TM-400 Device

Trabecular Metal™ Technology

ZIMMER BIOMET

Surgical Technique

Table of Contents

Description/Indications/Contraindications

Description

The TM-400 devices are manufactured entirely of *Trabecular Metal*™ (porous tantalum) and are available in a variety of cross-sectional geometries and sizes.

MATERIALS: Tantalum

Indications

The TM-400 Device is a Vertebral Body Replacement device intended for use in the thoracolumbar spine (T1–L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The TM-400 Device is intended for use with supplemental internal fixation systems, and may be used with autograft or allograft.

The TM-400 Device is also intended for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2–S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of a discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The TM-400 Device is intended for use with supplemental internal fixation and autogenous bone graft.

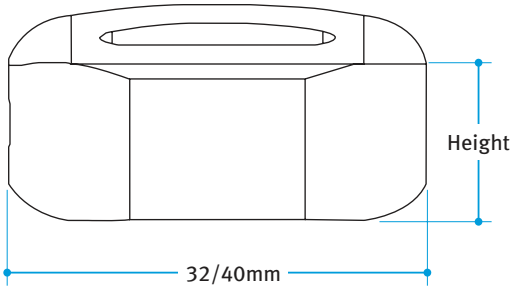
Contraindications

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

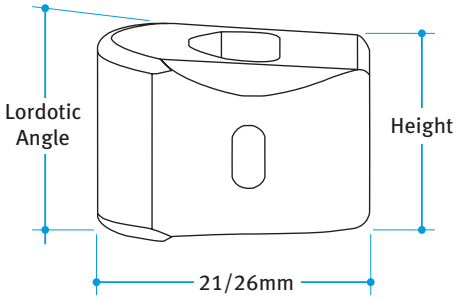
TM-400 Implants

Trabecular Metal Material Clinical Attributes

- Up to 80% porosity by volume – osteoconductive scaffold for biological fixation
- Elastic modulus closely matched to cancellous bone – improved load sharing
- High compressive strength – able to withstand physiological loading
- High coefficient of friction – initial stability to allow bone integration
- Unique porous tantalum composition – highly biocompatible



BACK



SIDE

21mm x 32mm Device

Lordotic Angles	Height									
	8mm*	9mm*	10mm	11mm	12mm	13mm	14mm	15mm	17.5mm	20mm
7˚	X	X	X	X	X	X	X	X	X	X
13˚	X	X	X	X	X	X	X	X		

** Lateral inserter slot not present on 8mm and 9mm sizes.*

26mm x 40mm Device

Lordotic Angles	Height									
	8mm	9mm	10mm	11mm	12mm	13mm	14mm	15mm	17.5mm	20mm
7˚	X	X	X	X	X	X	X	X	X	X

TM-400 Instruments

Implant Inserter
96-171-10001

Attaches to implant to facilitate insertion.

Tamp
96-209-10011

Advances the implant into its final position.

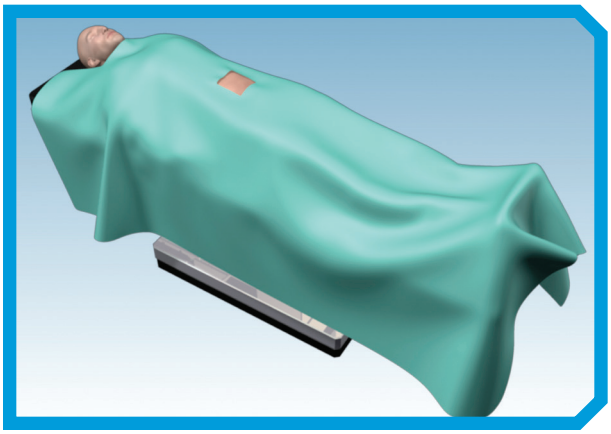
Anterior Implant Trial
96-151-series and 96-136-series
Lateral Implant Trial
96-161 series and 96-146-series

Identifies and confirms appropriate implant size.

Surgical Technique

Anterior Approach as an Interbody Fusion Device

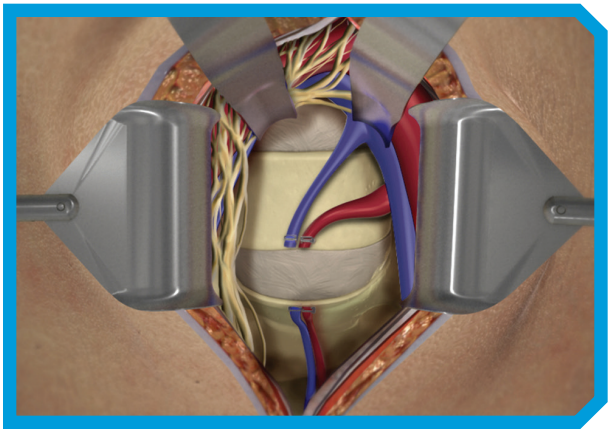
Step 1



Patient Positioning

Using a radiolucent operating table (i.e. Jackson Table), position the patient in a supine position with a pad under the lumbar spine to maintain lordosis.

