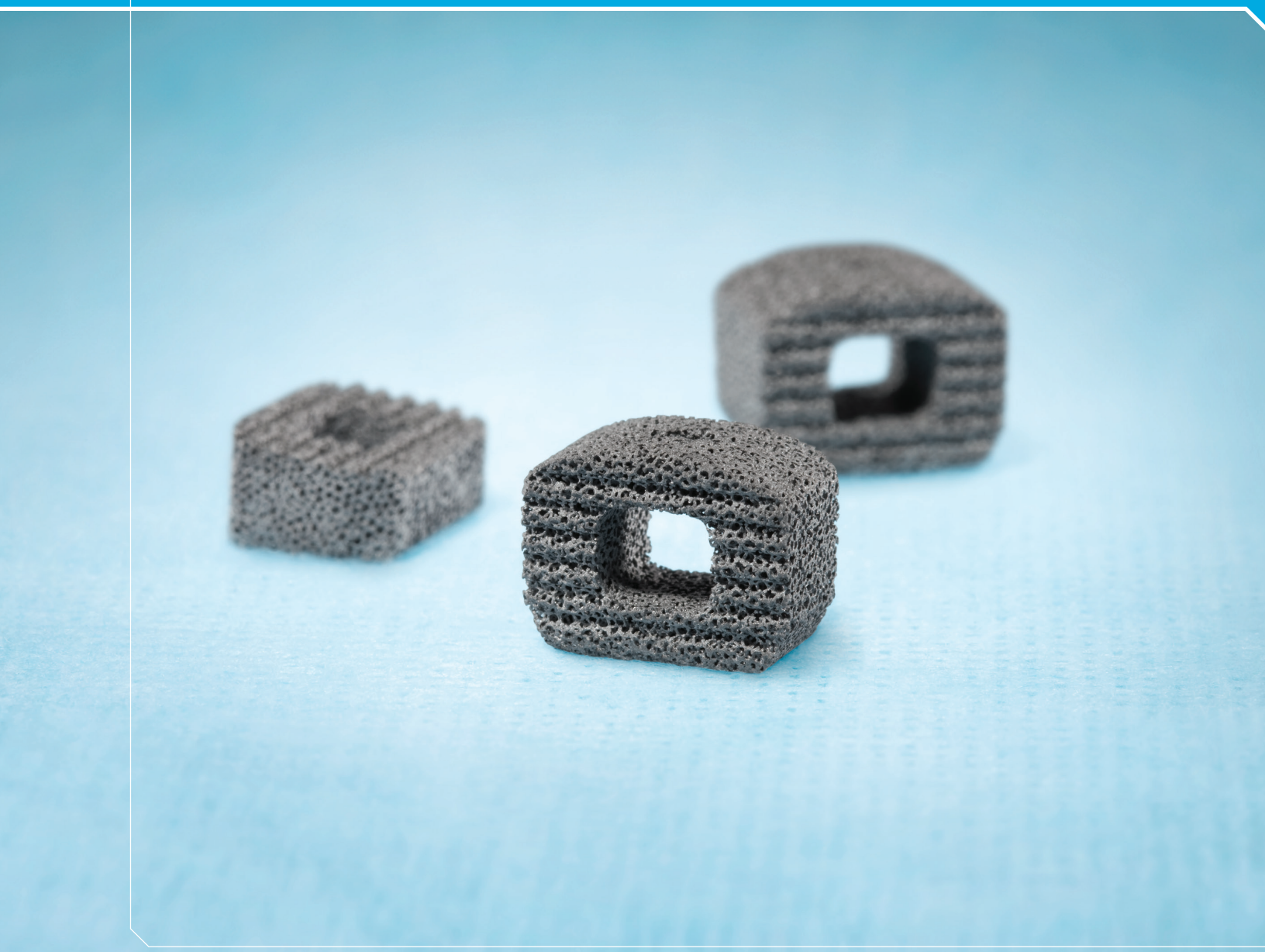
TM-S Fusion Device

Trabecular Metal™ Technology

zimmer

Surgical Technique



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Description

The TM-S Fusion Device is a single device manufactured wholly from Trabecular Metal porous tantalum. The device is a trapezoidal shape and is available in a variety of cross-sectional geometries and sizes. It is offered in a 7° included angle option and a 0° included angle option to help maintain the natural contour of the spine.

