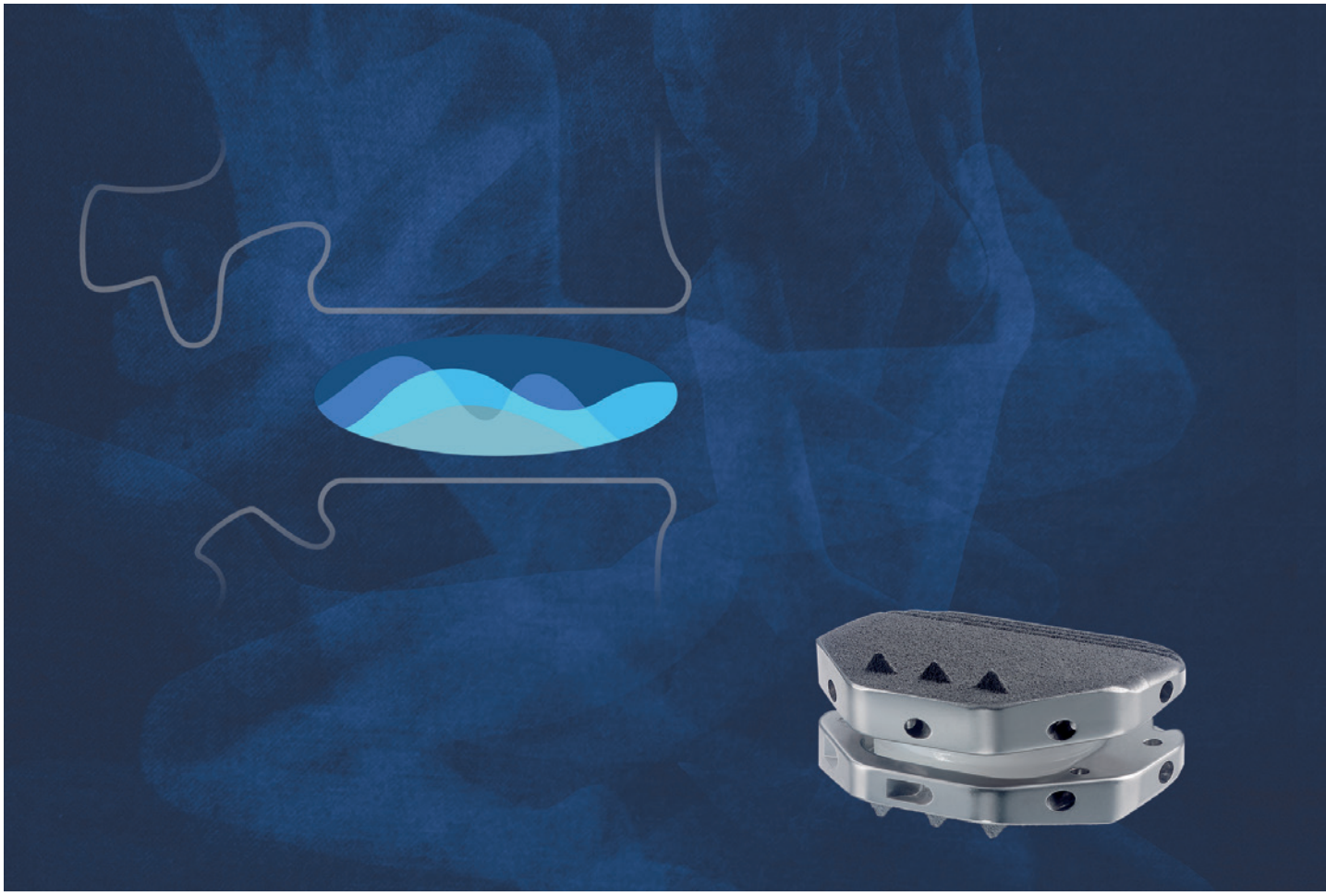
activL® Artificial Disc

Intelligent Motion Technology™ Ordering Information



AESCULAP®
Implant Systems

The First New Lumbar Total Disc Replacement FDA Approved in 10 Years

Indications for Use

The activL® Artificial Disc is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL® Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL® Artificial Disc should have failed at least six months of nonoperative treatment prior to implantation of the device.

Contraindications, Warnings and Precautions

The activL® Artificial Disc should not be implanted in patients with the following conditions:

