup>

## *Surgical Technique*

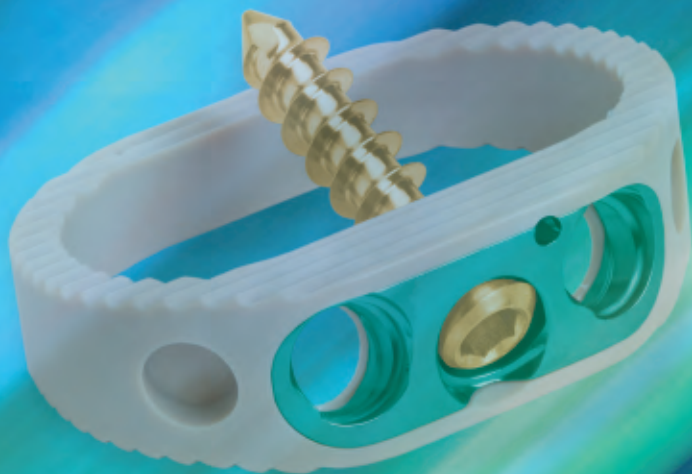


Available in Titanium and  
PEEK-**OPTIMA**<sup>®</sup>



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### Introduction

The **Solitaire** Anterior Spinal System, available in PEEK-OPTIMA® and Titanium, is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1.

#### Product Overview

The **Solitaire** Interbody Spacer assists fusions by developing an immediate mechanical fixation to adjacent vertebral bodies with three shallow, convergent angled cancellous bone screws. By providing a stable environment with a large, single-chambered opening and subsidence resistant design, the **Solitaire** Interbody Spacer offers surgeons an alternative to 360° procedures.

The **Solitaire** Interbody Spacer has a large, oblong shape, with flat grooved superior and inferior surfaces and a large medial opening. Lateral walls are perforated in the titanium version to enhance visualization and provide proper implant positioning. In the PEEK version, tantalum markers located in the posterior corners serve to facilitate visualization and desired implant positioning and an integrated titanium plate engages screw locking mechanism. The posterior wall is solid to provide a stable environment for fusion, and the anterior wall is perforated. The threads enable screws to develop a friction fit with the implant locking screws into the Interbody Spacer and passing through the superior and inferior medial openings to fixate the Interbody Spacer with the adjacent vertebral bodies.

There are three **Solitaire** Interbody Spacer footprints. The three available footprints (narrow - 28mm wide, medium - 34mm wide, and wide - 40mm wide) allow for a better anatomical fit and to help with resistance. They all have a consistent anterior end, and lateral curves designed to conform to the vertebral anatomy.

The consistent anterior end enables the same instruments to be used for all implant footprints.

Interbody Spacer heights range from 10mm–20mm in titanium and 12mm–20mm in **PEEK-OPTIMA**, in 2mm increments, with two lordotic angle options, 6° and 12°.

Implants are color-coded for height, and implant color is carried through height-specific instrumentation. Instrumentation includes instruments for site preparation, implant insertion and screw fixation (see also Anterior Discectomy Instruments).

The **Solitaire** Anterior Spinal System is indicated for vertebral body replacement (Titanium only) and intervertebral fusion (both Titanium and **PEEK-OPTIMA**). When used for vertebral body replacement, the **Solitaire** Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The **Solitaire** System is also indicated for treating fractures of the thoracic and lumbar spine. The **Solitaire** System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

As an intervertebral body fusion device designed for use with autograft, the **Solitaire** Anterior Spinal System is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.



## Design Features

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Designed to resist subsidence by covering up to 80% of the endplate

Immediate mechanical fixation to adjacent vertebral bodies, with no vertebral column profile

Large, single chamber design accommodates the fusion process



Shallow screw angle provides strong fixation by optimizing thread contact with cortical bone

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Many implantation options offer intraoperative flexibility

- Three different implant footprints
- Variety of screw lengths
- Two different lordotic angles
- 10mm–20mm heights



Narrow: 28mm wide



Medium: 34mm wide



Wide: 40mm wide

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### Screw Options

- Screw forms friction fit with spacer
- 5.5mm diameter screw with lengths from 20mm–35mm
- Cortical thread provides strong fixation with adjacent endplates and resists pullout



