

# Oracle Spacer. A PEEK spacer for lateral lumbar interbody fusion.

Anatomic shape

Self-distracting nose

Large central canal



# Oracle Spacer

The Oracle PEEK spacer is designed to meet the specific demands of lateral lumbar interbody fusion procedures. The spacer is available in 4 medial/lateral lengths, 5 heights, and 2 sagittal profiles to accommodate various patient anatomies.

## Features and Benefits

### Anatomic shape

Mimics the anatomy of the disc space

### Self-distracting nose

Allows for ease of insertion

### Large central canals

Accommodates autogenous bone graft to allow fusion to occur through the spacer

### Pyramidal teeth

Provides resistance to spacer migration

### Four radiographic marker pins

Enables visualization of spacer position

The medial/lateral marker pins are located approximately 3.85 mm from the edges of the spacer. The anterior/posterior marker pins are located approximately 2.25 mm from the edges of the spacer.



Two-level lateral view of Oracle and Pangea immediately postoperative.

## Indications

The Oracle Spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Oracle Spacer should be packed with autogenous bone graft (i.e. autograft).

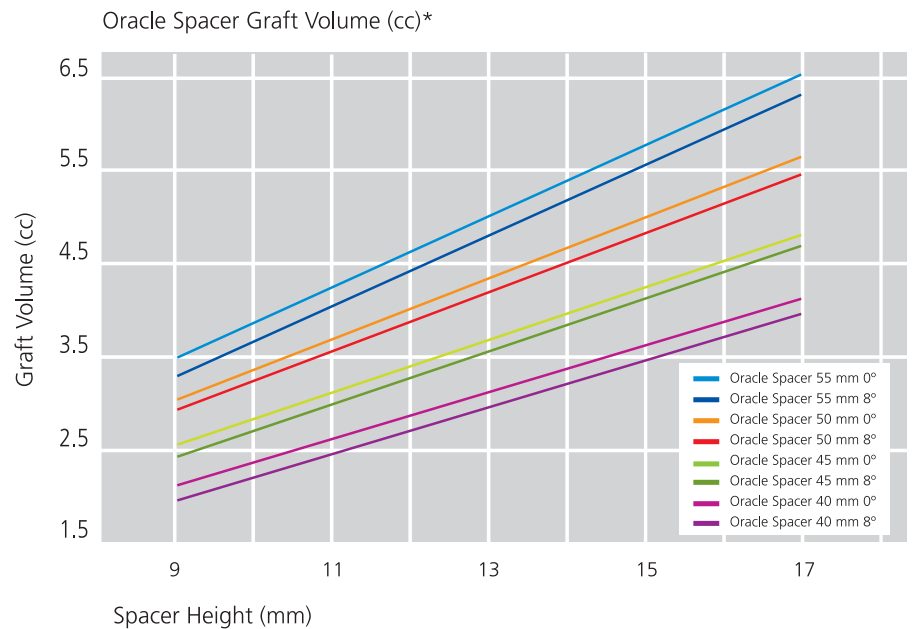
DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment.

The Oracle Spacer is intended to be used with Synthes supplemental fixation, e.g. TSLP, ATB, Antegra, Pangea, USS (including Click'X) and small stature USS.

# Graft Volume and Material

## Graft volume

The graph shows the approximate graft volume that Oracle Spacers will hold, depending on the dimensions and height. For example, 8° Oracle Spacers of 45 mm x 22 mm and 13 mm height will hold approximately 3.5 cc of graft material.



\*Calculations performed by Synthes Spine, West Chester, PA, 2007.

## Material

The Synthes Oracle Spacer is manufactured from a biocompatible polymer<sup>†</sup> material embedded with four radiopaque marker pins, which allows the surgeon to radiographically determine the exact position of the implant, both intraoperatively and postoperatively. The modulus of elasticity of the polymer is approximately between cancellous and cortical bone, which enables adequate compression of auto-graft in and around the implant, to aid in stress distribution and load sharing.

<sup>†</sup>polyetheretherketone (PEEK)

# Mechanical Testing Summary

## Testing

The design of the Oracle Spacer is based on sound engineering principles, extensive research of anatomical geometry from published literature, and mechanical testing.