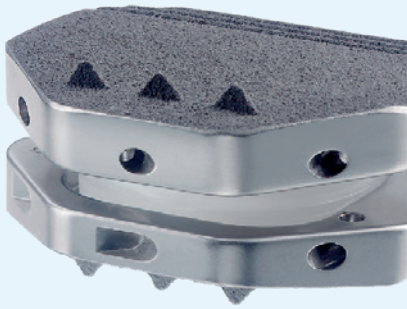
- Active systemic infection or localized infection near the surgical site.
- Osteoporosis or osteopenia defined as dual-energy X-ray absorptiometry (DEXA) bone mineral density T-score less than or equal to -1.0
- Allergy or sensitivity to the implant materials (cobalt, chromium, polyethylene, titanium, tantalum, or calcium phosphate)
- Isolated radiculopathy, especially due to herniated disc
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year)
- Extruded disc material with sequestrum (i.e., free disc fragment)
- Myelopathy
- Spinal stenosis
- Spinal deformity such as scoliosis
- Spondylolysis/isthmic spondylolisthesis, degenerative spondylolisthesis > Grade I, or segmental instability
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., current or prior vertebral fracture) or disease (e.g., ankylosing spondylitis)
- Facet ankylosis or facet joint degeneration
- Preoperative remaining disc height < 3 mm
- Symptoms attributed to more than one vertebral level
- Abdominal pathology that would preclude an anterior retroperitoneal approach
- Involved vertebral endplates dimensionally smaller than 31 mm in the medial-lateral and/or 26 mm in the anterior-posterior directions

For a complete list of Warnings, Precautions and Risks please visit www.aesculapimplantsystems.com

Features

- Intelligent Motion Technology™ combines natural motion with mechanical stability allowing clinically-stable translational and rotational movement
- Single-step insertion may save up to 10 minutes per procedure*

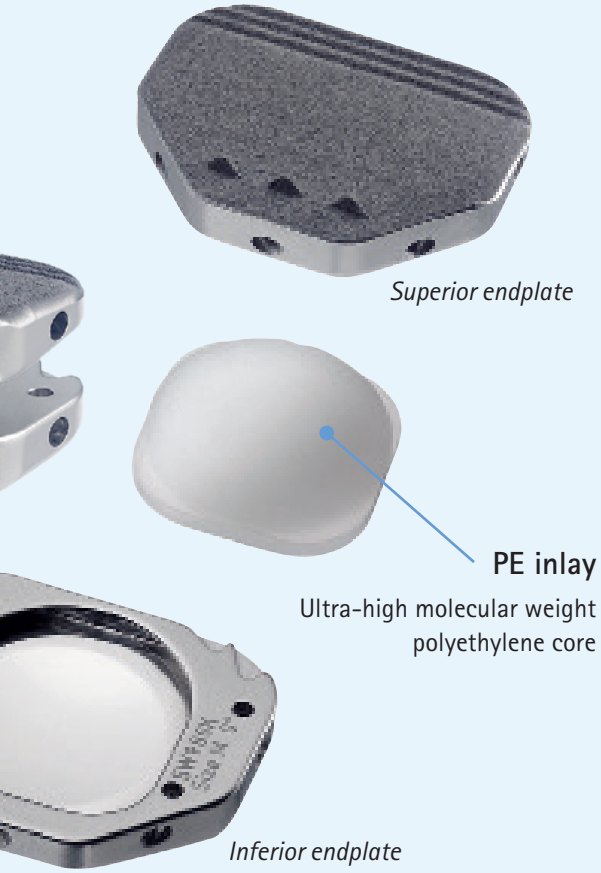
Constructs available in total heights of 8.5, 10, 12 and 14 mm



Bone-Sparing Spike Endplates

- Coated with Plasmapore® µ-CaP, a microporous titanium coating and a thin bioactive calcium phosphate surface finish
- Endplate designs specific for anatomical variations between L4/L5 and L5/S1

- Coated with Plasmapore® µ-CaP, a microporous titanium coating and a thin bioactive calcium phosphate surface finish for stability that starts at the surface
- Widest range of endplate configurations and construct heights to meet diverse anatomical needs



Superior endplate

PE inlay

Ultra-high molecular weight polyethylene core

Inferior endplate

*In the activL® IDE Trial, activL patients showed on average a 10 minute improvement in operative time compared to the study's control

Ordering Information

The implants are delivered sterile packed.

ST0565 – activL Implant Bank/ST0566 – activL Instruments

PE Inlay				
Height (mm)	8.5	10	12	14
PE inlay	SW965	SW966	SW967	SW968

The height shown corresponds to the height of the implant measured at the posterior end.

activL Spike Endplates						
Components (mm)			Size			
			S	M	L	XL
			(26x31)	(28x34.5)	(30x39)	(33x40)
Superior Plate	Angle	6°	SW971K	SW981K	SW991K	SW891K
		11°	SW972K	SW982K	SW992K	SW892K
Inferior Plate		0°	SW970K	SW980K	SW990K	SW890K
S1 Inferior Plate		5°	SW976K	SW986K	SW996K	SW888K

Four footprints, each available in total construct lordotic configurations of 6°, 11° and 16°

S 26 mm x 31 mm, allows 1.5 mm translation

M 28 mm x 34.5 mm, allows 2.0 mm translation

L 30 mm x 39 mm, allows 2.0 mm translation

XL 33 mm x 40 mm, allows 2.0 mm translation

"In the activL® Artificial Disc IDE Trial, an 8.5 mm total construct height was chosen in **87%** of cases as the best fit for the subjects' anatomy."

–Dr. Rolando Garcia
activL IDE Study Primary Investigator

Each surgeon must evaluate the appropriateness of the implant height for each patient.

Through collaborative excellence we will improve the quality of a patient's life and meet the needs of the changing healthcare environment.

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