Step 2



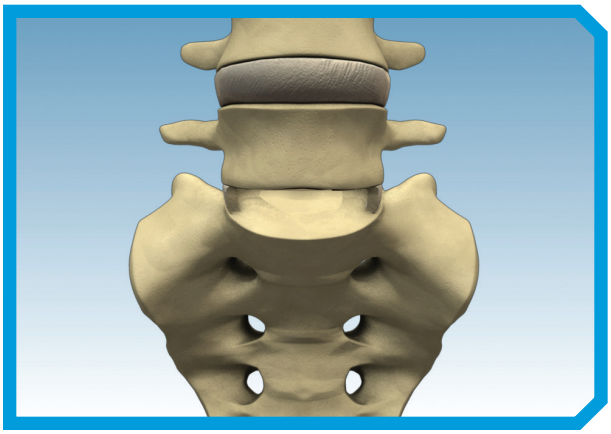
Exposure

Expose the L5/S1 level through a low transverse or paramedian incision. Then develop retroperitoneal plane to provide access to the anterior spine. For levels above L5/S1, it may be more appropriate to use a midaxillary incision aligned over the treatment level. Alternative exposures may be substituted based on surgeon preference or experience.

Standard general and/or vascular surgical instruments are used to perform the exposure down to the levels of the fusion. Standard instruments are also used to maintain the exposure via appropriate retractors.

Confirm exposure of correct segments by placing a needle into the intervertebral disc and taking a confirmatory X-Ray/Fluoro shot. Using anatomical landmarks, confim correct position. Use an X-Ray/Fluoro picture to identify midline of the vertebral bodies. If the needle is not positioned in the midline, adjust placement until it is. Mark the midline with a sterile pen on superior and inferior vertebral bodies for reference during the procedure.

Step 3



Annulotomy and Discectomy

Begin box discectomy by incising the annulus with a scalpel. The "box" should be centered around the midline and of sufficient width to accommodate the desired implant. Pituitary Rongeurs and Ring Curettes can be used to perform the discectomy.

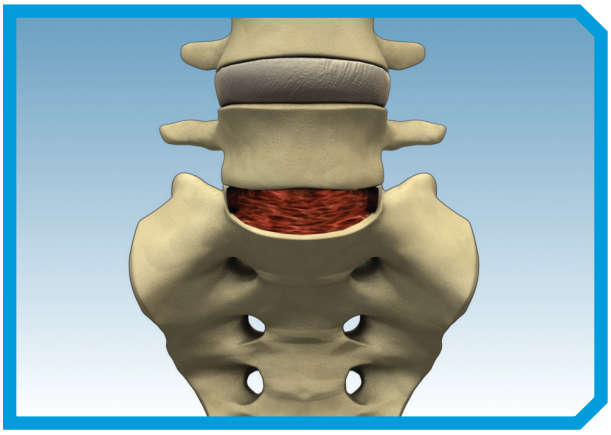
Continue to remove disc material until the posterior longitudinal ligament (PLL) is exposed. If necessary, incise the PLL to obtain additional distraction or to facilitate removal of herniated disc material from the spinal canal.

Note: *Care should be taken to ensure that all exposed blood vessels are properly retracted prior to discectomy so as to avoid unintended contact with the Curettes and Rongeurs.*

Note: *Ensure sharpness of Curettes and Rongeurs prior to use.*

Note: *Excessive force applied to the Curettes or Rongeurs can inadvertently rupture the disc annulus or damage the vertebral endplate.*

Step 4

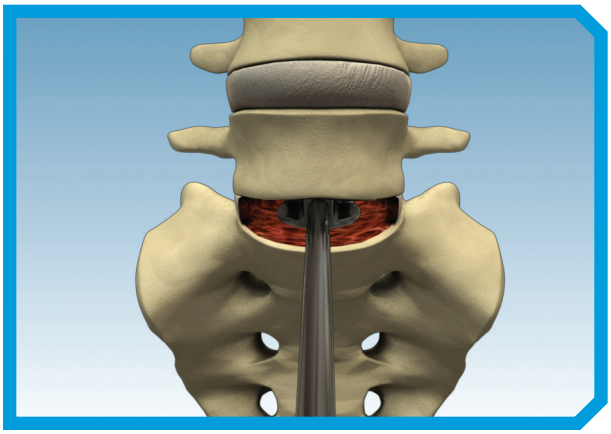


Endplate Preparation

Prepare the endplate by using Curettes and/or Burrs to remove the cartilaginous endplate to create a flat surface of bleeding bone. Remove the minimum amount of endplate to reach bleeding bone. Leave small anterior and posterior lips at each vertebra to prevent migration of the device.

