BARRICAID® PROSTHESIS
for Partial Anulus Replacement

Optimizing discectomy outcomes in high-risk patients

Prevent Reherniation. Preserve Disc.
“Today’s standard discectomy is performed in such manner that an opening almost always remains in the outer structure of the disc at the end of the surgery. The clinical literature reports a 2-18% reherniation rate at two years in the general discectomy population. Reherniation rates in patients with defects >6mm have been reported up to 27%.”

Univ.-Prof. Dr. med. Claudius Thomé
Chairman, Department of Neurosurgery
Medical University Innsbruck, Austria
Overcome the surgical dilemma...

THE REALITY OF LUMBAR DISCECTOMY

While widely perceived as a successful procedure, discectomy surgery has a high failure rate over time. Patient satisfaction in larger studies is only about 75% at 1 year, and roughly 20% of patients are re-operated by 10 years.

Failure results from one of two primary causes:
- Recurrence of symptoms associated with reherniation
- Chronic or worsening back pain

REHERNIATION

The overall risk of recurrent disc herniation varies between 2-18% in reported literature. There is strong evidence that reherniation rate is influenced by the size of the defect in the anulus. Patients with small or slit-type defects in the anulus have as low as 1% risk of recurrence while those with larger defects have between 18-27% risk.

POSTOPERATIVE PATIENT CHARACTERISTIC AND OUTCOME ASSESSMENTS ACCORDING TO FRAGMENT TYPE AND ANULAR DEFECT

Until the availability of anular closure technologies, surgeons had only one option to reduce the risk of recurrence in these larger defect patients – aggressive removal of the remaining nucleus. This technique is effective at decreasing the risk of reherniation, but at the cost of disc collapse and significantly worse clinical outcomes and lower patient satisfaction.

Chronic or worsening back pain following discectomy has been reported in the literature as another frequent failure mode, with rates between 7-37%.

When treating patients at higher risk of reherniation and/ or disc collapse, i.e. those patients that are presented with taller disc heights in combination with a large anular defect, the surgeon is confronted with a dilemma.

The surgeon can choose to remove as little nucleus as possible to maintain disc height and biomechanics, but this increases the risk of recurrent herniation. On the other hand, aggressively removing nucleus will reduce the risk of recurrence, but increase the risk of disc collapse and severe back pain.
“Our in-vitro study checked the reliability of Barricaid® under complex loading conditions. It emerged that the original intervertebral disc height, which had been significantly reduced by the prolapse, had to a large extent been restored thanks to the Barricaid® implant. The most important result, however, was that in no case did another herniated disc occur – even after 100,000 stress cycles. Barricaid® appears to close the defect and prevent reherniation.”

Prof. Dr. Hans-Joachim Wilke
Head of Spine Research Group
Institute of Orthopaedic Research and Biomechanics, University of Ulm Germany
...by closing the anular defect in high risk patients.

BARRICAID® PROSTHESIS DESIGN RATIONALE
With more than 5 years of clinical experience and over 3,000 implantations worldwide, the Barricaid® device is trending to be a safe and effective treatment to prevent reherniation in patients at highest risk. By replacing the defective region of the anulus, the Barricaid® prosthesis can significantly reduce the risk of recurrent herniation.

Patient Indication
• Active
• Tall disc (≥5mm)
• Large anular defect (≥5mm)
• L1-S1

Refer to IFU/labeling for complete cautions and indications.

Intelligent Design
• Multi-layer, flexible, woven polyester mesh
• Platinum-Iridium marker in mesh tip for visibility
• 8, 10, and 12mm size width covering most defects
• Titanium anchor securely fixed to proximal endplate. Does not interfere with MRI interpretation

Standardize Discectomy
• Enables a limited nucleotomy
• Maintain native nucleus to preserve the disc
• Fast and secured closure of the anular defect
“In particular, active patients with annular defect widths exceeding 5mm and a pre-operative intervertebral disc height of more than 5mm are most likely to benefit from Barricaid”

Dr. Peter Pál Varga
Director of the National Center for Spinal Disorders, Budapest Hungary
Adding only minutes to your discectomy

DEFECT MEASUREMENT
Measure size of anular defect following limited discectomy procedure. Patients with a large defect, i.e. 4-6mm in height and 5-12mm in width, are eligible for Barricaid®.

