FORZA®

PTC SPACER SYSTEM

Posterior & Transforaminal Lumbar Interbody Fusion

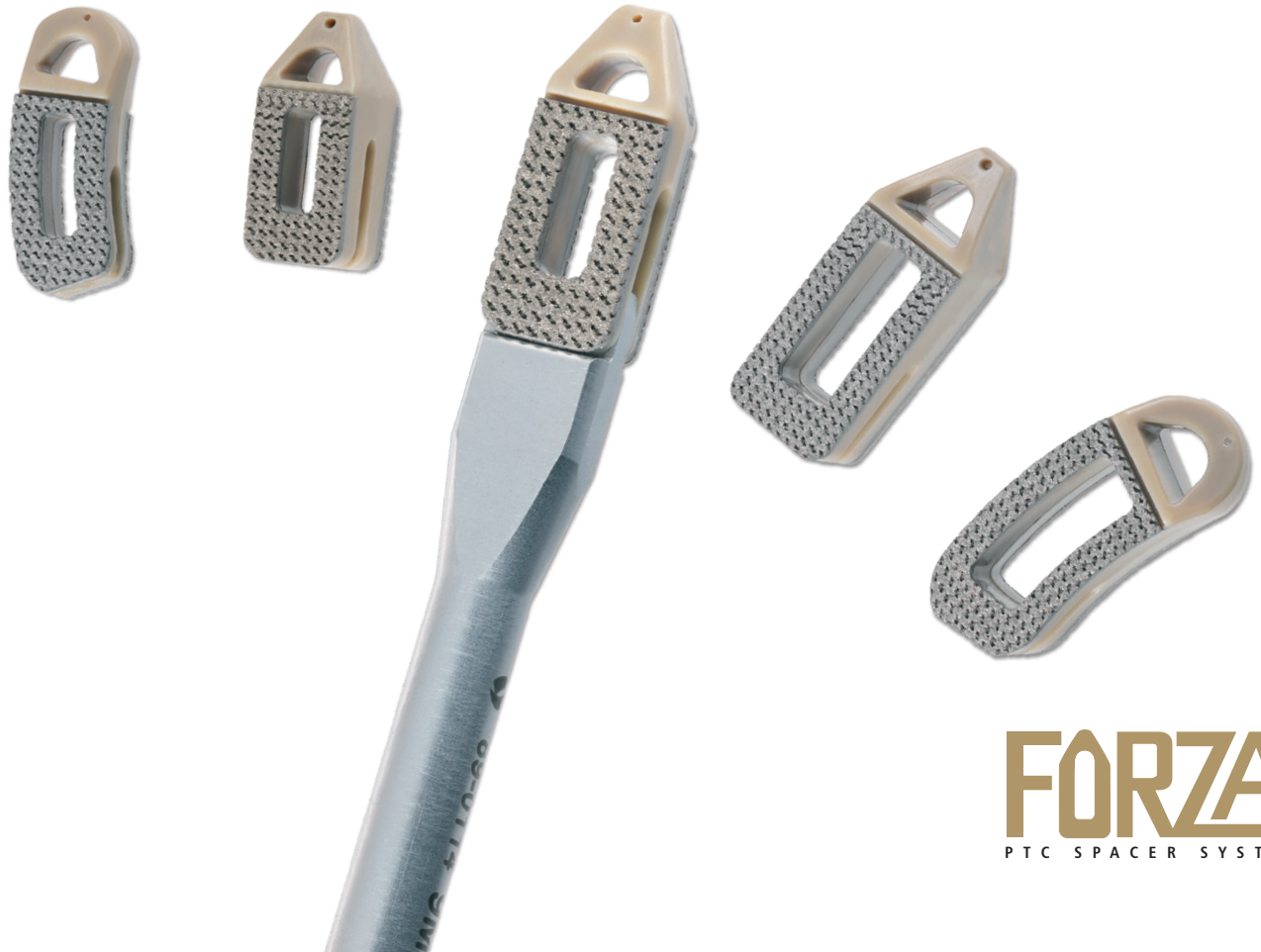
ORTHOFIX® | SPINE

System Overview

The FORZA® PTC Spacer System has been designed to help optimize Transforaminal Lumbar Interbody Fusion (TLIF), Posterior Lumbar Interbody Fusion (PLIF) and Oblique Lumbar Interbody Fusion procedures with surgeon designed implants and instruments. FORZA PTC Spacers offer a unique technology that combines PEEK and titanium into a porous interbody solution for the lumbar spine. This PEEK/Titanium hybrid is designed with a 3D porous endplate that allows the patient's bone to grow into its surface creating a bond between the implant and the patient's bone.

Special features of the FORZA PTC spacers include:

- 3D printed porous titanium endplates are designed to allow the patient's bone to grow into the porous plate
- PEEK core to obtain imaging properties while assessing fusion
- Threaded connection to the Implant Inserter with rail grooves for a secure hold
- Bulleted nose to assist with distraction
- Vertical tantalum marker 1mm from the end and titanium plates for clear in-situ implant positioning
- Large opening for packing bone grafting material



