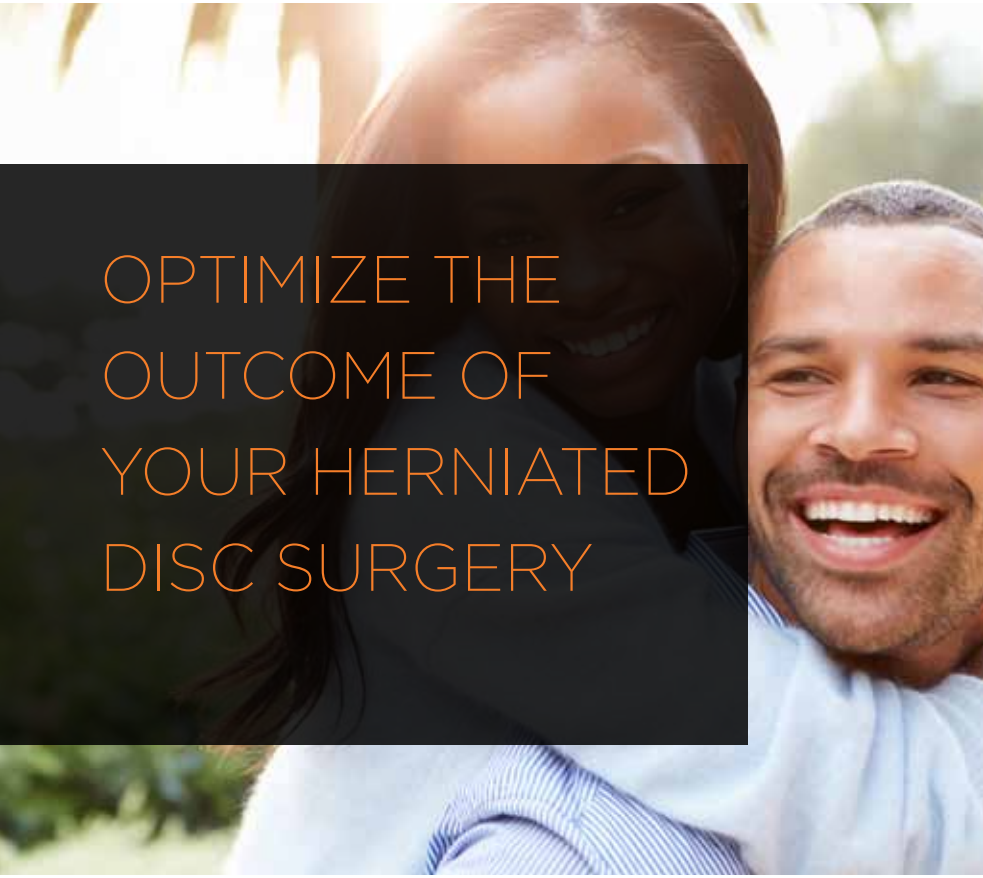
BARRICAID®
ANULAR CLOSURE



OPTIMIZE THE OUTCOME OF YOUR HERNIATED DISC SURGERY

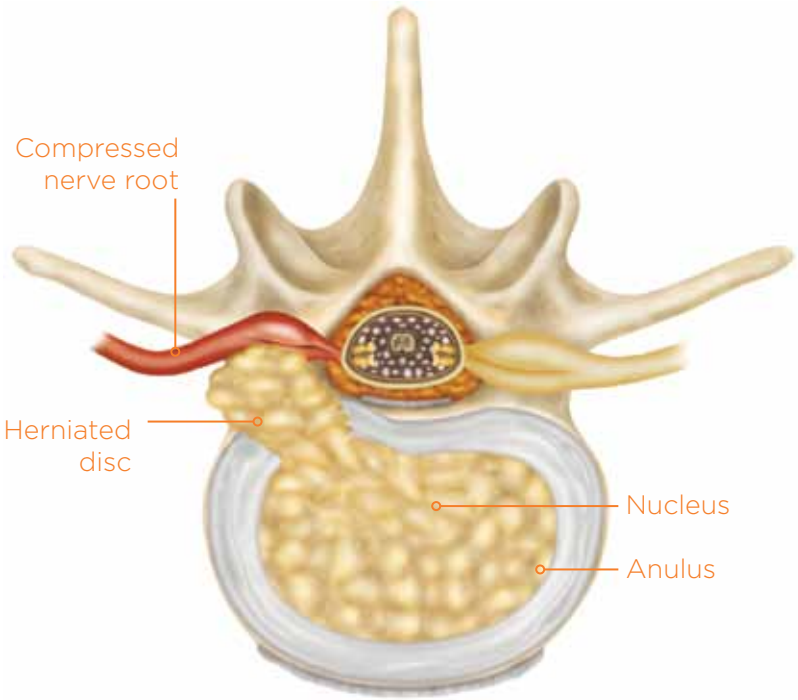
PATIENT EDUCATION

Disclaimer: This guide is designed to provide summary information about lumbar disc herniation, possible treatment, and use of the Barricaid® Anular Closure device. It is not a substitute for the advice and guidance of your physician. If you have any questions about your condition or the information in this guide, please consult your physician.

