ZIMMER BIOMET

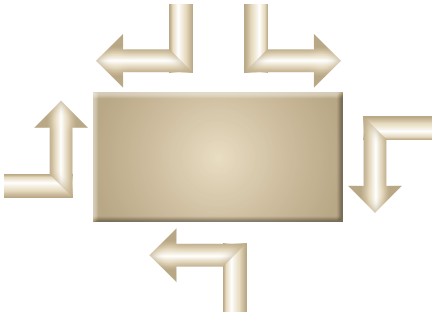
Your progress. Our promise.®

Spine Solutions

Trabecular Metal™ Material

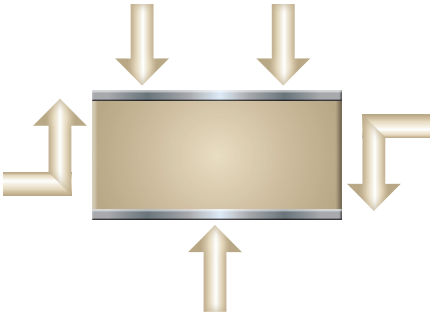
Experience transformational technology designed for three-dimensional bony in-growth[1,2]

TRADITIONAL MATERIAL



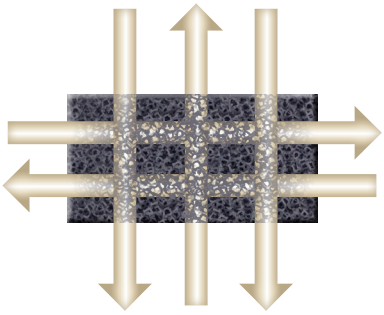
No bony on-growth or in-growth

TRADITIONAL MATERIAL
with textured surface



No bony in-growth, and bony on-growth on textured surface only

TRABECULAR METAL MATERIAL
Three-dimensional in-growth



Bony in-growth through the device*

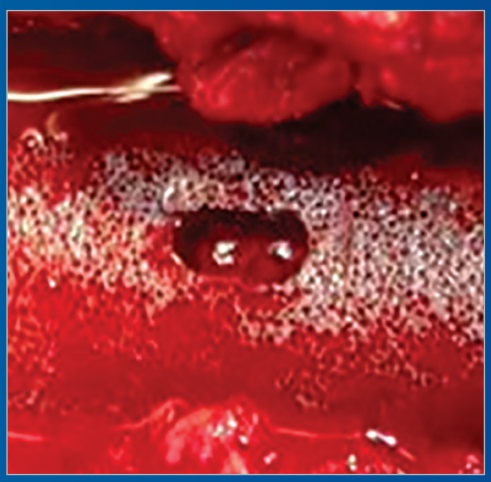
Trabecular Metal Material has a 100% open, porous structure engineered to support vascularization and bony in-growth.[1–3]

THE FEEL OF Confidence

Trabecular Metal Material's exclusive technology provides confidence in achieving bony in-growth and bridging. Due to its high coefficient of friction against cancellous bone, Trabecular Metal Material delivers tactile stability from the start.

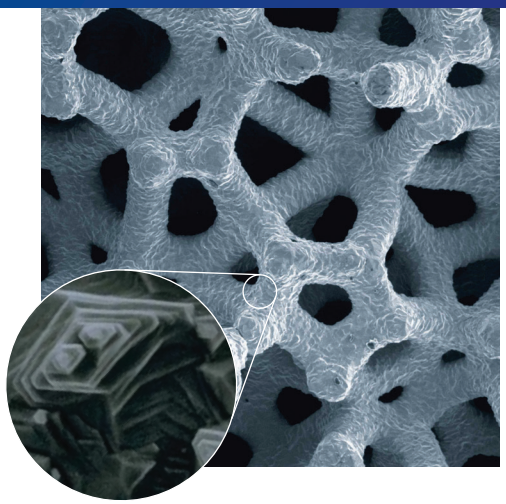
Bone Growth Requires Blood Flow

Whereas traditional nonporous materials limit blood flow through the implant, the porous tantalum composition of Trabecular Metal Material allows the ingress of blood.

