CONTINUED ACCESS STUDY SYNOPSIS

| | |
|---|---|
| **Title:** | Continued Access: A Prospective, Randomized, Multicenter Study to Demonstrate the Superiority of the Barricaid to Discectomy for Primary Lumbar Disc Herniation |
| **Short Title:** | A Study to Demonstrate the Superiority of the Barricaid to Discectomy for Lumbar Disc Herniation |
| **Protocol Number:** | (b)(4) [redacted] |
| **Study Treatment:** | Discectomy and surgical implantation of the Barricaid device |
| **Control Treatment** | Discectomy |
| **Study Design:** | Prospective, multi-center, randomized, controlled study |
| **Study Purpose:** | The purpose of this continued access surveillance of a prospective, randomized, multicenter superiority study is to evaluate the safety of the Barricaid when used in conjunction with discectomy, when compared to discectomy alone. |
| **Study Population:** | All subjects still enrolled in the original oUS study will be invited to participate in this continued access surveillance. Inclusion/Exclusion criteria for patients originally enrolled in the oUS RCT included: radiculopathy (with or without back pain), a positive straight leg raise (L4-5, L5-S1) or femoral stretch test (L1-2, L2-3, L3-4), and a posterior or posterolateral herniation at one level between L1 and S1 with radiographic confirmation of neural compression using MRI who were found to have an anular defect (post discectomy) which measured between 4mm and 6mm tall and between 6mm and 10mm wide, with a minimum posterior disc height of 5mm, and failed at least 6 weeks of conservative treatment. |
| **Number of Subjects:** | All subjects still enrolled in the original oUS study will be invited to participate in PAS #1. Of the 272 subjects randomized to receive the Barricaid device and the 278 subjects randomized to receive the control treatment, 243 Barricaid and 247 control randomized patients had not withdrawn consent or died or as of the 24 month visit. |
| **Study Hypotheses:** | Safety and effectiveness the Barricaid Anular Closure Device is maintained through 5 years when compared to treatment of discectomy alone. |
| **Number of Sites:** | Only sites participating in the original oUS study will participate in PAS #1. 21 sites are available for participation in PAS #1. |
| **Study Enrollment:** | Initial enrollment of the oUS RCT was completed by October 14, 2014. |
| **Study Duration:** | Subjects included in the original clinical investigation returned for follow-up visits at 6 weeks, and 3, 6, 12, and 24 months post-treatment to collect data for the primary evaluation of safety and effectiveness. Patients will be followed annually until each patient has reached the 60 month time point. Study duration is approximately 36 months as all patients have reached 24 |

| | |
|---|---|
| | months prior to the start of PAS #1. |
| **Data Collection/**<br><br>**Study Endpoints** | • Adverse Events<br>• Reoperations<br>• Symptomatic reherniations<br>• Device integrity failures<br>• Device migration failures<br>• VAS Leg Pain<br>• Oswestry Disability Index (ODI)<br>• VAS – Back Pain<br>• SF-36 PCS<br>• SF-36 MCS<br>• Radiographic assessments including: endplate changes and disc height |