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

Anterior

Anterolateral

Lateral

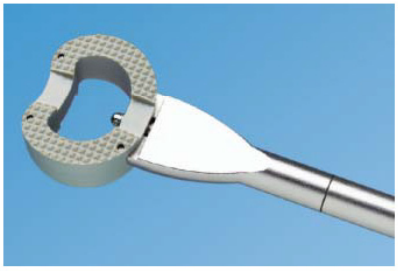
SYNTHES® Spine

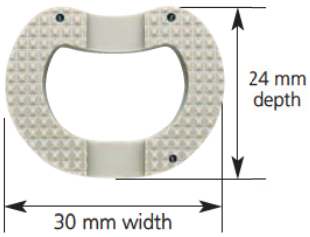
Instruments and implants approved by the AO Foundation

Vertebral Spacer – AR

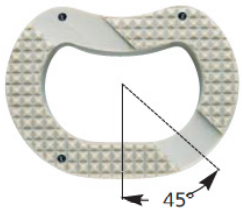
Features

- Biocompatible radiolucent polymer allows clear assessment of bony fusion
- Convex superior and inferior surfaces enhance anatomical interface with vertebral endplates
- Lordotic shape (8°) restores natural sagittal alignment
- Design allows simultaneous distraction and implant insertion
- Axial canal receives allograft 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 styles accommodate varying surgical approaches: anterior, anterolateral and lateral
- Three radiopaque marker pins enable radiographic visualization of implant position
- Heights from 9 mm through 21 mm, in 2 mm increments
- Axial footprint is 24 mm depth x 30 mm width

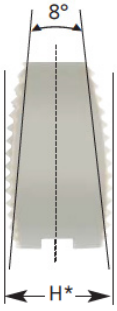




For anterior insertion



For anterolateral insertion



Lordotic design

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.

Contraindications

- Use of the Synthes Vertebral Spacer is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be a higher risk of implant failure.

* Height measured from top of teeth, as shown

Material

The Synthes Vertebral Spacer–AR 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–AR 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.

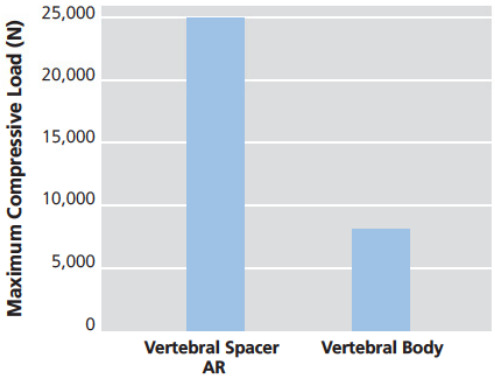


Figure 1. Compressive Strength

Testing

Testing was conducted to show that the Vertebral Spacer–AR can withstand clinically relevant loads in the lumbar spine. The ultimate compressive load that a vertebral body can withstand is 8,000 N.[1] Test results show that the Vertebral Spacer–AR can withstand maximum compressive loads of over 25,000 N (see Figure 1). Additionally, the Vertebral Spacer–AR passed fatigue compression testing conducted at clinically relevant loads for ten million cycles.[2]

Testing was also conducted to ensure that the Vertebral Spacer–AR 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–AR can withstand expulsion loads >700 N (see Figure 2).[2]

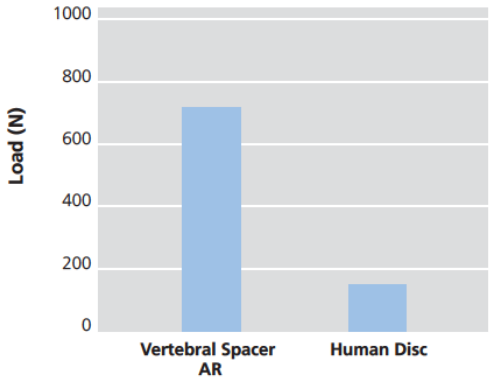


Figure 2. Pushout Strength

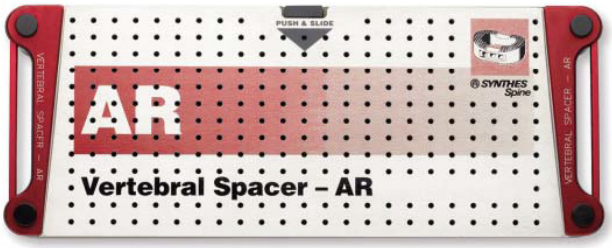
* Polyetheretherketone (PEEK)

1. O. Perey. "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. Bench test results not necessarily indicative of clinical results.
3. A.A. White and M.M. Panjabi. *Clinical Biomechanics of the Spine*. Philadelphia: Lippincott, William and Wilkins. 1990. 7, 9.

Vertebral Spacer – AR Implant Sets

118.804 **Vertebral Spacer–AR Implant Set**

304.922 Vertebral Spacer – AR Module Case

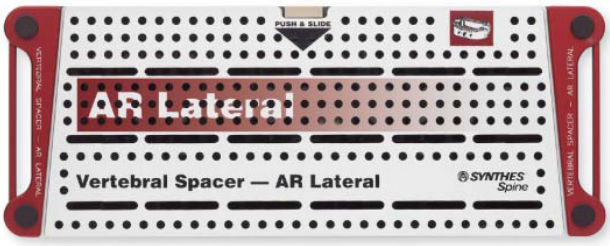


Vertebral Spacers–AR, 2 ea.

Anterior		Anterolateral	
	Height		Height
889.961	9 mm	889.971	9 mm
889.962	11 mm	889.972	11 mm
889.963	13 mm	889.973	13 mm
889.964	15 mm	889.974	15 mm
889.965	17 mm	889.975	17 mm
889.966	19 mm	889.976	19 mm
889.967	21 mm	889.977	21 mm

01.807.004 **Vertebral Spacer–AR Lateral Implant Set**

305.011 Vertebral Spacer–AR Lateral Module Case



Vertebral Spacers–AR, 3 ea.
Lateral

	Height
889.901	9 mm
889.902	11 mm
889.903	13 mm
889.904	15 mm
889.905	17 mm
889.906	19 mm
889.907	21 mm

Note: For additional information, please refer to package insert.
For detailed cleaning and sterilization instructions, please refer to
http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm
or to the below listed inserts, which will be included in the shipping container:
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- Processing Non-sterile Synthes Implants—DJ1304

SYNTHES® Spine

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
Mississauga, Ontario L5N 6P9
Telephone: (905) 567-0440
To order: (800) 668-1119
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