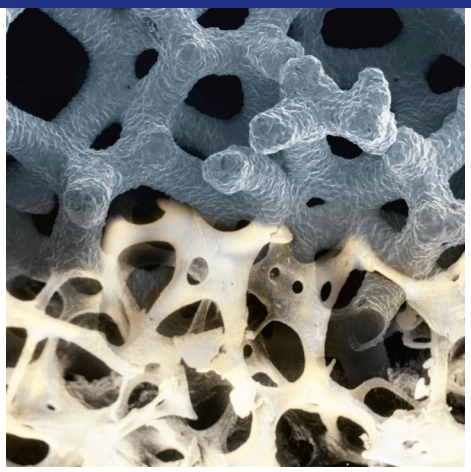


Trabecular Metal Implant after implantation

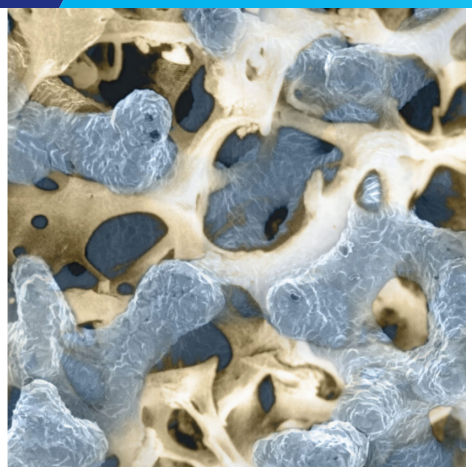
*In the United States, Trabecular Metal interbody implants are indicated for use with autogenous bone graft. Refer to product-specific Instructions for Use for cleared indications, contraindications, warnings and precautions.



Micro-textured surface



Structure similar to cancellous bone
(Artistic Representation)



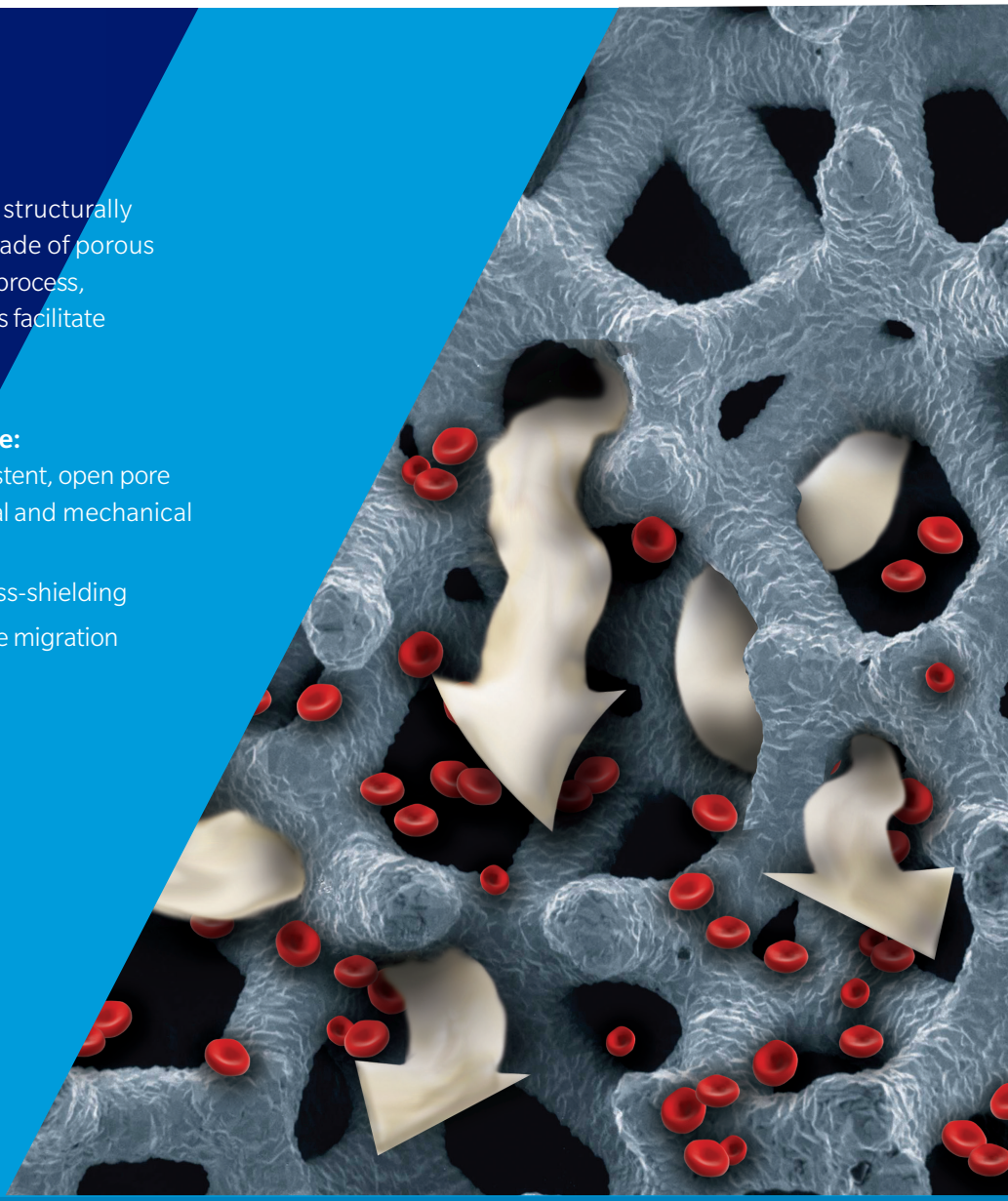
Bony in-growth through the Trabecular Metal Material
(Artistic Representation)