Note: *Excessive rasping of the vertebral endplate may result in subsidence and loss of segmental stability.*

Step 5



Implant Selection

One TM-400 Device is used per level. TM-400 implants are available in two footprints and two lordotic angles.

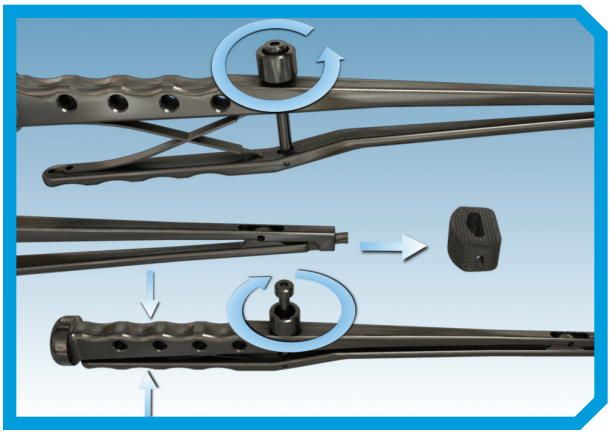
An estimate of the best footprint can be made from measurements of imaging studies as well as sequentially inserting one-piece Trials to determine the best fit.

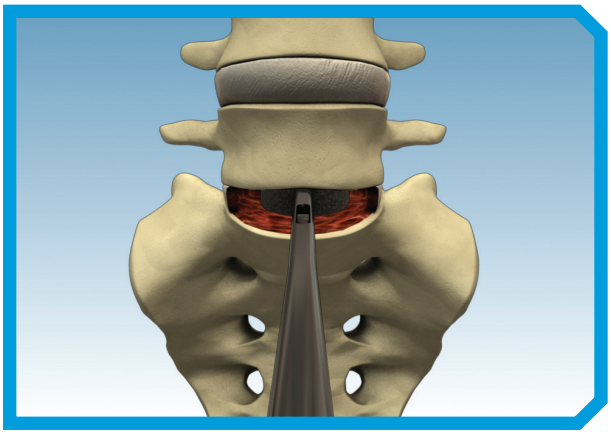
Note: ***The width, depth, and height of each Trial is identical in size to its corresponding implant.***

The “best fit” Trial should feel snug (not too tight or too loose) and provide the optimal amount of lordosis for the patient’s anatomy. Select the implant that corresponds to the “best-fit” Trial.

Note: ***If the Trial used is solidly engaged and difficult to reposition when properly positioned, the surgeon should consider implanting a device 1mm smaller than the Trial being used.***