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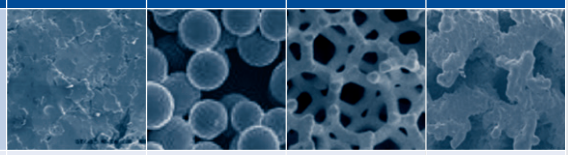
Potential Bone Ingrowth

FORZA PTC is designed to help facilitate bone ingrowth as suggested in an in-vivo ovine lumbar spinal fusion model. Other implants, such as plasma titanium coating, only offer potential for bone ongrowth. Scaffolds with higher porosity, larger pore size, and open pore structure are associated with greater bone ingrowth[1].

FORZA PTC vs Plasma Titanium Coatings

- 4x larger pores than Plasma titanium coatings (400 μm)[1,2]
- Designed with open pore structure[2,3]

Comparison with Commonly Used Surface Sprays and Porous Metals

	Plasma Sprayed Ti[1]	CoCr Beads[2]	Trabecular Metal[3]	PTC
				
Material	CP Ti	Co-28Cr-6Mo	Ta	Ti-6al-4V
Porosity	3-10%	35%	82%	50%
Pore Size	80-100 um	50-300 um	480 um	400 um

1. Vassilis, K., Kaplan, D. Porosity of 3D biomaterials scaffolds and osteogensis, Biomaterials 26 (2005) 5474-5491

2. Kurtz, S, "PEEK BIOMATERIALS HANDBOOKS", ELSEVIER, 2012

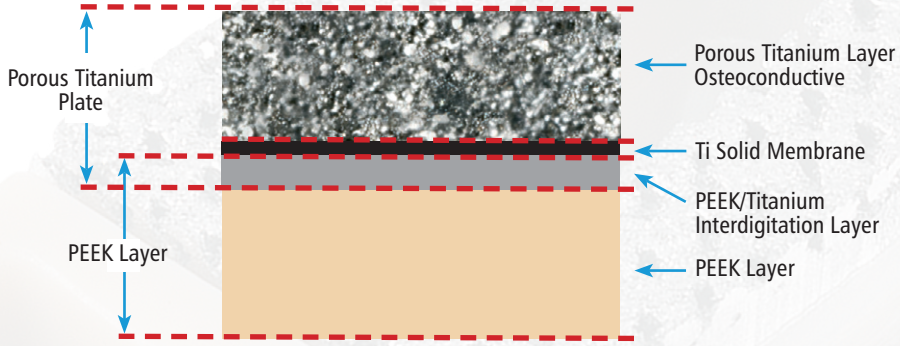
3. Shanbhag S, Rubash A, Jacobs J, "JOINT REPLACEMENT AND BONE RESORPTION, PATHOLOGY, BIOMATERIALS AND CLINICAL PRACTICE", Taylor and Francis, 2006

