



BARRICAID[®]

ANNULAR CLOSURE

Patient Education Brochure





This brochure will provide you with information about the Barricaid® Annular Closure Device (ACD), also referred to as “Barricaid,” a new treatment intended to reduce the incidence of reherniation and reoperation following primary limited lumbar discectomy procedures (excision of herniated intervertebral disc).

Your doctor will answer any questions you have regarding lumbar disc herniation and the Barricaid® ACD as a treatment for you.

This device is for R only and Federal law restricts this device to sale by or on the order of a physician.

Intrinsic Therapeutics
30 Commerce Way
Woburn, MA 01801
(781) 932-0222

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What is the lumbar spine and how does it normally work?

The human spine is part of the body's skeletal system that provides balance and stability, protects the spinal cord, and allows you to turn, stretch, and bend.

A normal spine allows you to move about freely and bend with flexibility. Your low back, or lumbar spine, is made up of five bones (vertebrae) which are numbered L1 to L5 and are stacked on top of each other to form a column (see Fig. 1). Each lumbar vertebra has a hole for the nerves that carry signals from your brain to the rest of your body. These nerve signals are responsible for talking to your brain about pain and telling your body to move. Below the lumbar spine includes the sacrum numbered as S1.

The spine's vertebrae (or bones) and discs absorb the impact from walking, climbing or jumping. The spinal cord runs through the spinal canal at the back of the spine and is protected by the vertebrae (see Fig. 2). Starting at L1-L2, the spinal cord branches into several nerves bundled together in nerve root sac, also called the dural sac.

The discs between the vertebrae act as shock absorbers to cushion impact and to keep the distance between the vertebral bodies. Each cartilage disc has a thick outer layer (annulus) that surrounds a soft gel-like center (nucleus).

A spinal joint consists of two vertebrae in the front of the spine separated by a flexible disc and two facet joints in the back of the spine. See figure 1 for a drawing of the lumbar spine.

