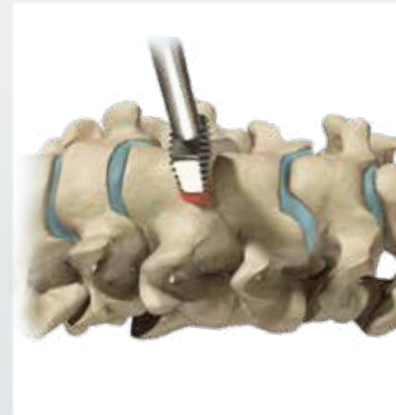


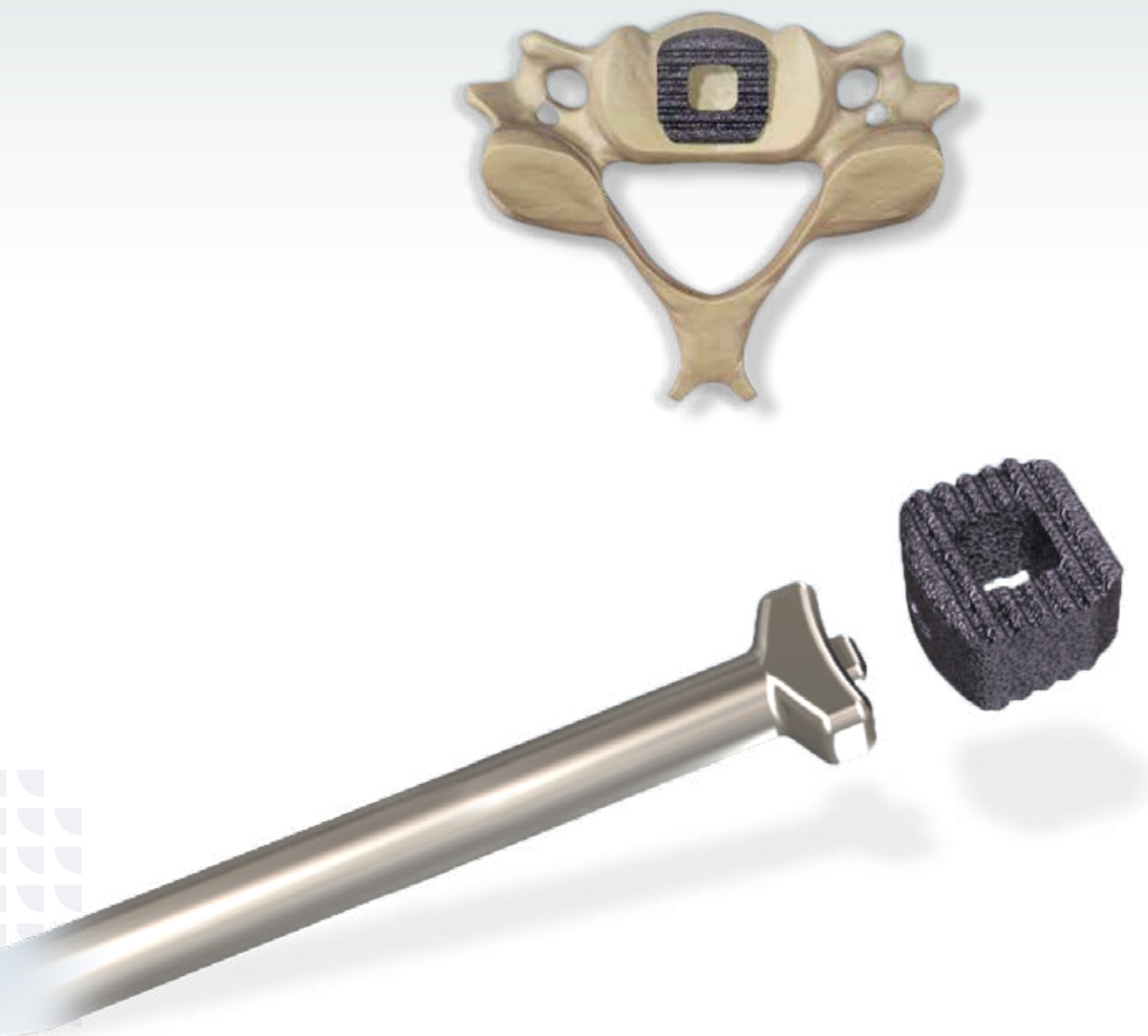
TM-S Fusion Device[®]