PTC Technology

PEEK Titanium Composite (PTC) Technology is a proprietary design and manufacturing method that incorporates the radiolucency and elasticity of PEEK with porous 3-dimensional metal resulting in a novel implant with the potential for bone tissue in-growth within the surgical site as suggested in an in-vivo ovine lumbar spinal fusion model. The proprietary manufacturing process creates macroscopic 3D pores with a microscopic roughened surface and nano-scale surface features on the porous titanium end plates. The nano-scale surface has been shown to increase proliferation and alkaline phosphatase activity (an early osteogenic differentiation marker) in human stem cells in vitro.* 3D printed titanium endplates with 400 micron pores and 50% porosity designed to help facilitate bone ingrowth as suggested in an in-vivo ovine lumbar spinal fusion model. The PTC endplates provide an open porous environment.

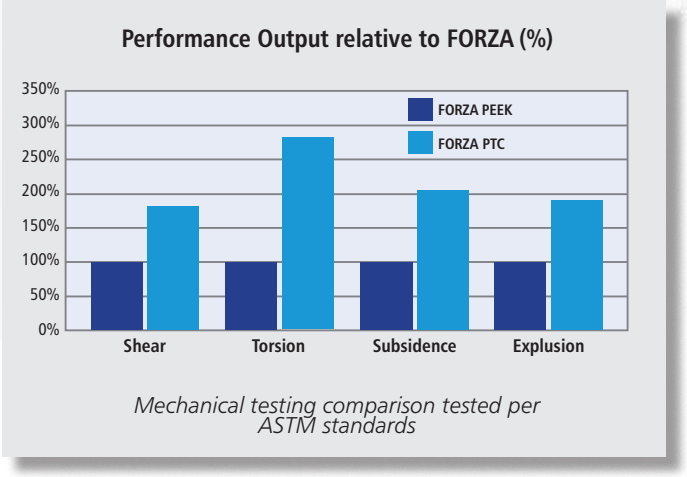
Advanced Design and Manufacturing

The pores of the 3-dimensional titanium endplates are specifically designed to size and interconnectivity requirements and are manufactured with 3D printing technology. The proprietary design creates a PEEK/Titanium inter-digitation layer that ensures an integrated and secure mechanical bond between the endplate and the PEEK core.



Mechanical Performance

The FORZA PTC implant outperforms its predicate in industry standard testing. All performance outputs were normalized to the FORZA® PEEK Spacer. The performances increase from as low as 70% in shear testing to as high as 180% in torsion test.

