Vista®-S
Device

zimmer

Surgical Technique

Solutions by the people of Zimmer Spine.
zimmerspine.com

Flexibility. Visualization. Simplicity.
From the people of Zimmer Spine.

The *Vista*-S Device is manufactured from *PEEK-OPTIMA*®, a load sharing, radiolucent, biocompatible material with strength and stability. Offered in six footprints (11x11mm, 11x14mm, 14x14mm, 13x16mm, 14x18mm and 15x20mm), heights from 4mm – 12mm and parallel and lordotic versions, *Vista*-S implants accommodate the varying anatomy of your patients. The unique shark tooth surface pattern reduces the risk of migration and the leading tapered edge helps facilitate insertion.

The *Vista*-S Device is compatible with the *Mergence*®-S universal instrumentation system which allows for trialing, endplate preparation and implant insertion in one easy to use system.

The *Vista*-S Device, a reliable solution brought to you by the people of Zimmer Spine.

Table of Contents

Description/Indications/Contraindications	1
Vista-S Implants	3
Mergence-S Instruments	5
Surgical Technique	7
Kit Contents	14
Warnings and Precautions	27

Description/Indications/Contraindications

Description

The *Vista*®-S Device is manufactured wholly from unfilled *PEEK-OPTIMA*® LT1, a polyetheretherketone. This material is a thermoplastic polycondensate, semicrystaline polymer. It is used in this device in the unfilled state (i.e. no glass or carbon fiber fill). Due to the radiolucent nature of *PEEK-OPTIMA*® LT1, three radiopaque markers made of tantalum are incorporated into the device to indicate the nose end and the superior and inferior corners of the opposite end for use in postoperative monitoring of device position.

The superior and inferior surfaces of the device have a textured surface to provide increased stability. The device is available in a variety of cross-sectional geometries and sizes. These implants offer two different included angle options to maintain the natural contour of the spine.

These implants are intended for single use only and must not be reused under any circumstances. Surgical instruments are also available to assist in the implantation of the device.

Indications

In the United States:

The *Vista*®-S Fusion Device is intended for use in skeletally mature patients with degenerative disc disease (DDD) with/without radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The *Vista*®-S Device is intended for use with supplemental spinal fixation systems and with autogenous bone graft. The *Vista*®-S Fusion Device is implanted via an anterior approach.

Outside the United States:

The *Vista*®-S Device is intended for use in anterior cervical discectomy and fusion (ACDF) procedures in patients with symptomatic cervical disc disease from the C3-C4 to the C7-T1 disc. The *Vista*®-S Device is intended for use with supplemental internal spinal fixation systems. The *Vista*®-S Device may be used with bone graft.

Contraindications

- Active local infection in or near the operative region.
- Active systemic infection and/or disease.
- Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.
- Prior surgical procedure using the desired operative approach.
- Spinal conditions other than cervical DDD.
- Current metastatic tumors of the vertebrae adjacent to the implant.
- Known or suspected sensitivity to the implant materials.
- Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism).
- Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs.
- Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions (e.g., current treatment for a psychiatric/psychosocial disorder, senile dementia, Alzheimer's disease, traumatic head injury).
- Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure, or complications in postoperative care. Neuromuscular disorders include spina bifida, cerebral palsy, and multiple sclerosis.
- Pregnancy.
- Patients unwilling to follow postoperative instructions, especially those in athletic and occupational activities.
- Morbid obesity.
- Symptomatic cardiac disease.
- Skeletal immaturity.
- Grossly distorted anatomy.
- Conditions other than those indicated.

Vista-S Implants

Vista-S Device implants are available in six footprints: 11mm x 11mm, 11mm x 14mm, 14mm x 14mm, 13mm x 16mm, 14mm x 18mm and 15mm x 20mm. All six sizes are available in vertical heights of 4mm to 12mm, in 1mm increments, except the 11mm x 11mm footprint which is offered from 4mm to 10mm. The height is measured from the posterior (shortest) aspect of the device. In addition, the implants are offered in a 7˚ included angle option and a 0˚ included angle option to help maintain the natural contour of the spine. The *Vista*-S Device has a central hole extending in the superior-inferior direction for placement of autogenous bone graft.

The device also has a small slot on its anterior face for mating with its insertion instrument. The *Vista*-S Device is manufactured wholly from unfilled *PEEK-OPTIMA* LT1. Due to its radiolucent nature, three radiopaque markers made of tantalum are incorporated into the device to indicate the nose end and the superior and inferior corners of the opposite end for use in postoperative monitoring of device position. The superior and inferior surfaces of the device have a textured surface to provide increased stability. The implants are intended for single use only and must not be reused under any circumstance.

***Vista*-S 7° Implant**
06-401 Series

***Vista*-S 0° Implant**
06-402 Series

Vista-S Implant Sizes

Length x Width (mm)	Height (mm)	Angle
11x11	4	0°, 7°
	5	0°, 7°
	6	0°, 7°
	7	0°, 7°
	8	0°, 7°
	9	0°, 7°
	10	0°, 7°
11x14	4	0°, 7°
	5	0°, 7°
	6	0°, 7°
	7	0°, 7°
	8	0°, 7°
	9	0°, 7°
	10	0°, 7°
	11	0°, 7°
	12	0°, 7°
14x14	4	0°, 7°
	5	0°, 7°
	6	0°, 7°
	7	0°, 7°
	8	0°, 7°
	9	0°, 7°
	10	0°, 7°
	11	0°, 7°
	12	0°, 7°

Length x Width (mm)	Height (mm)	Angle
13x16	4	0°, 7°
	5	0°, 7°
	6	0°, 7°
	7	0°, 7°
	8	0°, 7°
	9	0°, 7°
	10	0°, 7°
	11	0°, 7°
	12	0°, 7°
14x18	4	0°, 7°
	5	0°, 7°
	6	0°, 7°
	7	0°, 7°
	8	0°, 7°
	9	0°, 7°
	10	0°, 7°
	11	0°, 7°
	12	0°, 7°
15x20	4	0°, 7°
	5	0°, 7°
	6	0°, 7°
	7	0°, 7°
	8	0°, 7°
	9	0°, 7°
	10	0°, 7°
	11	0°, 7°
	12	0°, 7°

Mergence®-S Spinal Instrumentation Platform

The *Mergence*-S Instrumentation is designed to aid in the implantation of Zimmer Spine's *Vista*-S Device. The Smith-Robinson surgical technique is utilized with standard instruments, except those specifically related to the sizing and insertion of the *Vista*-S Device.

Lateral Grasping Inserter
96-106-00001

Implant Inserter option that attaches to the lateral sides of the implant.

Central Rotating Inserter
96-106-30001

Implant Inserter option that utilizes the central insertion slot.

General Tamp
96-105-00002

Assists in final implant placement by tamping directly down on the implant.