The superior and inferior surfaces of the device have a textured surface to provide increased stability. It 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 height is measured at the posterior aspect of the device.

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.

MATERIALS: Trabecular Metal (porous tantalum)

Indications

The TM-S Fusion Device is a cervical interbody fusion device indicated 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 TM-S device is intended for use with supplemental fixation systems and with autogenous bone graft. The TM-S Fusion Device is implanted via an anterior approach.

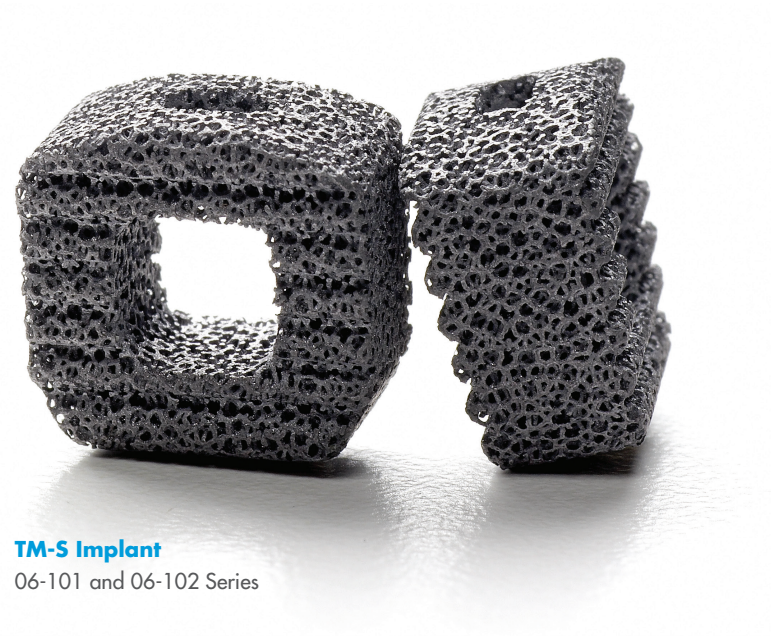
Contraindications

- 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 metal sensitivity.
- 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.

TM-S Implants

TM-S Fusion Device implants are available in three depth x width sizes: 11mm x 11mm, 11mm x 14mm and 14mm x 14mm. All three sizes are available in vertical heights of 4mm to 12mm, in 1mm increments. 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. TM-S 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 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.



TM-S Implant
06-101 and 06-102 Series

TM-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˚
	11	0˚, 7˚
	12	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˚

Mergence®-S Instruments

The *Mergence*-S Spinal Instrumentation Platform is designed to aid in the implantation of Zimmer Spine's TM-S Fusion Device. The Smith-Robinson surgical technique is utilized with standard instruments, except those specifically related to the sizing and insertion of the TM-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 (11mm x 11mm, 7°)

96-101-01041 to 96-101-01121

96-108-17041 to 96-108-17121

Assist in the measurement and preparation of the implant space.

Provisionals and Rasps (11mm x 14mm, 7°)

96-101-02041 to 96-101-02121

96-108-27041 to 96-108-27121

Assist in the measurement and preparation of the implant space.

Provisionals and Rasps (14mm x 14mm, 7°)

96-101-03041 to 96-101-03121

96-108-37041 to 96-108-37121

Assist in the measurement and preparation of the implant space.

Provisionals and Rasps (11mm x 11mm, 0°)

96-102-01041 to 96-102-01121

96-108-10041 to 96-108-10121

Assist in the measurement and preparation of the implant space.