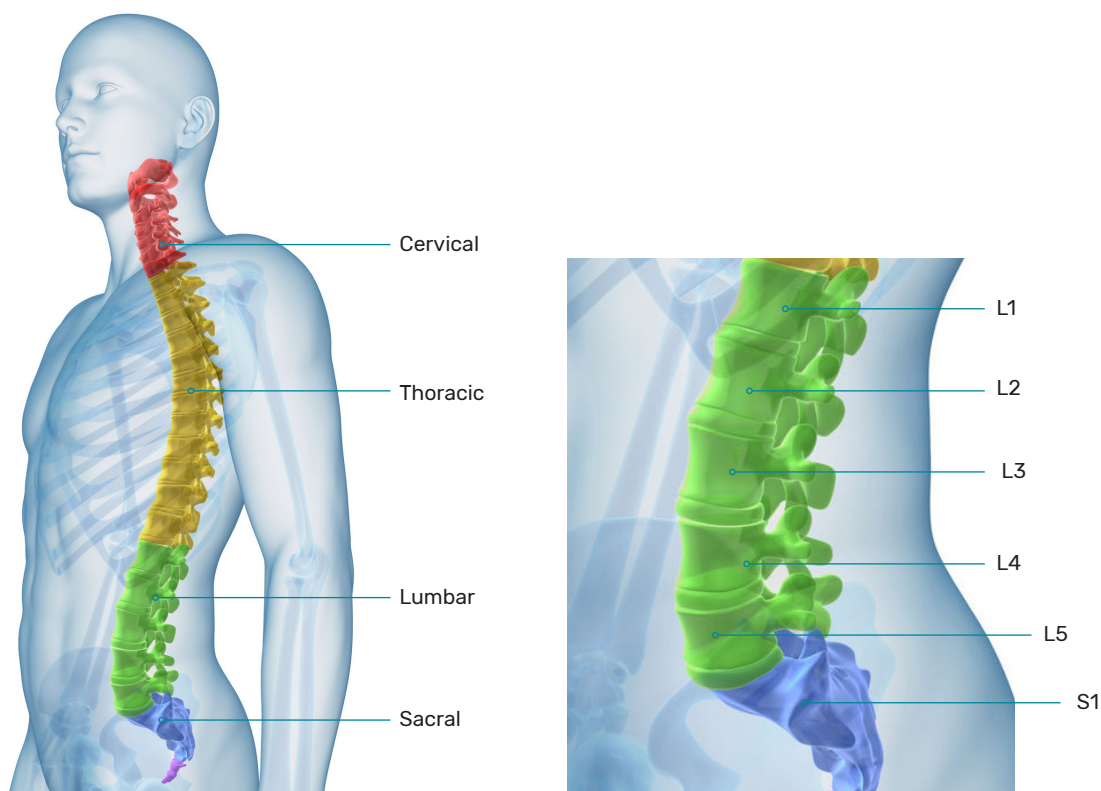


Figure 1. Side view of the spine (Note: Barricaid® Annular Closure device is only a treatment option for L4/L5 and L5/S1)

Smaller nerves branch out from the dural sac at each level