Step 6





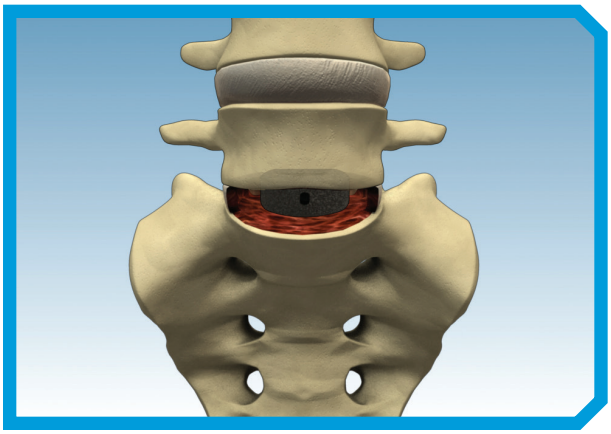
Implant Insertion

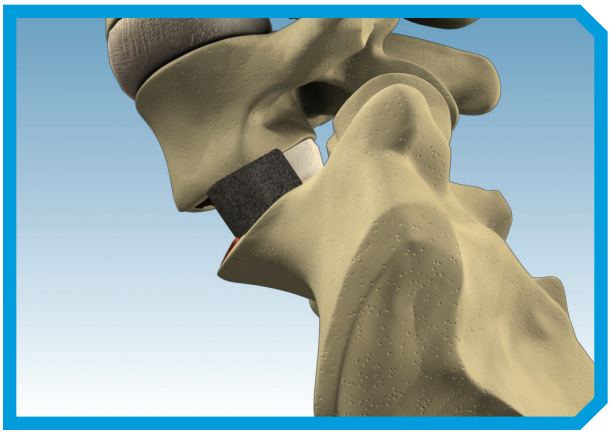
On the sterile table, pack the center of the selected implant with autogenous bone graft. Then, load the implant onto the Inserter. Ensure that the Inserter is fully loosened by rotating the top nut counter clockwise. Place the implant on the Inserter by aligning the anterior slot with the tip of the Inserter. Squeeze the Inserter handles together and rotate the top nut clockwise to secure the implant on the Inserter.

Insert the TM-400 implant such that it is centered about the midline. Insert the implant into the disc space by tapping with a mallet. Moderate tapping is required. The Inserter or Tamp can be used to final position the implant. If excessive force is required to insert, check the space to ensure that the endplate has been removed evenly. *Trabecular Metal* has a very high coefficient of friction and thorough discectomy is essential for smooth insertion. If the implant still meets with excessive resistance a change in implant size may be required. Excessive force can cause the implant to deform.

Caution: ***Care should be taken when inserting the Trial or implant into the disc space to avoid damaging anatomy, implants or instruments.***

Step 7





Final Positioning

In the final position, the implant should be slightly posterior to the anterior aspect of the vertebral body. Release the implant by rotating the top nut on the Inserter counter clockwise. Remove the instrument from the implant. Final radiographs (A/P & Lateral) should be taken at this time to ensure proper placement. Bone graft may be packed or placed in front of the device for radiographic visualization of fusion.

After the implant is in its final position, add supplemental fixation such as pedicle screws.

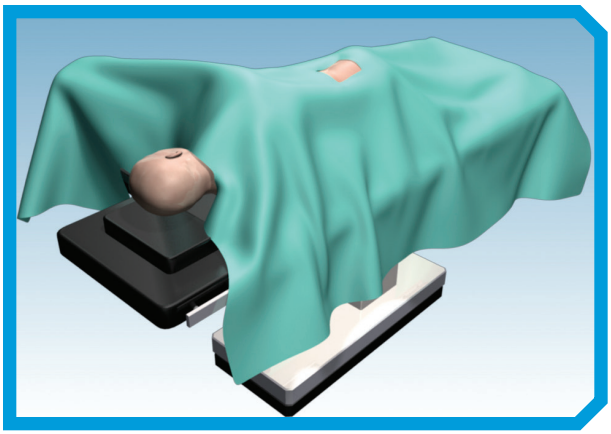
Implant Removal

Should removal of the device be determined necessary by the surgeon, an osteotome can be used at the interface between the implant and the superior and inferior endplates. This effectively cuts the fused column of bone graft held inside the implant at the level of the endplate.

Once the fused columns are completely cut, forceps can be used to remove the implant from the space. This may be done under slight distraction.

Lateral Approach as a Vertebral Body Replacement Device

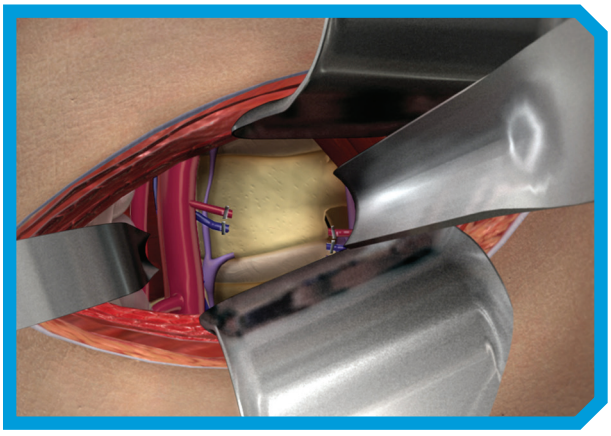
Step 1



Patient Positioning

While under general anesthesia, place the patient in the lateral decubitus position. Move the left arm forward to permit the scapula to rotate away from the posterior portion of the vertebral column. Place an auxillary roll under the right arm to minimize compression on the axillary artery, vein and nerve. Place another roll under the patient between the iliac crest and ribs to maintain the normal position of the spine. Placing a pillow between the patient's knees and slightly flexing the hips will help relax the psoas major muscle.