Provisionals and Rasps (11mm x 14mm, 0°)

96-102-02041 to 96-102-02121

96-108-20041 to 96-108-20121

Assist in the measurement and preparation of the implant space.

Provisionals and Rasps (14mm x 14mm, 0°)

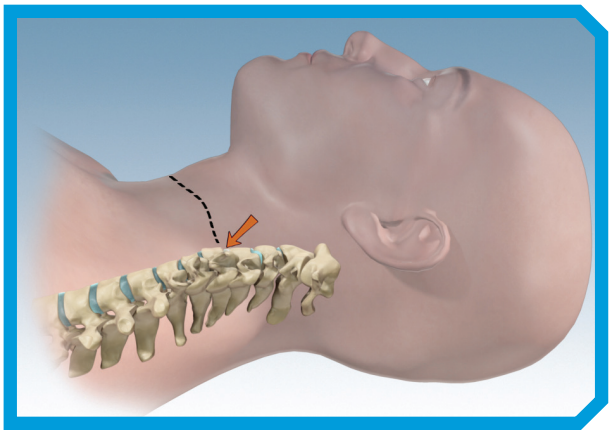
96-102-03041 to 96-102-03121

96-108-30041 to 96-108-30121

Assist in the measurement and preparation of the implant space.

Surgical Technique

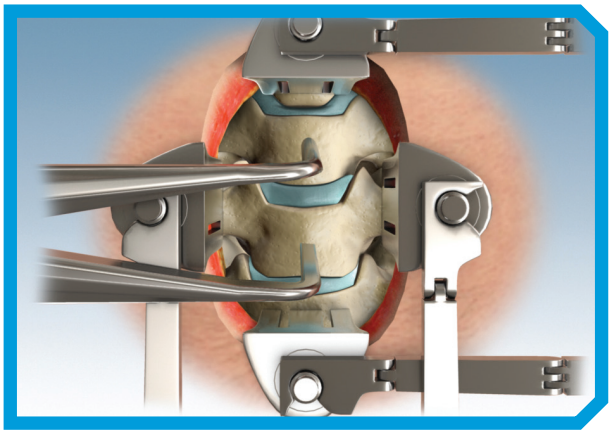
Step 1



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

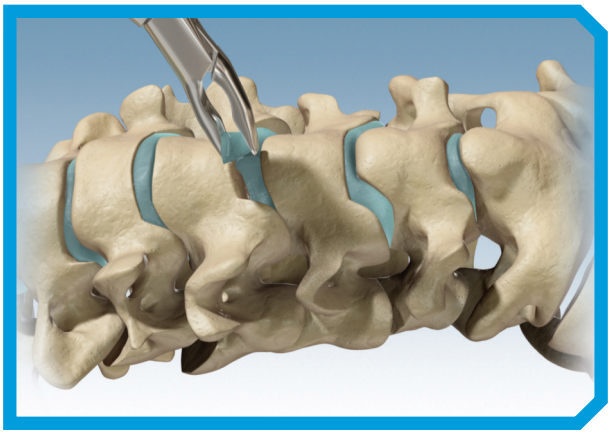


Exposure and Location

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

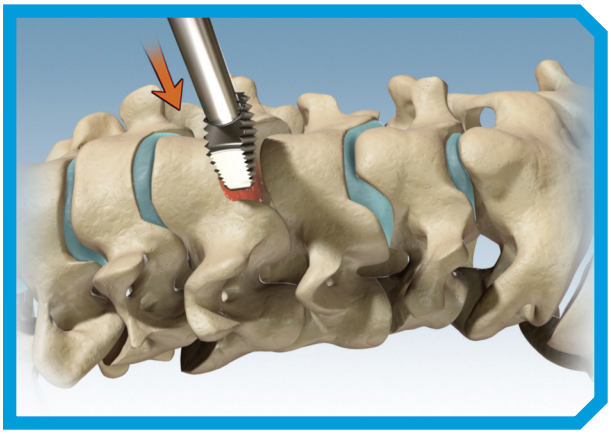


Discectomy

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

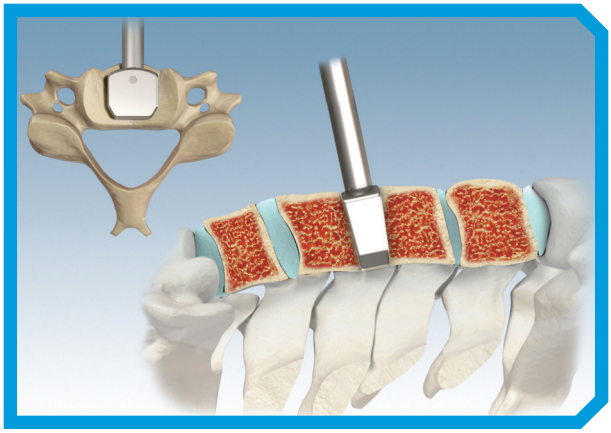


Endplate Preparation

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.

Caution: ***Using excessive force with the instrumentation can inadvertently rupture the posterior annulus or damage the vertebral endplates.***

