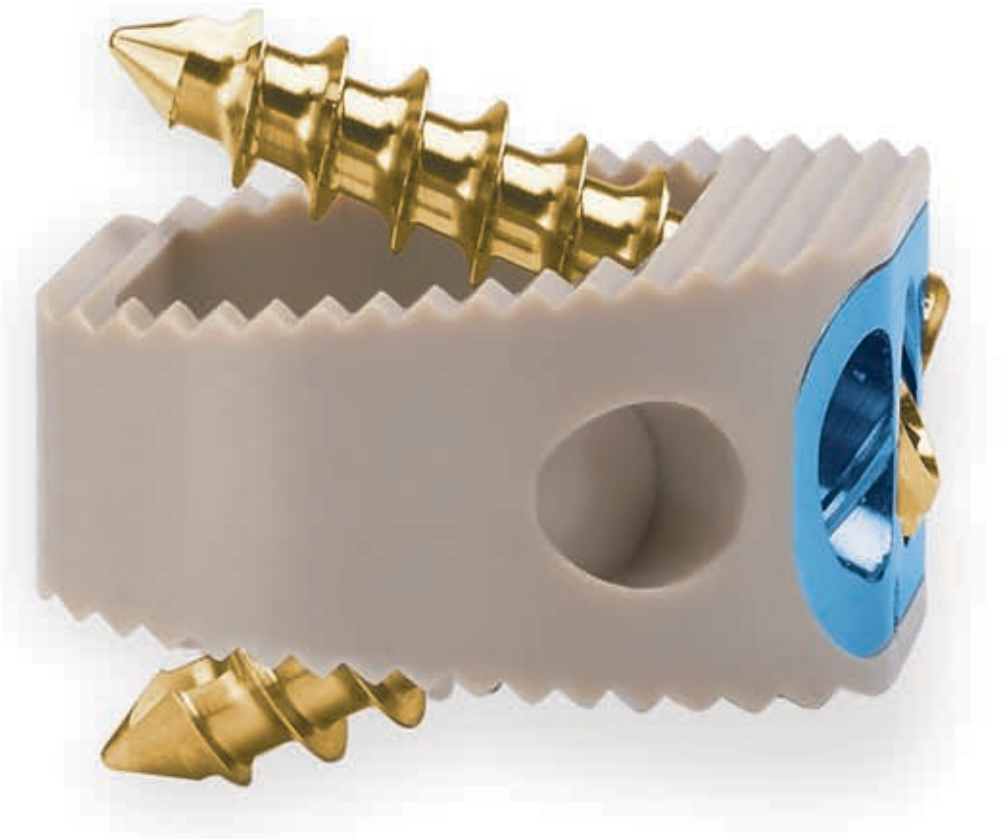
Surgical Technique

Solitaire™ Anterior Spinal System

Independent Stabilization for the Anterior Column

- Available in Titanium and PEEK-OPTIMA®



BIOMET® SPINE

Contents

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 acute convergent angled cancellous bone screws. By providing a stabile 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 implant to enhance visualization and provide proper implant positioning. In the PEEK implant, tantalum markers located in the posterior corners serve to facilitate visualization and desired implant positioning and an integrated titanium plate engages the screw locking mechanism. The posterior wall is solid to provide a stable environment for fusion, while 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.

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

Designed to resist subsidence
by covering 80% of the endplate

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

Large, single chamber design
accommodates the fusion process

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

Many implantation options offer intraoperative flexibility.

- Three implant footprints
- Variety of screw lengths
- Two lordotic angles (6°, 12°)
- 10mm-20mm heights

NOTE: 10mm available in Titanium Only.