and lead to specific areas of the body. See figure 2 for drawings of the spinal joint, lumbar spinal cord and the nerve branches at each level.

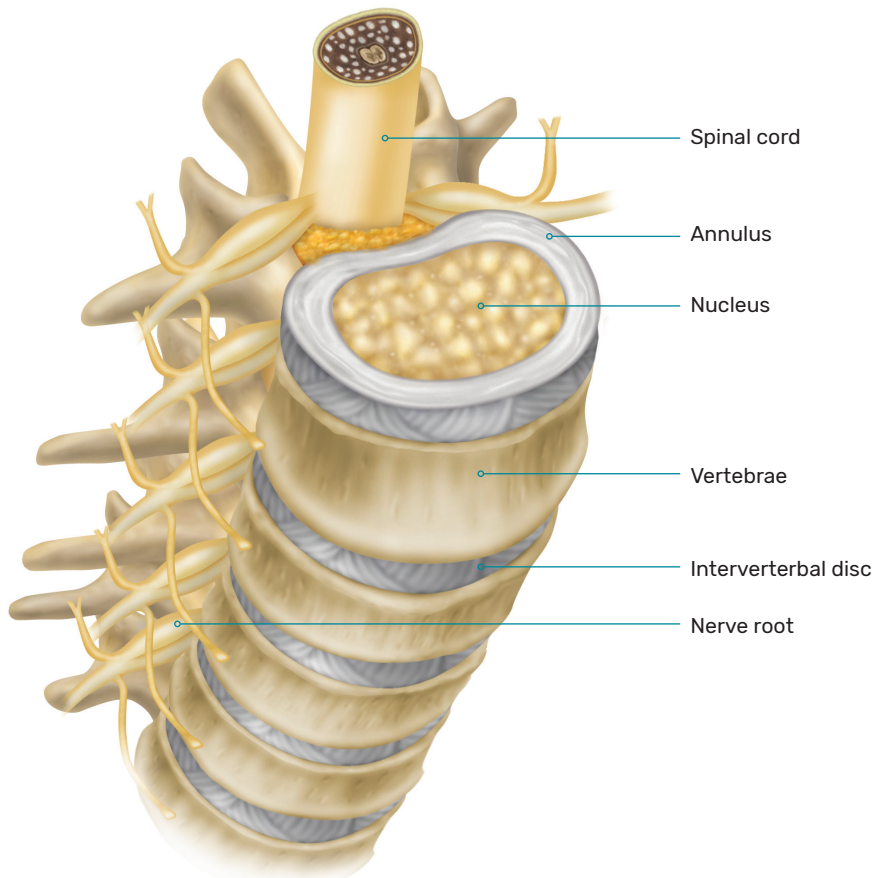
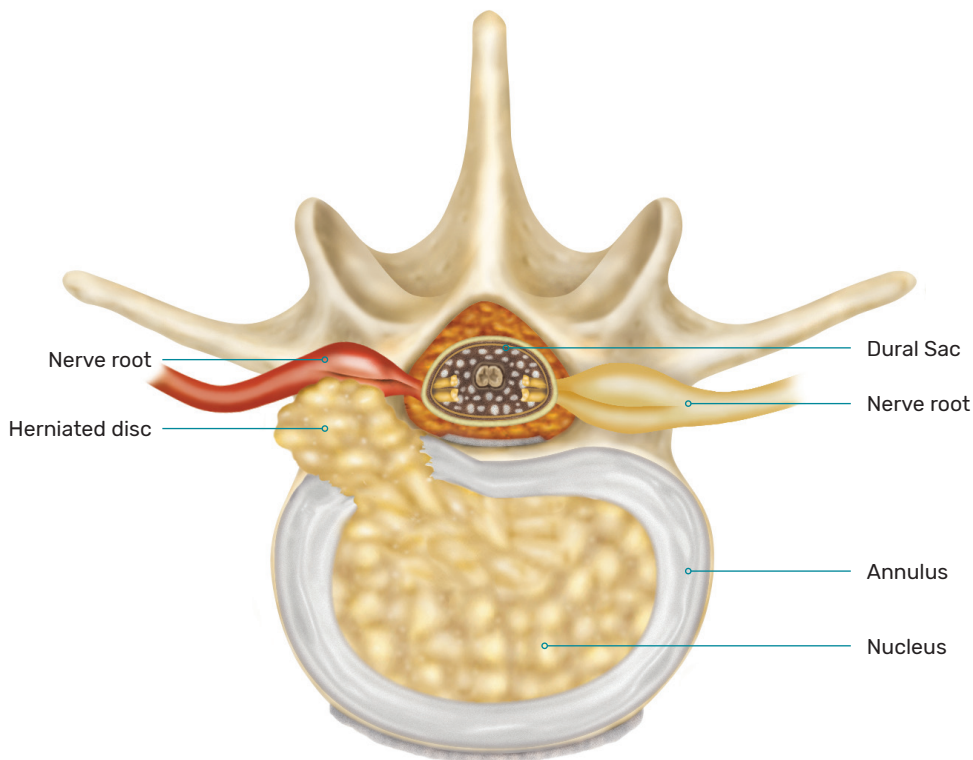


