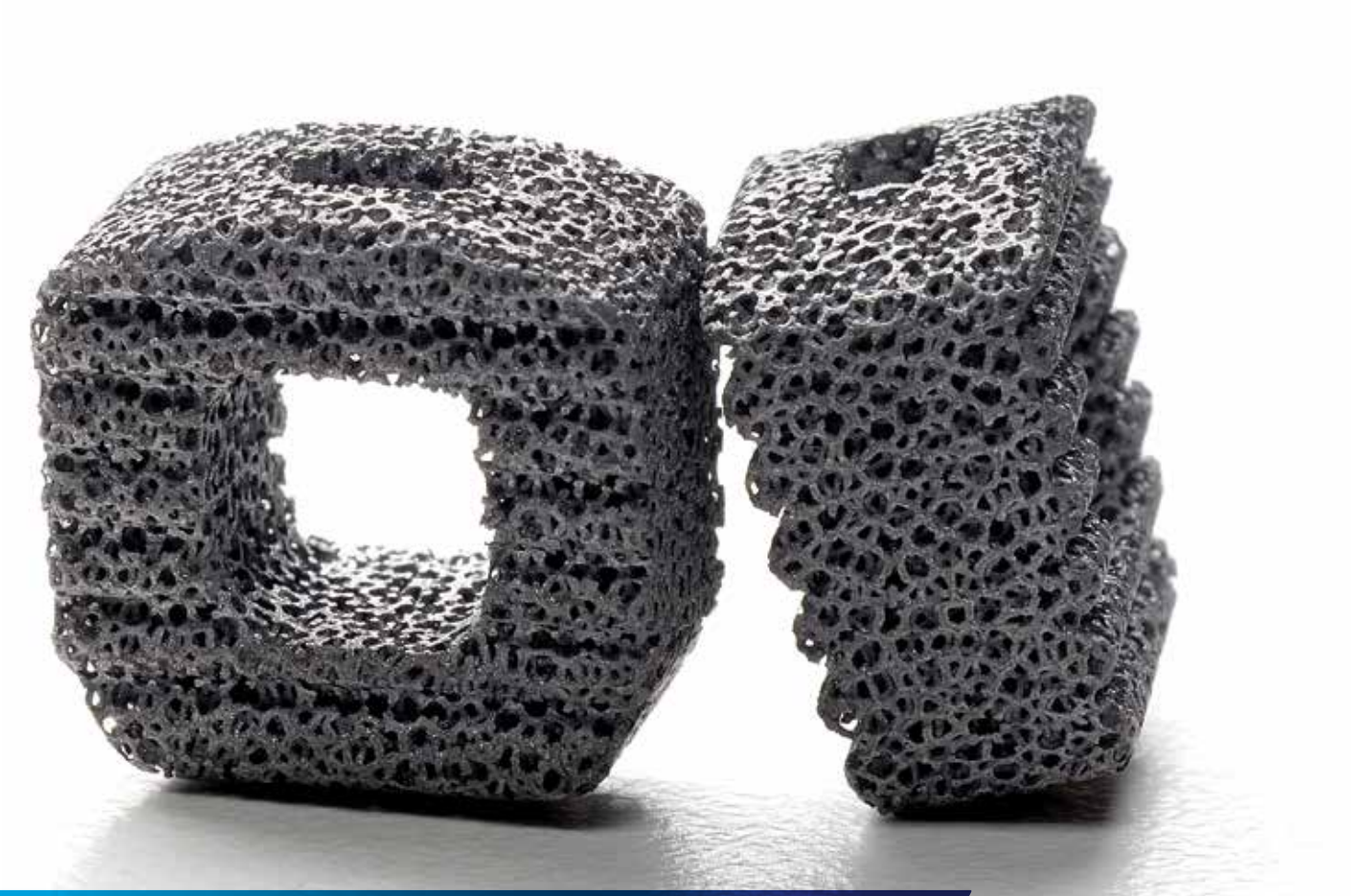
ZIMMER BIOMET

Your progress. Our promise.®



Cervical Solutions

TM-S Fusion Device

Trabecular Metal™ Technology

Surgical Technique Guide

TM-S Fusion Device
Trabecular Metal Technology

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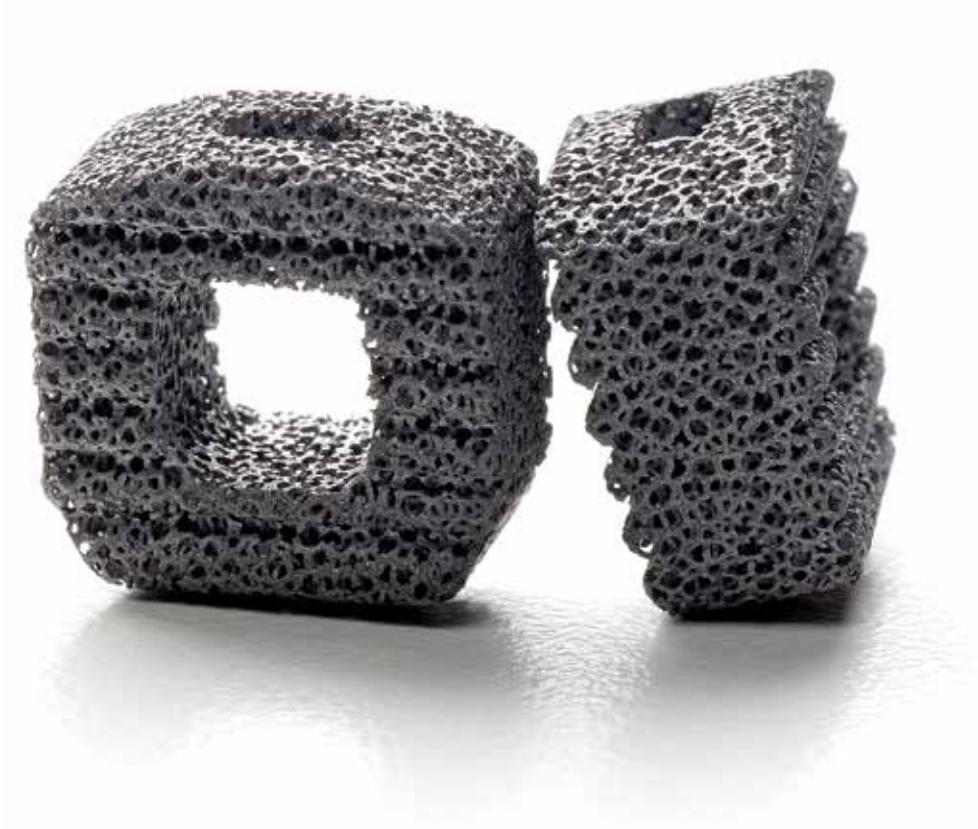
Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an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

IMPLANT OVERVIEW

Implant Overview

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



PREOPERATIVE PLANNING AND PATIENT POSITIONING

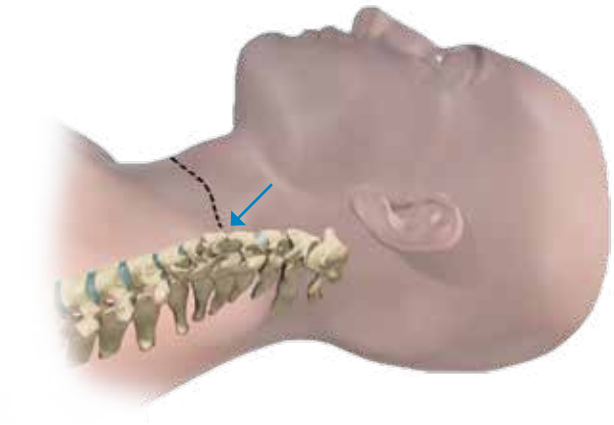


Figure 1
Identify vertebral level

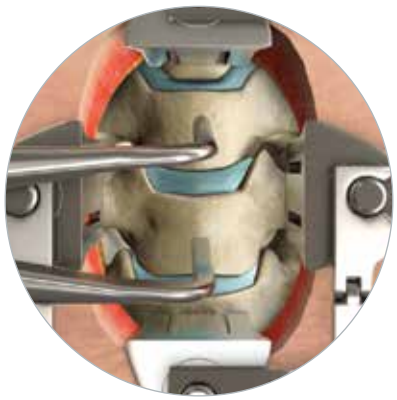


Figure 2
Exposure and location

STEP 1

- Preoperatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiography, magnetic resonance imaging (MRI), myelography, discography, patient history and physical examination.
- Place the patient in supine position.
- Support the posterior cervical spine to maintain normal lordosis and choose a right- or left-sided approach.
- Identify the symptomatic level and make a skin incision to the corresponding pathology.

STEP 2

- 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 with 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 vertebrae adjacent to the discectomy.

