

A man with a beard and short hair is running outdoors. He is wearing a dark grey long-sleeved athletic shirt and black shorts. He is smiling and looking towards the right. The background is a bright, hazy sunset over a body of water, with a stone wall and some greenery in the foreground. A teal vertical bar is on the left side of the page.

Patient's Guide

Lumbar Total Disc Replacement

activL[®]
Lumbar Disc

Your Life in Motion

Your life is in constant motion. It's always moving forward, never backward. That's why setbacks to your health can be so devastating. They stop you in your tracks while your life continues around you. Few health problems are as damaging to your continued movement as lower back pain. In fact, it's been identified as the single leading cause of disability worldwide.

The human body makes more than 40,000 individual movements every day. Every time you stand up, every time you pick up your child, and every time you shift in your chair, your body's natural mechanics work in precise coordination to produce those movements. Your lower spine, known as the lumbar spine, plays a critical role in both movement and weight-bearing. When it doesn't function properly, even simple activities can become difficult.

The Impact of Lower Back Pain

- According to the Bureau of Labor Statistics, back injuries account for nearly half of all musculoskeletal disorders in the workplace¹
- Americans spend at least \$50 billion each year on back pain²
- Lower back pain is the leading cause of time lost due to disability³
- About half of all working Americans report experiencing back pain each year⁴



YOUR BODY
MAKES MORE THAN
40,000 INDIVIDUAL
MOVEMENTS EVERY DAY.
KEEP IT MOVING.

Moments Missed

Back pain can interfere with everyday activities and special moments, from lifting your child to walking down the aisle or simply enjoying a quiet evening without discomfort. Yet many people still avoid seeking treatment, choosing to live with their pain instead of addressing it.⁵



**DON'T LET LOWER BACK
PAIN HOLD YOU BACK**

Treatment Options

Lumbar Total Disc Replacement

Your spine is one of the most important parts of your body and is also a common source of lower back pain. It is made up of 24 bones called vertebrae, with a gel-like cushion called a disc between each one. Spinal discs absorb shock, help hold the vertebrae together, and allow your spine to move naturally. When a disc becomes damaged, it can cause back pain. If left untreated, this pain may become severe and could limit daily activities, especially when it affects one of the lower two lumbar discs (L4-L5 or L5-S1).

Conservative treatments, such as physical therapy, are usually recommended first to treat lower back pain. In some cases, these approaches do not provide sufficient relief, leading patients to consider surgical options. Traditional surgery has often included spinal fusion, which fuses two or more vertebrae together to relieve pain by stopping motion in that part of the spine. While fusion can reduce pain, it does not restore your spine's natural movement.

For patients seeking an alternative to spinal fusion, the activL® Artificial Disc offers a different approach. Instead of stopping motion at the affected spinal level, the activL® Disc is designed to replace a damaged lumbar disc while preserving more natural movement. By maintaining motion in the spine, it may help patients regain comfort and get back to everyday activities more easily.

Ask if Lumbar Total Disc Replacement is Right for You

The **activL® Artificial Disc** *with Intelligent Motion Technology™* is engineered to closely replicate the natural biomechanics of a healthy human spine. It features a mobile ultra-high molecular weight polyethylene core that provides both natural motion and mechanical stability, enabling controlled translational and rotational movement. Unlike traditional approaches that may limit motion, the activL® Disc is designed to preserve it. In clinical trials, the disc was shown to improve back pain severity and patient quality of life.

The activL® Artificial Disc is not right for everyone. You should consult your spine surgeon to determine if this treatment is appropriate for you. Here are some questions that may help start the conversation:

1. Am I a candidate for activL® Artificial Disc replacement surgery?
2. Can you explain the activL® Artificial Disc technology in more detail?
3. How does the surgery work?
4. What are the risks and potential side effects?
5. What is the expected recovery time?
6. Will this procedure eliminate my pain?
7. Will I be able to return to normal activities?
8. How much will the surgery cost?