ALIGNMENT TRIAL
Use of Alignment Trial to validate adequate access to the disc space and confirm correct angle for Barricaid® implantation.

IMPLANTATION
Position of Barricaid® is confirmed under fluoroscopy.

Please refer to Barricaid® Surgeon Manual (SM009-EU-EN) for complete information on surgical implantation of Barricaid®.
A science driven approach

The Barricaid® was evaluated in two prospective, multicenter studies throughout Europe. Results of 75 implanted patients enrolled in these studies have been the subject of various scientific publications in peer-reviewed journals, including clinical and radiographic results up to two years.

GJ Bouma, M Barth, D Ledic, M Vilendecic
• Prospective, Non-Randomised, Single Arm
• 75 Barricaid patients
• Up to 24 months follow-up

SAFETY

X-Ray and MRI images two years after implantation of Barricaid® Prosthesis demonstrate secured positioning of implant.

EFFICACY

One (1.4%) reported symptomatic reherniation at mean follow up of 18.7m.

PAIN AND FUNCTION

Clinical outcomes for pain and function at 1 and 2 years post-operative compared favorably with other reports from literature.
Peer-reviewed Publications

   The High-Risk Discectomy Patient: Prevention Of Reherniation In Patients With Large Anular Defects Using An Anular Closure Device
   GJ Bouma, M Barth, D Ledic, M Vilendecic

   Can Prevention Of A Re-Herniation Be Investigated?: Establishment Of A Herniation Model And Experiments With An Anular Closure Device
   HJ Wilke, L Widmann, F Heuer, N Graf, S Rath

   Primary Limited Lumbar Discectomy with an Annulus Closure Device: One-Year Clinical and Radiographic Results from a Prospective, Multi-Center Study
   M Lequin, M Barth, C Thomé, GJ Bouma

   Protecting Facet Joints Post-Lumbar Discectomy: Barricaid Annular Closure Device Reduces Risk of Facet Degeneration
   M Trummer, S Eustacchio, M Barth, PD Klassen, S Stein

   Cost Savings Associated with Prevention of Recurrent Lumbar Disc Herniation: A Multi-Center Prospective Cohort Study
   SL Parker, G Grahovac, D Vukas, D Ledić, M Vilendecic, MJ McGirt

6. BSD Journal of Spinal Disorders and Techniques Publish Ahead of Print; DOI:10.1097/
   BSD.0b013e3182956ec5
   Effect Of A Novel Annular Closure Device (Barricaid) On Same Level Recurrent Disc Herniation And Disc Height Loss After Primary Lumbar Discectomy: Two-Year Results Of A Multi-Center Prospective Cohort Study
   SL Parker, G Grahovac, D Vukas, M Vilendecic, D Ledić, MJ McGirt, EJ Carragee

   Clinical Outcomes In Patients After Lumbar Disk Surgery With Annular Reinforcement Device: Two-Year Follow Up
   D Vukas, D Ledić, G Grahovac, Z Kolić, K Rotim, M Vilendečić

   Effect of Anular Closure on Disk Height Maintenance and Reoperated Recurrent Herniation Following Lumbar Discectomy: Two-Year Data
   D Ledić, D Vukas, G Grahovac, M Barth, GJ Bouma, M Vilendecic
Level I Randomized Controlled Trial

In December 2010, Intrinsic Therapeutics, Inc. initiated what will be one of the largest prospective spine studies ever run to demonstrate the clear benefit of using the Barricaid® in limited discectomy patients.

CONTRIBUTING CENTERS

21 clinical centers have contributed to the trial, including leading spine centers from Germany, The Netherlands, Belgium, Austria, Switzerland and France.

PATIENT POPULATION

In this superiority trial, patients are randomized intra-operatively 1:1 to receive either Barricaid® or limited discectomy alone. Patient enrollment has been concluded per the prospective statistical plan with 554 patients included in the trial.

ENDPOINTS

To be judged a success, the Barricaid® group will need to demonstrate statistical superiority in the study’s two co-primary endpoints:

1. Reherniation free survival
2. A composite endpoint of patient safety and effectiveness outcomes including improvement in leg pain, and Oswestry Disability Index (ODI), maintenance of disc height, maintenance of device integrity, reherniation free survival and lack of a reoperation at the target level.

