ROI-A®

Anterior Lumbar and Oblique Cages

Patient Education

HIGHRIDGE

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Individuals represented in the brochure are not actual patients.

Enjoying Life Without Back Pain

This patient information brochure is designed to give you some basic information on lower back anatomy, disc degeneration, and to help you better understand one treatment option for your back pain and related problems. Your doctor may have recommended that you consider surgery to relieve your pain and discomfort using the ROI-A® Anterior Lumbar Cage. This brochure will help answer some of the most commonly asked questions in preparation for and also after surgery, if your doctor has recommended the ROI-A Anterior Lumbar Cage.

This information should not be used as a substitute for talking with a doctor. Please consult your doctor with any questions about your symptoms or treatment options.

- The ROI-A Anterior Lumbar Cage was cleared for use in the United States in 2008. The anterior lumbar cage has been used to help more than 7,500 people worldwide.
- The ROI-A Oblique Cage was cleared for use in 2011. The oblique cage uses the same technology as the anterior lumbar cage.

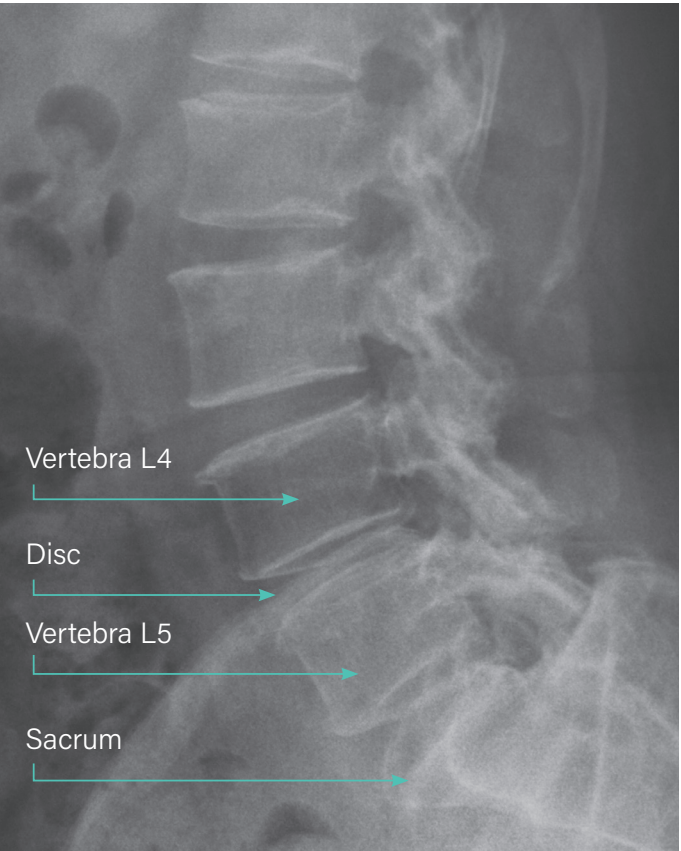
The Healthy Lower Back

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

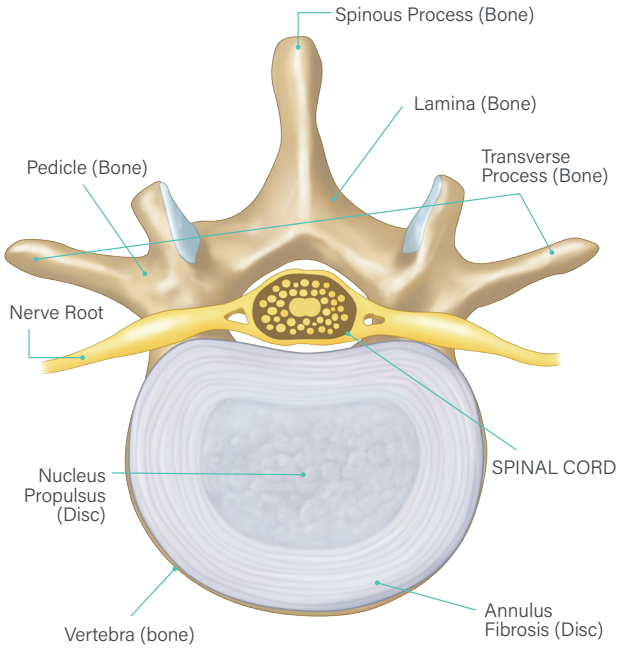
The bottom five bones of the spine (vertebrae) make up the lower back. The sacrum bone and tailbone (coccyx) are at the very bottom of the spine.

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.