CONTENTS

DIAGNOSIS

A herniated disc – sometimes known as a slipped or ruptured disc, refers to a problem with one or more of the soft cushions (discs) between the individual bones (vertebrae) that make up your spine. A spinal disc is a little like a jelly donut, with a softer, gel-like center (nucleus) encased within a tougher exterior (anulus).



A herniated disc occurs when some of the softer disc tissue pushes out (herniates) through a weakness in the tougher exterior. If the disc herniation is large enough, the disc tissue can press on the nerves that exit the spine near the disc herniation. This can result in shooting pain (sciatica), numbness or weakness in one or both legs and sometimes back pain.

If a course of nonsurgical treatments is not effective for relieving pain from a herniated disc, your doctor may recommend surgery.

SURGERY

The most typical surgery performed for a herniated disc is a discectomy. A small skin incision is made through which the surgeon inserts the surgical instruments.

During standard discectomy procedure your doctor will remove the portion of a herniated disc that is irritating or inflaming the nerve root, in order to relieve the pressure and reduce pain.

If confronted with a large hole in your disc, your doctor currently has two options:

- He or she can leave the inner disc in place, which may allow for initial pain relief and positive results. But in case of a large opening in the outer portion of the disc, the risk of a new herniation may be as high as 25%.
- Alternatively, completely removing all the tissue material in the disc reduces the risk of it herniating again, but may lead to disc collapse and severe back pain in the future.

Both options are left with a significant risk of needing subsequent surgery. This is in particular true for patients that are presented with a large hole in their anulus.

It is generally accepted that patients who undergo subsequent surgery fare much worse than patients who only needed one operation.

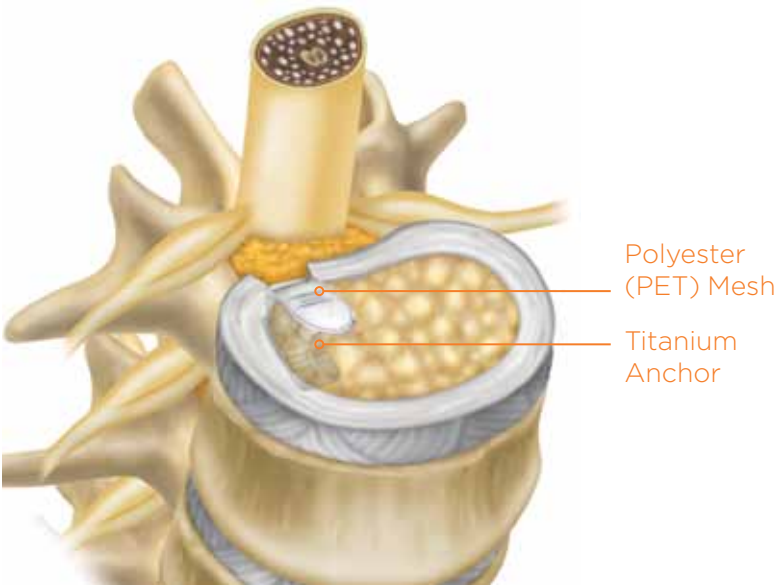
Herniated disc surgery does not repair the tear in the tougher exterior of the disc (anulus). In other words, it doesn't close the hole left after the protruding tissue has been removed. The pressure inside the disc – up to ten times that of a car tire – made it difficult, until now, to close the opening that remains after surgery.

The Barricaid® device is the first implant able to close the hole following discectomy surgery.

TREATMENT WITH BARRICAID

The Barricaid Anular Closure device is implanted following a standard discectomy. Once the ruptured portion of the disc is located, your surgeon will remove it and measure the hole left behind.

The size of this hole is very important: from 6mm you are at greater risk of a new herniation to occur. In this case your surgeon may decide to implant a Barricaid device, to close the hole in your disc.



The surgery is guided using x-ray images. Once the size of the hole is measured, the appropriate size of the implant is chosen. The small titanium anchor is inserted into the bone and the mesh forms a barrier that blocks the hole.

By anchoring the implant in bone, it withstands the high pressure in the disc, keeping the opening closed. With the hole closed, your surgeon can preserve as much nucleus (softer center) as possible inside your disc.

