



Get Your Life Back

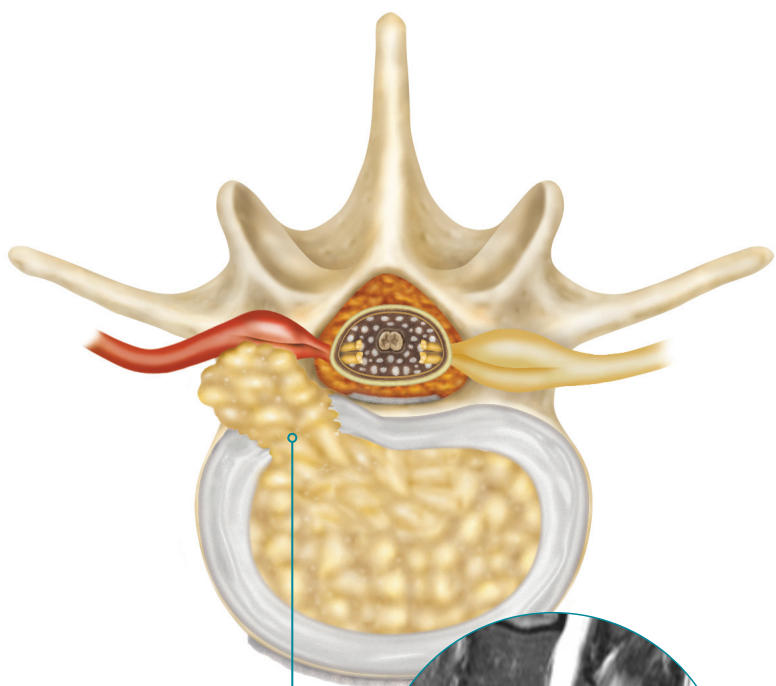
Experience
a proven innovation for
herniated disc surgery

An introduction guide

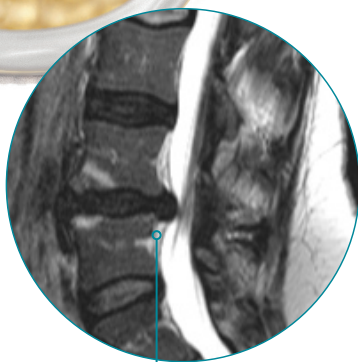
BARRICAID®
ANNULAR CLOSURE

Lumbar microdiscectomy surgery

You may already know that a herniated disc is often caused by an opening in the outer ring of an intervertebral disc. Tissue protrudes from this opening exerting pressure on the nerves, which causes pain.



Disc herniation causing pain



Herniation

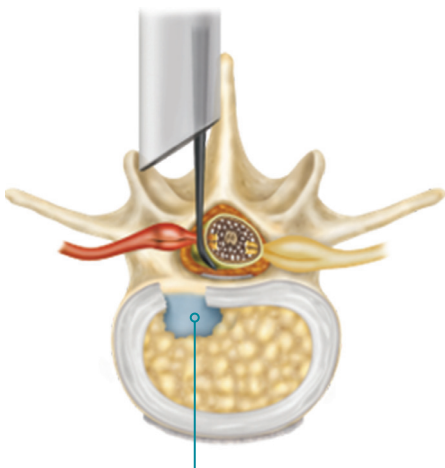
If non-surgical therapies have proven inadequate to treating your herniated disc type, a discectomy surgery might be an option for you. During this procedure, your surgeon will remove the protrusion through a small skin incision, which often proves effective in relieving your pain. But, there's a catch.

Am I at risk for a repeat herniation?

If the hole in your disc is larger than a standard pencil-top eraser (approximately 6mm) you stand a one-in-four chance of experiencing a repeat herniation, referred to as a reherniation - and a return to debilitating pain¹. Most reherniation episodes occur within two years of surgery.

Based on published literature, you stand a one-in-three chance of having such a hole² in your disc.

The good news is that Barricaid was developed specifically for discs with large holes. And it is designed to reduce the risk of a recurrence and associated pain and to minimize the chance of a repeat surgery.



Discectomy leaving a hole behind

1 in 3

herniated disc patients
have large holes

1 in 4

patients with large holes experience
reherniation and renewed pain

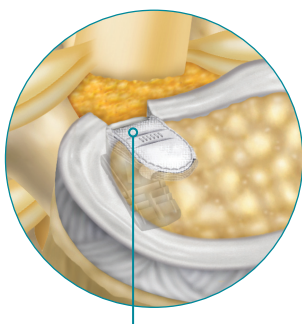
Barricaid offers a durable solution

The Barricaid implant breakthrough all started with inventor Greg Lambrecht, whose firsthand experience with his mother's recurrent disc herniations inspired him to search for a better solution. Lambrecht organized a team of world-renowned surgeons, scientists, clinical investigators, and medical advisors who spent two decades studying the large-hole dilemma, trying to help patients at high risk of recurrence following discectomy.

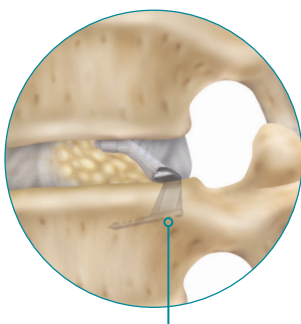


- 1 Polyester (PET) fabric designed to close the hole
- 2 Titanium bone anchor


The result is an implant that increases the chance of a more durable outcome of discectomy surgery. Because Barricaid anchors to healthy bone, it is designed to securely close a large hole following discectomy, while withstanding the enormous pressure exerted on the spinal disc - 10 times the pressure of the average car tire³.