Central Tamp
96-105-10001

Assists in final implant placement by tamping directly down on the implant while utilizing the central insertion slot.

Corner Tamp
96-105-20001

Assists in final implant placement by tamping down on the corners of the implant.

Provisionals and Rasps

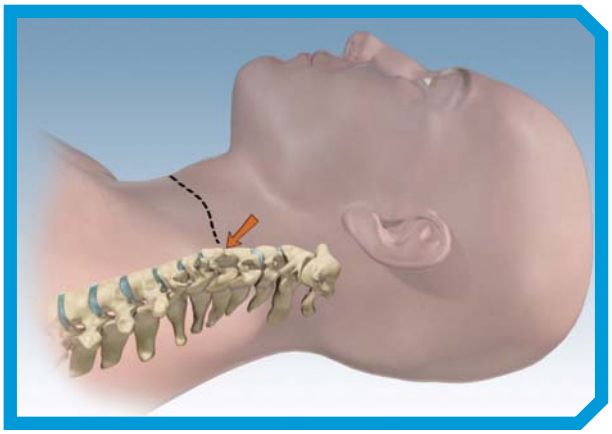
Assist in the measurement and preparation of the implant space. Color coded by footprint/angle.

Color	Size/Part Number Series
	11mm x 11mm, 7° 96-101-01041 to 96-101-01121 96-108-17041 to 96-108-17121
	11mm x 14mm, 7° 96-101-02041 to 96-101-02121 96-108-27041 to 96-108-27121
	14mm x 14mm, 7° 96-101-03041 to 96-101-03121 96-108-37041 to 96-108-37121
	13mm x 16mm, 7° 96-101-04041 to 96-101-04121 96-108-47041 to 96-108-47121
	14mm x 18mm, 7° 96-101-05041 to 96-101-05121 96-108-57041 to 96-108-57121
	15mm x 20mm, 7° 96-101-06041 to 96-101-06121 96-108-67041 to 96-108-67121

Color	Size/Part Number Series
	11mm x 11mm, 0° 96-102-01041 to 96-102-01121 96-108-10041 to 96-108-10121
	11mm x 14mm, 0° 96-102-02041 to 96-102-02121 96-108-20041 to 96-108-20121
	14mm x 14mm, 0° 96-102-03041 to 96-102-03121 96-108-30041 to 96-108-30121
	13mm x 16mm, 0° 96-102-04041 to 93-102-04121 96-108-40041-to 96-108-40121
	14mm x 18mm, 0° 96-102-05041 to 96-102-05121 96-108-50041 to 96-108-50121
	15mm x 20mm, 0° 96-102-06041 to 96-102-06121 96-108-60041 to 96-108-60121

Surgical Technique

Step 1

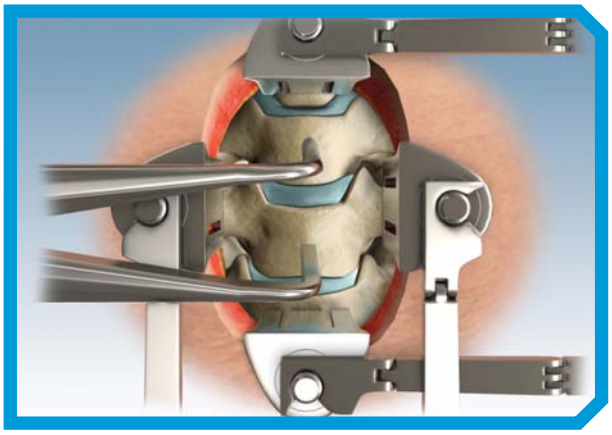


Pre-Operative Planning and Patient Positioning

Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, discography, patient history and physical examination.

Place the patient in a supine position. Support the posterior cervical spine to maintain normal lordosis and chose a right- or left-sided approach. Identify the symptomatic level and make a skin incision to the corresponding pathology.

Step 2

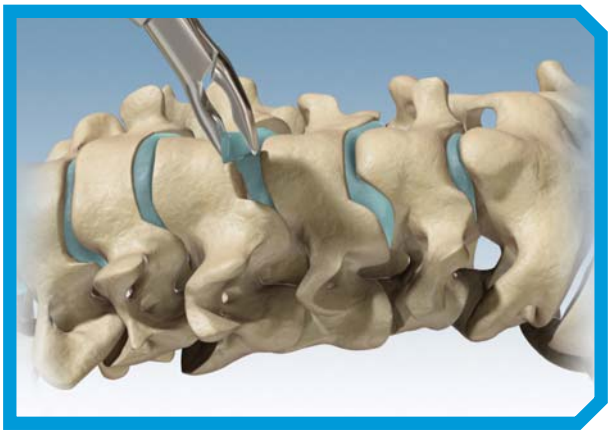


Exposure and Location

The anterior cervical anatomy is exposed in the standard fashion by identifying a dissection plane between the trachea and esophagus. Exposure is then held in place utilizing self-retaining retractors.

The proper level is confirmed using a needle as a marker and fluoroscopy imaging. A vertebral distractor can then be placed through the open incision in the adjacent vertebrae to the discectomy.

Step 3

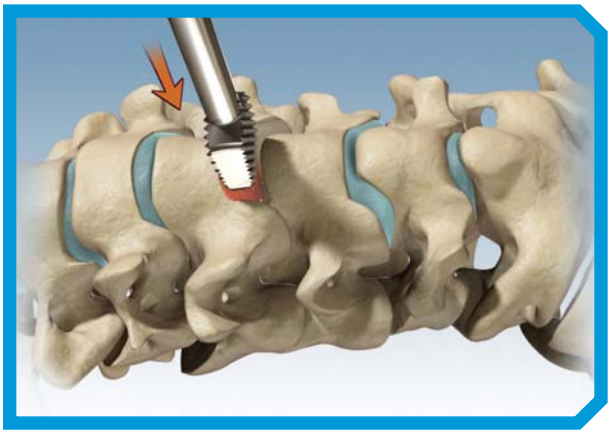


Discectomy

Perform a standard cervical discectomy and decompression by resecting the anterior longitudinal ligament over the corresponding vertebrae. Remove the anterior osteophytes followed by the anterior portion of the annulus fibrosis. Make a window corresponding to the size of the implant. Remove the intervertebral disc out to the uncovertebral joints using general instrumentation such as Curettes or Rongeurs. Distract the disc space. A Caspar Distractor is recommended for the distraction.