Figure 2. Front view of spine showing nerve branches branching out from spinal cord

What is a herniated disc?

A herniated disc – sometimes known as a slipped or ruptured disc – refers to a problem with one or more of the soft cartilage cushions (discs) between the bones (vertebrae) that make up your spine. A disc is a little like a jelly donut, with a soft, gel-like center (nucleus) inside of a tough outer part (annulus).

A herniated disc occurs when some of the softer disc material pushes out (herniates) through a weakness or hole in the tough outer part. If the disc herniation is large enough, the disc material can press on the nearby nerves. This can result in shooting pain (sciatica), numbness or weakness in one or both legs and sometimes causes back pain.



What is usually done about a herniated disc? Why might I need a surgery?

If you have leg pain caused by herniated lumbar discs, non-surgical alternatives include medicines such as non-steroidal anti-inflammatory drugs (NSAIDs), pain-killers, and steroids. Your doctor may also prescribe rest, exercise, and physical therapy, and most disc herniations will resolve within 6 weeks.

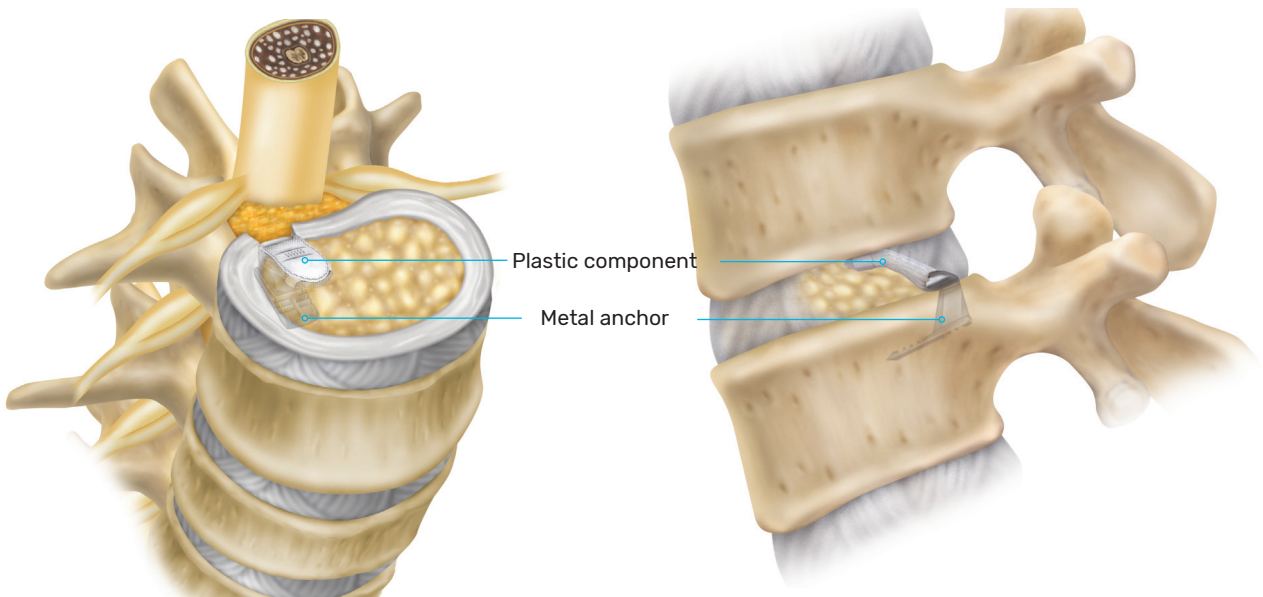
If your pain does not go away or gets worse, or if you start having nerve problems such as weakness or numbness, your doctor may prescribe surgery. Surgical options vary, depending on your disc herniation, how much back pain you have, and other factors. The most common surgery is discectomy, when your surgeon removes the damaged part of the disc from the back of the spine — through the muscles and bone. During discectomy, your doctor will remove the

part of the disc that is bothering or putting pressure on the nerve root. Your doctor does this to take away the pressure and lower your pain. Some studies have shown that if the hole in the annulus is big, there is a greater risk of having another herniation compared to a small hole. There are different options your doctor has if the hole in your annulus is big, including:

- He or she can leave the remaining inner disc (nucleus) in place.
- Another option is to take out all of the inner part of the disc (nucleus). This has been shown to reduce the chance of another herniation but may lead to the disc losing height and more back pain later on.
- Much less often your doctor may recommend a fusion or artificial disc replacement.

What is the Barricaid® annular closure device?

The Barricaid® annular closure device (ACD) is implanted following a regular discectomy if it is determined you are an appropriate candidate for treatment with this device. In this case, your surgeon may decide to implant a Barricaid® ACD to try to reduce the chances of the herniation from happening again.



Once you and your surgeon decide that this device may be good for your situation, your surgeon measures the size of the hole to see if you are at a higher risk of having another herniation and will choose the correct size of the implant. Your surgeon will then insert the small titanium (a type of metal) anchor into the bone, while the polyester (a type of plastic) mesh flap forms a barrier to try to block the hole. The surgery is guided by x-ray.

The goal of the discectomy part of the surgery is to reduce the pain and restore normal motion of your back. The goal of implanting the device is to help reduce the potential for a future herniation to occur again.

Who should be treated with Barricaid annular closure device?