Trabecular Metal™ Technology

Surgical Technique Guide



 **ZimVie**



TM-S Fusion Device
Trabecular Metal Technology

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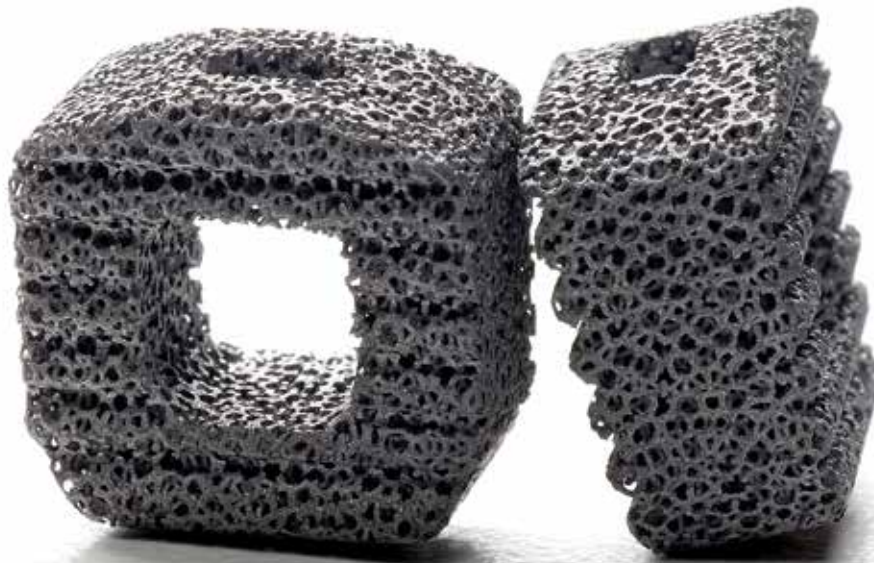
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ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent 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

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

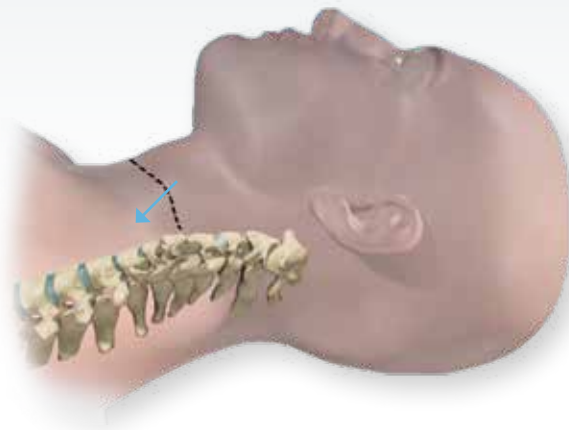


Figure 1
Identify vertebral level

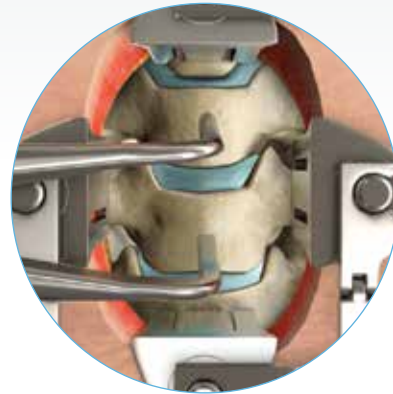


Figure 2
Exposure and location

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 chose 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

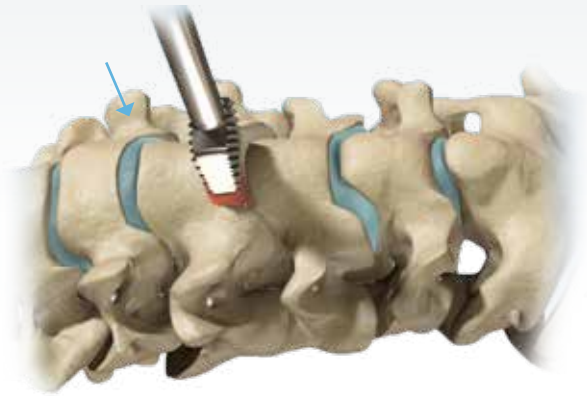


Figure 4
Endplate preparation

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.

