

Expert review with meta-analysis of randomized and nonrandomized controlled studies of Barricaid annular closure in patients at high risk for lumbar disc reherniation

# Expert Review of Medical Devices (2020)

https://doi.org/10.1080/17434440.2020.1745061

LE Miller, RT Allen, B Duhon, & KE Radcliff

#### Disclaimer:

This article contains off-label information. Other implant size besides the approved sizes are mentioned in the article. Specifically Barricaid ACD implant for its 8 mm and 10 mm sizes have been approved by the FDA. Please use medical discretion when reviewing this article.

#### Barricaid is approved for the following indications for use:

The Barricaid 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 which demonstrate neural compression using MRI to treat a large annular defect (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.

For complete risk-benefit information, please refer to www.barricaid.com/instructions-for-use

### Financial disclosure:

This paper was funded by Intrinsic Therapeutics. The following authors are paid consultants for Intrinsic Therapeutics:

Larry E. Miller

## **Abstract**

Introduction: Patients with lumbar disc herniation and associated sciatica are often referred for lumbar discectomy. The surgical defect in the annulus fibrosus is typically left unrepaired after lumbar discectomy. Patients with large postsurgical annular defects (≥6 mm width) have a higher risk of symptom recurrence and reoperation compared to those with small defects. In these high-risk patients, a treatment gap exists due to the lack of effective treatments for durable annulus fibrosus repair.

Areas covered: This article highlights the therapeutic need and summarizes clinical results of a bone-anchored annular closure device (Barricaid) that was designed to fill the treatment gap in patients with large postsurgical annular defects. Clinical results were summarized by means of a systematic review with meta-analysis of two randomized and two nonrandomized controlled studies.

**Expert opinion:** Professional societal recommendations and clinical study results support the adoption of bone-anchored annular closure for use in properly selected patients undergoing lumbar discectomy who are at high-risk for reherniation due to a large postsurgical defect in the annulus fibrosus. The risks of symptomatic reherniation and reoperation are approximately 50% lower in patients treated with lumbar discectomy and the Barricaid device compared to lumbar discectomy only, representing a clinically effective treatment strategy.





