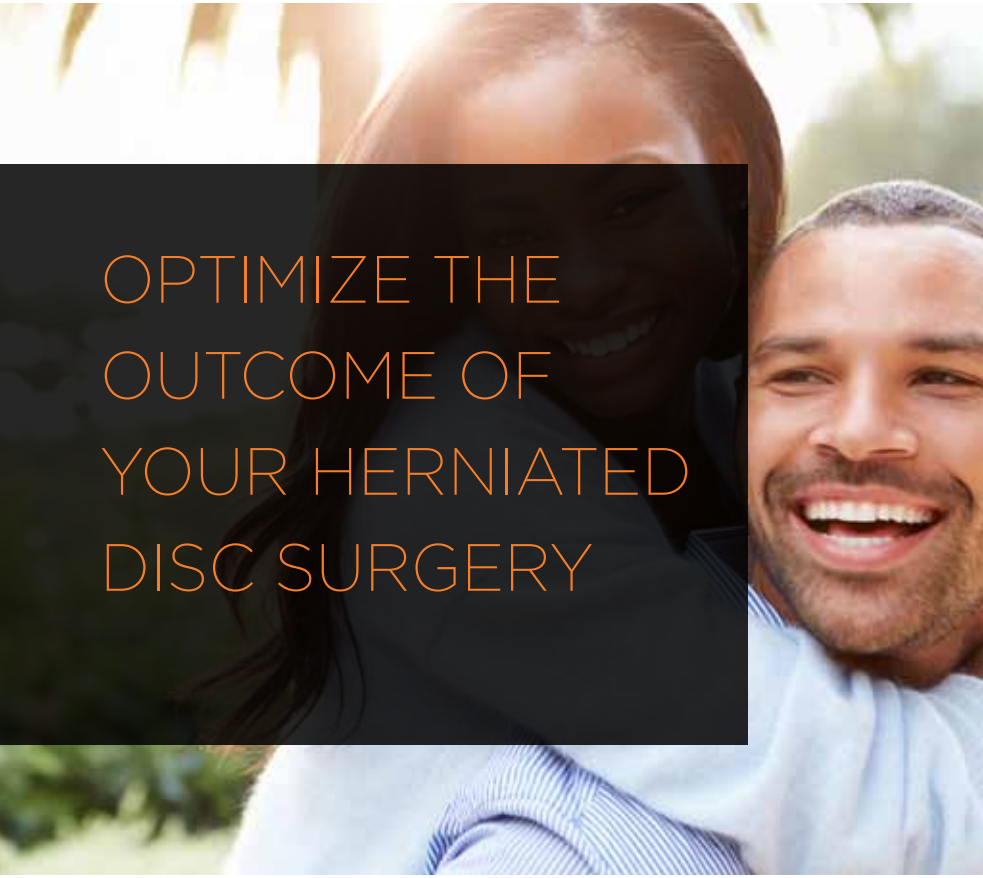
BARRICAID®
ANULAR CLOSURE



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 Prosthesis. 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.

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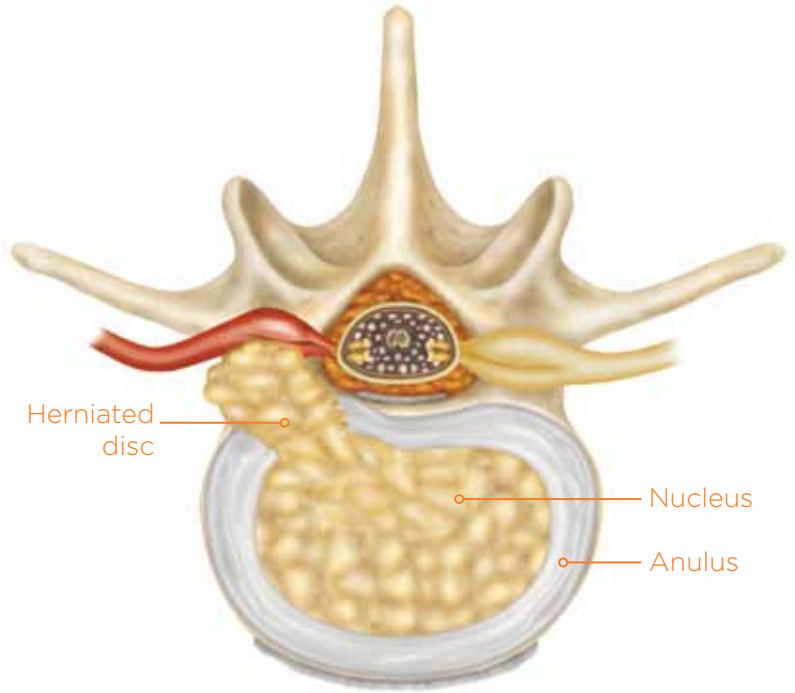
DIAGNOSIS

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).