***Caution:** Great care should be taken to ensure that all exposed blood vessels and nerves are properly retracted prior to the discectomy to avoid unintended contact with the Curettes and Rongeurs.*

Step 4



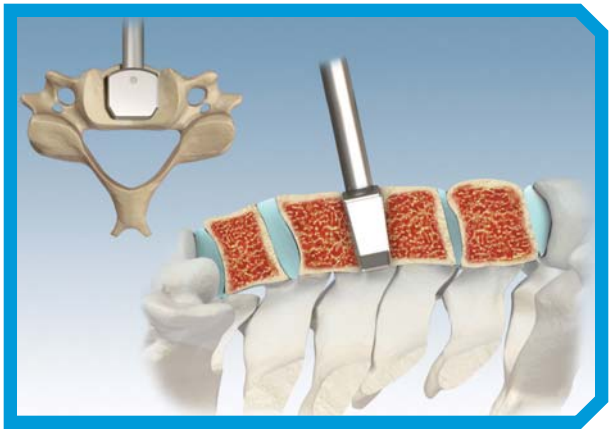
Endplate Preparation

Complete a neural decompression by trimming large posterior osteophytes (if present). Prepare the endplates by using the *Mergence*-S Size-Specific Rasps, standard curettes or burrs. Remove a minimal amount of the cartilaginous endplates to create a flat surface of bleeding bone.

***Note:** Fluoroscopy may be used to monitor the depth of the rasp intra-operatively.*

***Caution:** Using excessive force with the instrumentation can inadvertently rupture the posterior annulus or damage the vertebral endplates. Removal of the entire endplate can weaken the vertebral construct and may result in subsidence.*

Step 5



Implant Selection

Determine the implant size by measuring the disc space using the *Mergence*-S Provisionals (Trials). Insert a Provisional and select the size that sufficiently fits the disc space. The proper Provisional will tension the soft tissue crossing that selected disc space. Proper tension is determined by the amount of force necessary to fully seat the Provisional. If the Provisional seats without force, it is too small. Continue increasing the Provisional's size until force is necessary to fully seat the Provisional.

Note: ***Provisionals precisely match the dimensions of the*** Vista-***S implants.***

In 1993, An et. al. used cadaver studies to establish the optimal thickness for Smith-Robinson-type cervical fusion grafts. They concluded that the ideal thickness is approximately 2mm greater than the pre-operative measured disc height.

Caution: If the Provisional used within the disc space is solidly engaged and difficult to realign laterally when the proper position has been obtained within the disc space, consider implanting a device 1mm smaller than the Provisional being used.

Step 6

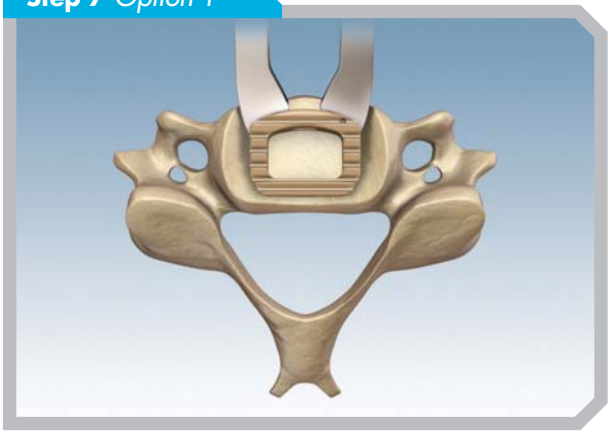
Bone Grafting

The hole in the center of the implant must be filled with autogenous bone harvested from the iliac crest.

Implant Insertion Options

Select an Implant Inserter to hold the device for final placement into the disc space.

Step 7 *Option 1*

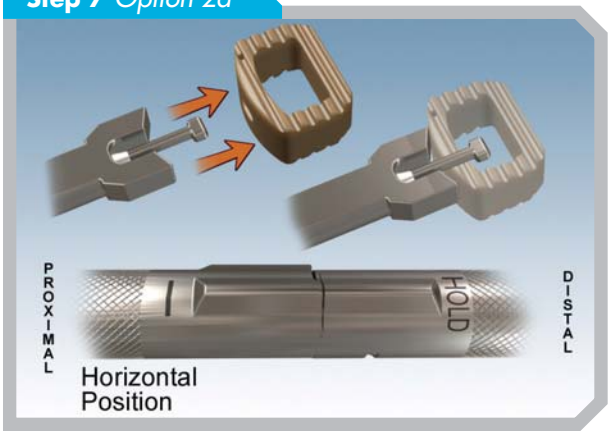


Lateral Grasping Inserter

Ensure that the Lateral Grasping Inserter is engaging the anterior convex edge of the device by evaluating the implant's geometry carefully. This Inserter has a flat bar at the proximal end to facilitate impaction.

***Note:** The Lateral Grasping Inserter is not compatible with the 13x16mm, 14x18mm, and 15x20mm footprint devices. It is also not compatible with all implants with a 4mm height.*

Step 7 *Option 2a*



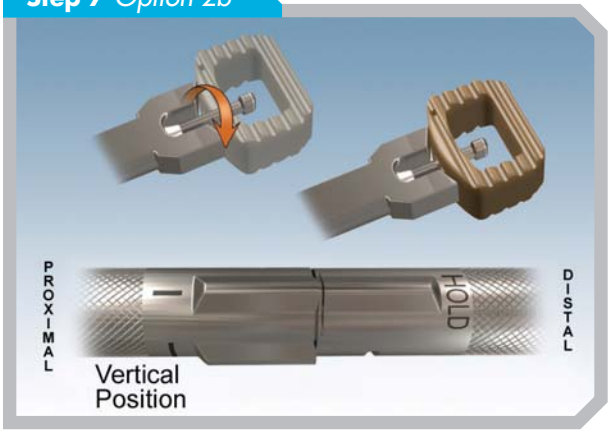
Central Rotating Inserter

Insert the tab of the *Mergence*-S Central Rotating Inserter into the slot located on the anterior convex face of the device.

When the proximal ridge is lined up with the distal ridge and the laser marking on the Central Rotating Inserter is in the horizontal position, the tab of the Inserter is in position to place or remove the implant from the Inserter.

***Note:** Image 2a shows the tab in a horizontal position, which allows for placement and removal of the implant.*

Step 7 *Option 2b*



Inserter Positioning

Hold the device onto the distal end of the Inserter. At the same time, rotate the proximal end of the Inserter clockwise until the vertical ridge is aligned with the distal ridge.

When the proximal ridge is lined up with the distal ridge and the laser marking is in the vertical position, the tab is in position to secure the implant to the Inserter.

***Note:** Image 2b shows the tab in a vertical position, which allows for securing the device onto the Inserter.*

Step 7 *Option 2c*

Securing the Central Rotating Inserter

Turn the knob clockwise until the device is secure on the Inserter. The implant can be placed into the space with the Inserter.

To remove the Inserter from the device, hold the proximal end of the Inserter securely and turn the knob counterclockwise until a stop is reached. Hold the distal end of the Inserter, and at the same time, rotate the proximal end counterclockwise until a stop is reached. Pull the Inserter away from the implant while keeping the Inserter parallel to the device.