## Instruments

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Modular Handle

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Narrow Width Trial

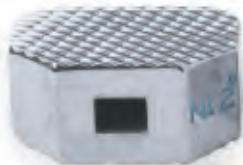


Medium Width Trial



Wide Width Trial

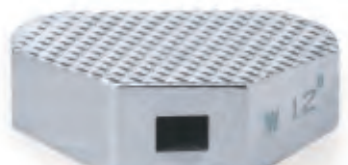
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Narrow Width Rasp



Medium Width Rasp



Wide Width Rasp

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Drill Guide

*Instruments (Continued)*

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Bone Graft Mold



Universal Drill



Universal Awl



Universal Driver



Rigid Awl



Rigid Drill



Rigid Driver



Z-Connect Ratchet Handle



Z-Connect T-Handle Ratchet



Z-Connect Torque Limiting Handle

***Surgical Technique***

1. Obtain anterior exposure per surgeon preference.
2. Expose and mark the midline of the intervertebral disc above and below the discectomy site and remove the entire intervertebral disc. If performing a partial vertebrectomy, remove the disc and portion of the adjacent vertebral body or bodies according to surgeon preference.

Curette And Bone Rasps (Figure 1 And Figure 2).

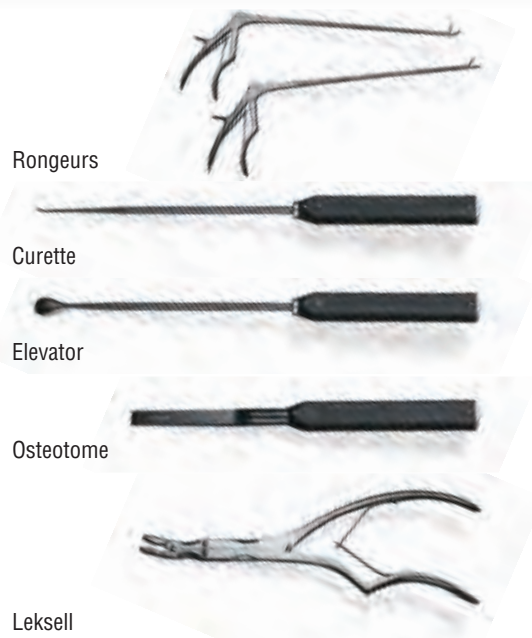


Figure 1



Figure 2

**New In This Step:**



Rongeurs

Curette

Elevator

Osteotome

Leksell

**Instruments In Anterior Discectomy Kit**

### *Surgical Technique (Continued)*

3. Distraction of the discectomy site is important to restore lordosis, open the neural foramen, and stabilize the implant. (Figure 3) Handles and tips can be added or removed from the distractor body by depressing the button while inserting the slotted end into the channels on the distractor. (Figure 4, 5) It is important to ensure that the tips or handles are securely locked into the channels on the distractor. The tips are labeled to indicate distal tip insertion depths. (Figure 6)

4. Remove the superficial layers of the cartilaginous end plates. This can be done with a variety of instruments such as scrapers, curettes, and rasps. Adequate preparation of the endplates is important to enhance vascular supply to the fusion site.

**CAUTION:** Aggressive cleaning of the endplate may remove excessive bone and weaken the endplate.



Figure 3



Figure 4



Figure 5



Figure 6

#### **New In This Step:**



Distractor

5. Once the end plate is fully prepared, the optimal implant width and height can be determined by using the width and height trials. The width trials are used first to determine the appropriate implant footprint to be utilized. Select the Narrow Width Trial, affix to the Modular Handle and insert into the discectomy site. If the Narrow Width Trial is too narrow, use incrementally wider footprints until an appropriate width is achieved. (Figure 7) The Trials can be easily attached to the modular handle, and have a smooth surface for safe insertion and removal.

Attach Trials to the modular handle by pulling the pull-pins on the handle, thus releasing the detents at the tip. Then place tip inside slot on Trial.



Figure 7

6. Select the 10mm Medium Trial, affix to the Modular Handle and insert into the fusion site. If the Trial is too small, use incrementally larger sizes until a tight fit is achieved. There should be no gaps between the prepared site and Trial. Use the largest size possible to ensure maximum stability. (Figure 8)



Figure 8

**O.R. Tips:** A lateral fluoro image can be utilized to illustrate posterior endplate contact with the Trial. Each 6° implant is approximately 2.5mm taller at the posterior end than the 12° implants.