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



Healthy lumbar vertebra (top-down view)



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

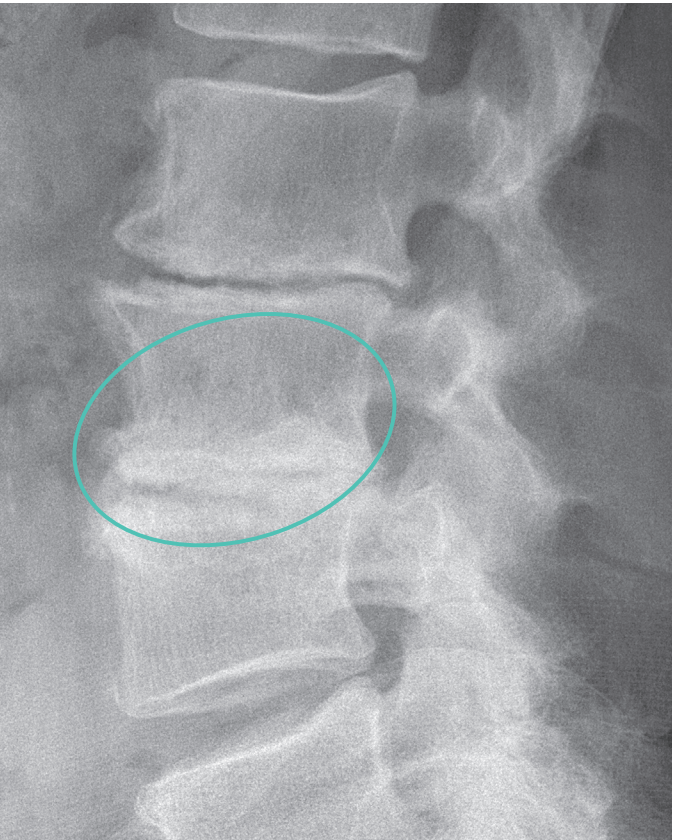
Degenerative Disc Disease

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

With Disc Degeneration:

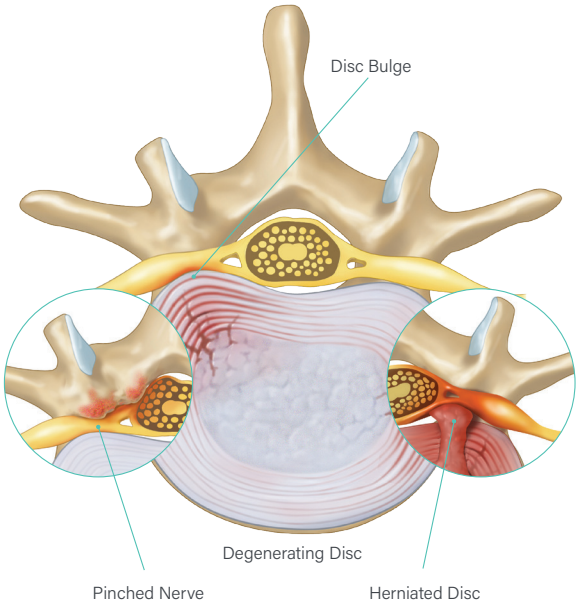
- The center of the disc takes in and holds less water. With less water, the disc cushions less.
- Tears can start to form on the disc's outer ring. When the disc tears, uncovered nerves can be bothered.
- With a weakened disc, the disc height can fall and change the spine's balance.

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



Back of spine

Unhealthy lumbar vertebra (top-down view)



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).

What is the ROI-A Cage?

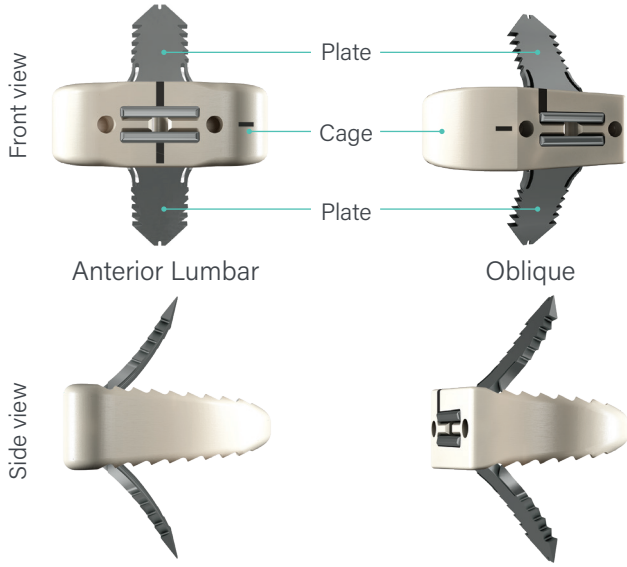
The ROI-A cage is made to:

- 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.
- Work by itself (stand-alone) with just the cage and its metal plates. If used stand-alone, there is no other plate used on the front of the spine or screws in the back of the spine.

The rectangular ROI-A cage is made from strong, medical grade plastic (polyether ether ketone). 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 stimulate fusion to grow.

The ROI-A 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 disc can fuse.

Your surgeon will choose between different sizes of the cage and plate to best match your anatomy. The surgeon will also choose between the anterior lumbar and oblique cages. The anterior lumbar cage is placed through the middle of the belly. The oblique cage is also placed through the belly, but slightly off-center, normally to the patient's left.