Narrow: 28mm wide

Medium: 34mm wide

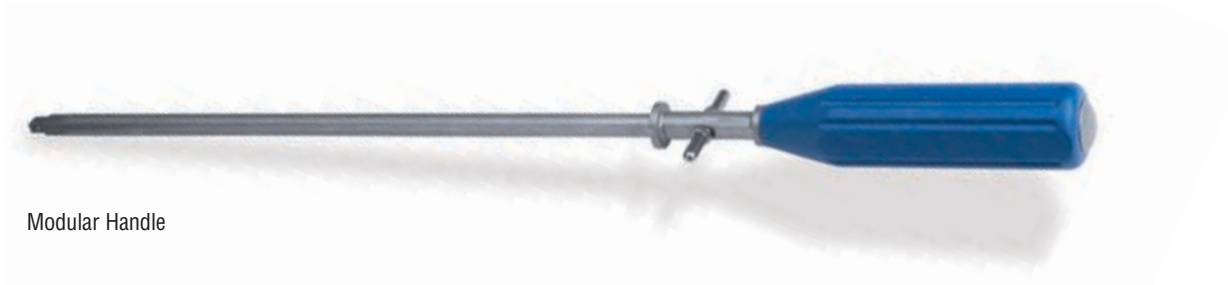
Wide: 40mm wide

Screw Options

- Screw forms friction fit to lock with spacer
- 5.5mm diameter screw with lengths 20mm, 22mm, 25mm, 27mm, 30mm, 35mm (measured from the base of the head)
- Cortical thread provides strong fixation with adjacent endplates and resists pullout

20mm 22mm 25mm 27mm 30mm

Instruments

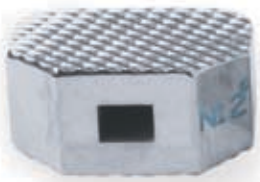


Modular Handle

Narrow Width Trial

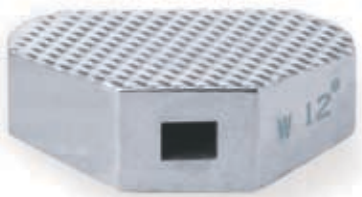
Medium Width Trial

Wide Width Trial



Narrow Width Rasp

Medium Width Rasp



Wide Width Rasp

Inserter Guide

Instruments (Continued)

Bone Graft Mold

Universal and Rigid Drills - 20mm, 25mm

Universal and Rigid Awls - 20mm, 25mm

Universal and Rigid Pentalobe Drivers

Guide Lock Tubes

Guide Lock Awls

Guide Lock Drills

Z-Connect Ratchet Handle

Z-Connect T-Handle Ratchet

Z-Connect Torque Limiting Handle

Step 1 – Exposure

Obtain anterior exposure per surgeon preference. 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.

Step 2 – Distraction

Distraction of the discectomy site is important to restore lordosis, open the neural foramen, and stabilize the implant. 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.

Figure 1

Step 3 – Trialing

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 1) The Trials can be easily attached 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.

Once footprint width is determined, select the 12mm Trial (if using the Titanium implant start with the 10mm 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 2)

Figure 2

O.R. Tips: A lateral fluoro image can be utilized to illustrate posterior endplate contact with the Trial. Each 6° implant is approximately 2.62mm less at the posterior end and the 12° implants are 5.24mm less posterior when compared to the anterior height.

Step 4 – Endplate Preparation

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 in order to expose bleeding bone. (Figure 3)

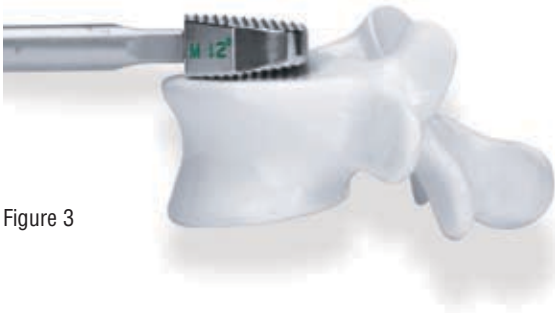


Figure 3

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

Step 5 – Bone Mold Assembly

Assemble the Mold Top to the Mold Base (Figure 4)

Figure 4

Step 6 – Implant Preparation

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.

Graft Volume

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

The Solitaire™ System offers two options for preparing screw holes based on surgeon preference.

Select the inserter guide that corresponds to the final implant size to be used. Inserter guides are color-coded to match a particular height of Spacer. The same inserter guide is utilized for all Spacer footprints for a particular height.

Attach implant to the inserter guide by matching the black dot on the inner part of the guide to the dot on the titanium portion of the implant (Figure 5). Hand tighten screw on guide. Attach modular handle, and use hex driver or Long T-Handle Hex guide driver to securely tighten guide to implant (Figure 6). Insert into disc space.

O.R. Tip:

Confirm proper orientation of guide to implant by dropping an awl or drill down one of the inserter guide tubes. The instrument should easily seat into the guide with no manipulation. (Figure 7)

Alternate Screw Prep – Using GOLD Guide Lock Tubes

Follow above steps to attach the inserter guide to the implant.

Once inserter guide is attached to implant, insert gold colored guide tubes through all three holes of inserter guide and screw into place. (Figure 8) Insert into disc space.