### New In This Step:



Modular Handle



Narrow Width Trials



Medium Width Trials



Wide Width Trials



Height Trials

## Surgical Technique (Continued)

- Once final sizing has been determined using the appropriate Trial, utilize the appropriate sized Trial Rasp to complete endplate preparation. Attach the Modular Handle to the Trial Rasp, and impact it into the discectomy site. Then, using the slap hammer, remove the Trial Rasp. Use the rasp a few times to expose bleeding bone. (Figure 9)

**CAUTION:** Aggressive cleaning of the endplate may remove excessive bone and weaken the endplate.



Figure 9

- Assemble the Mold Top to the Mold Base. (Figure 10)



Figure 10

**O.R. Tips:** Ensure the correct orientation of the bone mold base by verifying the taller (anterior) end of the cage will be mated to the shorter portion of the bone mold base.

### New In This Step:



Trial Rasp



Bone Graft Mold

9. Select the Drill Guide that corresponds to the final Implant size to be used. Drill guides are color coded to match a particular height of Spacer. The same Drill Guide is utilized for all Spacer footprints for a particular height. Connect to the Modular Handle.
10. Select the appropriate implant and attach to the Drill Guide. The Drill Guide can be tightened onto the implant by turning the Modular Handle in a clockwise orientation. Ensure the guide is “right side up” by sliding an awl through the medial guide tube through the implant. (Figure 11)



Figure 11

**O.R. Tips:**

- It is easiest to attach the guide to the implant by attaching it while the implant is still in the implant tray

11. Insert implant into Bone Mold assembly, and fill with desired autograft material, as determined by the surgeon. This can be facilitated through use of the Bone Graft Tamp. (Figure 12)

See table below for implant packing volumes.

**Graft Volume**

Height	Lordosis	Narrow	Medium	Wide
10	6°	2	3	3
	12°	2	3	3
12	6°	3	4	4
	12°	3	4	4
14	6°	4	5	5
	12°	4	5	5
16	6°	5	6	6
	12°	5	6	6
18	6°	6	7	7
	12°	6	7	7
20	6°	7	8	8
	12°	7	8	8

**New In This Step:**



Drill Guide



Narrow Spacers



Medium Spacers



Wide Spacers

**Surgical Technique (Continued)**

12. Impact the implant into the fusion site, taking care to align the medial screw hole with the previously marked midline. Release any distractors in use to ensure implant is fully engaged with endplates. (Figure 13)



Figure 12

**O.R. Tips:** The **Solitaire** Implant should be countersunk 1-2mm in order to provide additional safety for anterior vascular structures. Imaging should be used to confirm the desired position of the **Solitaire** Interbody Implant prior to preparing screw holes.

13. Insert Universal Joint or Rigid Awl into the Drill Guide's central screw hole and impact until the Awl hits the positive stop. Examine the implant site using an intraoperative lateral X-Ray to determine appropriately sized screws. The Awl length corresponds to 20mm long screws. Use the Universal Joint or Rigid Drill with the Drill Guide if desired to further prepare for screw fixation. (Figure 14)



Figure 13

**New In This Step:**



14. Affix an appropriate screw to the end of the Universal Joint or Rigid Driver. (Figure 15)



Figure 14

**O.R. Tips:** It is recommended that the **Solitaire** Interbody Spacer should be positioned so that one screw is inserted into the superior vertebral body and two screws are inserted into the inferior vertebral body. However, testing was conducted with the **Solitaire** Interbody Spacer 'upside down', and so it can be used in this configuration.

15. Place the screw into the central screw hole on the Drill Guide. Insert the screw until solid engagement of the cancellous thread occurs.



Figure 15

16. Torque screw to ensure engagement of the locking mechanism. The Torque Limiting Handle 'clicks' at approximately 55in-lb of force. (Figure 16)



Figure 16

**O.R. Tips:** Use the slap hammer to disengage the driver from the screw after torquing.

Repeat steps 13-16 of this procedure for the remaining two screws. (Figure 17)

Additional autograft material is then placed in front of the implant.



Figure 17

Imaging can be used to confirm the desired position of the **Solitaire** Screws prior to disconnecting the Drill Guide from the spacer.

**New In This Step:**



Z-Connect Torque Limiting Handle

## ***Surgical Technique (Continued)***

### **Closure And Postoperative Care**

A routine wound closure is then performed.