WHAT IS TRABECULAR METAL MATERIAL?

Trabecular Metal Material is a porous material structurally similar to cancellous bone. This material, made of porous tantalum using a proprietary manufacturing process, creates an osteoconductive scaffold that helps facilitate vascularization[2] and bony in-growth.

Trabecular Metal Material features include:

- Average porosity of up to 80% with a consistent, open pore structure designed to resemble the physical and mechanical properties of cancellous bone[1,2]
- Low modulus of elasticity to minimize stress-shielding
- High coefficient of friction to prevent device migration and expulsion



Blood flows through the Trabecular Metal structure
(Artistic Representation)

TRABECULAR METAL MATERIAL

With its unique combination of structure, function and physiology, Trabecular Metal Technology provides an innovative solution for spinal applications.

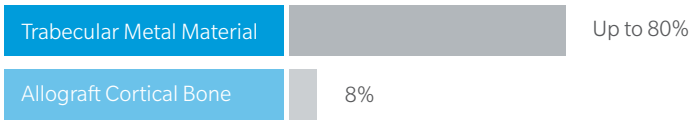
Structure

Promotes strength and positive bony in-growth.

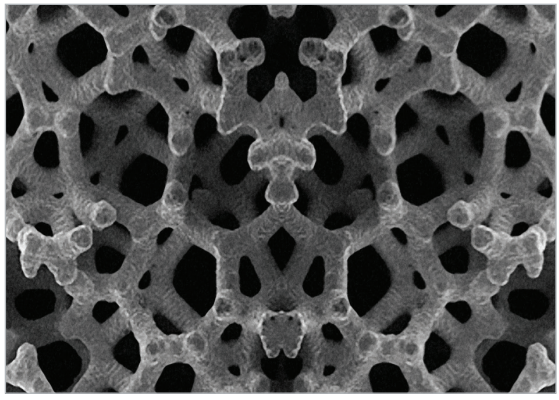
Porosity

- Up to 80% porous with an average pore size of 440 µm
- Average pore size of greater than 300 µm is required to support vascularization[2]

