activL® Artificial Disc with Intelligent Motion Technology™ Media Fact Sheet

What is it?

The activL Artificial Disc is the first lumbar total disc replacement with a mobile ultra high molecular weight polyethylene core. The device is used to reduce lower back pain caused by degenerative disc disease (DDD) by more closely mirroring the natural movement of the healthy human spine.

How does it work?

Surgeons insert the activL Artificial Disc in place of a shrinking or worn-out spinal disc that can be a source of pain in the lower back or legs. The surgery, unlike with fusion surgery, can relieve pain without permanently immobilizing the vertebrae in a patient's spine. The disc's mobile core shifts to adjust to human body movements and allows for a greater range of motion for patients.

What's it made of?

The disc consists of two metal endplates with a plastic insert between them. It has a proprietary Plasmapore® titanium coating with a rough calcium phosphate finish that spurs bone growth and improves implant stability.

Who does it help?

activL Artificial Disc is not right for every patient. At a base level, it is designed for adults suffering from DDD in their lower back who have not found pain relief from at least six months of non-surgical treatment. Surgeons will make a detailed assessment of other personal factors before recommending treatment.

Why do people need it?

Lower back pain is the most common type of pain for US adults, responsible for billions of dollars in medical costs and lost productivity every year. Six weeks after surgery, activL Artificial Disc patients in the clinical trial had nearly a threefold decrease in back pain and improved range of motion.

What makes it different?

- Unlike spinal fusion surgery, activL Artificial Disc helps address pain while also preserving spinal motion, which is important to the health of the rest of the spine and surrounding anatomy.
- The only lumbar replacement disc in the US that allows for translational and rotational movements in the spine.
- A range of sizes available to accommodate different body types, including a height of 8.5 mm – the lowest available on the market and the size of choice for 87 percent of patients in the clinical trial.

activL Artificial Disc Fast Facts

- Approved by FDA on June 15, 2015.
- 1st post-approval US surgery performed on August 17, 2015.
- More than 250 activL Artificial Disc surgeries performed in US.
- Nearly 8,000 surgeries performed outside the US in last 10 years.
- More than 100 surgeons in US certified to implant activL Artificial Disc based on FDA parameters.
- In the clinical trial, patients implanted with activL Artificial Disc were 14 percent more likely to succeed at 24 months than patients in the control group (implanted with other artificial discs), due largely in part to the range of motion outcomes.

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activL® Artificial Disc Intelligent Motion Technology™

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

Rx Federal (USA) law restricts this device to sale by or on the order of a physician.

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