

AVENUE[®] L
LATERAL LUMBAR CAGE
Patient Education



This patient information brochure will describe:

- How the lower back works.
- What happens when a disc wears out.
- How to help your back pain and related problems.

Your doctor may have said that Lateral Lumbar Interbody Fusion surgery using the Avenue® L Cage could help lessen your pain and discomfort. This brochure will help answer some of the most common questions before and after surgery.

This information should not take the place of talking with a doctor. Please go to your doctor with questions about how you are feeling. Talk to a doctor about the best way to help your back problem.

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The healthy lower back

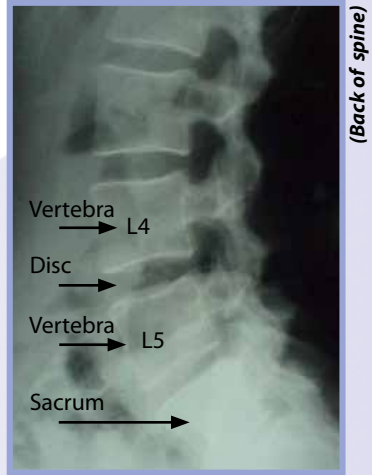
The lower back (lumbar spine) is made up of the bones, spinal cord, nerves, muscles, ligaments, and the system that carries blood.

The bottom five bones of the spine (vertebrae) make up the lower back. The sacrum bone and tailbone (coccyx) are at the very bottom of the spine.

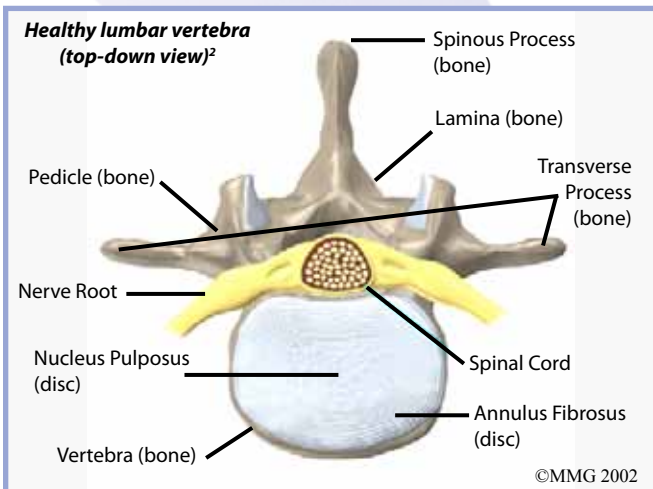
The bones of the lower back protect the spinal cord. The lower back carries the weight of the upper body. The lower back also helps absorb forces caused by movement.

Between each of the vertebrae there is a disc that acts as a pillow. The disc helps to cushion the bones moving together from the body's weight. The disc also allows the spinal bones to turn and move front-to-back and side-to-side.

Each disc has a strong outer ring (annulus fibrosus). The outer ring helps keep the disc's soft center (nucleus pulposus) in place. Disc problems can start from over-use, an accident, or just the wear and tear of everyday life.



X-ray (side-view) of a healthy lumbar spine¹



Degenerative Disc Disease



(Back of spine)

X-ray (side-view) of a lumbar spine showing degeneration

A person with Degenerative Disc Disease has a damaged disc that can be very painful.

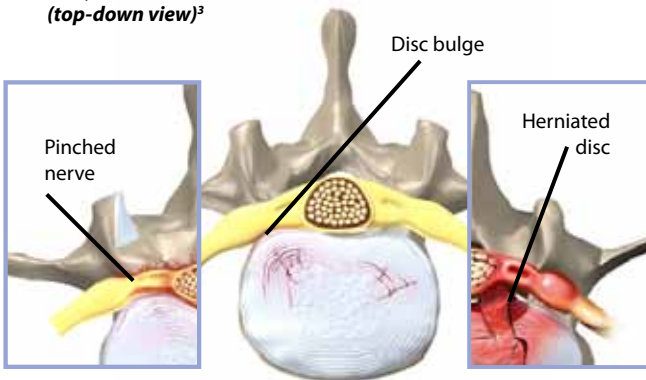
With disc degeneration:

- The center of the disc takes in and holds less water. With less water, the disc cushions less.
- Tears can start to form on the disc's outer ring. When the disc tears, uncovered nerves can be bothered.
- With a weakened disc, the disc height can fall and change the spine's balance.

Disc degeneration can cause the:

- Inner disc to squeeze through the outer disc ring (disc rupture or herniation).
- Spinal canal to narrow and pinch the cord and nerves (spinal canal stenosis).
- Spine to be less balanced.
- Smaller joints in the back of the spine to become bothered and cause pain during movement (articular facet syndrome).
- Spinal cord to be bothered causing a loss of feeling or movement (myelopathy).
- Nerve roots to be bothered causing pain or weakness and tingling in the buttocks and legs (radiculopathy).