Porosity



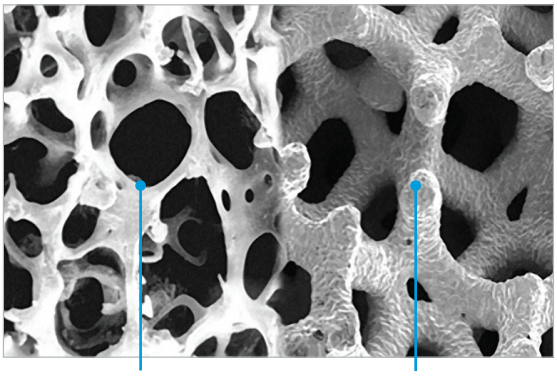
Average Pore Size



Consistent Pore Size and Structure

- The consistent and open pore structure provides for bony in-growth and vascularization.
- Textured (rough) surfaces have been shown to have a positive bone response including tissue in-growth and surface osteointegration compared to smooth surfaces in a variety of applications.[4–8]

Structure of Trabecular Metal Material Compared to Cancellous Bone



Trabecular Metal Material Surface Texture

Mechanical Properties

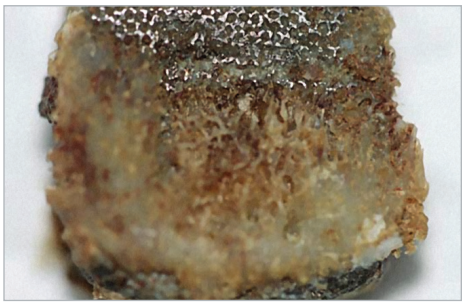
- Made from elemental tantalum
- Strength to withstand physiologic loads
- Ductility provides opposition to breakdown or failure

Compressive Strength (MPa)

REAL-LIFE RESULTS

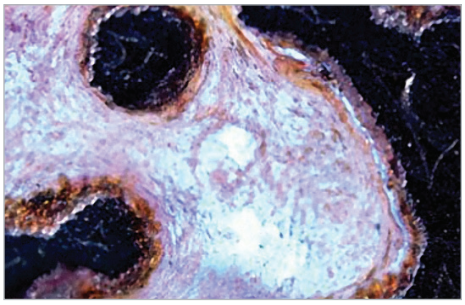
- Unique structural environment allows for bony in-growth with the potential for increased fixation
- Open-pore structure and fluid-flow characteristics facilitate osseointegration, bone remodeling and vascularization[1,2]
- Cervical Fusion Device example — 28 months postoperatively[9] with bony in-growth around and into the device

Analysis of Trabecular Metal Material Explant

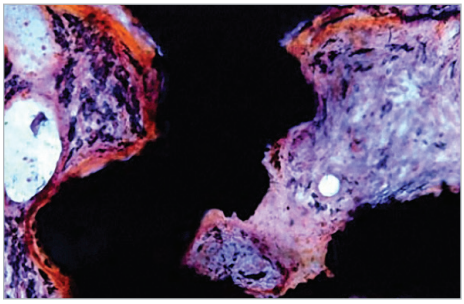


Axial view

Posterior view



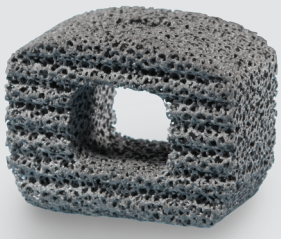
Magnified (100×) histological image showing bone growth into the porous Trabecular Metal Material structure



Magnified (100×) histological image showing bone growth up to the surface of the Trabecular Metal Material structure

Pink/Purple = Bone **Orange/Yellow** = Fibrous Tissue **Black** = Trabecular Metal Material

2017 marks 20 years of clinical history for Trabecular Metal Material.

