

# Posterior and Transforaminal Lumbar Interbody Fusion







The Forza<sup>®</sup> PTC Spacer System with NanoVate Technology 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 has an optimized porosity and pore size which creates a 3D printed porous titanium endplate surface designed to help facilitate bone ingrowth.\*\*

## Forza PTC Spacer Design Advantages:

- 3D porous titanium endplates with macro, micro, and nano-scale surface features
- 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 are designed to help facilitate bone ingrowth\*\*
- The endplates consist of interconnected gyroid structures analogous in form to trabecular bone which provide an open porous environment
- 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







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

\*\*As suggested in an in-vivo ovine lumbar spinal fusion model.

## **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<sup>1</sup>.

## FORZA PTC vs Plasma Titanium Coatings

- 4x larger pores than Plasma titanium coatings (400  $\mu$ m)<sup>1,2</sup>
- Designed with open pore structure<sup>2,3</sup>



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.



\* 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.



## Combining Innovative Technologies\* for Posterior and Transforaminal Lumbar Fusion



Forza PTC packed with Trinity ELITE<sup>™</sup> Allograft\*\*



## Forza PTC Standard Straight Implant Kit (89-7002)

Forza PTC Standard PLIF/TLIF Straight Implants				
Part #	Description	Qty		
9W X 23L 0° PLIF				
38-1007SP	9W X 23L X 7H, 0°	3		
38-1008SP	9W X 23L X 8H, 0°	3		
38-1009SP	9W X 23L X 9H, 0°	3		
38-1010SP	9W X 23L X 10H, 0°	3		
38-1011SP	9W X 23L X 11H, 0°	3		

### 9W X 23L 8° PLIF

38-7008SP	9W X 23L X 8H, 8°	3
38-7009SP	9W X 23L X 9H, 8°	3
38-7010SP	9W X 23L X 10H, 8°	3
38-7011SP	9W X 23L X 11H, 8°	3
38-7012SP	9W X 23L X 12H, 8°	3
38-7013SP	9W X 23L X 13H, 8°	3

### 9W X 27L 8° TLIF

38-9009SP	9W X 27L X 9H, 8°	2
38-9010SP	9W X 27L X 10H, 8°	2
38-9011SP	9W X 27L X 11H, 8°	2
38-9012SP	9W X 27L X 12H, 8°	2
38-9013SP	9W X 27L X 13H, 8°	2
38-9014SP	9W X 27L X 14H, 8°	2

**Note:** All implant footprints outside of the standard offering, are available upon request

\*The Forza PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft

\*\*Trinity ELITE Allograft is exclusively processed by MTF Biologics

## Forza PTC Standard Curved Implant Kit (89-7003)

Forza PTC Standard Curved Implants				
Part #	Description	Qty		
9W X 27L 0° TLIF				
38-1707SP	9W X 27L X 7H, 0°	2		
38-1708SP	9W X 27L X 8H, 0°	2		
38-1709SP	9W X 27L X 9H, 0°	2		
38-1710SP	9W X 27L X 10H, 0°	2		
38-1711SP	9W X 27L X 11H, 0°	2		
38-1712SP	9W X 27L X 12H, 0°	2		
9W X 27L 0° TLIF				
38-1808SP	11W X 27L X 8H, 0°	2		
38-1809SP	11W X 27L X 9H, 0°	2		
38-1810SP	11W X 27L X 10H, 0°	2		
38-1811SP	11W X 27L X 11H, 0°	2		
38-1812SP	11W X 27L X 12H, 0°	2		

#### 9W X 31L 8° TLIF 38-4508SP 2 9W X 27L X 8H, 8° 38-4509SP 9W X 27L X 9H, 8° 2 38-4510SP 9W X 27L X 10H, 8° 2 9W X 27L X 11H, 8° 2 38-4511SP 38-4512SP 9W X 27L X 12H, 8° 2 38-4513SP 9W X 27L X 13H, 8° 2

### Notes





# Please visit <u>Orthofix.com/IFU</u> for full information on indications for use, contraindications, warnings, precautions, adverse reactions information 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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