Step 7 *Option 2d*

Central Rotating Inserter Disassembly

Hold the distal end of the Inserter and rotate the proximal end clockwise until a stop is reached.

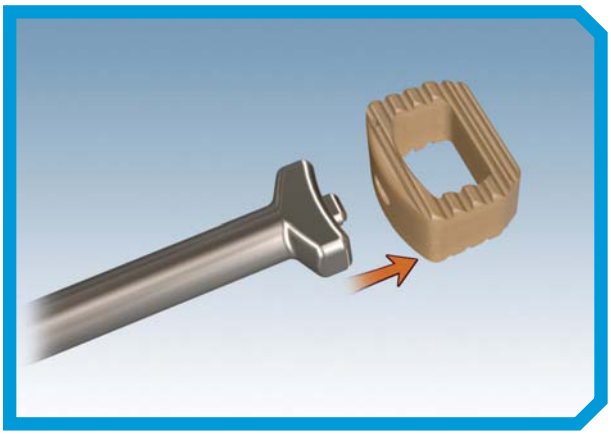
Pull the proximal end away from the distal end.

Pull the knob away from the proximal end.

Do not disassemble the Inserter any further.

Clean and sterilize the instrument per the Zimmer Manual Orthopedic Surgical Instrument Recommendations for Care, Cleaning, Maintenance and Sterilization (97-5000-170-00). This document can be ordered from Zimmer or found at www.zimmer.com.

Step 8a

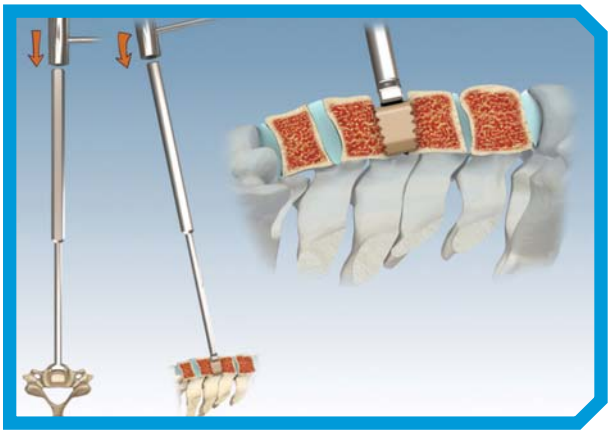


Final Implant Positioning

It may be necessary to use a *Mergence*-S Tamp for final implant seating. The concave surfaces of the Tamps match the convex anterior wall of the device. It may be necessary to tap moderately on the Tamp to fully seat the implant posteriorly. Tapping on the device should move the implant posteriorly. If no motion occurs, remove the device and check for an obstruction of bone or a narrow posterior opening.

Note: For implants with a vertical height of 4mm, the Central Rotating Inserter should be used for final implant positioning.

Step 8b



Tamp Options

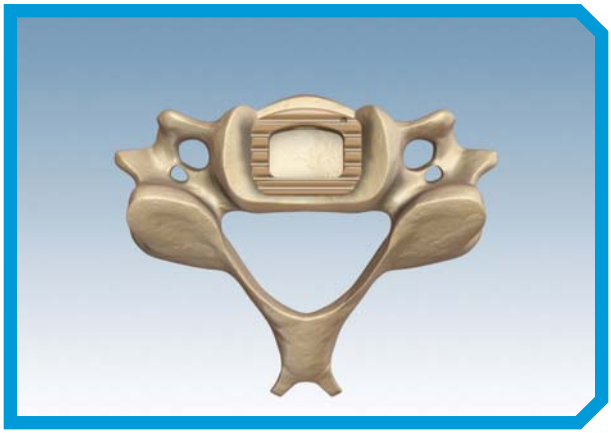
Central Tamp: Insert the tab into the slot on the anterior surface of the device to guide the direction of insertion.

General Tamp: The concave surface of the General Tamp is designed to match the convex anterior wall of the device.

Corner Tamp: The Corner Tamp may be used for lateral or rotational positioning.

Caution: The Central Tamp, General Tamp and Corner Tamp are not compatible with the 4mm height implants.

Step 9



Position Confirmation

Final placement of the implant should be slightly posterior to the anterior aspect of the vertebral bodies. Lateral and A/P radiographs may be taken to assure proper implant placement.

Caution: If difficulty inserting the Vista-S Device is encountered, do not vigorously tap on the implant. Excessive force on the implant may deform or damage the device. Rather, remove the implant and check for an impediment. Additional endplate preparation may be required.

Step 10

Supplemental Fixation

After implantation, anterior or posterior supplemental fixation must be used. Only titanium alloy (ASTM F-136) systems should be used.

Step 11

Post-Operative Management

See package insert for post-operative management regimen. (A summary can also be found in the Precautions section of this surgical technique.)

Step 12

Implant Removal or Revision

Should removal or revision of the device be determined necessary, an Osteotome can be used at the interface between the bone and both superior and inferior faces of the implant. This effectively cuts the fused column of bone at the level of the boundaries of the implant. Once the fused column is completely cut, a Forceps can be used to remove the implant from the space. This may be done under slight distraction. For a revision, follow the standard surgical technique.

Vista-S Devices

Vista-S Devices

Part Number	Description
06-401-01041	11mm x 11mm x 4mm 7° *Vista*-S Angled Device
06-401-01051	11mm x 11mm x 5mm 7° *Vista*-S Angled Device
06-401-01061	11mm x 11mm x 6mm 7° *Vista*-S Angled Device
06-401-01071	11mm x 11mm x 7mm 7° *Vista*-S Angled Device
06-401-01081	11mm x 11mm x 8mm 7° *Vista*-S Angled Device
06-401-01091	11mm x 11mm x 9mm 7° *Vista*-S Angled Device
06-401-01101	11mm x 11mm x 10mm 7° *Vista*-S Angled Device
06-402-01041	11mm x 11mm x 4mm 0° *Vista*-S Parallel Device
06-402-01051	11mm x 11mm x 5mm 0° *Vista*-S Parallel Device
06-402-01061	11mm x 11mm x 6mm 0° *Vista*-S Parallel Device
06-402-01071	11mm x 11mm x 7mm 0° *Vista*-S Parallel Device
06-402-01081	11mm x 11mm x 8mm 0° *Vista*-S Parallel Device
06-402-01091	11mm x 11mm x 9mm 0° *Vista*-S Parallel Device
06-402-01101	11mm x 11mm x 10mm 0° *Vista*-S Parallel Device
06-401-02041	11mm x 14mm x 4mm 7° *Vista*-S Angled Device
06-401-02051	11mm x 14mm x 5mm 7° *Vista*-S Angled Device
06-401-02061	11mm x 14mm x 6mm 7° *Vista*-S Angled Device
06-401-02071	11mm x 14mm x 7mm 7° *Vista*-S Angled Device
06-401-02081	11mm x 14mm x 8mm 7° *Vista*-S Angled Device
06-401-02091	11mm x 14mm x 9mm 7° *Vista*-S Angled Device
06-401-02101	11mm x 14mm x 10mm 7° *Vista*-S Angled Device
06-401-02111	11mm x 14mm x 11mm 7° *Vista*-S Angled Device
06-401-02121	11mm x 14mm x 12mm 7° *Vista*-S Angled Device
06-402-02041	11mm x 14mm x 4mm 0° *Vista*-S Parallel Device
06-402-02051	11mm x 14mm x 5mm 0° *Vista*-S Parallel Device
06-402-02061	11mm x 14mm x 6mm 0° *Vista*-S Parallel Device
06-402-02071	11mm x 14mm x 7mm 0° *Vista*-S Parallel Device
06-402-02081	11mm x 14mm x 8mm 0° *Vista*-S Parallel Device
06-402-02091	11mm x 14mm x 9mm 0° *Vista*-S Parallel Device
06-402-02101	11mm x 14mm x 10mm 0° *Vista*-S Parallel Device
06-402-02111	11mm x 14mm x 11mm 0° *Vista*-S Parallel Device
06-402-02121	11mm x 14mm x 12mm 0° *Vista*-S Parallel Device
06-401-03041	14mm x 14mm x 4mm 7° *Vista*-S Angled Device
06-401-03051	14mm x 14mm x 5mm 7° *Vista*-S Angled Device
06-401-03061	14mm x 14mm x 6mm 7° *Vista*-S Angled Device