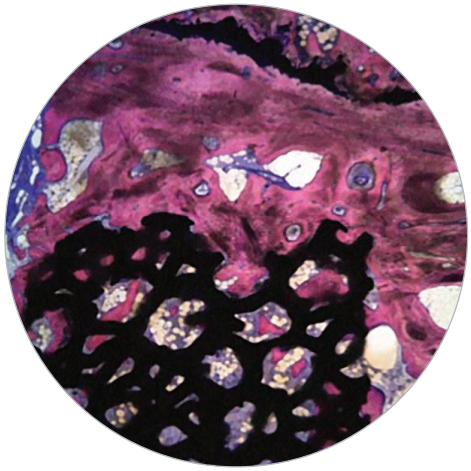


Preclinical Study

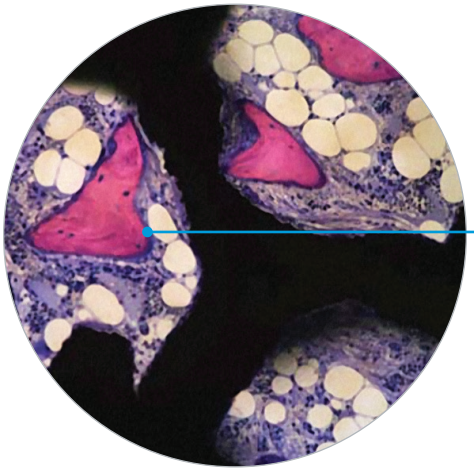
Results from a preclinical goat study comparing the TM-S Fusion Device to a PEEK control device in a single-level ACDF model with an anterior cervical plate showed increased bone growth with the TM-S Fusion Device (n=13) compared to the PEEK control (n=12). Histological results confirmed:

- Increased rate of bone remodeling within the graft hole of the TM-S Fusion Device (n=4 at 6 weeks, n=5 at 12 weeks) compared to the PEEK control device (n=4 at 6 weeks, n=4 at 12 weeks) at 6 and 12 weeks post implantation.[10]
- A greater amount of bone in direct contact with the TM-S Fusion Device (n=13) compared to the PEEK control (n=12).[11]
- Bone growth into the porous Trabecular Metal Material of the TM-S Fusion Device compared to no bone growth into the non-porous PEEK material of the control device.[12]

Histological analysis of the TM-S Cervical Fusion Device in a goat model for single-level ACDF with supplemental fixation.



Magnified (20×) histological image showing bone growth into the pores of the TM-S Cervical Fusion Device 12 weeks postoperatively



Magnified (100×) histological image showing bone remodeling occurring within the pores of the TM-S Cervical Fusion Device 12 weeks postoperatively

Pink = Bone tissue **Blue** = Fibrous tissue and cells **OB** = Evidence of osteoblast activity **Black** = Trabecular Metal Material

METAL COMPARISON

With its innovative structural and mechanical properties, Trabecular Metal Technology offers unique benefits when compared to other currently available spinal devices.

	Trabecular Metal	PEEK	Cortical Allograft	Titanium
High coefficient of friction	X			
Osteoconductive	X			
Micro-texture surface	X		X	
High compressive strength	X		X	X
High ductility	X			
Low modulus of elasticity	X	X		
No risk of disease transmission	X	X		X
Consistent implant quality	X	X		X

Function

Achieve stability while maintaining flexibility:

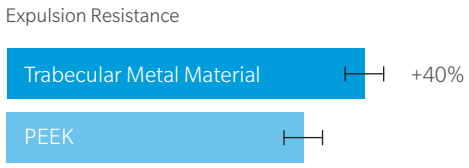
Enhanced Stability

- High coefficient of friction, 0.88 against cancellous bone, for more solid initial fixation[1]
- Reduced risk of migration and expulsion

Excellent Flexibility

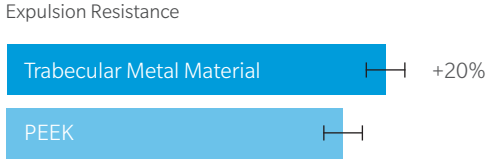
- Modulus of elasticity similar to cancellous bone
- Provides for more normal load transfer with the potential to minimize stress-shielding

Cervical Expulsion Resistance: Trabecular Metal vs. PEEK[13]



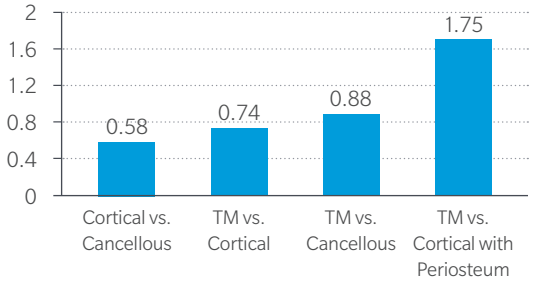
Cervical expulsion testing comparing PEEK to Trabecular Metal Material showed that an increased force of 40% was required to remove the Trabecular Metal device compared to the PEEK device.[13]