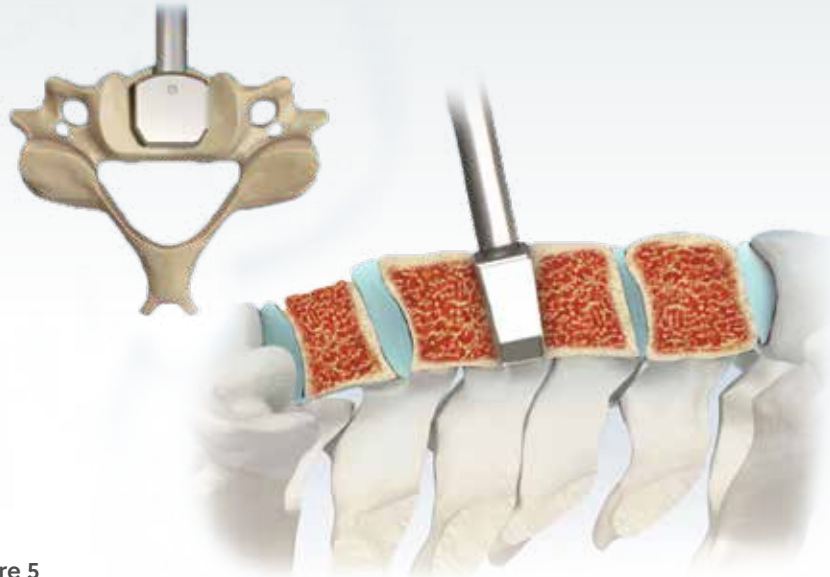


Figure 5
Implant selection

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 or choice of allograft.

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.

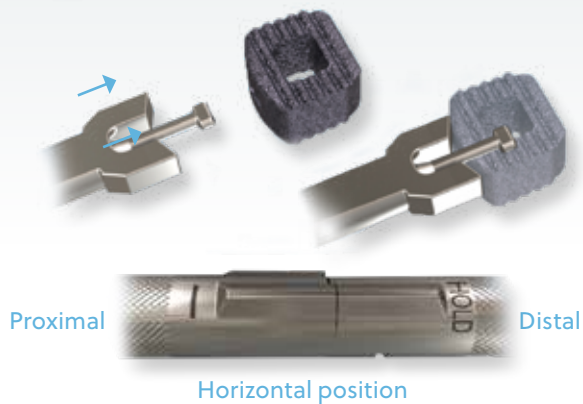


Figure 8
Central rotating inserter

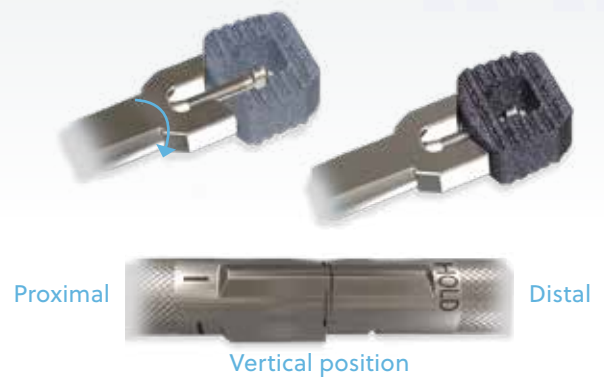


Figure 9
Inserter positioning

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)