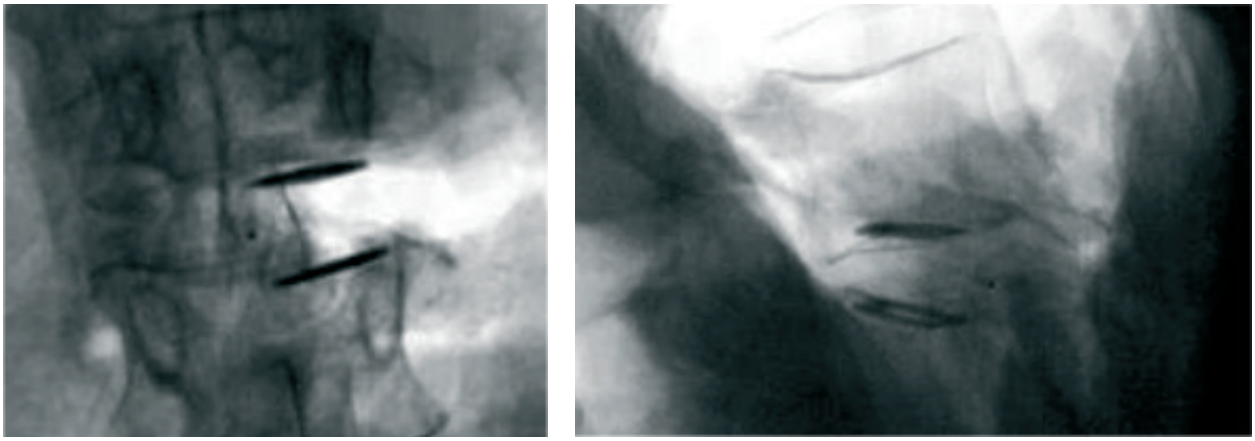


Mechanical testing comparison tested per ASTM standards

* In vitro performance may not be representative of clinical performance.

Imaging Advantage

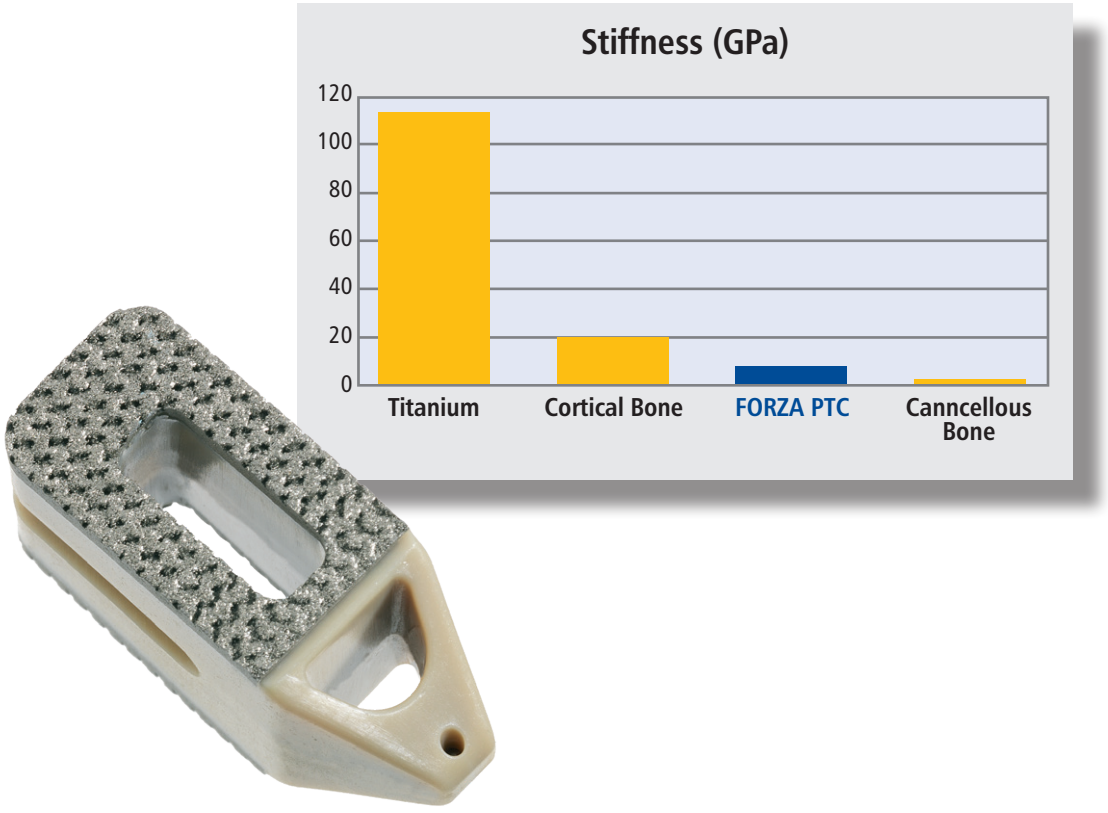
The core of FORZA PTC is made of PEEK to assess fusion post operatively. The titanium endplates are radiopaque for clear delineation of cage-endplate contact.