Barricaid® ACD is meant for patients at higher risk of another disc herniation and return of leg and possibly back pain.

Your surgeon can tell before surgery if the Barricaid® ACD may be right for you by measuring the height of your disc on an MRI scan. This must be at least 5mm tall. During surgery, it is not likely that you will have a large (5mm wide or wider) hole after your discectomy; however, if the hole in the outer part of your disc is 5mm wide or wider, you are at higher risk for another herniation over time. And while not all herniations may bother you, sometimes this new herniation may also cause pain, and maybe require another surgery in the future.

Herniated disc surgery does not repair the hole in the tougher outer part of the disc (annulus). In other words, it doesn't close the hole left after the bulging inner part has been removed. The Barricaid® ACD was designed to try and close the hole and reduce the risk of future herniations from happening.

Who should not be treated with the Barricaid® annular closure device (contraindications)?

- Tell your doctor if you think you have an infection. Your doctor should not implant the Barricaid® ACD if you have an active general infection or infection where the implant will be placed. (It is not allowed for use in patients with infections.)
- This surgery should not be done if you had a previous surgery in the same place in your spine.
- Tell your doctor if you think you have ever had any allergy to or if you have reacted to any metal, plastic or an implant. The Barricaid® ACD is made from titanium and polyester. You could be allergic to it. An allergic reaction to the implant might mean you would need more surgery to remove it. Your doctor should not implant this device in you if you might be allergic to it.
- Tell your doctor if you have problems with bone density (osteoporosis or osteopenia). The Barricaid® ACD cannot be implanted if you have this condition.
- Your doctor should only use this device if you already need a discectomy surgery to treat leg or back pain.
- Your doctor should not use the Barricaid® ACD should if you have lumbar spinal stenosis, or spinal deformities such as an abnormal curvature or “slip” of your spine.
- Your doctor should not implant the Barricaid® ACD if you have an unusual anatomy or structure in your spine that may make the surgery or placement of the device difficult or impossible.
- Your doctor should not implant the Barricaid® ACD if the height of your disc in the back is less than 5mm.

- Your doctor should not use the Barricaid® ACD in annular holes wider than 10mm, more narrow than 6mm, shorter than 4mm or taller than 6mm.
- The Barricaid® ACD should not be implanted in patients with insulin-dependent diabetes, peripheral neuropathy (damage to the nerves in the hands, feet, and arms), arterial insufficiency (a problem with the blood flow in your arteries), or a Body Mass Index (BMI) >40.

What are the warnings and precautions for use of the Barricaid® annular closure device?

Follow your doctor's instructions after your surgery. This will help you recover better. Each patient is different. Your doctor will know what's best for you. If you don't do what your doctor says after surgery, it may delay your recovery and cause you more pain.

Your doctor will understand the following warnings associated with the Barricaid® ACD and should explain them to you. Ask your doctor if you have any questions or concerns:

- The long-term effects of the Barricaid® ACD are not known.
- Your surgeon should not make the hole in your disc larger so that they can implant the Barricaid® ACD.
- Tell your doctor if you already had a previous surgery in the same place in your lower back. The potential for damage to your spinal nerves increases the more prior surgeries in the same disc.
- The Barricaid® ACD can only be implanted in adult patients since their bones are done growing.
- Your doctor should not implant the Barricaid® ACD if the surrounding bone appears damaged, weakened, or compromised in the area where the implant will be placed. Damage to the bone could be due to trauma, cancer, chemical imbalance or infection.
- This device should not be used if you have had constant pain in your leg that is worse than your back pain caused by compression of your nerves for over a year.
- The Barricaid® ACD should only be used in the lower part of the spine (in your lower back).
- The Barricaid® ACD and its delivery tool may not be re-sterilized or reused.
- To use the Barricaid® ACD, your doctor will have completed training with implanting the device and how to keep it sterile, complete knowledge of the structure and function of the spine, and experience with discectomy surgery.