SURGICAL APPROACH

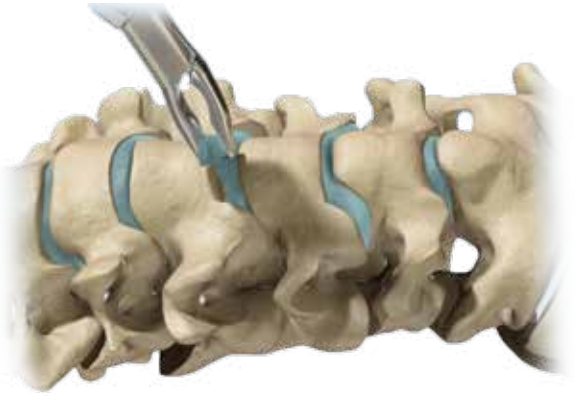


Figure 3
Discectomy

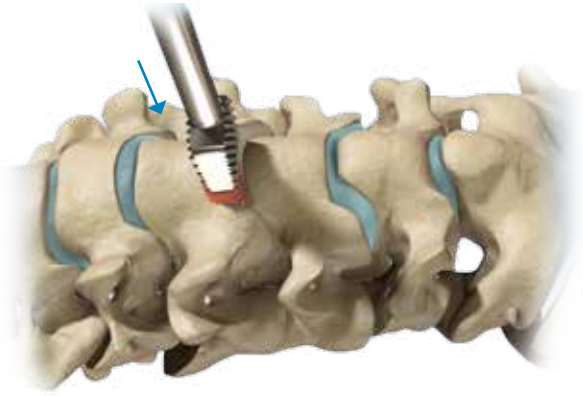


Figure 4
Endplate preparation

STEP 3

- 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: *Care should be taken to ensure that all exposed blood vessels and nerves are properly retracted before the discectomy to avoid unintended contact with the curettes and rongeurs.*

STEP 4

- 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.*

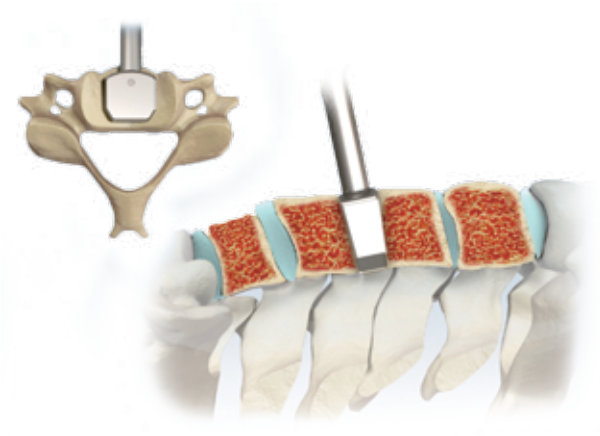


Figure 5
Implant selection

STEP 5

- 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 2 mm greater than the preoperative 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 1 mm smaller than the provisional being used.*

IMPLANT INSERTION OPTIONS

Figure 6
Bone grafting

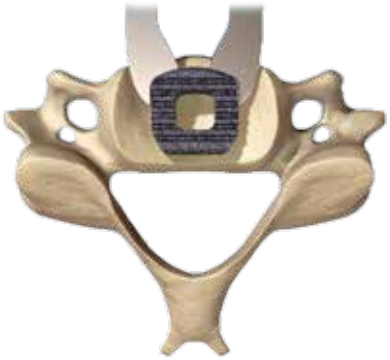


Figure 7
Lateral inserter

STEP 6

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

STEP 7, OPTION 1

- 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 06-101-01041, 06-101-02041, 06-102-0X041, 06-101-01051, 06-101-02051, 06-102-0X051 and 06-102-0X061 implants.*

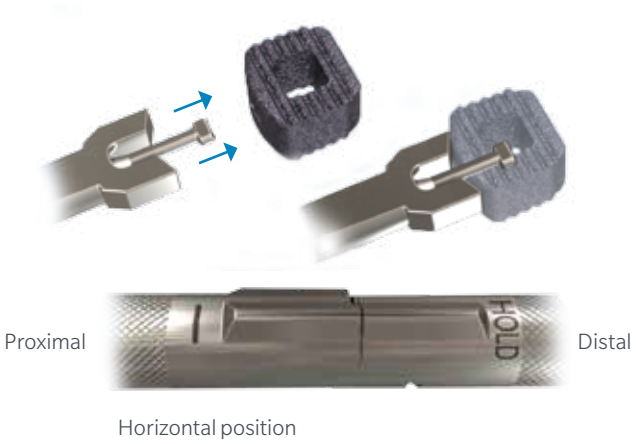


Figure 8
Central rotating inserter

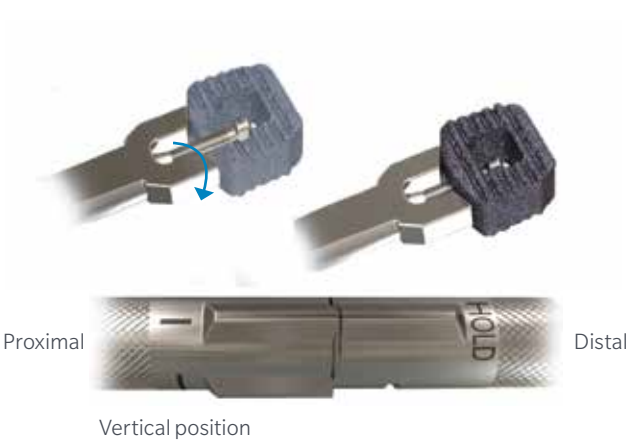


Figure 9
Inserter positioning

STEP 7, OPTION 2

- 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 aligned 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: *Figure 8 shows the tab in a horizontal position, which allows for placement and removal of implant.*

- 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 aligned 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: *Figure 9 shows the tab in a vertical position, which allows for securing the device onto the inserter.*