NOTE: If using this technique, you must use the GOLD TIP Awls and Drills that are associated with the guide lock tubes.

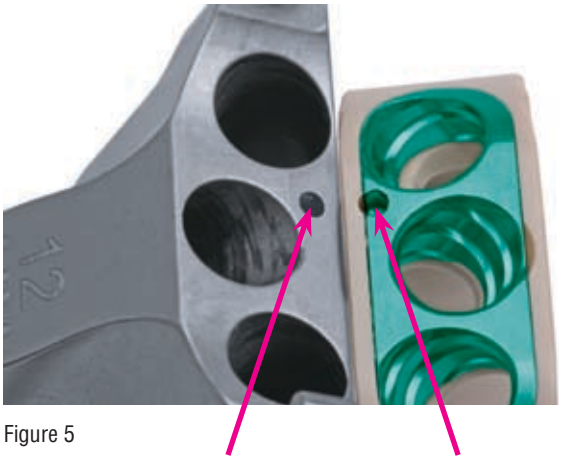


Figure 5

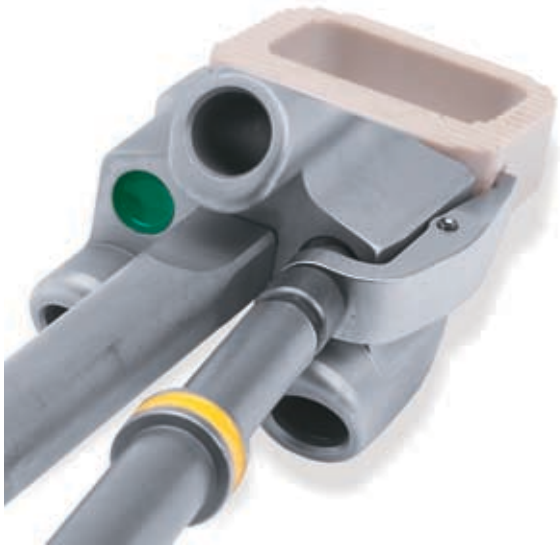


Figure 6

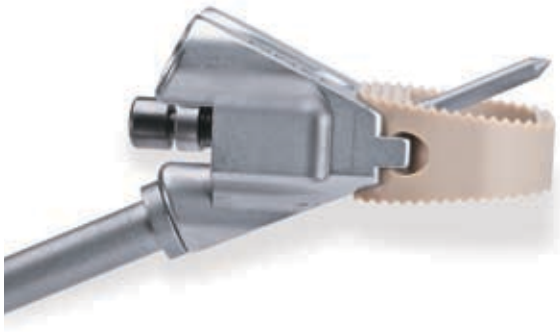


Figure 7

Figure 8

Step 7 – Implant Insertion

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 9)

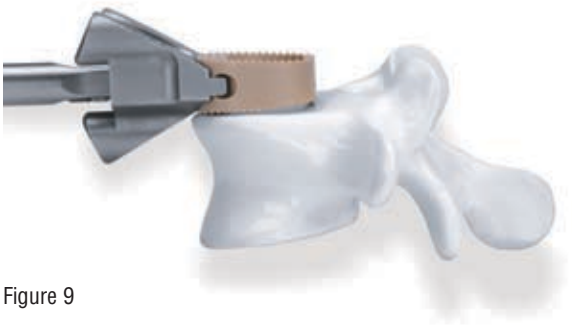


Figure 9

O.R. Tips:

The Solitaire™ Interbody Implant should be countersunk 1mm-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.

Step 8 – Screw Hole Preparation

Insert Universal Joint or Rigid Awl into the Inserter Guide's central screw hole and impact until the Awl hits the positive stop. Examine the implant site using an intra-operative lateral X-Ray to determine appropriately sized screws. The 20mm Awl length corresponds to 20mm long screws. Use the Universal Joint or Rigid Fishtail Drill with the Drill Guide if desired to further prepare for screw fixation. (Figure 10)

NOTE: If gold guide lock tubes are attached you must use the GOLD tip awls and drills that correspond with this technique. (Figure 11)

Figure 10

Figure 11

O.R. Tips:

If endplates are very concave, 25mm Awls and 25mm Fishtail Drills are also available and correspond to the length of the 25mm screws.

Step 9 – Screw Insertion

Affix an appropriate screw to the end of the Universal Joint or Rigid Pentalobe Driver. (Figure 12)

Figure 12

Step 10 – Final Tightening

NOTE: If using the gold guide lock tubes to prep the holes they need to be removed at this time.