## Compressive strength

Testing was conducted to show that the Oracle Spacer can withstand clinically relevant loads in the spine. The ultimate compressive strength of a vertebral body is 8,000 N.<sup>1</sup> Test results show that the Oracle Spacer can withstand compressive loads of  $49,519 \pm 9$  N (see Figure 1).<sup>2</sup> Additionally, the Oracle Spacer passed fatigue compression testing conducted at clinically relevant loads for 10 million cycles.<sup>3</sup>

## Resistance to expulsion

Testing was also conducted to ensure that the Oracle Spacer is capable of resisting expulsion at clinically relevant loads. The maximum shear force that the lumbar spine (human disc) can withstand is approximately 150 N.<sup>4</sup> Test results show that the Oracle Spacer can withstand expulsion loads of  $2,594 \pm 35$  N (see Figure 2).<sup>5</sup>

Figure 1

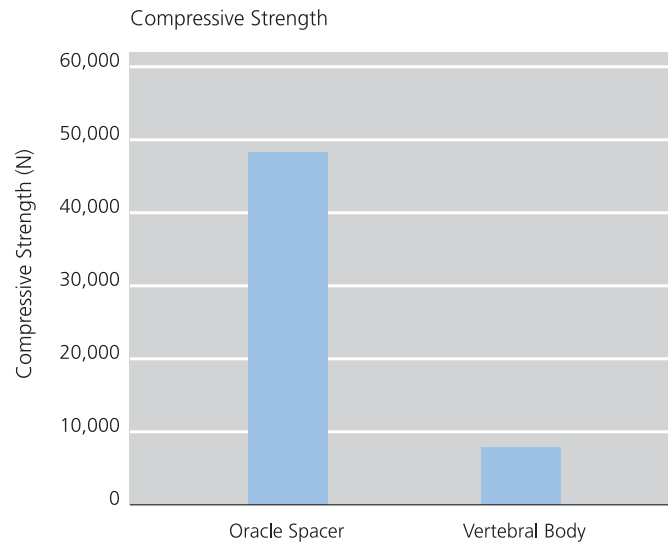
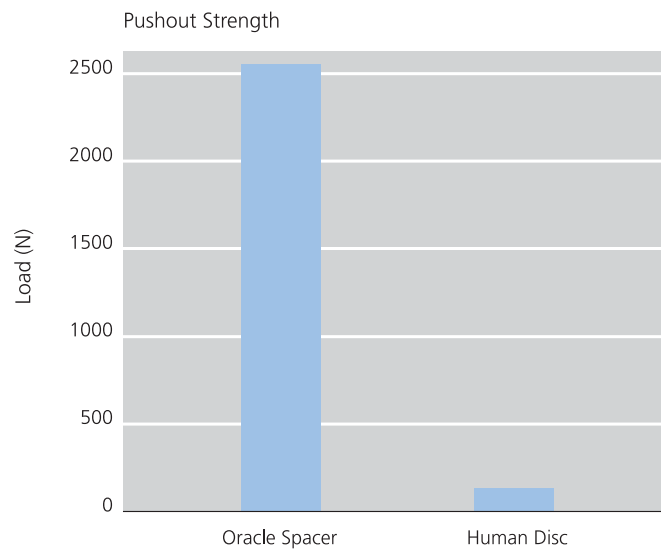


Figure 2

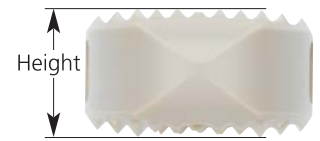
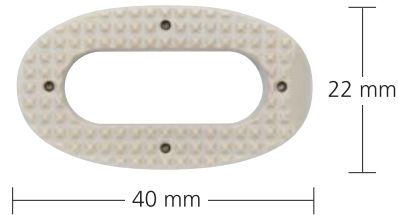


1. O. Pery. "Fracture of the Vertebral Endplate in the Lumbar Spine." *Acta. Orthop. Scand.* 1957; 25 (suppl.)
2. Testing performed at the Mechanical Testing Laboratory, Synthes Spine, West Chester, PA. 2006-MT06-346.
3. Testing performed at the Mechanical Testing Laboratory, Synthes Spine, West Chester, PA. 2006-MT06-347.
4. A.A. White and M.M. Panjabi. *Clinical Biomechanics of Spine.* Philadelphia. Lippincott, William and Wilkins. 1990. 7, 9.
5. Testing performed at the Mechanical Testing Laboratory, Synthes Spine, West Chester, PA. 2006-MT06-416.