FOLLOW-UP

This trial will be the most comprehensive study on discectomy patients ever performed, collecting all relevant clinical as well as radiographic data. The resulting data set should serve not only to demonstrate the superiority of the Barricaid®, but to analyze the impact of pre-operative data and intra-operative technique on the outcomes of discectomy.

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Clinical Cases

CASE 1
Gender: Male
Age: 33 years
Level/side herniation: L4/L5, Left
Defect size: 5 x 9mm
Pre-op VAS leg: left: 97, right: 4
2Y Post-op VAS leg: left: 0, right: 0
Pre-op VAS back: 14
2Y Post-op VAS back: 0
ODI: Pre-op: 62, 2Y post-op: 0

CASE 2
Gender: Male
Age: 52 years
Level/side herniation: L5/S1, Left
Defect size: 5 x 8 mm
Pre-op VAS leg: left: 73 , right: 1
2Y Post-op VAS leg: left: 0, right: 0
Pre-op VAS back: 74
2Y Post-op VAS back: 0
ODI: Pre-op: 54, 2Y post-op: 4

CASE 3
Gender: Female
Age: 53 years
Level/side herniation: L5/S1, Left
Defect size: 5 x 6 mm
Pre-op VAS leg: left: 94 , right: 1
2Y Post-op VAS leg: left: 2, right: 2
Pre-op VAS back: 21
2Y Post-op VAS back: 2
ODI: Pre-op: 54, 2Y post-op: 4
Patient Selection Criteria

PATIENT SELECTION

- Skeletally mature patients with disc herniations (primary or recurrent) between L1 and S1 with radiographic confirmation of neural compression using MRI.
- Radiculopathy (with or without back pain) with a positive Straight Leg Raise (L4-5, L5-S1) or Femoral Stretch Test (L1-2, L2-3, L3-4).
- At least six (6) weeks of failed, conservative treatment prior to surgery, in case of no neurological deficit, including physical therapy, use of anti-inflammatory medications at maximum specified dosage and/or administration of epidural/facet injections. In case of neurological deficit, surgery may be considered at earlier time point.
- Minimum posterior disc height of 5mm at the index level.
- Intra-operative confirmation of an anular defect that is between 4mm – 6mm in height and between 5mm – 12mm in width.

WARNINGS

- Do not implant the Barricaid prosthesis in case of spondylolisthesis and/or instability requiring stabilization.
- Do not use the Barricaid prosthesis in anular defects wider than 12mm or taller than 6mm.
- Do not implant the Barricaid prosthesis if subject has clinically compromised vertebral bodies in the lumbosacral region due to any traumatic, neoplastic, metabolic, or infectious pathology.
- Do not implant the Barricaid prosthesis in case of osteoporosis.
- Do not implant the Barricaid prosthesis in case of extra-foraminal herniations and any defect you cannot completely visualize.

THE IMPORTANCE OF DISC HEIGHT IN PATIENT SELECTION

- Patients with taller discs and more nucleus are more likely to benefit from the Barricaid’s potential to maintain disc height.
- Taller discs are likely to exhibit improved ranges of motion and less low back pain over collapsed discs.

THE EFFECT OF DEFECT SIZE ON PATIENT SELECTION

Potential Barricaid patients are intraoperatively screened for defect size and only those with larger defects are selected for Barricaid implantation.
# Barricaid® System

## REF. NR. | DESCRIPTION
---|---
BAR-D8-8X14 | Barricaid® Prosthesis, 8mm wide mesh, sterile, pre-loaded on delivery tool
BAR-D8-10X14 | Barricaid® Prosthesis, 10mm wide mesh, sterile, pre-loaded on delivery tool
BAR-D8-12X14 | Barricaid® Prosthesis, 12mm wide mesh, sterile, pre-loaded on delivery tool

## REF. NR. | DESCRIPTION
---|---
KIT-D4 | Instrument set for use with the Barricaid® system, non-sterile.
References

About Intrinsic Therapeutics

Intrinsic Therapeutics is dedicated to the science of spinal care with a focused mission: To offer surgeons and patients better options for treating painful disc herniations that cause sciatica and low back pain for millions of people worldwide.

Under the direction and guidance of our experienced management team and scientific advisory board, including renowned neuro and orthopedic surgeons from around the world, Intrinsic Therapeutics has developed the next generation of innovative disc closure solutions designed to improve patient outcomes.