Barricaid® was designed to prevent repeat herniation and subsequent surgery in patients with large holes in the anulus.

AM I A CANDICATE FOR BARRICAID®?

Barricaid is indicated for patients at greater risk of a new disc herniation, disc collapse and return of sciatica (back and leg pain).

Your surgeon can identify you as a potential candidate for the Barricaid before surgery by measuring your disc height on a Magnetic Resonance Imaging (MRI) scan. A minimum of 5mm disc height is required. During surgery, if your anular defect size (hole in the disc) is between 4-6mm tall, and 6-12mm wide, you are considered at greater risk for developing a new herniation over time.

The final decision about placing a Barricaid will always be taken during surgery.

WARNINGS AND PRECAUTIONS

There are a number of health risks that have been linked with standard discectomy surgery. They include:

- Breakdown of bone in the spine (vertebral bone resorption)
- Bulging or leaking of the soft material inside the spinal disc into the epidural space, which may compress or damage neural elements (reherniation).
- 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

There are also health risks that could occur after the Barricaid® device is placed in your spine. These risks include:

- Movement of some or all of the device from its original location into the epidural space, which may compress or damage nerves.
- Bulging or leaking of the soft material inside the spinal disc into the epidural space, which may compress or damage neural elements (reherniation).
- Sinking or settling of some or all of the device into the backbone.
- Movement of some or all of the device from its original location into the disc space.
- 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 due to less stress in the area.
- Fracture of bony structures.
- Fracture of the device.
- Sensitivity to the implant material or allergic reaction to a foreign body.
- Discomfort or abnormal sensations due to the presence of the device.
- Irritation of the nerve root, damage from placing or removing the device, or both.
- Excessive scar tissue formation.
- Operation to remove the device.
- Increased breakdown of bone in the spine (vertebral bone resorption).

CLINICAL RESULTS WITH BARRICAID®

The Barricaid device has been successfully implanted in patients since 2008. Over 6,000 patients have been treated with Barricaid to prevent recurrent herniation and subsequent surgery.

As part of its clinical introduction, the Barricaid has been studied in multiple clinical trials, including one of the largest level I superiority trials in spine. In this randomized controlled study, Barricaid was compared to the gold standard, discectomy surgery alone. Outcomes from these studies have led to a series of publications in leading medical journals and over one hundred scientific presentations at international medical conferences.

BARRICAID LEVEL I RANDOMIZED CONTROLLED TRIAL

A Randomized Controlled Trial (RCT) is a study where the patients being studied are randomly allocated to one of the study's treatment groups. In the Barricaid RCT one patient group received Barricaid and the other group discectomy surgery only.

This completed Level I (highest level of evidence) trial involved 554 patients with large holes in their anulus. 278 patients randomized to receive a discectomy-alone procedure (Control group), and 276 patients discectomy followed by Barricaid implantation (Treatment Group).

The patients treated with Barricaid had significantly fewer recurrent herniations, reoperations and device- or surgery-related serious adverse events.

BARRICAID PUBLICATIONS

- **Performance of an Anular Closure Device in a "Real-World", Heterogeneous, At-Risk, Lumbar Discectomy Population**

  Cureus 9(11): e1824. DOI 10.7759/cureus.1824; A Kursumovic, S Rath

- **Bone-anchored annular closure following lumbar discectomy reduces risk of complications and reoperations within 90 days of discharge**
  Journal of Pain Research 2017:10 2047–2055; PD Klassen, D T Bernstein, H-P Köhler, M P Arts, B Weiner, L E Miller, C Thomé

- **Effect of Anular Closure on Disk Height Maintenance and Reoperated Recurrent Herniation Following Lumbar Diskektomy: Two-Year Data**
  J Neurol Surg A 2015;76:211-218; D Ledic, D Vukas, G Grahovac, M Barth, GJ Bouma, M Vilendecic

- **The High-Risk Discectomy Patient: Prevention of Reherniation In Patients With Large Anular Defects Using An Anular Closure Device**
  Eur Spine J (2013) 22:1030–1036; GJ Bouma, M Barth, D Ledic, M Vilendecic

WHAT CAN YOU EXPECT AFTER SURGERY?

After surgery your rehabilitation may be no different than after a routine discectomy surgery. Your physician will provide you with a post-operative plan. This may include guidelines for your activity and possibly physical therapy. Your physician may perform follow-up examinations at scheduled intervals to evaluate your recovery.

QUESTIONS?

Consult your physician if you have any questions about your condition, your treatment, or the information contained in this pamphlet.

Further information on the Barricaid® Anular Closure can be found at **www.barricaid.com.**

Your Barricaid® Specialist

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