Your doctor will understand the following precautions associated with the Barricaid® ACD and should explain them to you. Your doctor should use precaution if implanting the Barricaid® ACD if:

- You have a herniation at more than one level in your back.

- You have back or leg pain from an unknown source
- You have Paget's disease, osteomalacia, or other metabolic bone disease
- You are pregnant
- You are taking medications known to potentially interfere with bone/soft tissue healing (e.g, steroids)
- You have rheumatoid arthritis, lupus, or other autoimmune diseases
- You have a systemic disease including AIDS, HIV, Hepatitis
- You have an active cancer
- You have any degenerative muscular or neurological condition such as Parkinson's disease, amyotrophic lateral sclerosis (ALS), or multiple sclerosis.

What are the risks and adverse events of discectomy in general, and of using the Barricaid® annular closure device in particular?

Standard discectomy surgery has some risks. They include:

- Breakdown of bone in the spine (vertebral bone resorption)
- Bulging or leaking of the soft material from inside the spinal disc, through the hole in the disc that the surgeon made, into the area around the spinal nerves. This is known as re-herniation. This may compress or damage nerves.
- Problems from anesthesia
- Problems with how blood moves about the body (circulatory problems)
- Blood clots
- Heart attack
- Stroke
- Death
- Pneumonia
- Spinal fluid leaks
- Blood vessel damage/bleeding
- Infection
- Leg pain
- Back pain
- Bruises

- Bladder problems
- Nerve problems
- Damage due to instrument breakage or malfunction

The Barricaid® ACD has some extra risks in addition to risks from discectomy. These risks include:

- Movement of some or all of the device from its original location into the space around the spinal nerves, which may compress or damage nerves.
- Movement of some or all of the device from its original location into the disc space.
- Sinking or settling of some or all of the device into the backbone.
- Separation of the mesh part of the device from the part that holds it in place.
- Loosening of the part of the device that holds it in place from the bone.
- Decrease in bone density.
- Fracture of surrounding bone.
- Fracture or breakage of the device.
- Allergic reaction to the stuff the implant is made from.
- Strange or uncomfortable feelings because the device is there.
- Irritation of, or damage to, the nerves from putting the implant in or taking it out.
- A lot of scar tissue.
- Operation to remove the device.
- Increased risk of breakdown of bone resulting in a void in the spinal bones (vertebrae).
- Improper positioning of the implant.
- The production of wear debris from the device breaking down which may cause problems with the surrounding bone.

It is important to understand that 1 in 5 people have these voids prior to surgery, but there is more than double the chance your spinal bones develop voids in them when using the device as compared to when only discectomy is performed. These voids may continue to grow for a few years, but the studies conducted have not shown any bad effects associated with these voids. The long-term effects of these voids have also not been studied past 5 years. It is unknown what happens after 5 years.

Has the Barricaid® annular closure device been tested in clinical trials?

The Barricaid® ACD has been implanted in patients outside the United States since 2008.

To learn about how patients with the device do after surgery and the use of the Barricaid® ACD, one major study was done to show that the device is safe and can reduce the number of repeat herniations in the right group of patients.

- The Barricaid® ACD was studied in a clinical trial in over twenty hospitals to study the safety and effects of the device in patients with herniated discs with radiculopathy (damage or

trouble with nerve function caused by pressure on one or both of the nerve roots near the vertebrae by the herniated disc).