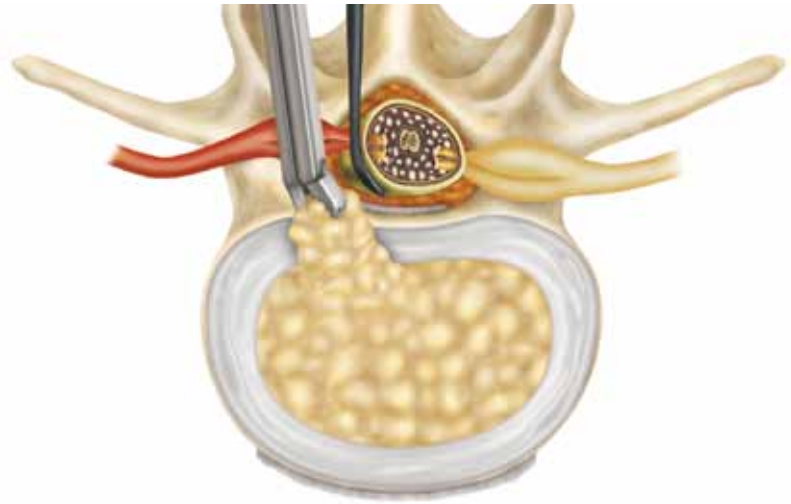


A herniated disc occurs when some of the softer disc tissue pushes out (herniates) through a weakness in the tougher exterior. If the disc herniation is large enough, the disc tissue can press on the nerves that exit the spine near the disc herniation. This can result in shooting pain (sciatica), numbness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

During standard herniated disc surgery 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 27%.
- 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.

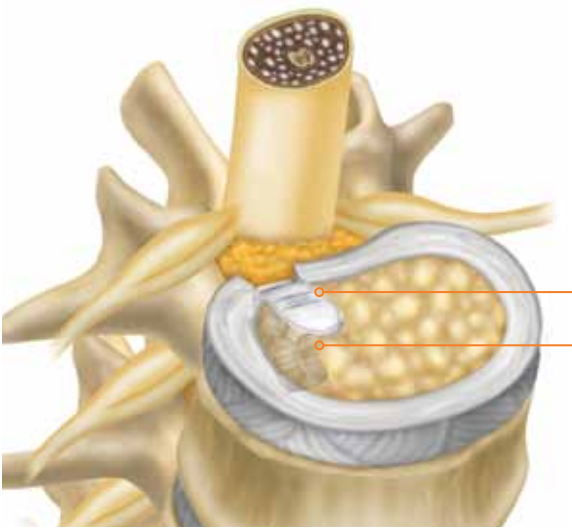
Herniated disc surgery does not repair the tear in the tougher exterior of the disc (anulus). In other words, it doesn't close the hole left after the protruding tissue has been removed. The pressure inside the disc – up to ten times that of a car tire – made it difficult, until now, to close the opening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

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

TREATMENT WITH BARRICAID®

The Barricaid® Anular Closure Prosthesis 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: if it's bigger than 5mm wide, you are at greater risk of a new herniation to occur. In this case your surgeon may decide to implant a Barricaid® Prosthesis, 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. This may help preserve normal freedom of movement, and may reduce the risk of back pain from the collapse of the disc.

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 an MRI scan. A minimum of 5mm disc height is required. During surgery, if your anular defect size (hole in the disc) is wider than 5mm, 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

- Bruises
- Bladder problems
- Problems related to nerves

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® Prosthesis has been successfully implanted in patients since 2008. As part of its clinical introduction, the Barricaid® Prosthesis has been studied in several clinical trials, which have led to a series of publications in leading medical journals and over ninety scientific presentations at international medical conferences.

In December 2010, over twenty European hospitals initiated a randomized controlled trial, looking to demonstrate the clear benefit of Barricaid® Anular Closure compared to the gold standard procedure (discectomy alone), in patients at highest risk of a new herniation. Two-year clinical results from 554 patients are expected before the end of 2016.

1. TWO PRIOR PROSPECTIVE STUDIES

- A prospective study is characterized by having its study objectives set out prior to start of the trial, and patient outcomes are captured at the time of the desired follow up point (versus being asked after the desired follow up time point, e.g. asking a patient how much pain he had 1 year ago)
- Two groups totaling 75 patients were treated with Barricaid® and followed for two years (coming back for regular check-ups) to check initial performance of the Barricaid® implant and its safety.
- The results of those studies have been published in peer-reviewed medical journals.
- Summary of the results:

1. Only 1 of 68 patients who came in for the two-year follow-up had a symptomatic recurrent herniation.
2. The device did not move inside the bone (vertebrae) and the metal anchor didn't break
3. In two cases mesh separated from the anchor and patients were reoperated with full patient recovery in both cases.
4. 2 years after the surgery, >90% of the patients maintained more

than ¾ of the height of their discs, as measured before surgery.

5. Significant improvements in function and leg pain were reported.

6. No unanticipated adverse device effects occurred in either study.

2. RANDOMIZED, CONTROLLED TRIAL

- A Randomized, controlled trial (RCT) is a study where the people being studied are randomly allocated to one or other of the different treatments under study, in this case one group of patients would receive Barricaid® and the other discectomy surgery only.
- The Barricaid® RCT has finished patient enrolment. With 554 patients included in the trial, it is one of the largest studies ever performed on patients undergoing discectomy surgery.
- The goal of this study is to demonstrate superiority of the Barricaid® treatment. That means the study should prove that patients treated with Barricaid® are significantly better off than those treated with discectomy surgery only. In real life it means that the patient group treated with Barricaid® should see fewer new herniations and fewer reoperations, hence demonstrating the implant to be safe and effective.
- 2 year follow-up for RCT patients will be completed in autumn 2016. First publications about the results of this study are expected in 2017.

3. STUDIES BASED ON "REAL-WORLD" CLINICAL EXPERIENCE

- A growing list of hospitals performing spine surgery is collecting real-world clinical data on Barricaid® and discectomy surgery alone. In the near future more scientific publications on Barricaid® are to be expected from these initiatives.

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.**

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