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient
- Pain medication
- NG tubes and/or Foley catheters are discontinued within 24 - 48 hours
- Diet is restricted to small amounts of liquids until return of bowel function is completed
- The patient is encouraged to ambulate as soon as possible  
The individual surgeon determines activity level
- Braces are to be used at each surgeon's discretion

### **Implant Removal**

Should it become necessary to remove the **Solitaire** Spacer, the following guidelines should be observed:

1. Soft tissue on the anterior surface of the implant should be removed.
2. Initially, Universal or Rigid Drivers should be used to remove screws.
3. Should screws become stripped, Screw Remover should be used to remove screws.
4. Once screws are removed, Implant Remover should be utilized to remove implant from wound site.

## Product Information

### Solitaire Titanium Implants

Catalog #	Implant
1400-0600	Ti Implant - 6° 10mm narrow
1400-0602	Ti Implant - 6° 12mm narrow
1400-0604	Ti Implant - 6° 14mm narrow
1400-0606	Ti Implant - 6° 16mm narrow
1400-0608	Ti Implant - 6° 18mm narrow
1400-0609	Ti Implant - 6° 20mm narrow*
1400-1200	Ti Implant - 12° 10mm narrow
1400-1202	Ti Implant - 12° 12mm narrow
1400-1204	Ti Implant - 12° 14mm narrow
1400-1206	Ti Implant - 12° 16mm narrow
1400-1208	Ti Implant - 12° 18mm narrow
1400-1209	Ti Implant - 12° 20mm narrow*
1400-0630	Ti Implant - 6° 10mm medium
1400-0632	Ti Implant - 6° 12mm medium
1400-0634	Ti Implant - 6° 14mm medium
1400-0636	Ti Implant - 6° 16mm medium
1400-0638	Ti Implant - 6° 18mm medium
1400-0639	Ti Implant - 6° 20mm medium*
1400-1230	Ti Implant - 12° 10mm medium
1400-1232	Ti Implant - 12° 12mm medium
1400-1234	Ti Implant - 12° 14mm medium
1400-1236	Ti Implant - 12° 16mm medium
1400-1238	Ti Implant - 12° 18mm medium
1400-1239	Ti Implant - 12° 20mm medium*
1400-0650	Ti Implant - 6° 10mm wide
1400-0652	Ti Implant - 6° 12mm wide
1400-0654	Ti Implant - 6° 14mm wide
1400-0656	Ti Implant - 6° 16mm wide
1400-0658	Ti Implant - 6° 18mm wide
1400-0659	Ti Implant - 6° 20mm wide*
1400-1250	Ti Implant - 12° 10mm wide
1400-1252	Ti Implant - 12° 12mm wide
1400-1254	Ti Implant - 12° 14mm wide
1400-1256	Ti Implant - 12° 16mm wide
1400-1258	Ti Implant - 12° 18mm wide
1400-1259	Ti Implant - 12° 20mm wide*

Catalog #	Implant
1400-1009	Screws - 20mm
1400-1011	Screws - 25mm
1400-1012	Screws - 30mm
1400-9902	<b>Solitaire</b> Titanium Implant Surgical Case
14-530011	PEEK Implant - 6° 12mm narrow
14-530012	PEEK Implant - 6° 14mm narrow
14-530013	PEEK Implant - 6° 16mm narrow
14-530014	PEEK Implant - 6° 18mm narrow
14-530015	PEEK Implant - 6° 20mm narrow
14-530021	PEEK Implant - 12° 12mm narrow
14-530022	PEEK Implant - 12° 14mm narrow
14-530023	PEEK Implant - 12° 16mm narrow
14-530024	PEEK Implant - 12° 18mm narrow
14-530025	PEEK Implant - 12° 20mm narrow
14-530041	PEEK Implant - 6° 12mm medium
14-530042	PEEK Implant - 6° 14mm medium
14-530043	PEEK Implant - 6° 16mm medium
14-530044	PEEK Implant - 6° 18mm medium
14-530045	PEEK Implant - 6° 20mm medium
14-530051	PEEK Implant - 12° 12mm medium
14-530052	PEEK Implant - 12° 14mm medium
14-530053	PEEK Implant - 12° 16mm medium
14-530054	PEEK Implant - 12° 18mm medium
14-530055	PEEK Implant - 12° 20mm medium
14-530071	PEEK Implant - 6° 12mm wide
14-530072	PEEK Implant - 6° 14mm wide
14-530073	PEEK Implant - 6° 16mm wide
14-530074	PEEK Implant - 6° 18mm wide
14-530075	PEEK Implant - 6° 20mm wide
14-530081	PEEK Implant - 12° 12mm wide
14-530082	PEEK Implant - 12° 14mm wide
14-530083	PEEK Implant - 12° 16mm wide
14-530084	PEEK Implant - 12° 18mm wide
14-530085	PEEK Implant - 12° 20mm wide
14-530140	<b>Solitaire</b> Implant In Soft Case