IMPLANT INSERTION OPTIONS *(continued)*

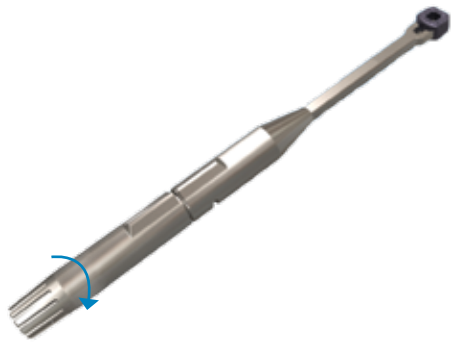


Figure 10
Securing central rotating inserter

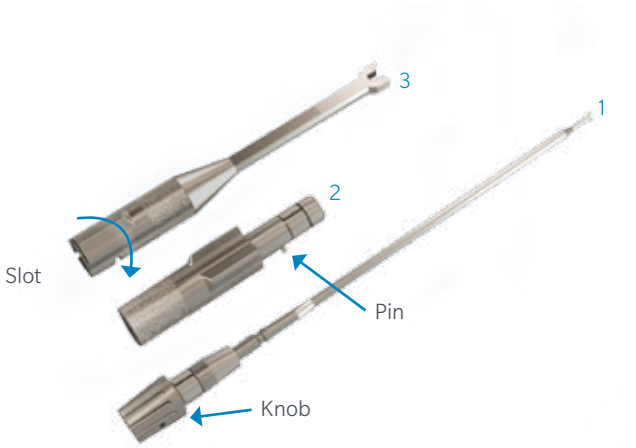


Figure 11
Central rotating inserter disassembly

STEP 7, OPTION 2 *(continued)*

- 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.*

- Hold the distal end of inserter (component 3) and rotate the proximal end (component 3) 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 instrument processing instructions found in the TM-S Fusion Device Package Insert (PI 046).

Central Rotating Inserter Reassembly

- Slide the distal end of component 1 into the proximal end of component 2 until the knob meets the proximal end of component 2. Apply force if necessary.
- Slide the distal end of the assembled components 1 and 2 into the proximal end of component 3 while aligning the pin on component 2 with the slot on component 3. Push them together until the pin reaches the end of the slot.

IMPLANT POSITIONING

Figure 12
Final implant positioning

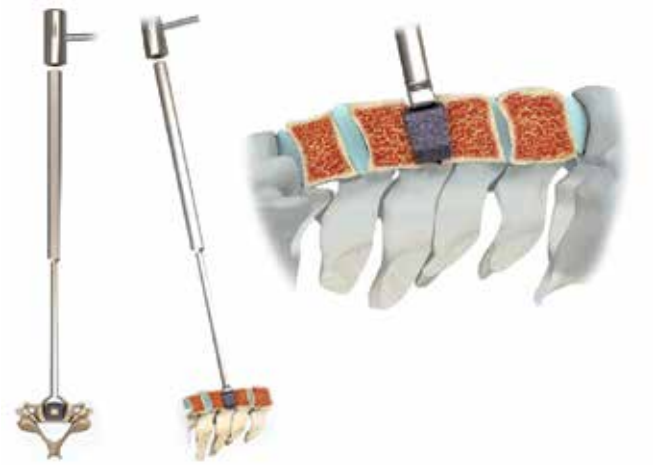


Figure 13
Tamp options

STEP 8

- 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 06-101-01041, 06-101-02041, 06-102-0X041 and 06-102-0X051, the central rotating inserter should be used for final implant positioning.*

- **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 06-101-01041, 06-101-02041, 06-102-0X041 and 06-102-0X051 implants.*

IMPLANT POSITIONING *(continued)*

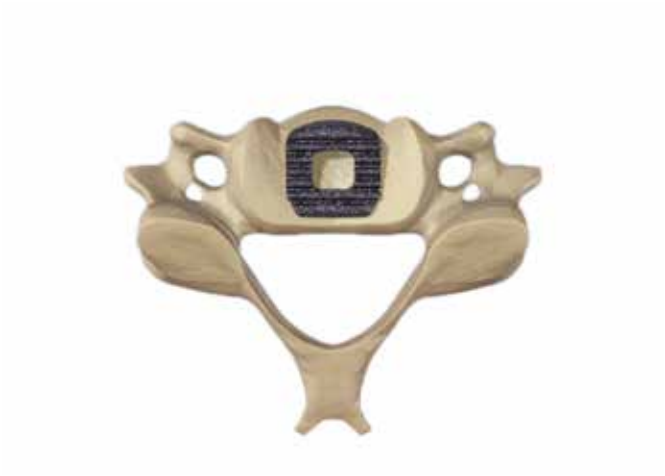


Figure 14
Position confirmation

STEP 9

- Final placement of the implant should be slightly posterior to the anterior aspect of the vertebral bodies. Lateral and anteroposterior radiographs may be taken to ensure proper implant placement.