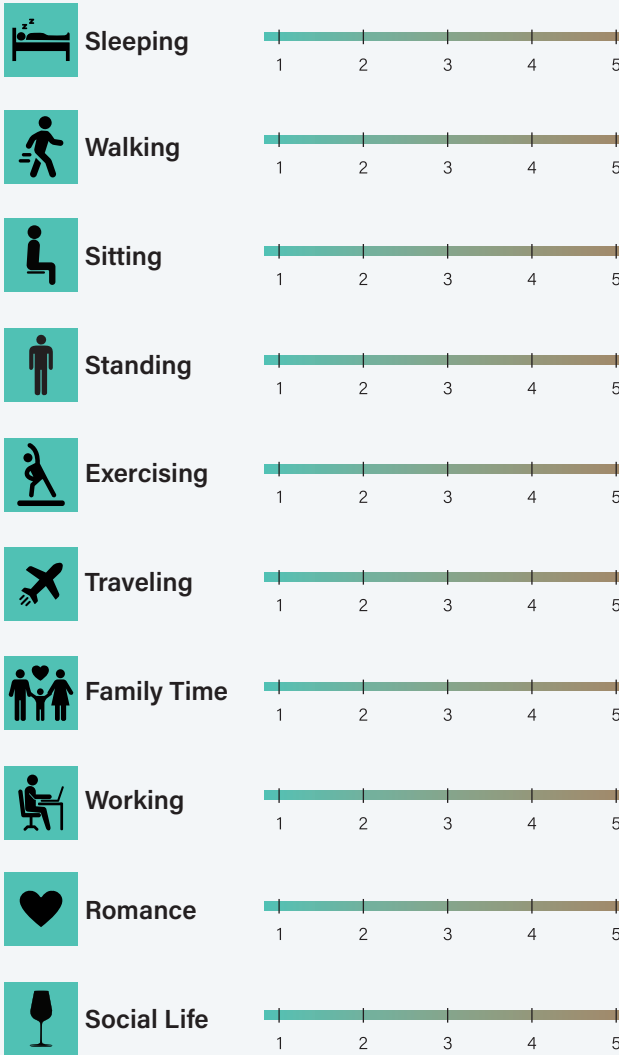


ASK YOUR SURGEON
IF ACTIVL[®] IS
RIGHT FOR YOU.

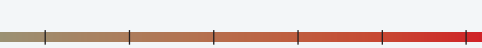
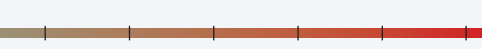
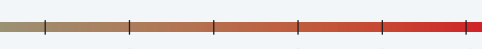
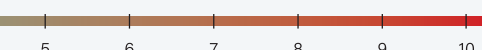
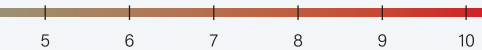
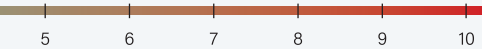


Motion Loss Index

The following Motion Loss Index is intended to help facilitate a conversation with your spine surgeon to help determine if your loss of motion and the pain you are experiencing might require you to seek further treatment.



Please rank the following categories on a scale of 1 to 10: **One** means that your lower back pain does not impact your activity in these areas. **Ten** means that you are completely impaired from participating.





**YOUR JOURNEY TO
BETTER MOVEMENT
STARTS HERE**

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

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

Visit [highridgemedical.com](https://www.highridgemedical.com) for more information on the activL® Artificial Disc.

References:

1. BLS, 2013.
2. In Project Briefs: Back Pain Patient Outcomes Assessment Team (BOAT). In MEDTEP Update, Vol. 1 Issue 1, Agency for Health Care Policy and Research, Rockville.
3. Extended report: The global burden of occupationally related low back pain: estimates from the Global Burden of Disease 2010 study, Annals of Rheumatic Diseases -March 2014.
4. Vallfors B. Acute, Subacute and Chronic Low Back Pain: Clinical Symptoms, Absenteeism and Working Environment. Scan J Rehab Med Suppl 1985; 11: 1-98.
5. "Move Forward" Low Back Pain Survey, American Physical Therapy Association, 2012.

For more information,
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Post-operative risks from surgery with activL include development of new pain, deterioration in neurological status. Contraindications include osteoporosis, osteopenia, allergy to implant materials, and spinal deformity. Full risks and contraindications can be found in system labeling.

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