Vertebral Spacer–CR. Vertebral body replacement device intended for use in the thoracolumbar spine.

Manufactured from a biocompatible radiolucent polymer

Large axial canal for osteobiologic material

SYNTHES® Instruments and implants approved by the AO Foundation
Features
- Biocompatible radiolucent polymer allows clear assessment of bony fusion
- Three sagittal profiles: parallel, lordotic, and convex
- Axial canal receives autograft or other graft material to allow fusion to occur through the implant
- Teeth on superior and inferior surfaces of implant are designed to provide secure engagement with adjacent vertebral bodies
- Three radiopaque marker pins enable radiographic visualization of implant position
- Heights from 5 mm through 12 mm, in 1 mm increments
- Axial footprint is 12.5 mm depth x 15 mm width

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.
Material
The Synthes Vertebral Spacer–CR 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–CR 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–CR can withstand clinically relevant loads in the spine. The ultimate compressive strength of a vertebral body is 8000 N.1 Test results show that two Vertebral Spacer–CR implants can withstand compressive loads of over 25,000 N (see Figure 1). Additionally, the Vertebral Spacer–CR passed fatigue compression testing conducted at clinically relevant loads for ten million cycles.2

Testing was also conducted to ensure that the Vertebral Spacer–CR 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–CR can withstand expulsion loads of 780 N (see Figure 2).4

*Polyetheretherketone (PEEK)
2. Testing performed at the Mechanical Testing Laboratory, Synthes Spine, West Chester, PA. Mechanical Test #MT02-077.
4. Testing performed at the Mechanical Testing Laboratory, Synthes Spine, West Chester, PA. Mechanical Test #MT02-180.
304.920  **Vertebral Spacer–CR Module Case**

Vertebral Spacers–CR, 2 ea.

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