CE 0120

Vista-S Devices, continued

Part Number	Description
06-401-03071	14mm x 14mm x 7mm 7° *Vista*-S Angled Device
06-401-03081	14mm x 14mm x 8mm 7° *Vista*-S Angled Device
06-401-03091	14mm x 14mm x 9mm 7° *Vista*-S Angled Device
06-401-03101	14mm x 14mm x 10mm 7° *Vista*-S Angled Device
06-401-03111	14mm x 14mm x 11mm 7° *Vista*-S Angled Device
06-401-03121	14mm x 14mm x 12mm 7° *Vista*-S Angled Device
06-402-03041	14mm x 14mm x 4mm 0° *Vista*-S Parallel Device
06-402-03051	14mm x 14mm x 5mm 0° *Vista*-S Parallel Device
06-402-03061	14mm x 14mm x 6mm 0° *Vista*-S Parallel Device
06-402-03071	14mm x 14mm x 7mm 0° *Vista*-S Parallel Device
06-402-03081	14mm x 14mm x 8mm 0° *Vista*-S Parallel Device
06-402-03091	14mm x 14mm x 9mm 0° *Vista*-S Parallel Device
06-402-03101	14mm x 14mm x 10mm 0° *Vista*-S Parallel Device
06-402-03111	14mm x 14mm x 11mm 0° *Vista*-S Parallel Device
06-402-03121	14mm x 14mm x 12mm 0° *Vista*-S Parallel Device
06-401-04041	13mm x 16mm x 4mm 7° *Vista*-S Angled Device
06-401-04051	13mm x 16mm x 5mm 7° *Vista*-S Angled Device
06-401-04061	13mm x 16mm x 6mm 7° *Vista*-S Angled Device
06-401-04071	13mm x 16mm x 7mm 7° *Vista*-S Angled Device
06-401-04081	13mm x 16mm x 8mm 7° *Vista*-S Angled Device
06-401-04091	13mm x 16mm x 9mm 7° *Vista*-S Angled Device
06-401-04101	13mm x 16mm x 10mm 7° *Vista*-S Angled Device
06-401-04111	13mm x 16mm x 11mm 7° *Vista*-S Angled Device
06-401-04121	13mm x 16mm x 12mm 7° *Vista*-S Angled Device
06-402-04041	13mm x 16mm x 4mm 0° *Vista*-S Parallel Device
06-402-04051	13mm x 16mm x 5mm 0° *Vista*-S Parallel Device
06-402-04061	13mm x 16mm x 6mm 0° *Vista*-S Parallel Device
06-402-04071	13mm x 16mm x 7mm 0° *Vista*-S Parallel Device
06-402-04081	13mm x 16mm x 8mm 0° *Vista*-S Parallel Device
06-402-04091	13mm x 16mm x 9mm 0° *Vista*-S Parallel Device
06-402-04101	13mm x 16mm x 10mm 0° *Vista*-S Parallel Device
06-402-04111	13mm x 16mm x 11mm 0° *Vista*-S Parallel Device
06-402-04121	13mm x 16mm x 12mm 0° *Vista*-S Parallel Device
06-401-05041	14mm x18mm x 4mm 7° *Vista*-S Angled Device
06-401-05051	14mm x 18mm x 5mm 7° *Vista*-S Angled Device

CE 0120

Part Number	Description
06-401-05061	14mm x 18mm x 6mm 7° *Vista*-S Angled Device
06-401-05071	14mm x 18mm x 7mm 7° *Vista*-S Angled Device
06-401-05081	14mm x 18mm x 8mm 7° *Vista*-S Angled Device
06-401-05091	14mm x 18mm x 9mm 7° *Vista*-S Angled Device
06-401-05101	14mm x 18mm x 10mm 7° *Vista*-S Angled Device
06-401-05111	14mm x 18mm x 11mm 7° *Vista*-S Angled Device
06-401-05121	14mm x 18mm x 12mm 7° *Vista*-S Angled Device
06-402-05041	14mm x 18mm x 4mm 0° *Vista*-S Parallel Device
06-402-05051	14mm x 18mm x 5mm 0° *Vista*-S Parallel Device
06-402-05061	14mm x 18mm x 6mm 0° *Vista*-S Parallel Device
06-402-05071	14mm x 18mm x 7mm 0° *Vista*-S Parallel Device
06-402-05081	14mm x 18mm x 8mm 0° *Vista*-S Parallel Device
06-402-05091	14mm x 18mm x 9mm 0° *Vista*-S Parallel Device
06-402-05101	14mm x 18mm x 10mm 0° *Vista*-S Parallel Device
06-402-05111	14mm x 18mm x 11mm 0° *Vista*-S Parallel Device
06-402-05121	14mm x 18mm x 12mm 0° *Vista*-S Parallel Device
06-401-06041	15mm x 20mm x 4mm 7° *Vista*-S Angled Device
06-401-06051	15mm x 20mm x 5mm 7° *Vista*-S Angled Device
06-401-06061	15mm x 20mm x 6mm 7° *Vista*-S Angled Device
06-401-06071	15mm x 20mm x 7mm 7° *Vista*-S Angled Device
06-401-06081	15mm x 20mm x 8mm 7° *Vista*-S Angled Device
06-401-06091	15mm x 20mm x 9mm 7° *Vista*-S Angled Device
06-401-06101	15mm x 20mm x 10mm 7° *Vista*-S Angled Device
06-401-06111	15mm x 20mm x 11mm 7° *Vista*-S Angled Device
06-401-06121	15mm x 20mm x 12mm 7° *Vista*-S Angled Device
06-402-06041	15mm x 20mm x 4mm 0° *Vista*-S Parallel Device
06-402-06051	15mm x 20mm x 5mm 0° *Vista*-S Parallel Device
06-402-06061	15mm x 20mm x 6mm 0° *Vista*-S Parallel Device
06-402-06071	15mm x 20mm x 7mm 0° *Vista*-S Parallel Device
06-402-06081	15mm x 20mm x 8mm 0° *Vista*-S Parallel Device
06-402-06091	15mm x 20mm x 9mm 0° *Vista*-S Parallel Device
06-402-06101	15mm x 20mm x 10mm 0° *Vista*-S Parallel Device
06-402-06111	15mm x 20mm x 11mm 0° *Vista*-S Parallel Device
06-402-06121	15mm x 20mm x 12mm 0° *Vista*-S Parallel Device