\* Denotes special order items

## Product Information (Continued)

### Solitaire Instruments

Catalog #	Instrument
1000-9007	Slotted Mallet
1000-9010	Bone Graft Tamp
1300-9004	Torque Limiting T-Handle
1400-9530	Trial 10mm, 12°, narrow
1400-9550	Trial 10mm, 6°, medium
1400-9552	Trial 12mm, 6°, medium
1400-9554	Trial 14mm, 6°, medium
1400-9556	Trial 16mm, 6°, medium
1400-9558	Trial 18mm, 6°, medium
1400-9559	Trial 20mm, 6°, medium*
1400-9560	Trial 10mm, 12°, medium
1400-9562	Trial 12mm, 12°, medium
1400-9564	Trial 14mm, 12°, medium
1400-9566	Trial 16mm, 12°, medium
1400-9568	Trial 18mm, 12°, medium
1400-9569	Trial 20mm, 12°, medium*
1400-9590	Trial 10mm, 12°, wide
1400-9630	Rasp 10mm, 12°, narrow
1400-9632	Rasp 12mm, 12°, narrow
1400-9634	Rasp 14mm, 12°, narrow
1400-9636	Rasp 16mm, 12°, narrow
1400-9638	Rasp 18mm, 12°, narrow
1400-9639	Rasp 20mm, 12°, narrow*
1400-9660	Rasp 10mm, 12°, medium
1400-9662	Rasp 12mm, 12°, medium
1400-9664	Rasp 14mm, 12°, medium
1400-9666	Rasp 16mm, 12°, medium
1400-9668	Rasp 18mm, 12°, medium
1400-9669	Rasp 20mm, 12°, medium*
1400-9690	Rasp 10mm, 12°, wide
1400-9692	Rasp 12mm, 12°, wide

Catalog #	Instrument
1400-9694	Rasp 14mm, 12°, wide
1400-9696	Rasp 16mm, 12°, wide
1400-9698	Rasp 18mm, 12°, wide
1400-9699	Rasp 20mm, 12°, wide*
1400-9166	Bone Mold Top
1400-9167	Bone Mold Base
60189	Parallel Action Distractor
60169	30° Distractor Handle A
60170	30° Distractor Handle B
60198	Distractor Tip A
60199	Distractor Tip B
1400-9270	T-Handle, Ratchet, Z-Connect
1400-9280	Handle, Ratchet, Z-Connect
1400-9290	Removal Tool
1400-9710	Insertor Guide 10mm
1400-9712	Insertor Guide 12mm
1400-9714	Insertor Guide 14mm
1400-9716	Insertor Guide 16mm
1400-9718	Insertor Guide 18mm
1400-9720	Insertor Guide 20mm*
1400-9221	Drill, U-joint
1400-9131	Awl, U-joint
1400-9241	Screwdriver, U-joint
1400-9211	Drill, Rigid
1400-9450	Awl, Rigid
1400-9460	Driver, Rigid
1400-9470	Modular Handle
1400-9490	Screw Remover
1400-9440	Implant Remover
1400-9901	Instrument Tray

\* Denotes special order items

## *Indications For Use*

The **Solitaire** Anterior Spinal System is indicated for vertebral body replacement (Titanium only) and intervertebral fusion (both Titanium and **PEEK-OPTIMA**). When used for vertebral body replacement, the **Solitaire** Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The **Solitaire** System is also indicated for treating fractures of the thoracic and lumbar spine. The **Solitaire** System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

As an intervertebral body fusion device designed for use with autograft, the **Solitaire** Anterior Spinal System is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

For information on:

- INDICATIONS FOR USE
- CONTRAINDICATIONS
- WARNINGS AND PRECAUTIONS
- STERILIZATION

Please refer to the **Solitaire** Anterior Spinal System Package Insert.

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

The **Solitaire** Anterior Spinal System Surgical Technique is presented to demonstrate the surgical technique utilized by J. Abbott Byrd, III, M.D. Biomet Spine, as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.







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