- The study was a prospective (forward looking in time) randomized controlled trial (RCT) where patients received a normal discectomy and the Barricaid® ACD or the normal discectomy surgery alone (control group). Which treatment they got was decided randomly by a computer toward the end of the surgery, after the hole in the disc was measured. There were a total of 554 patients participating, with 272 patients in the Barricaid® ACD group and 278 patients in the control group. The trial was focused on patients with a higher risk of a repeat herniation because of a large hole in the annulus.
- Study results:
 - **Herniation:** Patients treated with the Barricaid had significantly fewer reherniations than those patients who did not receive the device. Not all of these reherniations caused pain but were seen in the pictures the doctor took.
 - **Symptomatic herniation:** Symptomatic reherniations result in increased pain, functional loss, and/or increased hospital visits or additional surgeries. Patients treated with the Barricaid had a significantly fewer symptomatic herniations than those patients who did not receive the device and had discectomy alone. In other words, patients treated with the Barricaid had fewer reherniations that caused symptoms such as pain and additional surgeries. Through three years, the rate of symptomatic reherniations in patients treated with the Barricaid was approximately half that of discectomy alone.
 - **Additional Surgery:** Patients treated with the Barricaid had fewer reoperations than patients treated with discectomy alone. 39 Barricaid patients had reoperations. 57 discectomy-only patients (no Barricaid) had reoperations. For additional surgeries specifically for reherniation, there were a total of 33 reoperations in 24 Barricaid patients because of reherniation compared to 62 such reoperations in 47 Control patients.
 - **Issues with the Device:** There were a total of 51 device issues reported, 27 of these caused the patient symptoms. Of the total issues reported, 7 were related to the metal anchor (breaking and/or moving), and 44 were related to the polymer (moving and/or detaching).
 - **VAS (leg pain) improved due to discectomy:** This is the most important evaluation method to see if the effects of the herniation have been properly treated. Both the patients treated with the Barricaid and those who weren't showed the same improvement of pain scores because of the discectomy procedure. Low rates of post-operative pain are because of the discectomy procedure, not the Barricaid.

What are the potential risks and adverse effects associated with using the Barricaid® annular closure device?

Some of the most common adverse events associated with the Barricaid and/or surgery through 3 years in this randomized clinical study, and the rates in both Barricaid® ACD and Control (discectomy only) patient groups were:

Hazard	Harm	How often this happened in Barricaid® ACD patients?	How often this happened in discectomy only group?
Risks Related to Surgery or the Device Seen Through 3 Years After Surgery			
Fracture, damage or remodeling of nearby anatomy, including bone structures or soft tissues during or after surgery	Nerve or spinal injury	2 of 267 patients	4 of 283 patients
	Injury, accidental (trauma)	1 of 267 patients	1 of 283 patients
Tears in the tissue surrounding and protecting the spinal nerves (dural leaks)	Dural tear or CSF leak	15 of 267 patients	12 of 283 patients
Fever or infection	Infection – superficial	2 of 267 patients	3 of 283 patients
	Infection – deep	1 of 267 patients	2 of 283 patients
Device Malfunctions	Migration/detachment of the plastic part of the device	28 of 267 patients	
	Migration/fracture of the metal part of the device	5 of 267 patients	
	Other (difficulty implanting the device)	1 of 267 patients	
New or worsened back or leg pain	Back and Leg Pain	19 of 267 patients	10 of 283 patients
	Non-specific	1 of 267 patients	0 of 283 patients
	Back pain	45 of 267 patients	57 of 283 patients
	Leg pain	32 of 267 patients	37 of 283 patients
Blood loss, blood vessel damage, or a localized collection of blood outside the blood vessels (hematoma)	Hematoma	3 of 267 patients	2 of 283 patients
	Bleeding	2 of 267 patients	0 of 283 patients
Reherniation	Reherniation at index the level	29 of 267 patients	78 of 283 patients
Neurological deterioration	Clinically significant neurological deterioration	21 of 267 patients	18 of 283 patients
Bone Voids	Bone Erosion	48 of 267 patients	4 of 283 patients
Lumbar (back) Related Musculoskeletal Issues	Facet syndrome, spinal instability, scoliosis, and other radiographic findings	10 of 267 patients	9 of 283 patients
Non-lumbar (back) Related Musculoskeletal Issues	Hip, knee, foot/ankle, neck, and upper extremity pain or injuries	19 of 267 patients	20 of 283 patients

What are the expected outcomes of the surgery?