Place the screw into the central screw hole on the Inserter Guide. Insert each screw until solid engagement of the cancellous thread occurs. Torque each screw to ensure engagement of the locking mechanism. The Torque Limiting Handle 'clicks' at approximately 55in-lb of force. (Figure 13)

Additional autograft material may then be placed in front of the implant.

Figure 13

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', so it can be used in this configuration
- Inserter Guide may be removed intra-operatively in order to visualize positioning of the implant and screws within the vertebral body under fluoroscopy
- Final tightening (torquing) of screws can be done with or without inserter guide attached
- Use the slap hammer to disengage the driver from the screw after torquing

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.

Solitaire™ PEEK Implants – Catalog # 14-530141

Catalog #	Description	Qty/Kit
14-530011	PEEK Implant – 6° 12mm Narrow	2
14-530012	PEEK Implant – 6° 14mm Narrow	2
14-530013	PEEK Implant – 6° 16mm Narrow	2
14-530014	PEEK Implant – 6° 18mm Narrow	2
14-530015	PEEK Implant – 6° 20mm Narrow	0*
14-530021	PEEK Implant – 12° 12mm Narrow	2
14-530022	PEEK Implant – 12° 14mm Narrow	2
14-530023	PEEK Implant – 12° 16mm Narrow	2
14-530024	PEEK Implant – 12° 18mm Narrow	2
14-530025	PEEK Implant – 12° 20mm Narrow	0*
14-530041	PEEK Implant – 6° 12mm Medium	2
14-530042	PEEK Implant – 6° 14mm Medium	2
14-530043	PEEK Implant – 6° 16mm Medium	2
14-530044	PEEK Implant – 6° 18mm Medium	2
14-530045	PEEK Implant – 6° 20mm Medium	0*
14-530051	PEEK Implant – 12° 12mm Medium	2
14-530052	PEEK Implant – 12° 14mm Medium	2
14-530053	PEEK Implant – 12° 16mm Medium	2
14-530054	PEEK Implant – 12° 18mm Medium	2
14-530055	PEEK Implant – 12° 20mm Medium	0*

Catalog #	Description	Qty/Kit
14-530071	PEEK Implant – 6° 12mm Wide	2
14-530072	PEEK Implant – 6° 14mm Wide	2
14-530073	PEEK Implant – 6° 16mm Wide	2
14-530074	PEEK Implant – 6° 18mm Wide	2
14-530075	PEEK Implant – 6° 20mm Wide	0*
14-530081	PEEK Implant – 12° 12mm Wide	2
14-530082	PEEK Implant – 12° 14mm Wide	2
14-530083	PEEK Implant – 12° 16mm Wide	2
14-530084	PEEK Implant – 12° 18mm Wide	2
14-530085	PEEK Implant – 12° 20mm Wide	0*

* Denotes Special Order Item

Solitaire™ Titanium Implants – Catalog # 55500162

Catalog #	Description	Qty/Kit
1400-0600	Ti Implant – 6° 10mm Narrow	2
1400-0602	Ti Implant – 6° 12mm Narrow	2
1400-0604	Ti Implant – 6° 14mm Narrow	2
1400-0606	Ti Implant – 6° 16mm Narrow	2
1400-0608	Ti Implant – 6° 18mm Narrow	2
1400-0609	Ti Implant – 6° 20mm Narrow	0*
1400-1200	Ti Implant – 12° 10mm Narrow	2
1400-1202	Ti Implant – 12° 12mm Narrow	2
1400-1204	Ti Implant – 12° 14mm Narrow	2
1400-1206	Ti Implant – 12° 16mm Narrow	2
1400-1208	Ti Implant – 12° 18mm Narrow	2
1400-1209	Ti Implant – 12° 20mm Narrow	0*
1400-0630	Ti Implant – 6° 10mm Medium	2
1400-0632	Ti Implant – 6° 12mm Medium	2
1400-0634	Ti Implant – 6° 14mm Medium	2
1400-0636	Ti Implant – 6° 16mm Medium	2
1400-0638	Ti Implant – 6° 18mm Medium	2
1400-0639	Ti Implant – 6° 20mm Medium	0*
1400-1230	Ti Implant – 12° 10mm Medium	2
1400-1232	Ti Implant – 12° 12mm Medium	2
1400-1234	Ti Implant – 12° 14mm Medium	2
1400-1236	Ti Implant – 12° 16mm Medium	2
1400-1238	Ti Implant – 12° 18mm Medium	2
1400-1239	Ti Implant – 12° 20mm Medium	0*
1400-0650	Ti Implant – 6° 10mm Wide	2
1400-0652	Ti Implant – 6° 12mm Wide	2
1400-0654	Ti Implant – 6° 14mm Wide	2
1400-0656	Ti Implant – 6° 16mm Wide	2
1400-0658	Ti Implant – 6° 18mm Wide	2
1400-0659	Ti Implant – 6° 20mm Wide	0*
1400-1250	Ti Implant – 12° 10mm Wide	2
1400-1252	Ti Implant – 12° 12mm Wide	2
1400-1254	Ti Implant – 12° 14mm Wide	2
1400-1256	Ti Implant – 12° 16mm Wide	2
1400-1258	Ti Implant – 12° 18mm Wide	2
1400-1259	Ti Implant – 12° 20mm Wide	0*