Lumbar Expulsion Resistance: Trabecular Metal vs. PEEK[13]

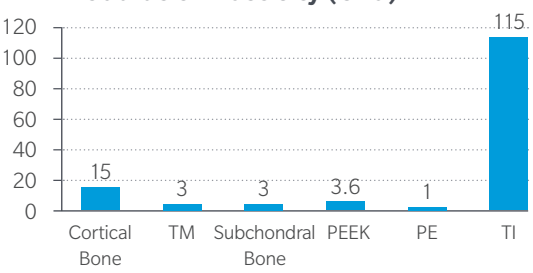


Lumbar expulsion testing comparing PEEK to Trabecular Metal Material showed an increased force of 20% was required to remove the Trabecular Metal device compared to the PEEK device.[13]

Coefficient of Friction



Modulus of Elasticity (GPa)



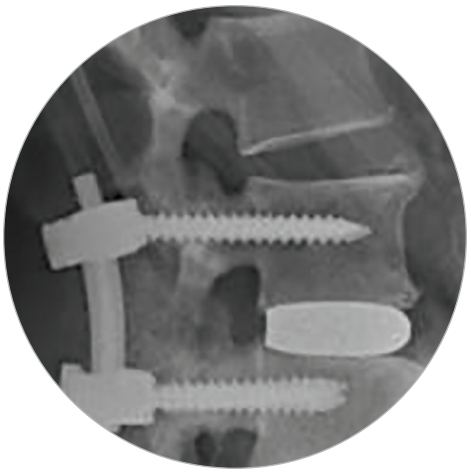
IMAGING

X-Ray

Evaluating bone-device interface

Clinical Significance:

Sentinel signs, a lack of radiolucent lines at the implant-endplate interface, and appearance of the stability of anterior or posterior hardware support the existence of fusion. Flexion/extension films may be used to evaluate angular and translational motion of the segments to be fused.



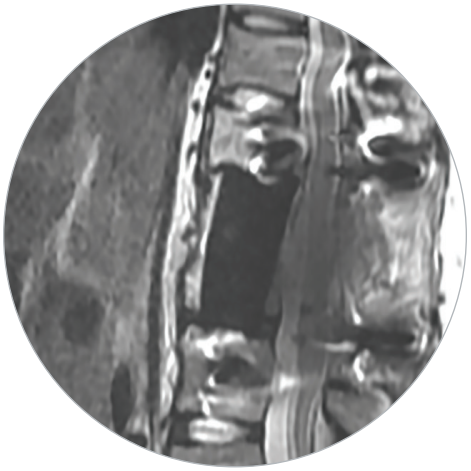
X-Ray

MRI Scan

Evaluating soft tissues around the device

Clinical Significance:

Trabecular Metal Material causes the least artifact and image distortion of any orthopedic metal.[14]



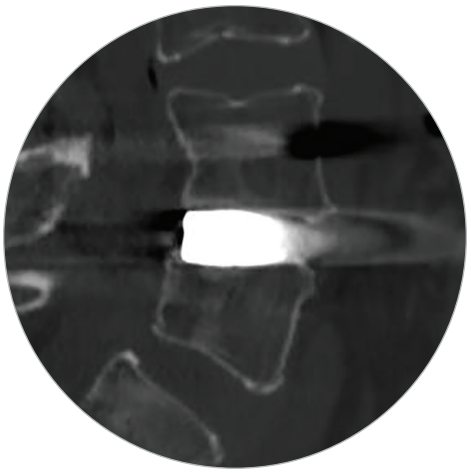
MRI

CT Scan

Evaluating bone-implant interface

Clinical Significance:

Coronal, sagittal and axial reformations suggested; coronal and sagittal views have less artifact than axial. Metal artifact reduction software can be used to reduce image scatter.



CT

TRABECULAR METAL IMPLANT PORTFOLIO

Trabecular Metal Material is available in a range of shapes and sizes to accommodate surgeon preference.