# Oracle Spacer Dimensions

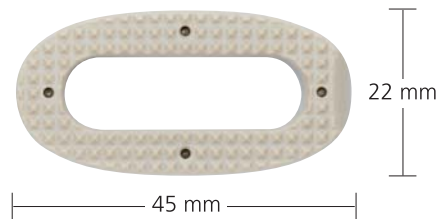
## Oracle Spacers, 40 mm x 22 mm

	Lordotic Angle	Height
08.809.209	0°	9 mm
08.809.211	0°	11 mm
08.809.213	0°	13 mm
08.809.215	0°	15 mm
08.809.217	0°	17 mm



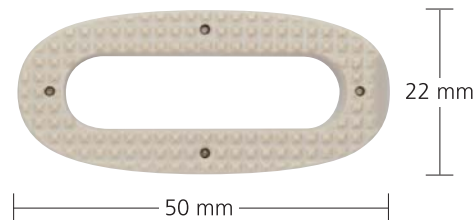
## Oracle Spacers, 45 mm x 22 mm

	Lordotic Angle	Height
08.809.229	0°	9 mm
08.809.231	0°	11 mm
08.809.233	0°	13 mm
08.809.235	0°	15 mm
08.809.237	0°	17 mm



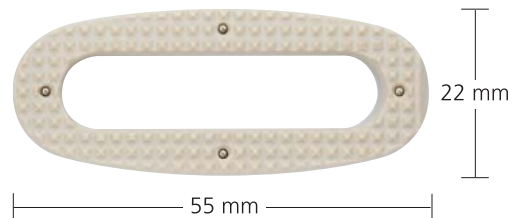
## Oracle Spacers, 50 mm x 22 mm

	Lordotic Angle	Height
08.809.249	0°	9 mm
08.809.251	0°	11 mm
08.809.253	0°	13 mm
08.809.255	0°	15 mm
08.809.257	0°	17 mm



## Oracle Spacers, 55 mm x 22 mm

	Lordotic Angle	Height
08.809.269	0°	9 mm
08.809.271	0°	11 mm
08.809.273	0°	13 mm
08.809.275	0°	15 mm
08.809.277	0°	17 mm

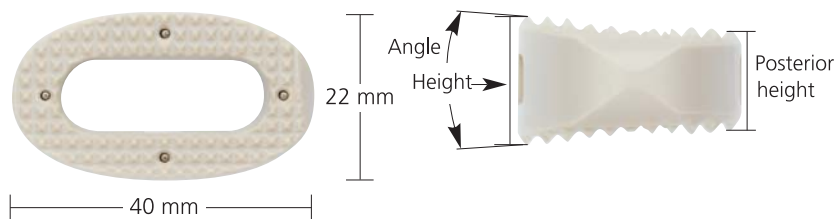


Note: Total combined height of teeth is 2 mm.  
Spacers shown actual size.

## Oracle Spacer Dimensions continued

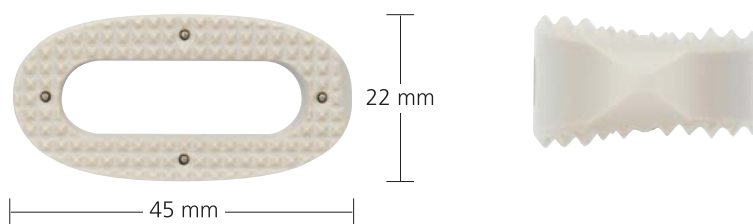
### Oracle Spacers, 40 mm x 22 mm

	Lordotic Angle	Height	Posterior Height
08.809.609	8°	9 mm	6 mm
08.809.611	8°	11 mm	8 mm
08.809.613	8°	13 mm	10 mm
08.809.615	8°	15 mm	12 mm
08.809.617	8°	17 mm	14 mm