Step 5



Implant Selection

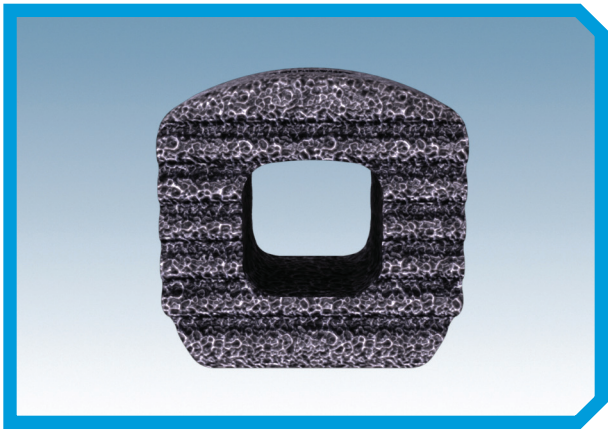
Determine the implant size by measuring the disc space using the *Mergence*-S Provisionals (Trials). Insert a Provisional and select the size that sufficiently fits the disc space. The proper Provisional will tension the soft tissue crossing that selected disc space. Proper tension is determined by the 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 TM-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



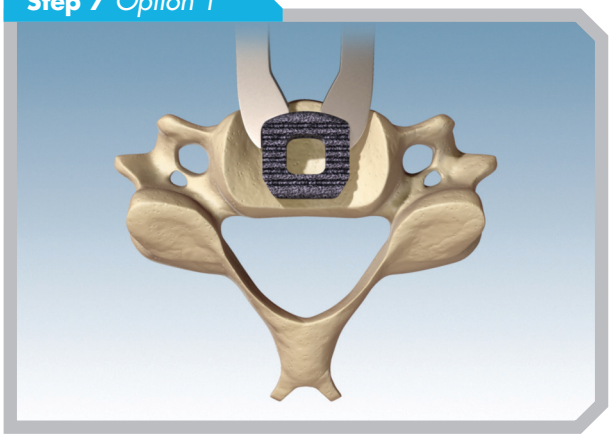
Bone Grafting

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*

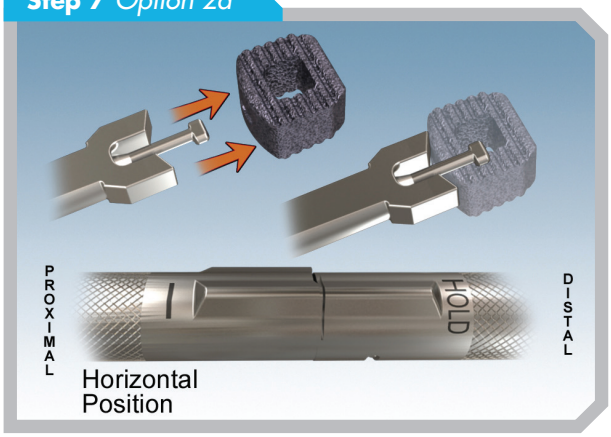


Lateral Inserter

Ensure that the Lateral 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 Inserter is not compatible with the 06-101-0X041, 06-102-0X041, 06-101-0X051, 06-102-0X051, and 06-102-0X061 implants.*