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

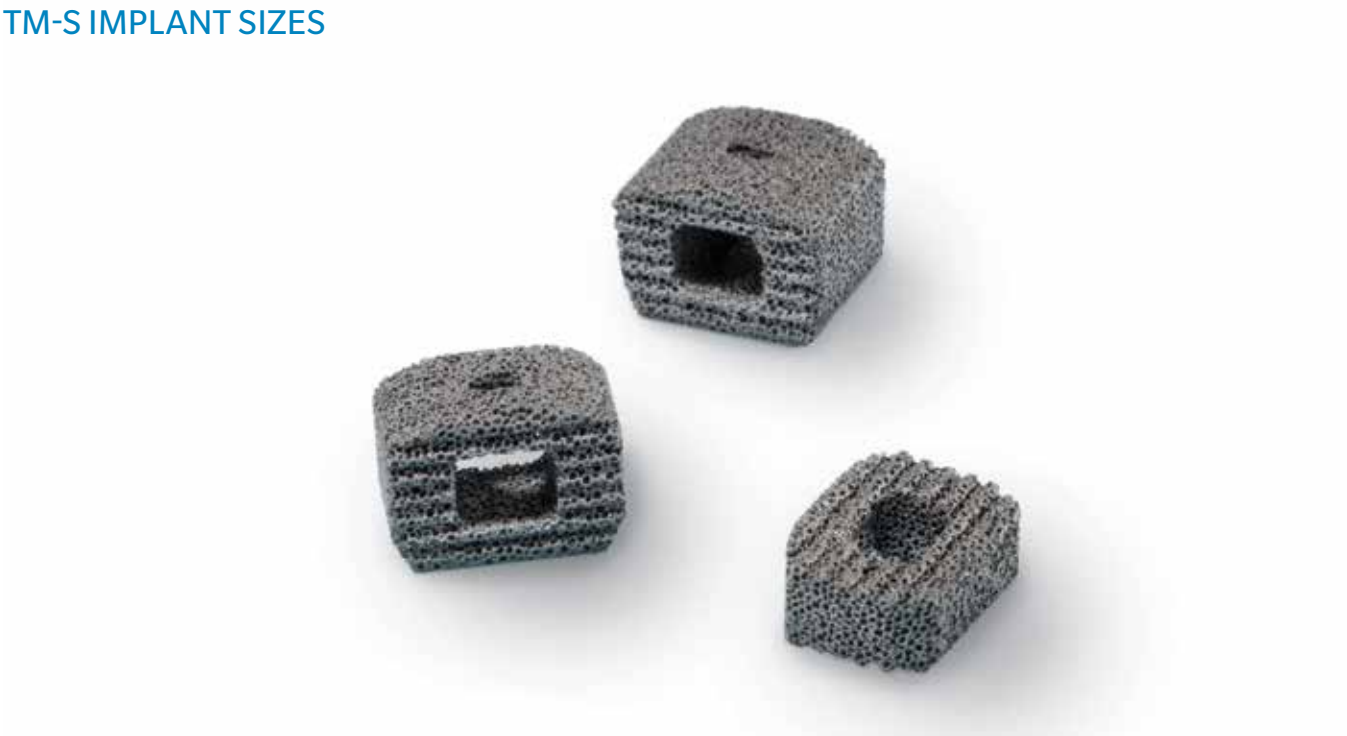
Supplemental Fixation

- 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.

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 IMPLANT SIZES



LENGTH × WIDTH	HEIGHT	ANGLE
11 mm × 11 mm	4 mm	0°, 7°
11 mm × 11 mm	5 mm	0°, 7°
11 mm × 11 mm	6 mm	0°, 7°
11 mm × 11 mm	7 mm	0°, 7°
11 mm × 11 mm	8 mm	0°, 7°
11 mm × 11 mm	9 mm	0°, 7°
11 mm × 11 mm	10 mm	0°, 7°
11 mm × 11 mm	11 mm	0°, 7°
11 mm × 11 mm	12 mm	0°, 7°

LENGTH × WIDTH	HEIGHT	ANGLE
11 mm × 14 mm	4 mm	0°, 7°
11 mm × 14 mm	5 mm	0°, 7°
11 mm × 14 mm	6 mm	0°, 7°
11 mm × 14 mm	7 mm	0°, 7°
11 mm × 14 mm	8 mm	0°, 7°
11 mm × 14 mm	9 mm	0°, 7°
11 mm × 14 mm	10 mm	0°, 7°
11 mm × 14 mm	11 mm	0°, 7°
11 mm × 14 mm	12 mm	0°, 7°

LENGTH × WIDTH	HEIGHT	ANGLE
14 mm × 14 mm	4 mm	0°, 7°
14 mm × 14 mm	5 mm	0°, 7°
14 mm × 14 mm	6 mm	0°, 7°
14 mm × 14 mm	7 mm	0°, 7°
14 mm × 14 mm	8 mm	0°, 7°
14 mm × 14 mm	9 mm	0°, 7°
14 mm × 14 mm	10 mm	0°, 7°
14 mm × 14 mm	11 mm	0°, 7°
14 mm × 14 mm	12 mm	0°, 7°

MERGENCE-S INSTRUMENTS

The Mergence-S Spinal Instrumentation Platform is designed to aid in the implantation of the TM-S Fusion Device. The Smith-Robinson surgical technique is used with standard instruments, except those specifically related to the sizing and insertion of the TM-S Fusion Device. Provisionals and rasps are provided to assist in the measurement and preparation of the implant space.