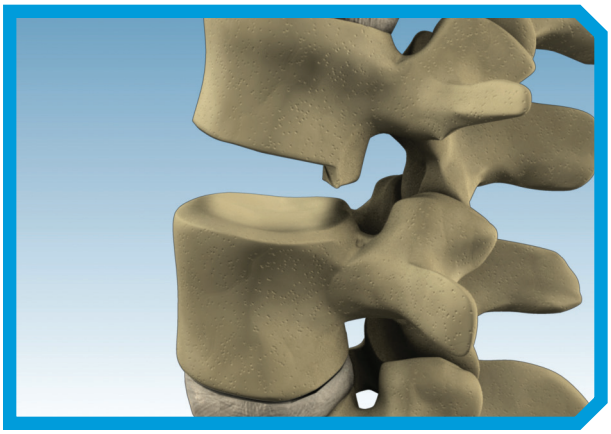
Step 2



Exposure

Use the transpleural approach in the thoracic region; use the standard retroperitoneal approach in the thoracolumbar region. In the transpleural approach, make the skin incision two ribs above the affected segment. After thoracotomy, incise the parietal pleura overlying the vertebral bodies and ligate the exposed segmental vessels. In the lower thoracic and high lumbar region, utilize a rib resection with a retroperitoneal approach. Reach the lower lumbar region with a mid-flank incision with retroperitoneal dissection. Retract the psoas muscle posteriorly to the junction of the pedicle and the vertebral body and medially retract the aorta after ligation of the segmental vessels at the appropriate levels. Control the ascending lumbar vein to allow displacement of the vessels.

Step 3



Discectomy and Vertebral Body Removal

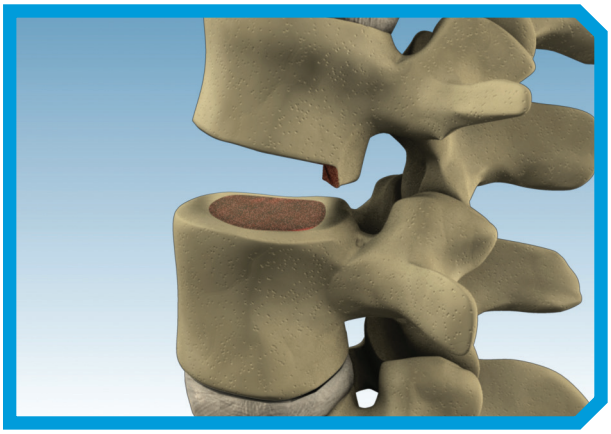
Resect the disc directly adjacent to the affected segment as well as the damaged or diseased portion of the vertebral body (partial vertebrectomy). Rongeurs and Curettes can be used to perform the discectomy and resection. Decompress the spinal canal at this time.

Note: ***Care should be taken to ensure that all exposed blood vessels are properly retracted prior to discectomy so as to avoid unintended contact with the Curettes and Rongeurs.***

Note: ***Ensure sharpness of Curettes and Rongeurs prior to use.***

Note: ***Excessive force applied to the Curettes or Rongeurs can inadvertently rupture the disc annulus or damage the vertebral endplate.***

Step 4

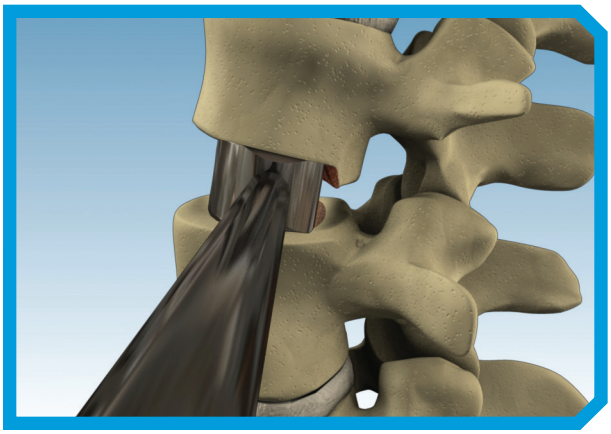


Endplate Preparation

Prepare the endplate by using Curettes and/or Burrs to remove the cartilaginous endplate to create a flat surface of bleeding bone. Remove the minimum amount of endplate to reach bleeding bone. Leave small anterior and posterior lips at each vertebra to prevent migration of the device.