Step 7 *Option 2a*



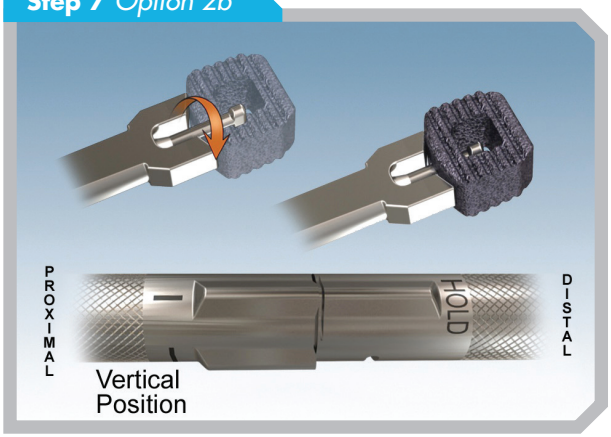
Central Rotating Inserter

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 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 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.

Caution: Excessive force on the Inserter can damage the instrument or the device.

Step 7 *Option 2d*

Central Rotating Inserter Disassembly

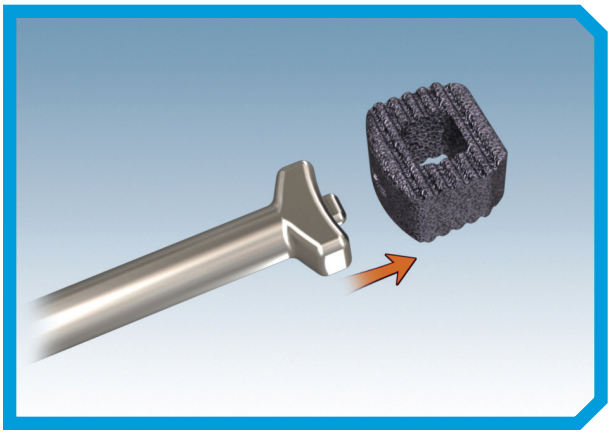
Hold the distal end of Inserter and rotate the proximal end clockwise until a stop is reached. Pull the proximal end away from the distal end.

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

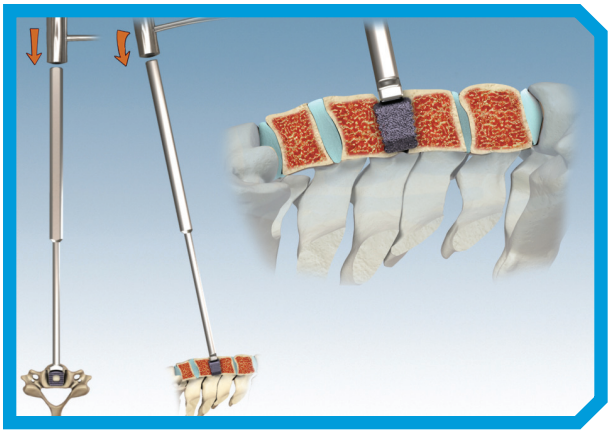


Final Implant Positioning

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 06-101-0X041, 06-102-0X041, and 06-102-0X051, the Central Rotating Inserter should be used for final implant positioning.