Unhealthy lumbar vertebra (top-down view)³



Degenerating disc

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What is the Avenue L Cage?

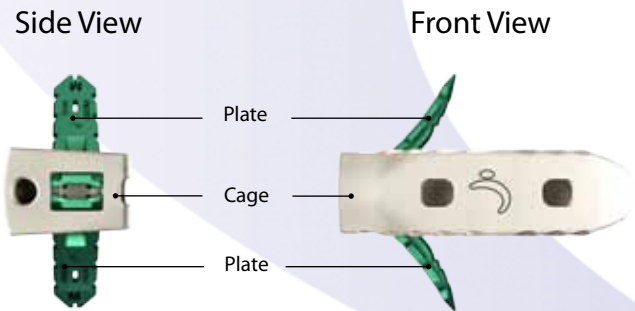
The Avenue L Cage is made to:

- Take the place of a worn out disc to help bone grow from one vertebra to another (fusion). Fusion stops most movement at that disc level.
- Bring the disc height back to a normal level. A normal disc height helps un-pinch nerves.

The rectangular Avenue L Cage is made from strong, medical grade plastic (polyether ether ketone, or PEEK). The top and bottom of the cage have teeth that fit into the bone. The teeth help to stop the cage from moving. During surgery, the middle of the cage is filled with bone graft to help the bone to grow between the two vertebrae.

The Avenue L Cage can be used with metal plates. The plates are made from medical grade titanium. The plates go through the cage and into the bone above and below the problem disc. The plates help hold the cage in place until the bone can grow. Additional screws will be placed in the vertebral bones to help resist movement until the fusion occurs.

Your surgeon will choose between different sizes of the cage and plate to best match your body.



Who can receive an Avenue L Cage?

The Avenue L Cage:

- Is for adults; the bones must be fully grown.
- Takes the place of a degenerated disc that is causing pain. Degeneration needs to be proven by patient history and the study of X-ray or MRI images.
- Takes the place of one or two damaged discs in the lower back from levels L2 to S1 (Sacrum).
- Is for people who are still having pain after having tried six months of other medical treatments before surgery.

Do I need surgery?

Have you:

- Already tried physical therapy or medicine for at least six months to stop the pain?
- Met the rules for someone who may receive an Avenue L?

If so, your doctor may say surgery is the next, best step. Or perhaps your doctor has decided that more damage to your back may happen without surgery. Surgery with the Avenue L cage may help stop your pain and other side effects from a damaged disc.



Who should not have surgery with a cage in the lower back?

If you have any of the following, you should not have surgery with the Avenue L:

- A fever or a serious, long-term, full-body, or one-area infection.
- Metal allergies or a past reaction to what the cage and plate are made from: PEEK-OPTIMA® or titanium.
- Bone with a lower density (severe osteopenia).
- Pregnancy.
- A past fusion at the same level(s) of the lower back that need to be operated on again.
- Unable to follow directions after surgery, including changing your activity level.
- Anything that would increase the difficulty of putting a cage in the lower back, like:
 - Other medical health issues.
 - Problems with going into a deep sleep during surgery (anesthesia).
 - A known problem that happens during surgery.



What are the problems the Avenue L Cage surgery can cause?

You should talk to your doctor about having surgery with the Avenue L. As with any surgery, there are things that can go wrong. This list does not cover everything that can go wrong with a surgery, but problems could include:

- A cage break.
- A loose cage or a cage that starts moving (fusion may not occur).
- The loss of movement (paralysis) or nerve health getting worse.
- The growth of unhealthy soft tissue (lesion) or new pain because of the surgery.
- Damage to blood vessels, nerves (such as loss of sexual function or infertility), and organs.
- Damage during surgery, causing unhealthy tissue to grow around the nerves and the dura matter of the spine (lesion).
- Infection on the skin or deep inside the body.
- Swelling, heat, redness, or pain (inflammation).
- A lump of blood in a blood vessel going back to the heart (venous thrombosis). A lump of blood can block the main blood vessel leaving the lung or one of its branches (pulmonary embolism).
- Heart attack.
- A pocket of blood outside the blood vessels (hematoma).
- Weakened wound healing.
- The need for another surgery to fix damage from the first surgery.
- The need for another implant on the front or back of the bones of the lower back.
- If bone graft is taken out at another part of the body, there can be pain and/or infection at the place of the cut.

The above list of side effects is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

Preparing for my lateral surgery

Follow your doctor's directions when getting ready for your surgery. Here is a to-do list for before surgery. Your doctor's directions may be different:

- Check that the medicine(s) you are taking will still be OK to take after having surgery on your lower back.
- Take time before going to the hospital to arrange your life for after surgery:
 - Move anything you use a lot to an easy to reach spot.
 - Arrange to have family or friends around to help you.
- You will likely be told not to eat or drink the night before the surgery.
- Ask your doctor to tell you what to expect from this surgery. Talk to your doctor about how this surgery may help you.