Note: ***Excessive rasping of the vertebral endplate may result in subsidence and loss of segmental stability.***

Step 5



Implant Selection

Note: ***The 8mm and 9mm 21 X 32 TM-400 devices do not have a lateral insertion hole.***

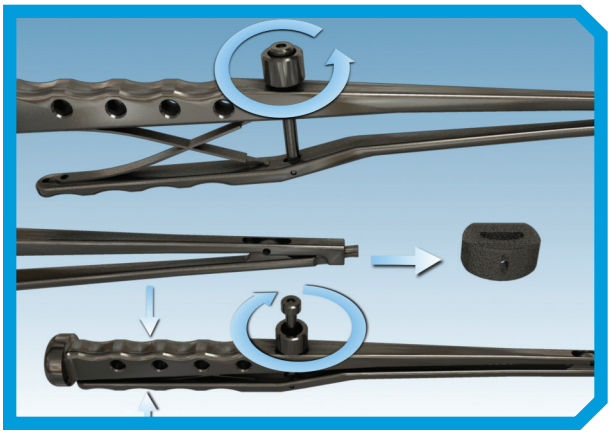
One TM-400 Device is used per level. TM-400 implants are available in two footprints and two lordotic angles. An estimate of the best footprint can be made from measurements of imaging studies as well as sequentially inserting one-piece Trials to determine the best fit.

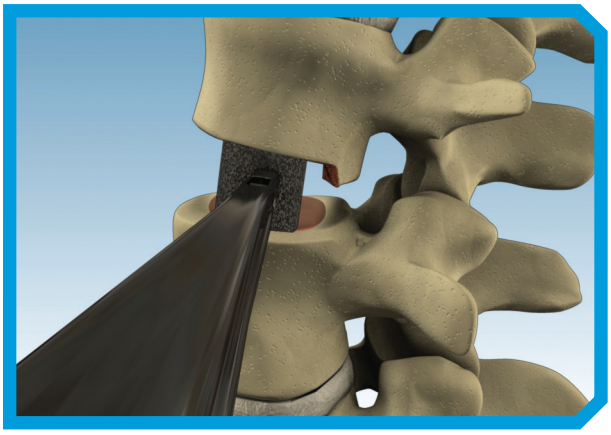
Note: ***The width, depth, and height of each Trial is identical in size to its corresponding implant.***

The "best fit" Trial should feel snug (not too tight or too loose) and provide the optimal amount of lordosis for the patient's anatomy. Select the implant that corresponds to the "best-fit" Trial.

Note: ***If the Trial used within the disc space is solidly engaged and difficult to reposition when proper position within disc space has been obtained, the surgeon should consider implanting a device 1mm smaller than the Trial being used.***

Step 6





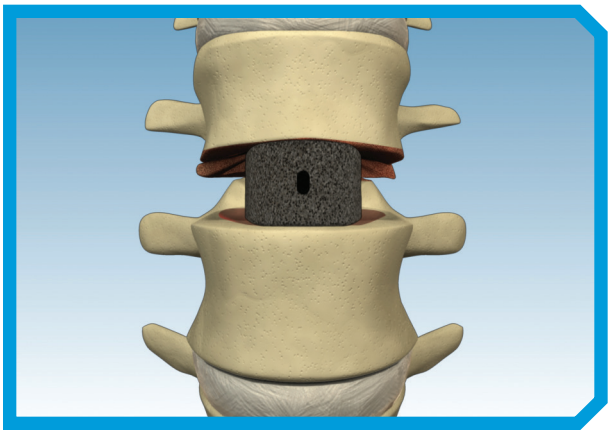
Insertion

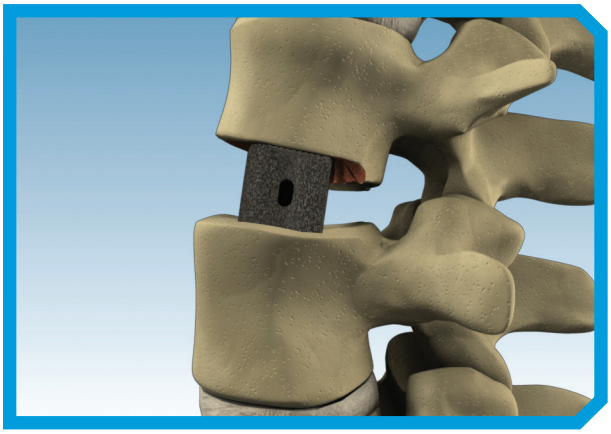
On the sterile table, pack the center of the selected implant with bone graft. Then, load the implant onto the Inserter. Ensure that the Inserter is fully loosened by rotating the top nut counter clockwise. Place the implant on the inserter by aligning the lateral slot with the tip of the inserter. Squeeze the Inserter handles together and rotate the top nut clockwise to secure the implant on the Inserter.