*Denotes Special Order Item

Solitaire™ Standard Instruments – Catalog # 14-530148

Catalog #	Description	Qty/Kit
1400-9750	Inserter Guide 10mm	1
1400-9752	Inserter Guide 12mm	1
1400-9754	Inserter Guide 14mm	1
1400-9756	Inserter Guide 16mm	1
1400-9758	Inserter Guide 18mm	1
1400-9465	Hex Guide Driver	1
1400-9132	20mm Universal Awl	1
1400-9451	20mm Rigid Awl	1
1400-9212	20mm Rigid Drill (Fishtail)	1
1400-9222	20mm Universal Drill (Fishtail)	1
14-530144	Pentalobe Driver, Rigid	1
14-530145	Pentalobe Driver, U-Joint	1
1400-9270	T-Handle, Ratchet, Z-Connect	1
1300-9004	Torque T-Handle	1
1400-9490	Screw Remover	1
14-530106	Pentalobe Screws – 20mm	10
14-530108	Pentalobe Screws – 22mm	10
14-530111	Pentalobe Screws – 25mm	10
14-530113	Pentalobe Screws – 27mm	10
14-530116	Pentalobe Screws – 30mm	10
14-530121	Pentalobe Screws – 35mm	0*
560169	Ionic 30° Distractor Handle A	1
560170	Ionic 30° Distractor Handle B	1
560189	AIS Anterior Distractor Large	1
560198	Ionic Single Tip A	1
560199	Ionic Single Tip B	1
1000-9007	Slotted Mallet	1
1400-9280	Straight Handle, Ratchet, Z-Connect	1
1400-9290	Implant Removal Tool	1
1000-9010	Bone Graft Tamp	1
1400-9167	Template Mold Base	1
1400-9170	Bone Mold Base	1
1400-9470	Modular Handle	2

Catalog #	Description	Qty/Kit
1400-9530	Trial 10mm, 12° Narrow	1
1400-9532	Trial 12mm, 12° Narrow	1
1400-9534	Trial 14mm, 12° Narrow	1
1400-9536	Trial 16mm, 12° Narrow	1
1400-9538	Trial 18mm, 12° Narrow	1
1400-9539	Trial 20mm, 12° Narrow	0**
1400-9550	Trial 10mm, 6° Medium	1
1400-9552	Trial 12mm, 6° Medium	1
1400-9554	Trial 14mm, 6° Medium	1
1400-9556	Trial 16mm, 6° Medium	1
1400-9558	Trial 18mm, 6° Medium	1
1400-9559	Trial 20mm, 6° Medium	0**
1400-9560	Trial 10mm, 12° Medium	1
1400-9562	Trial 12mm, 12° Medium	1
1400-9564	Trial 14mm, 12° Medium	1
1400-9566	Trial 16mm, 12° Medium	1
1400-9568	Trial 18mm, 12° Medium	1
1400-9569	Trial 20mm, 12° Medium	0**
1400-9590	Trial 10mm, 12° Wide	1
1400-9592	Trial 12mm, 12° Wide	1
1400-9594	Trial 14mm, 12° Wide	1
1400-9596	Trial 16mm, 12° Wide	1
1400-9598	Trial 18mm, 12° Wide	1
1400-9599	Trial 20mm, 12° Wide	0**
1400-9630	Rasp 10mm, 12° Narrow	1
1400-9632	Rasp 12mm, 12° Narrow	1
1400-9634	Rasp 14mm, 12° Narrow	1
1400-9636	Rasp 16mm, 12° Narrow	1
1400-9638	Rasp 18mm, 12° Narrow	1
1400-9639	Rasp 20mm, 12° Narrow	0**