Lateral Grasping Inserter	PART NUMBER
	96-106-00001

Central Rotating Inserter	PART NUMBER
	96-106-30001

General Tamp	PART NUMBER
	96-105-00002

Corner Tamp	PART NUMBER
	96-105-20001

Central Tamp	PART NUMBER
	96-105-10001

Provisionals and Rasps*

LENGTH × WIDTH	ANGLE	COLOR
11 mm × 11 mm	7°	Blue
11 mm × 11 mm	0°	White
11 mm × 14 mm	7°	Yellow
11 mm × 14 mm	0°	Green
14 mm × 14 mm	7°	Red
14 mm × 14 mm	0°	Black

**Available in multiple sizes to assist in the measurement and preparation of the implant space. Color coded for easy identification.*

TM-S IMPLANTS

TM-S Fusion Devices

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

CE 0120

TM-S IMPLANTS *(continued)*

TM-S Fusion Devices *(continued)*

DESCRIPTION	PART NUMBER
TM-S Angled Device, 14 mm × 14 mm × 4 mm, 7°	06-101-03041
TM-S Angled Device, 14 mm × 14 mm × 5 mm, 7°	06-101-03051
TM-S Angled Device, 14 mm × 14 mm × 6 mm, 7°	06-101-03061
TM-S Angled Device, 14 mm × 14 mm × 7 mm, 7°	06-101-03071
TM-S Angled Device, 14 mm × 14 mm × 8 mm, 7°	06-101-03081
TM-S Angled Device, 14 mm × 14 mm × 9 mm, 7°	06-101-03091
TM-S Angled Device, 14 mm × 14 mm × 10 mm, 7°	06-101-03101
TM-S Angled Device, 14 mm × 14 mm × 11 mm, 7°	06-101-03111
TM-S Angled Device, 14 mm × 14 mm × 12 mm, 7°	06-101-03121
TM-S Parallel Device, 14 mm × 14 mm × 4 mm, 0°	06-102-03041
TM-S Parallel Device, 14 mm × 14 mm × 5 mm, 0°	06-102-03051
TM-S Parallel Device, 14 mm × 14 mm × 6 mm, 0°	06-102-03061
TM-S Parallel Device, 14 mm × 14 mm × 7 mm, 0°	06-102-03071
TM-S Parallel Device, 14 mm × 14 mm × 8 mm, 0°	06-102-03081
TM-S Parallel Device, 14 mm × 14 mm × 9 mm, 0°	06-102-03091
TM-S Parallel Device, 14 mm × 14 mm × 10 mm, 0°	06-102-03101
TM-S Parallel Device, 14 mm × 14 mm × 11 mm, 0°	06-102-03111
TM-S Parallel Device, 14 mm × 14 mm × 12 mm, 0°	06-102-03121

CE 0120

TM-S KIT CONTENTS

Mergence-S Instrument Kit (96-121-10001)

DESCRIPTION	PART NUMBER
Angled Provisional, 11 mm × 11 mm × 5 mm	96-101-01051
Angled Provisional, 11 mm × 11 mm × 6 mm	96-101-01061
Angled Provisional, 11 mm × 11 mm × 7 mm	96-101-01071
Angled Provisional, 11 mm × 11 mm × 8 mm	96-101-01081
Angled Provisional, 11 mm × 11 mm × 9 mm	96-101-01091
Angled Provisional, 11 mm × 11 mm × 10 mm	96-101-01101
Parallel Provisional, 11 mm × 11 mm × 5 mm	96-102-01051
Parallel Provisional, 11 mm × 11 mm × 6 mm	96-102-01061
Parallel Provisional, 11 mm × 11 mm × 7 mm	96-102-01071
Parallel Provisional, 11 mm × 11 mm × 8 mm	96-102-01081
Parallel Provisional, 11 mm × 11 mm × 9 mm	96-102-01091
Parallel Provisional, 11 mm × 11 mm × 10 mm	96-102-01101
Angled Provisional, 11 mm × 14 mm × 5 mm	96-101-02051
Angled Provisional, 11 mm × 14 mm × 6 mm	96-101-02061
Angled Provisional, 11 mm × 14 mm × 7 mm	96-101-02071
Angled Provisional, 11 mm × 14 mm × 8 mm	96-101-02081
Angled Provisional, 11 mm × 14 mm × 9 mm	96-101-02091
Angled Provisional, 11 mm × 14 mm × 10 mm	96-101-02101
Parallel Provisional, 11 mm × 14 mm × 5 mm	96-102-02051
Parallel Provisional, 11 mm × 14 mm × 6 mm	96-102-02061
Parallel Provisional, 11 mm × 14 mm × 7 mm	96-102-02071
Parallel Provisional, 11 mm × 14 mm × 8 mm	96-102-02081
Parallel Provisional, 11 mm × 14 mm × 9 mm	96-102-02091
Parallel Provisional, 11 mm × 14 mm × 10 mm	96-102-02101

