Lumbar Total Disc Replacement
A Patient's Guide

Your life in motion

AESCULAP
Implant Systems
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 keeps whizzing by. 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, and its connection with the pelvis, is where the majority of weight-bearing and movement takes place. When your lumbar spine doesn’t work properly, your life’s motion stops.

Don’t believe it? Look at the facts:

- According to the Bureau of Labor Statistics, back injuries account for nearly half of all musculoskeletal disorders in the workplace\(^1\)
- Americans spend at least $50 billion each year on back pain\(^2\)
- Lower back pain is the top cause for time lost due to disability (calculated by adding years lost as a result of the number of years lived with disability)\(^3\)
- One-half of all working Americans admit to having back pain symptoms each year.\(^4\)
- According to Giammatteo et al., when fused, the L5-S1 disc can compromise up to 70% of total spinal movement\(^5\)

\(^{1}\) 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
Our lives are often measured not in years, but in moments. Think of the moments you could miss if you suffer from debilitating back pain.

- Playing catch with your children
- Walking your daughter down the aisle on her wedding day
- Feeling the accomplishment of hiking up a mountain
- Finding that perfect golf swing
- Taking a long walk on the beach with your significant other
- Sitting comfortably to read a book or watch TV at night
- Being able to brush your teeth without having to take pain medicine

Back pain can rob you of all of these moments. Yet many people avoid getting proper treatment. More than a third of Americans never see a doctor to treat their back pain. They'd rather miss moments than confront their pain.6

What do you want to do with your life?

The spine is one of the most important parts of your body and is often the source of lower back pain. It is made up of 24 bones called vertebrae. Between each vertebra is a gel-like cushion called a disc. Spinal discs help absorb shock in the spine and also act as ligaments that hold the vertebrae together and allow for some mobility. When a spinal disc becomes damaged it often causes lower back pain. When left untreated, that pain can become intense and debilitating. This is especially true when the degeneration involves one of the lower two lumbar discs (L4-L5 or L5-S1).

Conservative treatment such as physical therapy is typically recommended to treat lower back pain.

In some severe cases, this treatment does not help relieve pain. Until recently, surgical treatment for severe cases of lower back pain was limited to spinal fusion. In this procedure, vertebrae in your spine are intentionally immobilized to relieve pain. This procedure usually eliminates the painful motion of your spine. What it does not do is restore the natural motion of your spine.
The activL® Artificial Disc with Intelligent Motion Technology™ is the first lumbar artificial disc with a mobile ultra high molecular weight polyethylene core. It replaces the disc in your spine and rather than eliminating all motion, it uses the patient’s individualized biomechanics to continually adjust to match the normal motion of the lumbar disc in response to physiological movement. It works to add more natural motion back into a patient’s body. In clinical trials the disc improved back pain severity and quality of life for patients.

For more information on the activL Artificial Disc, please visit www.soactivesofast.com.

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

1. Am I candidate for the activL Artificial Disc replacement surgery?
2. Can you explain the activL Artificial Disc technology in further detail?
3. How does the surgery work?
4. What are the risks and potential side effects?
5. What is the recovery time?
6. Will this eliminate my pain?
7. Will I be able to go back to fairly normal activities?
8. How much will the surgery cost?
The following Motion Loss Index is intended to 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 one to ten:
One means that your lower back pain does not impact your activity in these areas. Ten means that you are completely impaired from participating.

Once you and your spine surgeon determine that you are a candidate for total disc replacement, learn more about reimbursement for this procedure:
Indications and Contraindications

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
- Spondylosis/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

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