*Denotes Special Order Item

**Supplemental Tray

Solitaire™ Standard Instruments

Catalog # 14-530148 (Continued)

Catalog #	Description	Qty/Kit
1400-9659	Rasp 10mm, 12° Medium	1
1400-9660	Rasp 12mm, 12° Medium	1
1400-9662	Rasp 14mm, 12° Medium	1
1400-9664	Rasp 16mm, 12° Medium	1
1400-9666	Rasp 18mm, 12° Medium	1
1400-9669	Rasp 20mm, 12° Medium	0**
1400-9690	Rasp 10mm, 12° Wide	1
1400-9692	Rasp 12mm, 12° Wide	1
1400-9694	Rasp 14mm, 12° Wide	1
1400-9696	Rasp 16mm, 12° Wide	1
1400-9698	Rasp 18mm, 12° Wide	1
1400-9699	Rasp 20mm, 12° Wide	0**

Solitaire™ Supplemental Instruments

Catalog # 14-531320

Catalog #	Description	Qty/Kit
14-530143	T-Handle Hex Guide Driver	1
14-531300	Guidelock Tubes (Gold)	3
14-531301	Guidelock Drill, 20mm Rigid	1
14-531302	Guidelock Drill, 25mm Rigid	1
14-531304	Guidelock Drill, 20mm U-Joint	1
14-531305	Guidelock Drill, 25mm U-Joint	1
14-531307	Guidelock Awl, 20mm Rigid	1
14-531308	Guidelock Awl, 25mm Rigid	1
14-531310	Guidelock Awl, 20mm U-Joint	1
14-531311	Guidelock Awl, 25mm U-Joint	1
1400-9133	25mm Universal Awl	1
1400-9452	25mm Rigid Awl	1
1400-9213	25mm Rigid Drill (Fishtail)	1
1400-9223	25mm Universal Drill (Fishtail)	1

**Supplemental Tray

Catalog #	Description	Qty/Kit
1400-9520	Trial 10mm, 6° Narrow	1
1400-9522	Trial 12mm, 6° Narrow	1
1400-9524	Trial 14mm, 6° Narrow	1
1400-9526	Trial 16mm, 6° Narrow	1
1400-9528	Trial 18mm, 6° Narrow	1
1400-9529	Trial 20mm, 6° Narrow	1
1400-9539	Trial 20mm, 12° Narrow	1
1400-9569	Trial 20mm, 12° Medium	1
1400-9580	Trial 10mm, 6° Wide	1
1400-9582	Trial 12mm, 6° Wide	1
1400-9584	Trial 14mm, 6° Wide	1
1400-9586	Trial 16mm, 6° Wide	1
1400-9588	Trial 18mm, 6° Wide	1
1400-9589	Trial 20mm, 6° Wide	1
1400-9599	Trial 20mm, 12° Wide	1
1400-9620	Rasp 10mm, 6° Narrow	1
1400-9622	Rasp 12mm, 6° Narrow	1
1400-9624	Rasp 14mm, 6° Narrow	1
1400-9626	Rasp 16mm, 6° Narrow	1
1400-9628	Rasp 18mm, 6° Narrow	1
1400-9629	Rasp 20mm, 6° Narrow	1
1400-9650	Rasp 10mm, 6° Medium	1
1400-9652	Rasp 12mm, 6° Medium	1
1400-9654	Rasp 14mm, 6° Medium	1
1400-9656	Rasp 16mm, 6° Medium	1
1400-9658	Rasp 18mm, 6° Medium	1
1400-9659	Rasp 20mm, 6° Medium	1
1400-9669	Rasp 20mm, 12° Medium	1
1400-9680	Rasp 10mm, 6° Wide	1
1400-9682	Rasp 12mm, 6° Wide	1
1400-9684	Rasp 14mm, 6° Wide	1
1400-9686	Rasp 16mm, 6° Wide	1
1400-9688	Rasp 18mm, 6° Wide	1
1400-9689	Rasp 20mm, 6° Wide	1
1400-9699	Rasp 20mm, 12° Wide	1
1400-9760	Inserter Guide 20mm	1

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 1 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 skeletally mature and have had six months of non-operative treatment.

For information on:

- INDICATIONS FOR USE
- CONTRAINDICATIONS
- 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.

Further Information

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

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www.biometspine.com

Notes:

At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

Solitaire™ Anterior Spinal System
Independent Stabilization for the Anterior Column

To learn more about this product,
contact your local Biomet Sales Representative today.

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