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TM-S KIT CONTENTS *(continued)*

Mergence-S Instrument Kit (96-121-10001) *(continued)*

DESCRIPTION	PART NUMBER
Central Rotating Inserter	96-106-30001
Lateral Grasping Inserter	96-106-00001
CSG Inserter	07.00558.001
General Tamp	96-105-00002
Central Tamp	96-105-10001
Corner Tamp	96-105-20001
Starter Rasp, 11 mm × 11 mm	96-108-01001
Angled Rasp, 11 mm × 11 mm × 5 mm	96-108-17051
Angled Rasp, 11 mm × 11 mm × 6 mm	96-108-17061
Angled Rasp, 11 mm × 11 mm × 7 mm	96-108-17071
Angled Rasp, 11 mm × 11 mm × 8 mm	96-108-17081
Angled Rasp, 11 mm × 11 mm × 9 mm	96-108-17091
Angled Rasp, 11 mm × 11 mm × 10 mm	96-108-17101
Parallel Rasp, 11 mm × 11 mm × 5 mm	96-108-10051
Parallel Rasp, 11 mm × 11 mm × 6 mm	96-108-10061
Parallel Rasp, 11 mm × 11 mm × 7 mm	96-108-10071
Parallel Rasp, 11 mm × 11 mm × 8 mm	96-108-10081
Parallel Rasp, 11 mm × 11 mm × 9 mm	96-108-10091
Parallel Rasp, 11 mm × 11 mm × 10 mm	96-108-10101
Starter Rasp, 11 mm × 14 mm	96-108-02001
Angled Rasp, 11 mm × 14 mm × 5 mm	96-108-27051
Angled Rasp, 11 mm × 14 mm × 6 mm	96-108-27061
Angled Rasp, 11 mm × 14 mm × 7 mm	96-108-27071
Angled Rasp, 11 mm × 14 mm × 8 mm	96-108-27081
Angled Rasp, 11 mm × 14 mm × 9 mm	96-108-27091
Angled Rasp, 11 mm × 14 mm × 10 mm	96-108-27101
Parallel Rasp, 11 mm × 14 mm × 5 mm	96-108-20051
Parallel Rasp, 11 mm × 14 mm × 6 mm	96-108-20061
Parallel Rasp, 11 mm × 14 mm × 7 mm	96-108-20071
Parallel Rasp, 11 mm × 14 mm × 8 mm	96-108-20081
Parallel Rasp, 11 mm × 14 mm × 9 mm	96-108-20091
Parallel Rasp, 11 mm × 14 mm × 10 mm	96-108-20101

CE

Mergence-S Instrument Kit (96-261-20001)

14 mm × 14 mm

DESCRIPTION	PART NUMBER
Starter Rasp, 14 mm × 14 mm	96-108-03001
Angled Rasp, 14 mm × 14 mm × 5 mm	96-108-37051
Angled Rasp, 14 mm × 14 mm × 6 mm	96-108-37061
Angled Rasp, 14 mm × 14 mm × 7 mm	96-108-37071
Angled Rasp, 14 mm × 14 mm × 8 mm	96-108-37081
Angled Rasp, 14 mm × 14 mm × 9 mm	96-108-37091
Angled Rasp, 14 mm × 14 mm × 10 mm	96-108-37101
Parallel Rasp, 14 mm × 14 mm × 5 mm	96-108-30051
Parallel Rasp, 14 mm × 14 mm × 6 mm	96-108-30061
Parallel Rasp, 14 mm × 14 mm × 7 mm	96-108-30071
Parallel Rasp, 14 mm × 14 mm × 8 mm	96-108-30081
Parallel Rasp, 14 mm × 14 mm × 9 mm	96-108-30091
Parallel Rasp, 14 mm × 14 mm × 10 mm	96-108-30101

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Angled Provisional, 14 mm × 14 mm × 5 mm	96-101-03051
Angled Provisional, 14 mm × 14 mm × 6 mm	96-101-03061
Angled Provisional, 14 mm × 14 mm × 7 mm	96-101-03071
Angled Provisional, 14 mm × 14 mm × 8 mm	96-101-03081
Angled Provisional, 14 mm × 14 mm × 9 mm	96-101-03091
Angled Provisional, 14 mm × 14 mm × 10 mm	96-101-03101
Parallel Provisional, 14 mm × 14 mm × 5 mm	96-102-03051
Parallel Provisional, 14 mm × 14 mm × 6 mm	96-102-03061
Parallel Provisional, 14 mm × 14 mm × 7 mm	96-102-03071
Parallel Provisional, 14 mm × 14 mm × 8 mm	96-102-03081
Parallel Provisional, 14 mm × 14 mm × 9 mm	96-102-03091
Parallel Provisional, 14 mm × 14 mm × 10 mm	96-102-03101