Vertical tantalum marker 1mm from the end, titanium plates for clear in-situ implant positioning

Bone-Like Elastic Modulus

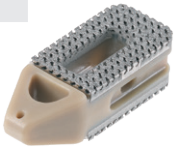
The elastic modulus of FORZA PTC is between cortical and cancellous bone. The design and geometry of the FORZA PTC spacer minimizes the risk of subsidence when compared to FORZA PEEK device with similar geometry. Metals, such as titanium, are much stiffer than cortical bone which may create stress shielding.



Available in 10 footprints

Straight Spacers (PLIF & TLIF)

Profile	Height	Lordosis
9mm x 23mm	7mm - 14mm	0°
9mm x 23mm	8mm - 14mm	8°
9mm x 27mm	7mm - 14mm	0°
9mm x 27mm	9mm - 14mm	8°
11mm x 27mm	7mm - 14mm	0°
11mm x 31mm	7mm - 14mm	0°



Curved Spacers (TLIF)

Profile	Height	Lordosis
9mm x 27mm	7mm - 14mm	0°
9mm x 27mm	8mm - 14mm	8°
11mm x 27mm	7mm - 14mm	0°
11mm x 31mm	7mm - 14mm	0°

9x23 Straight 0°

Part #	Description
38-1007SP	9W X 23L X 7H 0°
38-1008SP	9W X 23L X 8H 0°
38-1009SP	9W X 23L X 9H 0°
38-1010SP	9W X 23L X 10H 0°
38-1011SP	9W X 23L X 11H 0°
38-1012SP	9W X 23L X 12H 0°
38-1013SP	9W X 23L X 13H 0°
38-1014SP	9W X 23L X 14H 0°

9x23 Straight 8°

Part #	Description
38-7008SP	9W X 23L X 8H, 8°
38-7009SP	9W X 23L X 9H, 8°
38-7010SP	9W X 23L X 10H, 8°
38-7011SP	9W X 23L X 11H, 8°
38-7012SP	9W X 23L X 12H, 8°
38-7013SP	9W X 23L X 13H, 8°
38-7014SP	9W X 23L X 14H, 8°

9x27 Straight 0°

Part #	Description
38-3007SP	9W X 27L X 7H, 0°
38-3008SP	9W X 27L X 8H, 0°
38-3009SP	9W X 27L X 9H, 0°
38-3010SP	9W X 27L X 10H, 0°
38-3011SP	9W X 27L X 11H, 0°
38-3012SP	9W X 27L X 12H, 0°
38-3013SP	9W X 27L X 13H, 0°
38-3014SP	9W X 27L X 14H, 0°

9x27 Straight 8°

Part #	Description
38-9009SP	9W X 27L X 9H, 8°
38-9010SP	9W X 27L X 10H, 8°
38-9011SP	9W X 27L X 11H, 8°
38-9012SP	9W X 27L X 12H, 8°
38-9013SP	9W X 27L X 13H, 8°
38-9014SP	9W X 27L X 14H, 8°

9x27 Curved 0°

Part #	Description
38-1707SP	9W X 27L X 7H, 0°
38-1708SP	9W X 27L X 8H, 0°
38-1709SP	9W X 27L X 9H, 0°
38-1710SP	9W X 27L X 10H, 0°
38-1711SP	9W X 27L X 11H, 0°
38-1712SP	9W X 27L X 12H, 0°
38-1713SP	9W X 27L X 13H, 0°
38-1714SP	9W X 27L X 14H, 0°

9x27 Curved 8°

Part #	Description
38-4508SP	9W X 27L X 8H, 8°
38-4509SP	9W X 27L X 9H, 8°
38-4510SP	9W X 27L X 10H, 8°
38-4511SP	9W X 27L X 11H, 8°
38-4512SP	9W X 27L X 12H, 8°
38-4513SP	9W X 27L X 13H, 8°
38-4514SP	9W X 27L X 14H, 8°