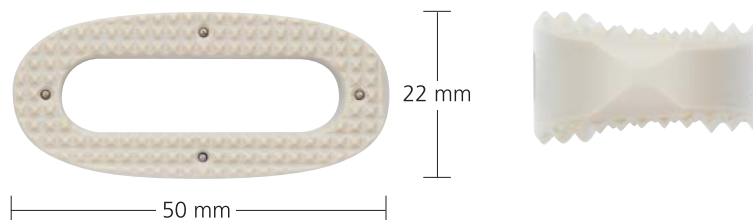
### Oracle Spacers, 45 mm x 22 mm

	Lordotic Angle	Height	Posterior Height
08.809.629	8°	9 mm	6 mm
08.809.631	8°	11 mm	8 mm
08.809.633	8°	13 mm	10 mm
08.809.635	8°	15 mm	12 mm
08.809.637	8°	17 mm	14 mm



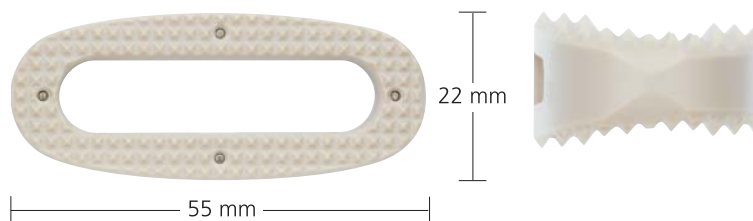
### Oracle Spacers, 50 mm x 22 mm

	Lordotic Angle	Height	Posterior Height
08.809.649	8°	9 mm	6 mm
08.809.651	8°	11 mm	8 mm
08.809.653	8°	13 mm	10 mm
08.809.655	8°	15 mm	12 mm
08.809.657	8°	17 mm	14 mm



### Oracle Spacers, 55 mm x 22 mm

	Lordotic Angle	Height	Posterior Height
08.809.669	8°	9 mm	6 mm
08.809.671	8°	11 mm	8 mm
08.809.673	8°	13 mm	10 mm
08.809.675	8°	15 mm	12 mm
08.809.677	8°	17 mm	14 mm



Note: Total combined height of teeth is 2 mm.

Spacers shown actual size.

# Oracle Implant Set (01.809.001)

## Graphic Case

60.809.001 Graphic Case, for Oracle Implants  
(Includes implant trays 60.809.005  
and 60.809.006)

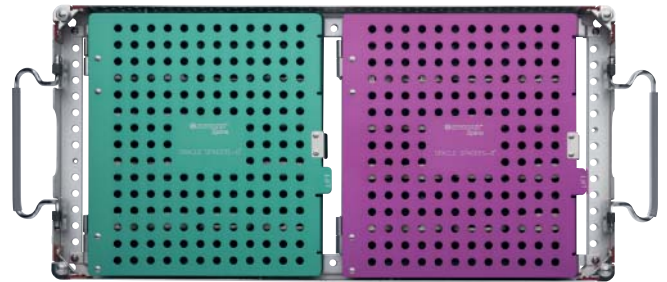
## Implants

Oracle Spacers, 2 ea.

		Dimensions (mm)	Height (mm)
0° Angle	8° Angle		
08.809.229	08.809.629	45 x 22	9
08.809.231	08.809.631	45 x 22	11
08.809.233	08.809.633	45 x 22	13
08.809.235	08.809.635	45 x 22	15
08.809.237	08.809.637	45 x 22	17
08.809.249	08.809.649	50 x 22	9
08.809.251	08.809.651	50 x 22	11
08.809.253	08.809.653	50 x 22	13
08.809.255	08.809.655	50 x 22	15
08.809.257	08.809.657	50 x 22	17

## Also Available

08.809.209	08.809.609	40 x 22	9
08.809.211	08.809.611	40 x 22	11
08.809.213	08.809.613	40 x 22	13
08.809.215	08.809.615	40 x 22	15
08.809.217	08.809.617	40 x 22	17
08.809.269	08.809.669	55 x 22	9
08.809.271	08.809.671	55 x 22	11
08.809.273	08.809.673	55 x 22	13
08.809.275	08.809.675	55 x 22	15
08.809.277	08.809.677	55 x 22	17



Note: For additional information, please refer to package insert.



Synthes Spine  
1302 Wrights Lane East  
West Chester, PA 19380  
Telephone: (610) 719-5000  
To order: (800) 523-0322  
Fax: (610) 251-9056

Synthes (Canada) Ltd.  
2566 Meadowpine Boulevard  
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To order: (800) 668-1119  
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