Vertebral Body Replacement (VBR) Devices:

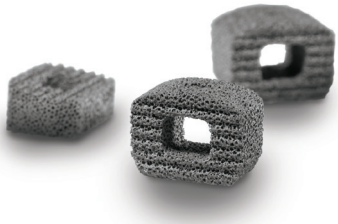
TM-400

VBR-S

VBR-21/L

Cervical Interbody Fusion Device:

TM-S



Lumbar Interbody Fusion Devices:

TM Ardis®

TM-400

References:

1. Bobyn JD, Hacking SA, Chan SP, et al. Characterization of new porous tantalum biomaterial for reconstructive orthopaedics. *Scientific Exhibition: 66th Annual Meeting of the American Academy of Orthopaedic Surgeons*; 1999; Anaheim, CA.
2. Karageorgiou V, Kaplan D. Porosity of biomaterial scaffolds and osteogenesis. *Biomaterials*. 2005;26: 5474–5491.
3. In the United States, the TM Ardis®, TM-S and TM-400 Systems are indicated for use with autogenous bone graft as an intervertebral body fusion device at one (TM-S) or one or two contiguous levels (TM Ardis System, TM-400) with supplemental fixation.
4. D. D. Deligianni, N. Katsala, S. Ladas, D. Sotiropoulou, J. Amedee, and Y. F. Missirlis. Effect of surface roughness of the titanium alloy Ti–6Al–4V on human bone marrow cell response and on protein adsorption. 1 June 2001, pages 1241–1251.
5. M. Wong, J. Eulenberger, R. Schenk, E. Hunziker. Effect of surface topology on the osseointegration of implant materials in trabecular bone. 13 SEP 2004. *Journal of Biomedical Materials Research*.
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7. Von Recum, A.F.; Van Kooten, T.G. The influence of micro-topography on cellular response and the implications for silicone implants. *Journal of Biomaterials Science*. Volume 7, Number 2, 1996, pp. 181–198(18)
8. M.M. Shalabi, A. Gortemaker, M.A. Van't Hof, J.A. Jansen, N.H.J. Creugers. Implant Surface Roughness and Bone Healing: a Systematic Review. *JDR* June 2006 vol. 85 no. 6 496–500
9. Independent data provided by Medical Device Research. Patient underwent revision ACDF surgery.
10. Mineral apposition rate (MAR) data show the TM-S animals had a greater average MAR in the graft hole region at each time point compared to the PEEK animals. Within the graft hole region, there was a statistically significant difference ($p \leq 0.05$) in MAR between the two device groups at 6 and 12 weeks; (n=4 in all groups, graft hole data were normalized to host bone MAR). *T*-tests were utilized to compare the MAR within the graft hole, at each time point, to determine if a significant difference existed between the two types of implants.
11. There were greater amounts of bone in direct contact with the TM-S implants within each region of interest (cranial and caudal to the implant, dorsal and ventral to the implant, and within the graft hole of the implant) at each time point (n=5 in the 12-week TM-S cohort and n=4 in the 6 and 26 week groups). A total percent of bone in direct apposition (contact) with the edges of the implants (sum of all regions of interest) was computed for both TM and PEEK implants, and reported as the Total Appositional Bone Index (ABI). Animals with a TM-S device had significantly greater ($p \leq 0.05$) amounts of bone in direct contact with the Trabecular Metal Implants at 6, 12 and 26 weeks compared to the PEEK devices. For "Total ABI," a comparison was made at each time point using a mixed effects linear regression.
12. Bone growth into the Trabecular Metal Material of the TM-S devices was statistically different ($p \leq 0.05$) than the non-porous PEEK implants at 6, 12 and 26 weeks. Since PEEK is non-porous and bone cannot grow into the PEEK material, a value of 0.0 was used for the PEEK implants within this comparison (n=5 in the 12-week TM-S cohort and n=4 in the 6 and 26 week groups).
13. Data on file at Zimmer Biomet Spine, Inc.
14. Saiz. P, Roberston DD, Konz R. L. Imaging in Patients with Trabecular Metal Spinal Devices. 1564, 2010 *White Paper*.

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

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