11x27 Straight 0°

Part #	Description
38-4007SP	11W X 27L X 7H, 0°
38-4008SP	11W X 27L X 8H, 0°
38-4009SP	11W X 27L X 9H, 0°
38-4010SP	11W X 27L X 10H, 0°
38-4011SP	11W X 27L X 11H, 0°
38-4012SP	11W X 27L X 12H, 0°
38-4013SP	11W X 27L X 13H, 0°
38-4014SP	11W X 27L X 14H, 0°

11x27 Curved 0°

Part #	Description
38-1807SP	11W X 27L X 7H, 0°
38-1808SP	11W X 27L X 8H, 0°
38-1809SP	11W X 27L X 9H, 0°
38-1810SP	11W X 27L X 10H, 0°
38-1811SP	11W X 27L X 11H, 0°
38-1812SP	11W X 27L X 12H, 0°
38-1813SP	11W X 27L X 13H, 0°
38-1814SP	11W X 27L X 14H, 0°

11x31 Straight 0°

Part #	Description
38-6007SP	11W X 31L X 7H, 0°
38-6008SP	11W X 31L X 8H, 0°
38-6009SP	11W X 31L X 9H, 0°
38-6010SP	11W X 31L X 10,H 0°
38-6011SP	11W X 31L X 11,H 0°
38-6012SP	11W X 31L X 12H, 0°
38-6013SP	11W X 31L X 13H, 0°
38-6014SP	11W X 31L X 14H, 0°

11x31 Curved 0°

Part #	Description
38-4207SP	11W X 31L X 7H, 0°
38-4208SP	11W X 31L X 8H, 0°
38-4209SP	11W X 31L X 9H, 0°
38-4210SP	11W X 31L X 10H, 0°
38-4211SP	11W X 31L X 11H, 0°
38-4212SP	11W X 31L X 12H, 0°
38-4213SP	11W X 31L X 13H, 0°
38-4214SP	11W X 31L X 14H, 0°

Streamlined Instrumentation

- Firm connection to the implant.
- All Inserters provide great visualization capability.
- Modular Implant Inserter with different handle angle locations to match surgeon preference.
- MIS Inserter for improved visualization in tight spaces.
- Monolithic implant trials for speed and efficiency.

Refer to Forza/Forza PTC operative technique for instrument part numbers and descriptions.

Corner Tamp

Articulating Tamp

Curette

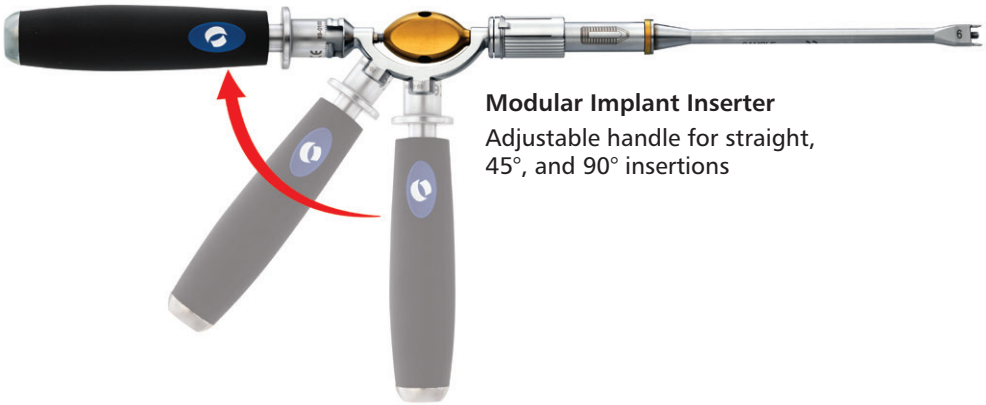
Straight Trial

Monolithic Inserter
(Order by Request)

Rotating Cutter

MIS Inserter

Paddle Distractor



Modular Implant Inserter
Adjustable handle for straight, 45°, and 90° insertions

Please visit Orthofix.com/IFU for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

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