CE 0120

Mergence-S Kit Contents

Module Number 96-121-10001

Mergence-S Instruments

Part Number	Description	Standard Kit Quantity
96-106-30001	Central Rotating Inserter	1
96-106-00001	Lateral Grasping Inserter	1
07.00558.001	CSG Inserter	1
96-105-00002	General Tamp	1
96-105-10001	Central Tamp	1
96-105-20001	Corner Tamp	1
96-108-01001	11x11mm Starter Rasp	1
96-108-17051	11x11x5mm Angled Rasp	1
96-108-17061	11x11x6mm Angled Rasp	1
96-108-17071	11x11x7mm Angled Rasp	1
96-108-17081	11x11x8mm Angled Rasp	1
96-108-17091	11x11x9mm Angled Rasp	1
96-108-17101	11x11x10mm Angled Rasp	1
96-108-10051	11x11x5mm Parallel Rasp	1
96-108-10061	11x11x6mm Parallel Rasp	1
96-108-10071	11x11x7mm Parallel Rasp	1
96-108-10081	11x11x8mm Parallel Rasp	1
96-108-10091	11x11x9mm Parallel Rasp	1
96-108-10101	11x11x10mm Parallel Rasp	1
96-108-02001	11x14mm Starter Rasp	1
96-108-27051	11x14x5mm Angled Rasp	1
96-108-27061	11x14x6mm Angled Rasp	1
96-108-27071	11x14x7mm Angled Rasp	1
96-108-27081	11x14x8mm Angled Rasp	1
96-108-27091	11x14x9mm Angled Rasp	1
96-108-27101	11x14x10mm Angled Rasp	1
96-108-20051	11x14x5mm Parallel Rasp	1
96-108-20061	11x14x6mm Parallel Rasp	1
96-108-20071	11x14x7mm Parallel Rasp	1
96-108-20081	11x14x8mm Parallel Rasp	1
96-108-20091	11x14x9mm Parallel Rasp	1
96-108-20101	11x14x10mm Parallel Rasp	1

CE

Part Number	Description	Standard Kit Quantity
96-101-01051	11x11x5mm Angled Provisional	1
96-101-01061	11x11x6mm Angled Provisional	1
96-101-01071	11x11x7mm Angled Provisional	1
96-101-01081	11x11x8mm Angled Provisional	1
96-101-01091	11x11x9mm Angled Provisional	1
96-101-01101	11x11x10mm Angled Provisional	1
96-102-01051	11x11x5mm Parallel Provisional	1
96-102-01061	11x11x6mm Parallel Provisional	1
96-102-01071	11x11x7mm Parallel Provisional	1
96-102-01081	11x11x8mm Parallel Provisional	1
96-102-01091	11x11x9mm Parallel Provisional	1
96-102-01101	11x11x10mm Parallel Provisional	1
96-101-02051	11x14x5mm Angled Provisional	1
96-101-02061	11x14x6mm Angled Provisional	1
96-101-02071	11x14x7mm Angled Provisional	1
96-101-02081	11x14x8mm Angled Provisional	1
96-101-02091	11x14x9mm Angled Provisional	1
96-101-02101	11x14x10mm Angled Provisional	1
96-102-02051	11x14x5mm Parallel Provisional	1
96-102-02061	11x14x6mm Parallel Provisional	1
96-102-02071	11x14x7mm Parallel Provisional	1
96-102-02081	11x14x8mm Parallel Provisional	1
96-102-02091	11x14x9mm Parallel Provisional	1
96-102-02101	11x14x10mm Parallel Provisional	1

CE 0120

Module Number 96-261-30001

Mergence-S Instruments: 4mm,11mm,12mm Heights

Part Number	Description	Standard Kit Quantity
96-108-17041	11x11x4mm Angled Rasp	1
96-108-17111	11x11x11mm Angled Rasp	1
96-108-17121	11x11x12mm Angled Rasp	1
96-108-10041	11x11x4mm Parallel Rasp	1
96-108-10111	11x11x11mm Parallel Rasp	1
96-108-10121	11x11x12mm Parallel Rasp	1
96-108-27041	11x14x4mm Angled Rasp	1
96-108-27111	11x14x11mm Angled Rasp	1
96-108-27121	11x14x12mm Angled Rasp	1
96-108-20041	11x14x4mm Parallel Rasp	1
96-108-20111	11x14x11mm Parallel Rasp	1
96-108-20121	11x14x12mm Parallel Rasp	1
96-108-37041	14x14x4mm Angled Rasp	1
96-108-37111	14x14x11mm Angled Rasp	1
96-108-37121	14x14x12mm Angled Rasp	1
96-108-30041	14x14x4mm Parallel Rasp	1
96-108-30111	14x14x11mm Parallel Rasp	1
96-108-30121	14x14x12mm Parallel Rasp	1

CE

Part Number	Description	Standard Kit Quantity
96-101-01041	11x11x4mm Angled Provisional	1
96-101-01111	11x11x11mm Angled Provisional	1
96-101-01121	11x11x12mm Angled Provisional	1
96-102-01041	11x11x4mm Parallel Provisional	1
96-102-01111	11x11x11mm Parallel Provisional	1
96-102-01121	11x11x12mm Parallel Provisional	1
96-101-02041	11x14x4mm Angled Provisional	1
96-101-02111	11x14x11mm Angled Provisional	1
96-101-02121	11x14x12mm Angled Provisional	1
96-102-02041	11x14x4mm Parallel Provisional	1
96-102-02111	11x14x11mm Parallel Provisional	1
96-102-02121	11x14x12mm Parallel Provisional	1
96-101-03041	14x14x4mm Angled Provisional	1
96-101-03111	14x14x11mm Angled Provisional	1
96-101-03121	14x14x12mm Angled Provisional	1
96-102-03041	14x14x4mm Parallel Provisional	1
96-102-03111	14x14x11mm Parallel Provisional	1
96-102-03121	14x14x12mm Parallel Provisional	1