What can I expect after surgery?

Ask your doctor to describe how you will feel and what you will need to do after surgery. Due to the minimally invasive nature of this procedure, most patients are able to sit, stand and walk the evening after surgery. You can expect some soreness at the incision site immediately after surgery. Most lateral surgery patients are discharged from the hospital the day after surgery. This can be delayed if your physician determines that you need additional care. You may get better faster if you follow your doctor's directions and exercise with the help of a physical therapist.

Set up a time to visit your doctor to check your healing. Your doctor may take X-rays to see if the cage has moved. At later visits, the doctor may also take X-rays to see if bone has grown through the cage (fusion).

What will my surgery cut (incision) look like?

The procedure is usually performed through one or two small incisions in the side directly above the disc that is being treated.

When can I start driving and moving normally?

Get direction from your doctor on when it is OK to return to your normal life movements. In most cases, a lower back surgery on only one or two discs will not change your ability to twist or bend in any major way.

Will my Avenue L affect travel through airport security?

It is very unlikely that the metal in the plates and additional implants will set off airport security detectors. However, the Transportation Security Administration (TSA) rules state, "TSA Security Officers will need to resolve all alarms associated with metal implants."



Common benefits of Lateral Lumbar Interbody Fusion (LLIF) over other fusion surgeries for the lower back

- Reduced operative time - The LLIF procedure can be successfully completed in as little as one hour, reducing the amount of anesthesia time.
- Reduced blood loss and minimal scarring - the procedure allows for less cutting of muscles and tissues, resulting in reduced blood loss.
- Reduced postoperative pain - The LLIF procedure does not require large cuts through the sensitive back muscles, bones, or ligaments to place the cage. Instead the surgeon will get to the spine through the side. Many patients are usually walking the same day after surgery.
- Reduced hospital stay - Patients are typically walking the same day after surgery and require only an overnight stay in the hospital, compared to several days of immobility and hospitalization typical of traditional approaches where more muscles are cut and a larger incision is made in the skin.

Glossary: description of medical words

Annulus Fibrosus - The outer protective ring of a spinal *disc*, which covers the soft center (*nucleus pulposus*). Made from tough rings of fiber.

Blood Vessels - Flexible tubes that carry blood throughout the body.

Bone Graft - Bone from the patient's own body that is used to fill the inside of a *cage*.

Cage - Medical implant made from plastic, metal, or bone that is used to fill the disc space for *fusion*.

Disc - Soft pad of cartilage between each *vertebrae* of the spine. The discs hold the bones apart, act as cushions, and allow the *vertebrae* to move.

Fusion - After spine surgery, when two *vertebrae* grow together into one long bone, stopping movement at that level.

Incision - A cut in the skin made during surgery.

Ligaments - A short strip of tough, flexible tissue that connects two bones.

LLIF - Lateral Lumbar Interbody Fusion

Lumbar Spine - Lower back.

Nucleus Pulposus - Jelly-like center of a spinal *disc*.

Nerves - Fibers that move messages to and from the brain controlling feeling and movement. Nerve fibers connect the skin, organs, muscles, and glands through the *spinal cord* to the brain.

Psoas - A long muscle located on the side of the lumbar spine.

Sacrum and Tailbone - The “sit” bones of the spine. The sacrum is at the bottom of the spine, beneath the *lumbar vertebrae*. The sacrum is shaped like a triangle. The tailbone (coccyx) is at the very bottom of the spine.

Spinal Cord - Bundle of spinal *nerves*. The spinal cord starts at the bottom of the brain and runs to the lower back. The spinal cord moves messages between the brain and the rest of the body.

Vertebrae - The 33 bones that form the spine. Each vertebra has three parts: the body to help carry weight, the arch (lamina) to protect the *spinal cord*, and the transverse processes for *ligament* attachment.

For additional information please visit:
www.ldrmedical.com

Indications:

The Avenue® L Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with or without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g. pedicle screws). The device system is intended to be used with autograft to facilitate fusion.

This information should not take the place of talking with a doctor. Please go to your doctor with questions about how you are feeling. Talk to a doctor about the best way to help your spine problem.

LDR, LDR Spine, LDR Médical, Avenue, BF+, BF+(Ph), Bi-Pack, C-Plate, Easyspine, Laminotome, L90, MC+, Mobi, Mobi-C, Mobi-L, Mobidisc, ROI, ROI-A, ROI-C, ROI-MC+, ROI-T, SpineTune and VerteBRIDGE are trademarks or registered trademarks of LDR Holding Corporation or its affiliates in France, the United States, and other countries.

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