Insert the implant into the void by tapping with a mallet. Moderate tapping is required. The Inserter or Tamp can be used to final position the implant. If excessive force is required to insert, check the space to ensure that the endplate has been removed evenly. *Trabecular Metal* has a very high coefficient of friction, and a thorough site preparation is essential for smooth insertion. If the implant still meets with excessive resistance a change in implant size may be required. Excessive force can cause the implant to deform.

Caution: ***Care should be taken when inserting the Trial or implant into the disc space to avoid damaging anatomy, implants or instruments.***

Step 7





Final Positioning

In the final position, the implant should be slightly posterior to the anterior aspect of the vertebral body. Release the implant by rotating the top nut on the Inserter counter clockwise. Remove the instrument from the implant. Final radiographs (A/P & Lateral) should be taken at this time to ensure proper placement. Bone graft may be packed or placed in front of the device for radiographic visualization of fusion.

After the implant is in its final position, add supplemental fixation such as pedicle screws.

Implant Removal

Should removal of the device be determined necessary by the surgeon, an osteotome can be used at the bone/implant interface. This effectively cuts the fused column of bone graft held inside the implant. Once the fused columns are completely cut, forceps can be used to remove the implant from the space. This may be done under slight distraction.

Kit Contents

Kit Number 96-269-40001

Small Foot Print - 7°

Part Number	Description	Standard Kit Quantity
96-151-32082	TM-400 ANTERIOR TRIAL 21X32mm 7° 8mm	1
96-151-32092	TM-400 ANTERIOR TRIAL 21X32mm 7° 9mm	1
96-151-32102	TM-400 ANTERIOR TRIAL 21X32mm 7° 10mm	1
96-151-32112	TM-400 ANTERIOR TRIAL 21X32mm 7° 11mm	1
96-151-32122	TM-400 ANTERIOR TRIAL 21X32mm 7° 12mm	1
96-151-32132	TM-400 ANTERIOR TRIAL 21X32mm 7° 13mm	1
96-151-32142	TM-400 ANTERIOR TRIAL 21X32mm 7° 14mm	1
96-151-32152	TM-400 ANTERIOR TRIAL 21X32mm 7° 15mm	1
96-151-32172	TM-400 ANTERIOR TRIAL 21X32mm 7° 17.5mm	1
96-151-32202	TM-400 ANTERIOR TRIAL 21X32mm 7° 20mm	1
96-161-32081	TM-400 LATERAL TRIAL 21X32mm 7° 8mm	1
96-161-32091	TM-400 LATERAL TRIAL 21X32mm 7° 9mm	1
96-161-32101	TM-400 LATERAL TRIAL 21X32mm 7° 10mm	1
96-161-32111	TM-400 LATERAL TRIAL 21X32mm 7° 11mm	1
96-161-32121	TM-400 LATERAL TRIAL 21X32mm 7° 12mm	1
96-161-32131	TM-400 LATERAL TRIAL 21X32mm 7° 13mm	1
96-161-32141	TM-400 LATERAL TRIAL 21X32mm 7° 14mm	1
96-161-32151	TM-400 LATERAL TRIAL 21X32mm 7° 15mm	1
96-161-32171	TM-400 LATERAL TRIAL 21X32mm 7° 17.5mm	1
96-161-32201	TM-400 LATERAL TRIAL 21X32mm 7° 20mm	1

CE 1639

Part Number	Description	Standard Kit Quantity
96-209-10011	Tamp	1
96-171-10001	Spinal Implant Inserter Assembly	1

CE

Kit Number 96-269-50001

Small Foot Print - 13˚

Part Number	Description	Standard Kit Quantity
96-136-32082	TM-400 ANTERIOR TRIAL 21X32mm 13° 8mm	1
96-136-32092	TM-400 ANTERIOR TRIAL 21X32mm 13° 9mm	1
96-136-32102	TM-400 ANTERIOR TRIAL 21X32mm 13° 10mm	1
96-136-32112	TM-400 ANTERIOR TRIAL 21X32mm 13° 11mm	1
96-136-32122	TM-400 ANTERIOR TRIAL 21X32mm 13° 12mm	1
96-136-32132	TM-400 ANTERIOR TRIAL 21X32mm 13° 13mm	1
96-136-32142	TM-400 ANTERIOR TRIAL 21X32mm 13° 14mm	1
96-136-32152	TM-400 ANTERIOR TRIAL 21X32mm 13° 15mm	1
96-146-32081	TM-400 LATERAL TRIAL 21X32mm 13° 8mm	1
96-146-32091	TM-400 LATERAL TRIAL 21X32mm 13° 9mm	1
96-146-32101	TM-400 LATERAL TRIAL 21X32mm 13° 10mm	1
96-146-32111	TM-400 LATERAL TRIAL 21X32mm 13° 11mm	1
96-146-32121	TM-400 LATERAL TRIAL 21X32mm 13° 12mm	1
96-146-32131	TM-400 LATERAL TRIAL 21X32mm 13° 13mm	1
96-146-32141	TM-400 LATERAL TRIAL 21X32mm 13° 14mm	1
96-146-32151	TM-400 LATERAL TRIAL 21X32mm 13° 15mm	1