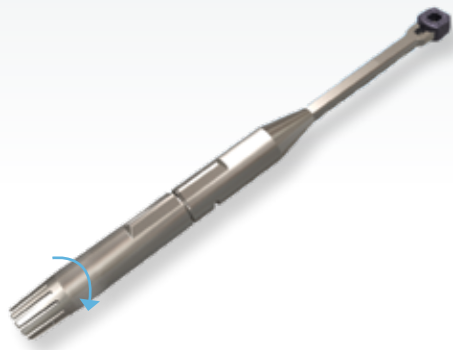


Figure 10
Securing central rotating inserter

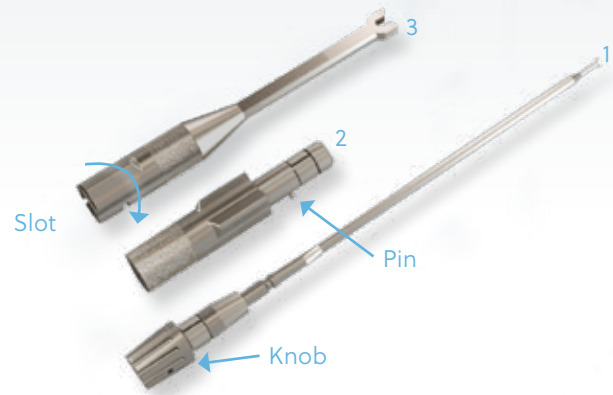


Figure 11
Central rotating inserter disassembly

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.*

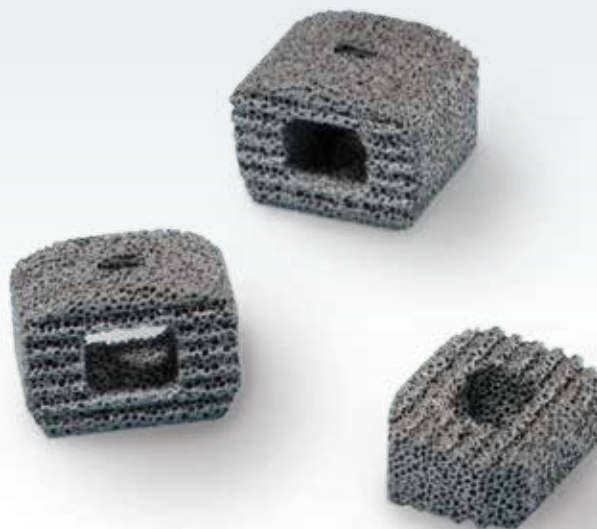
Supplemental Fixation

- 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 Tamp | PART NUMBER |
| | 96-105-10001 |



| | |
|----------------------------------|--------------|
| Central Rotating Inserter | PART NUMBER |
| | 96-106-30001 |



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 |



| | |
|---------------------|--------------|
| General Tamp | PART NUMBER |
| | 96-105-00002 |



| | |
|--------------------|--------------|
| Corner Tamp | PART NUMBER |
| | 96-105-20001 |

*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 Cervical 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 |



TM-S Implants (continued)

TM-S Cervical 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 |



TM-S Kit Contents

Mergence-S Instrument Kit (96-121-1001)

| 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 |



TM-S Kit Contents (continued)

Mergence-S Instrument Kit (96-121-1001) (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 |



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 |



| | |
|---|--------------|
| 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 |



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 |

CE₀₁₂₀

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.

Important Information on the TM-S Fusion Device (continued)

- 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.

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 ZimVie. 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.

For more information, visit [ZimVie.com](https://www.zimvie.com)



Manufactured by:
Zimmer Trabecular
Metal Technology, Inc.
10 Pomeroy Rd.
Parsippany, NJ 07054
201.818.1800

Distributed by:
Zimmer Biomet Spine, Inc.
10225 Westmoor Drive
Westminster, CO 80021
[ZimVie.com](https://www.zimvie.com)



BIOMET 3i DENTAL IBERICA S.L.U
WTC Almeda Park. Edif. 4 Planta 2
Tirso de Molina 40
08940 Cornellà de Llobregat
Barcelona, Spain
+900 800 303



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