CE 0120

Module Number 96-261-20001

Mergence-S Instruments: 14x14mm

Part Number	Description	Standard Kit Quantity
96-108-03001	14x14mm Starter Rasp	1
96-108-37051	14x14x5mm Angled Rasp	1
96-108-37061	14x14x6mm Angled Rasp	1
96-108-37071	14x14x7mm Angled Rasp	1
96-108-37081	14x14x8mm Angled Rasp	1
96-108-37091	14x14x9mm Angled Rasp	1
96-108-37101	14x14x10mm Angled Rasp	1
96-108-30051	14x14x5mm Parallel Rasp	1
96-108-30061	14x14x6mm Parallel Rasp	1
96-108-30071	14x14x7mm Parallel Rasp	1
96-108-30081	14x14x8mm Parallel Rasp	1
96-108-30091	14x14x9mm Parallel Rasp	1
96-108-30101	14x14x10mm Parallel Rasp	1

CE

96-101-03051	14x14x5mm Angled Provisional	1
96-101-03061	14x14x6mm Angled Provisional	1
96-101-03071	14x14x7mm Angled Provisional	1
96-101-03081	14x14x8mm Angled Provisional	1
96-101-03091	14x14x9mm Angled Provisional	1
96-101-03101	14x14x10mm Angled Provisional	1
96-102-03051	14x14x5mm Parallel Provisional	1
96-102-03061	14x14x6mm Parallel Provisional	1
96-102-03071	14x14x7mm Parallel Provisional	1
96-102-03081	14x14x8mm Parallel Provisional	1
96-102-03091	14x14x9mm Parallel Provisional	1
96-102-03101	14x14x10mm Parallel Provisional	1

CE 0120

Module Number 07.02231.401

Vista-S Extended Footprint Basic Instrument Set (13x16 & 14x18)

Part Number	Description	Standard Kit Quantity
96-108-40041	13x16x4 Parallel Bone Rasp	1
96-108-50041	14x18x4 Parallel Bone Rasp	1

CE

96-105-00002	General Tamp	1
96-105-10001	Central Tamp	1
96-106-30001	Central Rotating Inserter	1
96-101-04041	13x16x4 Angled Provisional	1
96-101-04051	13x16x5 Angled Provisional	1
96-101-04061	13x16x6 Angled Provisional	1
96-101-04071	13x16x7 Angled Provisional	1
96-101-04081	13x16x8 Angled Provisional	1
96-101-04091	13x16x9 Angled Provisional	1
96-101-04101	13x16x10 Angled Provisional	1
96-101-04111	13x16x11 Angled Provisional	1
96-101-04121	13x16x12 Angled Provisional	1
96-101-05041	14x18x4 Angled Provisional	1
96-101-05051	14x18x5 Angled Provisional	1
96-101-05061	14x18x6 Angled Provisional	1
96-101-05071	14x18x7 Angled Provisional	1
96-101-05081	14x18x8 Angled Provisional	1
96-101-05091	14x18x9 Angled Provisional	1
96-101-05101	14x18x10 Angled Provisional	1
96-101-05111	14x18x11 Angled Provisional	1
96-101-05121	14x18x12 Angled Provisional	1
96-102-04041	13x16x4 Parallel Provisional	1
96-102-04051	13x16x5 Parallel Provisional	1
96-102-04061	13x16x6 Parallel Provisional	1
96-102-04071	13x16x7 Parallel Provisional	1
96-102-04081	13x16x8 Parallel Provisional	1
96-102-04091	13x16x9 Parallel Provisional	1

CE 0120

Vista-S Extended Footprint Basic Instrument Set (13x16 & 14x18), continued

Part Number	Description	Standard Kit Quantity
96-102-04101	13x16x10 Parallel Provisional	1
96-102-04111	13x16x11 Parallel Provisional	1
96-102-04121	13x16x12 Parallel Provisional	1
96-102-05041	14x18x4 Parallel Provisional	1
96-102-05051	14x18x5 Parallel Provisional	1
96-102-05061	14x18x6 Parallel Provisional	1
96-102-05071	14x18x7 Parallel Provisional	1
96-102-05081	14x18x8 Parallel Provisional	1
96-102-05091	14x18x9 Parallel Provisional	1
96-102-05101	14x18x10 Parallel Provisional	1
96-102-05111	14x18x11 Parallel Provisional	1
96-102-05121	14x18x12 Parallel Provisional	1

CE 0120

Module Number 07.02232.401

Mergence-S 13x16 & 14x18 Rasp Auxiliary Set

Part Number	Description	Standard Kit Quantity
96-108-47041	13x16x4 Angled Bone Rasp	1
96-108-47051	13x16x5 Angled Bone Rasp	1
96-108-47061	13x16x6 Angled Bone Rasp	1
96-108-47071	13x16x7 Angled Bone Rasp	1
96-108-47081	13x16x8 Angled Bone Rasp	1
96-108-47091	13x16x9 Angled Bone Rasp	1
96-108-47101	13x16x10 Angled Bone Rasp	1
96-108-47111	13x16x11 Angled Bone Rasp	1
96-108-47121	13x16x12 Angled Bone Rasp	1
96-108-57041	14x18x4 Angled Bone Rasp	1
96-108-57051	14x18x5 Angled Bone Rasp	1
96-108-57061	14x18x6 Angled Bone Rasp	1
96-108-57071	14x18x7 Angled Bone Rasp	1
96-108-57081	14x18x8 Angled Bone Rasp	1
96-108-57091	14x18x9 Angled Bone Rasp	1
96-108-57101	14x18x10 Angled Bone Rasp	1
96-108-57111	14x18x11 Angled Bone Rasp	1
96-108-57121	14x18x12 Angled Bone Rasp	1
96-108-40051	13x16x5 Parallel Bone Rasp	1
96-108-40061	13x16x6 Parallel Bone Rasp	1
96-108-40071	13x16x7 Parallel Bone Rasp	1
96-108-40081	13x16x8 Parallel Bone Rasp	1
96-108-40091	13x16x9 Parallel Bone Rasp	1
96-108-40101	13x16x10 Parallel Bone Rasp	1
96-108-40111	13x16x11 Parallel Bone Rasp	1
96-108-40121	13x16x12 Parallel Bone Rasp	1
96-108-50051	14x18x5 Parallel Bone Rasp	1
96-108-50061	14x18x6 Parallel Bone Rasp	1
96-108-50071	14x18x7 Parallel Bone Rasp	1
96-108-50081	14x18x8 Parallel Bone Rasp	1
96-108-50091	14x18x9 Parallel Bone Rasp	1
96-108-50101	14x18x10 Parallel Bone Rasp	1
96-108-50111	14x18x11 Parallel Bone Rasp	1
96-108-50121	14x18x12 Parallel Bone Rasp	1