Who can receive an ROI-A cage?

The ROI-A Anterior Lumbar and Oblique Cages:

- Are for adults; the bones must be fully grown.
- Take 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.
- Take the place of one or two damaged discs in the lower back from levels L2 to S1 (Sacrum).
- Can be used to fuse one disc or two discs that are next to each other.
- Are for people who are still having pain. The patient should have tried six months of other medical treatments before having surgery.

Your doctor may recommend surgery if you:

- Already tried physical therapy or medicine for at least six months to stop the pain
- Meet the criteria for someone who may receive an ROI-A

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 ROI-A may help stop your pain and other side effects from a damaged disc.

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

If you have any of the following, you should not have surgery with the ROI-A:

- 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®, tantalum, or titanium.
- Bone with a lower amount of minerals (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 end the helpfulness of putting a cage in the lower back, like:

- Other medical health issues.
- Problems with going into the deep sleep for surgery (anesthesia).
- A known problem that happens during surgery.

ROI-A Cage Surgerical Risks

What are the problems the ROI-A Cage surgery can cause?

You should talk to your doctor about having surgery with the ROI-A. As with any surgery, there are things that can go wrong when getting the ROI-A cage. 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.

Commonly Asked Questions

Preparing for my ROI-A 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; follow your doctors instructions.

- 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 will my surgery incision look like?

The incision will likely be three to five inches long. The doctor will usually make a cut in the belly in the up-and-down direction. The incision for the:

- ROI-A Anterior Lumbar Cage will be near the middle of the belly, just to the side of the belly button.
- ROI-A Oablique Cage will be made off-center, normally more to the left of the patient's belly button.

What can I expect after surgery?

Ask your doctor to describe how you will feel and what you will need to do after surgery. Replacing your disc(s) with the ROI-A is a major surgery. Getting better will take time. How fast you get better depends on your age, your general health, and the reason for the surgery. Your doctor may recommend exercise with the help of a physical therapist. As with any surgery, it is extremely important to follow your doctor's direction after surgery.

Here are some examples of directions to follow after surgery. Your doctor's directions may be different:

- Sit, stand, and walk the night after surgery.
- Take medicine (by mouth) for pain or sickness of the stomach (nausea) as needed.
- Wear a tight-fitting medical wrap (brace) for your low back. The brace will fit from below the chest to the hips. The brace helps to hold the lower back and stop movement. You will likely wear the brace for up to a few weeks after surgery.
- Wear the brace when showering. The brace may be taken off after the shower to lightly bathe the skin under the brace.
- Put a new, clean bandage onto the cut (incision) five days after surgery. The doctor or nurse may show you how to change the bandage.
- Talk to your doctor about a physical therapy plan. You will need to know when and how you can start moving more often.
- 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).

Commonly Asked Questions

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 ROI-A affect travel through airport security?

It is very unlikely that the metal in the ROI-A plates 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."

How does the ROI-A compare to other fusion surgeries for the lower back that use a metal plate or screws?

For lower back fusion, doctors can also choose:

- A cage to replace the disc made from either metal, bone, or plastic.
- Plus additional implants to keep the cage in place.

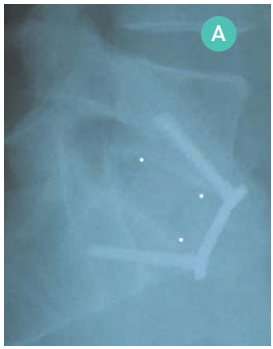
The additional implants needed would either be a:

- Metal plate with screws on the front of the spine.
- Metal screws (pedicle screws) put through the back of the spine.

If the doctor uses a plate on the front of the spine **(image A)**, screws are put into the bones both above and below the damaged disc. The surgical cut needs to be large enough for the doctor to see both vertebras.

If the doctor uses metal screws in the back of the spine **(image B)**, first the incision in the belly is closed. A second cut is made in the back, allowing the doctor to put in screws. The ROI-A uses strong plates **(image C)**. The plates help hold the cage in place until the fusion can grow.

- The cut in the belly needs to be just big enough to put in the ROI-A cage. The plates go straight through the cage and curve up into the bone.
- The ROI-A does not stick out in front of the disc space like a plate does.
- The ROI-A does not need a second cut in the back, like an anterior cage with pedicle screws would need.



X-ray of a cage with metal plate on the front of the spine with four screws[4]

X-ray of a cage with four screws put through the back of the spine

X-ray of an ROI-A cage

Glossary

Description of medical words

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

Anterior Lumbar - Front (anterior) of the lower back (lumbar). The direction the surgeon will put the cage into the lumbar disc space, from the front.

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.

Lumbar Spine - Lower back.

Nucleus Propulsus - 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.

Oblique - The angled direction the surgeon will put the cage into the lumbar disc space, to the side of the belly button.

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 s pinal cord, and the transverse processes for ligament attachment.

For more information, visit highridgemedical.com

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