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TM-S KIT CONTENTS *(continued)*

Mergence-S Instrument Kit (96-261-30001)

4 mm, 11 mm, 12 mm Heights

DESCRIPTION	PART NUMBER
Parallel Bone Rasp, 11 mm × 11 mm × 4 mm	96-108-10041
Parallel Bone Rasp, 11 mm × 11 mm × 11 mm	96-108-10111
Parallel Bone Rasp, 11 mm × 11 mm × 12 mm	96-108-10121
Angled Bone Rasp, 11 mm × 11 mm × 4 mm	96-108-17041
Angled Bone Rasp, 11 mm × 11 mm × 11 mm	96-108-17111
Angled Bone Rasp, 11 mm × 11 mm × 12 mm	96-108-17121
Parallel Bone Rasp, 11 mm × 14 mm × 4 mm	96-108-20041
Parallel Bone Rasp, 11 mm × 14 mm × 11 mm	96-108-20111
Parallel Bone Rasp, 11 mm × 14 mm× 12 mm	96-108-20121
Angled Bone Rasp, 11 mm × 14 mm × 4 mm	96-108-27041
Angled Bone Rasp, 11 mm × 14 mm × 11 mm	96-108-27111
Angled Bone Rasp, 11 mm × 14 mm × 12 mm	96-108-27121
Parallel Bone Rasp, 14 mm × 14 mm × 4 mm	96-108-30041
Parallel Bone Rasp, 14 mm × 14 mm × 11 mm	96-108-30111
Parallel Bone Rasp, 14 mm × 14 mm × 12 mm	96-108-30121
Angled Bone Rasp, 14 mm × 14 mm × 4 mm	96-108-37041
Angled Bone Rasp, 14 mm × 14 mm × 11 mm	96-108-37111
Angled Bone Rasp, 14 mm × 14 mm × 12 mm	96-108-37121

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Angled Provisional, 11 mm × 11 mm × 4 mm	96-101-01041
Angled Provisional, 11 mm × 11 mm × 11 mm	96-101-01111
Angled Provisional, 11 mm × 11 mm × 12 mm	96-101-01121
Angled Provisional, 11 mm × 14 mm × 4 mm	96-101-02041
Angled Provisional, 11 mm × 14 mm × 11 mm	96-101-02111
Angled Provisional, 11 mm × 14 mm × 12 mm	96-101-02121
Angled Provisional, 14 mm × 14 mm × 4 mm	96-101-03041
Angled Provisional, 14 mm × 14 mm × 11 mm	96-101-03111
Angled Provisional, 14 mm × 14 mm × 12 mm	96-101-03121
Parallel Provisional, 11 mm × 11 mm × 4 mm	96-102-01041
Parallel Provisional, 11 mm × 11 mm × 11 mm	96-102-01111
Parallel Provisional, 11 mm × 11 mm × 12 mm	96-102-01121
Parallel Provisional, 11 mm × 14 mm × 4 mm	96-102-02041
Parallel Provisional, 11 mm × 14 mm × 11 mm	96-102-02111
Parallel Provisional, 11 mm × 14 mm × 12 mm	96-102-02121
Parallel Provisional, 14 mm × 14 mm × 4 mm	96-102-03041
Parallel Provisional, 14 mm × 14 mm × 11 mm	96-102-03111
Parallel Provisional, 14 mm × 14 mm × 12 mm	96-102-03121

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IMPORTANT INFORMATION ON THE TM-S FUSION DEVICE

Device 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.

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

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 6 weeks of nonoperative 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 using an anterior approach.

Contraindications

- Active local infection in or near the operative region.
- Active systemic infection and/or disease.
- Severe osteoporosis or insufficient density that, 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 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 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.

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 or other patient conditions that could affect 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. In addition, the packaging and implant should be inspected for damage before implantation.

IMPORTANT INFORMATION ON THE TM-S FUSION DEVICE *(continued)*

Surgeon Precautions *(continued)*

- In the event that removal of the implant is considered (e.g., because of loosening, fracture, migration of the implant, infection, increased pain), the risks and benefits must be weighed carefully. 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 before use. Care must be taken not to over-tighten the implant-inserter assembly. In addition, care must be taken not to manipulate the inserter-implant interface in a manner not recommended by the surgical technique.
- The surgeon must ensure that the implant is properly seated before 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. Noncompliance 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 after 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.
- Nonsteroidal anti-inflammatory and steroidal drugs should be avoided for at least 45 days, or as directed by a physician, postoperatively.

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 caused by 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, because corrosion can 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 Biomet. 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.

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

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

The CE mark is valid only if it is also printed on the product label.

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