CE

Module Number 07.02233.401

Mergence-S 15x20 Rasp & Provisional Prep Set

Part Number	Description	Standard Kit Quantity
96-108-60041	15x20x4 Parallel Bone Rasp	1
96-108-60051	15x20x5 Parallel Bone Rasp	1
96-108-60061	15x20x6 Parallel Bone Rasp	1
96-108-60071	15x20x7 Parallel Bone Rasp	1
96-108-60081	15x20x8 Parallel Bone Rasp	1
96-108-60091	15x20x9 Parallel Bone Rasp	1
96-108-60101	15x20x10 Parallel Bone Rasp	1
96-108-60111	15x20x11 Parallel Bone Rasp	1
96-108-60121	15x20x12 Parallel Bone Rasp	1
96-108-67041	15x20x4 Angled Bone Rasp	1
96-108-67051	15x20x5 Angled Bone Rasp	1
96-108-67061	15x20x6 Angled Bone Rasp	1
96-108-67071	15x20x7 Angled Bone Rasp	1
96-108-67081	15x20x8 Angled Bone Rasp	1
96-108-67091	15x20x9 Angled Bone Rasp	1
96-108-67101	15x20x10 Angled Bone Rasp	1
96-108-67111	15x20x11 Angled Bone Rasp	1
96-108-67121	15x20x12 Angled Bone Rasp	1

CE

Part Number	Description	Standard Kit Quantity
96-102-06041	15x20x4 Parallel Provisional	1
96-102-06051	15x20x5 Parallel Provisional	1
96-102-06061	15x20x6 Parallel Provisional	1
96-102-06071	15x20x7 Parallel Provisional	1
96-102-06081	15x20x8 Parallel Provisional	1
96-102-06091	15x20x9 Parallel Provisional	1
96-102-06101	15x20x10 Parallel Provisional	1
96-102-06111	15x20x11 Parallel Provisional	1
96-102-06121	15x20x12 Parallel Provisional	1
96-101-06041	15x20x4 Angled Provisional	1
96-101-06051	15x20x5 Angled Provisional	1
96-101-06061	15x20x6 Angled Provisional	1
96-101-06071	15x20x7 Angled Provisional	1
96-101-06081	15x20x8 Angled Provisional	1
96-101-06091	15x20x9 Angled Provisional	1
96-101-06101	15x20x10 Angled Provisional	1
96-101-06111	15x20x11 Angled Provisional	1
96-101-06121	15x20x12 Angled Provisional	1

CE 0120

Warnings and Precautions

Warnings

- Surgery is not always successful. Preoperative symptoms may not be relieved or may worsen. Surgical knowledge of the procedure and the device are important, as is patient selection. Patient compliance is also important. Tobacco and alcohol abuse may lead to unsuccessful results.
- Appropriate device selection is crucial to obtain proper fit and to decrease the stress placed on the implant.
- Delayed healing can lead to fracture or breakage of the implants due to increased stress and material fatigue. Patients must be fully informed of all the risks associated with the implant and the importance of following postoperative instructions regarding weight bearing and activity levels to facilitate proper bone growth and healing.
- The implant must be handled carefully following manufacturer's instructions to prevent damage to the implant.
- Implants must not be modified or otherwise processed in any way.
- Once a device has been implanted, it must never be reused. If the package is damaged, opened, or if the expiration date has passed, but the device is not used, the device must be returned to Zimmer. The device must not be resterilized by the end user.
- Results may be worse with multilevel disease. Supplemental fixation is required. The surgeon must be familiar with fixation techniques and appropriate hardware.
- The surgeon must be familiar with the appropriate technique to implant the supplemental internal fixation and the appropriate hardware.
- MRI Compatibility
  - The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.
  - The *Vista*-S Device has not been evaluated for safety or compatibility in the MR environment.
  - The *Vista*-S Device has not been tested for heating or migration in the MR environment.

Surgeon Precautions

- The implantation of an intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

- The surgeon must have a thorough knowledge of the mechanical and material limitations of semicrystaline polymeric surgical implants and be thoroughly familiar with the surgical technique for implanting the *Vista*-S Device for the given Indications for Use.
- The surgeon should be familiar with the various devices and instruments and verify that all are available before beginning the surgery. Additionally, the packaging and implant should be inspected for damage prior to implantation.
- In the event that removal of the implant is considered (e.g. due to loosening, fracture, migration of the implant; infection; increased pain, etc.), the risks versus benefits must be carefully weighed. Such events can occur even after healing, especially in more active patients. Appropriate postoperative care must be given following implant removal to avoid further complication.
- The surgeon must be thoroughly familiar with the options for supplemental internal fixation systems and the associated surgical techniques.
- Implants must be fully seated within the inserter prior to use. Care must be taken not to over-tighten the implant-inserter assembly. Additionally, care must be taken not to manipulate the inserter implant interface in a way not recommended by the surgical technique.
- The surgeon must ensure the implant is properly seated prior to closing of the soft tissue.
- Extreme caution must be used around the spinal cord, nerve roots and blood vessels.

Patient Precautions

- Postoperative care instructions are extremely important and must be followed carefully. Non-compliance with postoperative care instructions could lead to failure of the device, and the possibility of additional surgery to remove the device.
- The patient should limit activities that result in overhead lifting, repetitive neck bending (especially neck extension) and heavy lifting until a physician determines solid bony fusion is achieved.
- An orthotic brace may be worn following surgery for support. The attending physician, based upon each patient's clinical progress, will determine whether a brace is appropriate and, if necessary, the length of time the brace is prescribed.
- Non-steroidal anti-inflammatory and steroidal drugs should be avoided for at least 45 days, or as directed by a physician, postoperatively.

Solutions by the people of Zimmer Spine.

You are devoted to helping your patients reduce their pain and improve their lives. And the people of Zimmer Spine are devoted to you. We are dedicated to supporting you with best-in-class tools, instruments and implants. We are driven by the opportunity to share our unrivaled education and training. We are committed partners who will do everything in our power to assist you in your quest to provide the absolute best in spinal care. And we can be counted on always to act with integrity as ethical partners who are worthy of your trust. We are the people of Zimmer Spine.

Disclaimer:
This documentation 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.

Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects for each product.

LIP047 Rev. C

PEEK-OPTIMA® Polymer is a trademark of Invibio Ltd.

Manufactured by:

Zimmer TMT
10 Pomeroy Road
Parsippany, NJ 07054
201.818.1800

Distributed by:

Zimmer Spine
7375 Bush Lake Road
Minneapolis, MN 55439
800.655.2614

zimmerspine.com

L1379 Rev. E (2014-06)
(851S-1001-00)