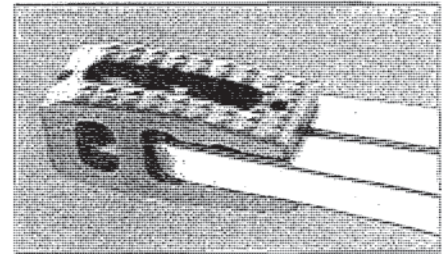
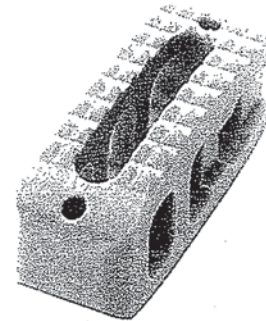


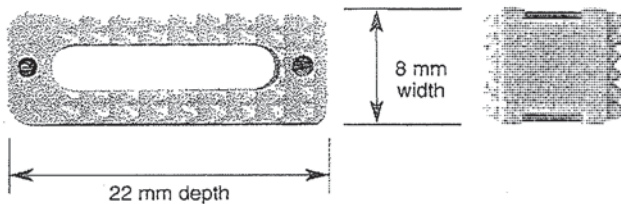
Vertebral Spacer-PR

Features

- Biocompatible radiolucent polymer allows clear assessment of bony fusion
- Convex superior and inferior surfaces enhance anatomical interface with vertebral endplates
- Axial canal receives autograft or other graft material to allow fusion to occur through the implant
- Saw-tooth pattern on superior and inferior surfaces of implant is designed to provide secure engagement with adjacent vertebral bodies
- Two radiopaque marker pins enable radiographic visualization of implant position
- Heights from 7 mm through 17 mm, in 2 mm increments
- Axial footprint is 22 mm depth x 8 mm width



Vertebral Spacer-PR and implant holder



Convex surfaces

FOR REFERENCE ONLY.

Indications

The Vertebral Spacer 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 Vertebral Spacer is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix and USS (including Click'X™). The interior of the spacer component of the Vertebral Spacer can be packed with bone. The Vertebral Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.



Original Instruments and Implants of the Association for the Study of Internal Fixation—AO ASIF

Material

The Synthes Vertebral Spacer-PR is manufactured from a biocompatible radiolucent polymer material, which allows the surgeon to radiographically assess the presence of fusion in the segment in which the Vertebral Spacer-PR has been implanted. Radiopaque marker pins assist the surgeon in determining the exact position of the implant, both intraoperatively and postoperatively. The modulus of elasticity of the polymer approximates that of human cortical bone, which enables adequate compression of autograft in and around the implant, allowing better stress distribution and proper load sharing.

Testing

Testing was conducted to show that the Vertebral Spacer-PR can withstand clinically relevant loads in the lumbar spine. The ultimate compressive strength of a vertebral body is 8000 N.¹ Test results show that two Vertebral Spacer-PR implants can withstand compressive loads of $15,068 \pm 71$ N (see Figure 1). Additionally, the Vertebral Spacer-PR passed fatigue compression testing conducted at clinically relevant loads for ten million cycles.²

Testing was also conducted to ensure that the Vertebral Spacer-PR was capable of resisting expulsion at clinically relevant loads. The maximum shear force that the lumbar spine (human disc) can withstand is approximately 150 N.³ Test results show that the Vertebral Spacer-PR can withstand expulsion loads of 1305 N (see Figure 2).²

Figure 1

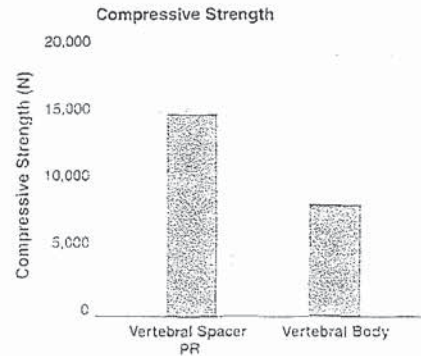
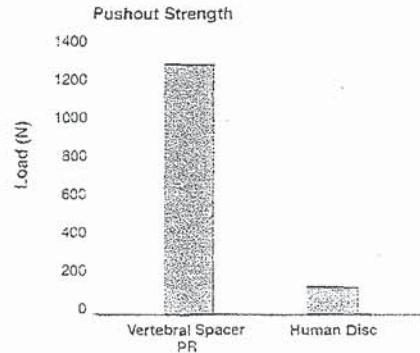


Figure 2



Vertebral Spacer-PR Implant Set [118.802]

Vertebral Spacers-PR, 4 ea.

	HEIGHT
889.844	7 mm
889.845	9 mm
889.846	11 mm
889.847	13 mm
889.848	15 mm
889.849	17 mm



Vertebral Spacer-PR
Module Case [304.921]

1. O. Perry. "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.
3. A.A. White and M.M. Panjabi. *Clinical Biomechanics of the Spine.* Philadelphia: Lippincott, William and Wilkins. 1990. 7. 9.

SYNTHES Spine
1690 Russell Road,
Paoli, PA 19301-1262
Telephone: (610) 647-9700
Fax: (610) 251-9056
To Order: (800) 523-0322

SYNTHES (CANADA) LTD.
111 Brunel Road, Suite 110
Mississauga, Ontario L4Z 1X3
Telephone: (905) 568-1711
Fax: (905) 568-1662
To Order: (800) 668-1119

 **SYNTHES**
Spine