Your doctor will give you their expectations of your outcomes after surgery. The discectomy procedure should help improve your leg pain quickly although you may continue to have some pain after the operation. You should not be able to tell if you have a Barricaid® ACD implanted. The outcomes of your surgery may depend on how you were doing before surgery and how long you were experiencing any symptoms.

How do I prepare for surgery?

Your doctor will give you instructions to let you know how to prepare for your surgery. You should follow these instructions before the operation. This surgery may or may not require an overnight stay in the hospital.

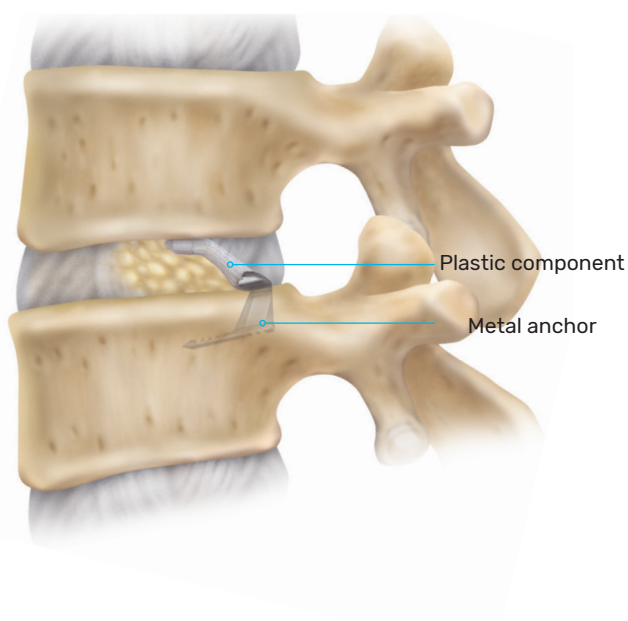
What will happen during your Barricaid® annular closure device surgery?

The Barricaid® ACD is implanted in the spine, at the end of a standard lumbar disc herniation surgery (discectomy). The surgery is guided using x-rays to make sure the implant is placed the right way.

Once the size of the hole in your disc is measured to see if you have a large defect, the correct size of the implant is chosen. There are two sizes of the mesh: 8mm, and 10mm.

To make sure that there is enough room to place the implant, your surgeon will first use a surgical tool called a Sizing Trial in the appropriate size (8, or 10mm).

The small metal anchor is inserted into the bone and the plastic flap covers the hole. Below is a side-view picture of a spine joint showing the Barricaid® ACD implanted.



What will happen after your Barricaid® annular closure device surgery?

After your surgery, your doctor will give you a plan for your recovery as well as how to care for your incision. This may include limits for your activity or recommendation for physical therapy as well as how to change the dressing on your wound. Your doctor will perform follow-up visits at normal times to see how your wound is healing and to check to see how your recovery is going.

Having the Barricaid® ACD implanted should not prevent you from having routine x-rays or a standard MRI safely. However, since MRI machines can vary you should consult with your physician regarding appropriate testing.

When should I call my doctor?

Some pain and discomfort after surgery is normal. Before surgery you should discuss with your doctor about when to call with problems after surgery. You should call your doctor immediately if you have redness or tenderness of your surgical site, or have too much pain, are sick to your stomach and vomit, or have a fever.

Talk to your doctor

While this brochure is meant to provide you with information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice. If you have any questions about the Barricaid, please call or see your doctor, who is the only one qualified to diagnose and treat your spinal condition. As with any surgical procedure, you should select a doctor who is experienced in performing the specific surgery that you are considering.

If you have any questions about the Barricaid® ACD, you may ask your doctor. For additional information, please visit www.barricaid.com.

Intrinsic Therapeutics, Inc.

30 Commerce Way
Woburn, MA 01801 USA
+1 781 932 0222
info@barricaid.com
www.barricaid.com

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