Barricaid closing the hole



Barricaid affixed to vertebral bone

A woman with dark hair, smiling, is shown from the chest up, wearing a light blue cardigan. She is in a garden setting with various flowers, including a prominent pink and white dahlia in the foreground. The background is softly blurred, showing more greenery and flowers.

**”
It feels great
to be in a
position to live
a pain-free life
again.**

**Kim, enthusiastic
gardener, has relied on
Barricaid since 2018.**

Kim never looks back.

Designed to prevent reherniation

The spinal disc serves as a cushion in your back that is filled with a material called nucleus pulposus (nucleus). The more nucleus inside the disc, the taller and healthier the cushion. Studies have shown that aggressive removal of disc tissue during surgery is correlated with increased risk of disc collapse, which is associated with back pain over time⁴. Barricaid allows your surgeon to avoid aggressive removal your natural disc, while also significantly reducing the risk of the most common complication for this surgery, a repeat herniation. You have less than half the risk of having a repeat surgery for reherniation when Barricaid is part of your treatment plan¹.

5 years

length of a clinical study that led
to FDA approval

554

patients were studied to demonstrate a
60% reduction in reoperations
for repeat herniation

Key questions about the Barricaid treatment

How to know if I need Barricaid as part of my surgery?

Your spine surgeon may be able to determine, based on your pre-operative imaging, if you have a disc that may benefit from Barricaid. If you do, the hole in your disc will be measured during surgery. If the hole is small you are considered at low risk of a recurrent herniation and thus you will not need closure with the Barricaid implant. You will only benefit from Barricaid in case of a large hole being identified, which is measured and confirmed during surgery.

Is Barricaid safe and does it work?

The Barricaid implant was rigorously tested in multiple clinical studies and approved for use by the U.S. Food and Drug Administration (FDA). In fact, the Barricaid reduced the risk for a reoperation caused by a repeat herniation by 60%, when compared to patients that did not receive the Barricaid implant¹.

Standard discectomy surgery, with or without Barricaid, has some risks. Studies have shown that using Barricaid reduces the chance of reherniation, readmission to the hospital and repeat surgery. In the same studies, the Barricaid has shown risks such as device-related issues and development of a void in the spinal bones (vertebrae). Imaging findings showed 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 important that you discuss all of the risks and benefits with your surgeon. Also see for complete SAFETY INFORMATION: <https://www.barricaid.com/instructions-for-use>

Is there still a risk of reherniation and reoperation following a Barricaid surgery?

Although Barricaid greatly reduces the risk of reherniation and associated reoperation rates, the risk is not reduced to zero. Barricaid will not prevent a reherniation in every single case. When reoperation is necessary, studies demonstrated that

whether or not a Barricaid is implanted: 1) the same surgical treatment options exist, 2) there is no difference in the rate of complications either during or after surgery, and 3) patients experienced similar outcomes⁵. In other words, clinical trials indicate that there are no increased risks during or after the reoperation procedure when comparing Barricaid patients to those who did not receive an implant.

Will Barricaid change my recovery time or post-surgery therapy?

Clinical studies showed that recovery outcomes were similar between discectomy surgeries with or without Barricaid.



”

I enjoy doing
everything,
without any
pain

Andreas, construction
supervisor, has relied on
Barricaid since 2013.

Andreas never looks back.

Worth the wait

You are learning about Barricaid because you may benefit from this treatment option in having your chances of a repeat herniation and reoperation significantly reduced. Barricaid has been rigorously tested in multiple clinical studies and is approved by the FDA for the uses we describe in this introduction guide and on our website (barricaid.com). If your condition matches the profile of a Barricaid patient, the clinical evidence supports its use.

Since Barricaid is a new and innovative treatment option, some insurance companies may not yet be familiar with the Barricaid device and data. Therefore they may initially deny your request to include Barricaid in your surgical plan. That's where our patient support team comes in. They are experts at working with you, your surgeon, and your insurance company to navigate the prior authorization process.

Health insurance plans vary. Depending on your specific circumstances, the prior authorization process may vary from patient to patient. Ask your surgeon for more information about our patient advocacy program or contact us directly through www.barricaid.com to get started.



Talk to your doctor

Every person has unique details about them that come together to create a patient profile. Your lifestyle, job, activities, pain tolerance, body type, and defects in your spine are part of your profile. It is important that you and your surgeon discuss all of the benefits, risks and alternatives to the discectomy surgery based on your patient profile so that you are able to make an informed decision about the best treatment for you.

While this introduction guide is meant to provide you with additional information to aid in your discussion with your doctor to decide whether Barricaid is a good treatment option, 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 you are considering.

If you have any questions about the Barricaid treatment or how to get access to Barricaid, you may ask your doctor. For additional information, please visit www.barricaid.com.



INDICATIONS

The Barricaid implant is indicated for reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation and confirmed by history, physical examination, and imaging studies that demonstrate neural compression using MRI to treat a large annular hole (between 4-6mm tall and between 6-10mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

WARNING: This product has labeling limitations. See package insert for additional warnings, precautions and possible adverse effects. Please refer to the package insert and other labeling for a complete list of indications, contraindications, precautions and warnings (www.barricaid.com/us-en/instructions). For further information on Barricaid, contact your doctor.

Literature references

1. Thomé C et al, The Spine Journal 2018
2. Miller L et al, Spine 2018
3. Wilke HJ et al, Spine 2013
4. Watters W et al, Spine 2009
5. Klassen PD et al, World Neurosurgery 2019

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