Step 8b



Tamp Options

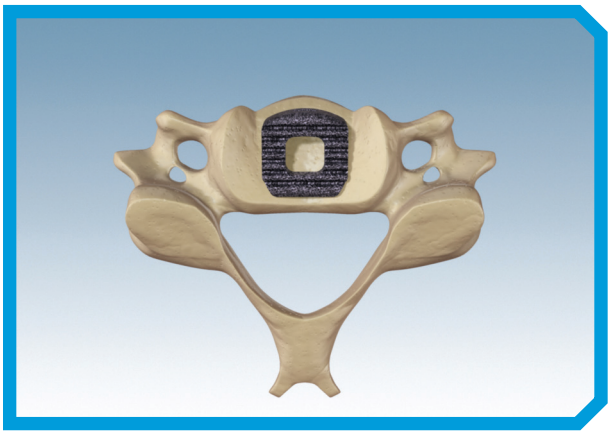
Central Tamp: Insert the tab into the slot on the anterior surface of the device to guide the direction of insertion.

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 06-101-0X041, 06-102-0X041, and 06-102-0X051 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 TM-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. Care must be taken to avoid using dissimilar metals in contact with one another as corrosion may occur.

Step 11

Post-Operative Management

See package insert for post-operative management regimen.

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, 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.

TM-S Kit Contents

TM-S Fusion Devices

Part Number	Description
06-101-01041	11mm x 11mm x 4mm 7° TM-S Angled Device
06-101-01051	11mm x 11mm x 5mm 7° TM-S Angled Device
06-101-01061	11mm x 11mm x 6mm 7° TM-S Angled Device
06-101-01071	11mm x 11mm x 7mm 7° TM-S Angled Device
06-101-01081	11mm x 11mm x 8mm 7° TM-S Angled Device
06-101-01091	11mm x 11mm x 9mm 7° TM-S Angled Device
06-101-01101	11mm x 11mm x 10mm 7° TM-S Angled Device
06-101-01111	11mm x 11mm x 11mm 7° TM-S Angled Device
06-101-01121	11mm x 11mm x 12mm 7° TM-S Angled Device
06-102-01041	11mm x 11mm x 4mm 0° TM-S Parallel Device
06-102-01051	11mm x 11mm x 5mm 0° TM-S Parallel Device
06-102-01061	11mm x 11mm x 6mm 0° TM-S Parallel Device
06-102-01071	11mm x 11mm x 7mm 0° TM-S Parallel Device
06-102-01081	11mm x 11mm x 8mm 0° TM-S Parallel Device
06-102-01091	11mm x 11mm x 9mm 0° TM-S Parallel Device
06-102-01101	11mm x 11mm x 10mm 0° TM-S Parallel Device
06-102-01111	11mm x 11mm x 11mm 0° TM-S Parallel Device
06-102-01121	11mm x 11mm x 12mm 0° TM-S Parallel Device
06-101-02041	11mm x 14mm x 4mm 7° TM-S Angled Device
06-101-02051	11mm x 14mm x 5mm 7° TM-S Angled Device
06-101-02061	11mm x 14mm x 6mm 7° TM-S Angled Device
06-101-02071	11mm x 14mm x 7mm 7° TM-S Angled Device
06-101-02081	11mm x 14mm x 8mm 7° TM-S Angled Device
06-101-02091	11mm x 14mm x 9mm 7° TM-S Angled Device
06-101-02101	11mm x 14mm x 10mm 7° TM-S Angled Device
06-101-02111	11mm x 14mm x 11mm 7° TM-S Angled Device
06-101-02121	11mm x 14mm x 12mm 7° TM-S Angled Device
06-102-02041	11mm x 14mm x 4mm 0° TM-S Parallel Device
06-102-02051	11mm x 14mm x 5mm 0° TM-S Parallel Device
06-102-02061	11mm x 14mm x 6mm 0° TM-S Parallel Device
06-102-02071	11mm x 14mm x 7mm 0° TM-S Parallel Device
06-102-02081	11mm x 14mm x 8mm 0° TM-S Parallel Device
06-102-02091	11mm x 14mm x 9mm 0° TM-S Parallel Device