CE 1639

Part Number	Description	Standard Kit Quantity
96-209-10011	Tamp	1
96-171-10001	Spinal Implant Inserter Assembly	1

CE

Kit Number 96-269-60001

Large Foot Print - 7°

Part Number	Description	Standard Kit Quantity
96-151-40082	TM-400 ANTERIOR TRIAL 26X40mm 7° 8mm	1
96-151-40092	TM-400 ANTERIOR TRIAL 26X40mm 7° 9mm	1
96-151-40102	TM-400 ANTERIOR TRIAL 26X40mm 7° 10mm	1
96-151-40112	TM-400 ANTERIOR TRIAL 26X40mm 7° 11mm	1
96-151-40122	TM-400 ANTERIOR TRIAL 26X40mm 7° 12mm	1
96-151-40132	TM-400 ANTERIOR TRIAL 26X40mm 7° 13mm	1
96-151-40142	TM-400 ANTERIOR TRIAL 26X40mm 7° 14mm	1
96-151-40152	TM-400 ANTERIOR TRIAL 26X40mm 7° 15mm	1
96-151-40172	TM-400 ANTERIOR TRIAL 26X40mm 7° 17.5mm	1
96-151-40202	TM-400 ANTERIOR TRIAL 26X40mm 7° 20mm	1
96-161-40081	TM-400 LATERAL TRIAL 26X40mm 7° 8mm	1
96-161-40091	TM-400 LATERAL TRIAL 26X40mm 7° 9mm	1
96-161-40101	TM-400 LATERAL TRIAL 26X40mm 7° 10mm	1
96-161-40111	TM-400 LATERAL TRIAL 26X40mm 7° 11mm	1
96-161-40121	TM-400 LATERAL TRIAL 26X40mm 7° 12mm	1
96-161-40131	TM-400 LATERAL TRIAL 26X40mm 7° 13mm	1
96-161-40141	TM-400 LATERAL TRIAL 26X40mm 7° 14mm	1
96-161-40151	TM-400 LATERAL TRIAL 26X40mm 7° 15mm	1
96-161-40171	TM-400 LATERAL TRIAL 26X40mm 7° 17.5mm	1
96-161-40201	TM-400 LATERAL TRIAL 26X40mm 7° 20mm	1

CE 1639

Part Number	Description	Standard Kit Quantity
96-209-10011	Tamp	1
96-171-10001	Spinal Implant Inserter Assembly	1

CE

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.

1. Appropriate device selection is crucial to obtain proper fit and to decrease the stress placed on the implant.
2. The implant must be handled carefully following manufacturer's instructions.
3. Care must be taken to avoid using dissimilar metals in contact with one another, as corrosion may occur. Fixation instrumentation used to stabilize the components must be made of compatible materials, such as titanium or titanium alloy. Corrosion may accelerate metal fatigue and lead to failure of the implant.
4. Implants should not be modified or otherwise processed in any way.
5. Once a device has been implanted, it must never be reused. If the package is damaged or opened, but the device is not used, the device must be returned to Zimmer Biomet. The device should not be resterilized.
6. Results may be worse with multilevel disease. Supplemental fixation is required for Intervertebral Body Fusion applications and Vertebral Body Replacement applications. The surgeon should be familiar with fixation techniques and appropriate hardware. Only supplemental fixation made of titanium or titanium alloy should be used with *Trabecular Metal* devices.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Precautions

1. The surgeon must have a thorough knowledge of the mechanical and metallurgical limitations of metallic surgical implants and be thoroughly familiar with the surgical technique for implanting the TM-400 for the given Indications for Use.
2. In the event that removal of the implant is considered (e.g. due to loosening, fracture, corrosion or migration of the implant; infection; increased pain, etc.), the risks versus benefits should 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.
3. The surgeon must be thoroughly familiar with the options for supplemental internal fixation systems and the associated surgical techniques.
4. Based on the fatigue testing results, the physician/surgeon should consider the level(s) of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
5. The components of this system should not be used with components of any other system or manufacturer.

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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For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

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