CE 0120

Part Number	Description
06-102-02101	11mm x 14mm x 10mm 0° TM-S Parallel Device
06-102-02111	11mm x 14mm x 11mm 0° TM-S Parallel Device
06-102-02121	11mm x 14mm x 12mm 0° TM-S Parallel Device
06-101-03041	14mm x 14mm x 4mm 7° TM-S Angled Device
06-101-03051	14mm x 14mm x 5mm 7° TM-S Angled Device
06-101-03061	14mm x 14mm x 6mm 7° TM-S Angled Device
06-101-03071	14mm x 14mm x 7mm 7° TM-S Angled Device
06-101-03081	14mm x 14mm x 8mm 7° TM-S Angled Device
06-101-03091	14mm x 14mm x 9mm 7° TM-S Angled Device
06-101-03101	14mm x 14mm x 10mm 7° TM-S Angled Device
06-101-03111	14mm x 14mm x 11mm 7° TM-S Angled Device
06-101-03121	14mm x 14mm x 12mm 7° TM-S Angled Device
06-102-03041	14mm x 14mm x 4mm 0° TM-S Parallel Device
06-102-03051	14mm x 14mm x 5mm 0° TM-S Parallel Device
06-102-03061	14mm x 14mm x 6mm 0° TM-S Parallel Device
06-102-03071	14mm x 14mm x 7mm 0° TM-S Parallel Device
06-102-03081	14mm x 14mm x 8mm 0° TM-S Parallel Device
06-102-03091	14mm x 14mm x 9mm 0° TM-S Parallel Device
06-102-03101	14mm x 14mm x 10mm 0° TM-S Parallel Device
06-102-03111	14mm x 14mm x 11mm 0° TM-S Parallel Device
06-102-03121	14mm x 14mm x 12mm 0° TM-S Parallel Device

CE 0120

Module Number 96-121-10001

Mergence-S Instruments

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

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

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

Part Number	Description	Standard Kit Quantity
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 96-261-30001

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

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

CE

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

CE 0120

Mergence-*S* Instruments: 4mm, 11mm, 12mm Heights (cont'd)

Part Number	Description	Standard Kit Quantity
96-101-03121	14x14x12mm Provisional - Angled	1
96-102-01041	11x11x4mm Provisional - Parallel	1
96-102-01111	11x11x11mm Provisional - Parallel	1
96-102-01121	11x11x12mm Provisional - Parallel	1
96-102-02041	11x14x4mm Provisional - Parallel	1
96-102-02111	11x14x11mm Provisional - Parallel	1
96-102-02121	11x14x12mm Provisional - Parallel	1
96-102-03041	14x14x4mm Provisional - Parallel	1
96-102-03111	14x14x11mm Provisional - Parallel	1
96-102-03121	14x14x12mm Provisional - Parallel	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.
- Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- Appropriate device selection is crucial to obtain proper fit and to decrease the stress placed on the implant.
- Components of competitive spinal systems should not be used with the TM-S Fusion Device.
- 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 the manufacturer's instructions to prevent damage to the implant.
- Implants must not be modified or otherwise processed in any way.
- Care must be taken to avoid using dissimilar metals in contact with one another as corrosion may occur. Additional fixation instrumentation that is used to stabilize the affected level must be made of compatible materials, such as Titanium or Titanium alloy. Corrosion may accelerate metal fatigue and lead to failure of the implant.
- Once a device has been implanted, it must never be reused. If the package is damaged or opened but the device is not used, or if the expiration date has passed, the device must be returned to Zimmer. The device must not be resterilized by the end user.
- 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 TM-S Fusion Device has not been evaluated for safety or compatibility in the MR environment.
  - The TM-S Fusion Device has not been tested for heating or migration in the MR environment.
- This surgical procedure requires the use of supplemental fixation systems to stabilize the fusion site.

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 the fatigue testing results, the physician/surgeon should consider the level 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 surgical implants made of Trabecular Metal and be thoroughly familiar with the surgical technique for implanting the TM-S Fusion 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 that 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.

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.

LIP-45 Rev. D

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