



NICO/BRAINPATH™ FAQs

The Facts

The NICO BrainPath technology is part of a unique neurosurgical approach that provides atraumatic access to the brain and is helping to redefine the notion of “inoperable” when it comes to brain surgery. More than 300 neurosurgeons are now trained on this technology and are now able to operate on abnormalities within the white matter of the brain. The surgical and short-term outcomes that impact patients’ quality of life have both physicians and patients praising the new approach. Improved quality of life was noted as the number one patient priority in a recent 1,800 patient survey conducted by the National Brain Tumor Society (NBTS).

What is NICO?

NICO stands for Neurosurgical Intervention Company. It is also the name of the company’s first patient who underwent surgery using NICO’s first commercial device, the Myriad®. NICO Corporation is an Indianapolis-based medical device company with medical devices — particularly the NICO BrainPath — designed to provide atraumatic access to brain abnormalities.

What is the genesis of the company?

The founders of NICO previously worked together at Suros Surgical Systems—a medical device company that pioneered the Automated Tissue Excision and Collection (ATEC) breast biopsy system. This technology changed the standard of breast care for high-risk women when it was introduced in 2004, providing physicians with the ability to biopsy and completely resect abnormal breast tissue in the MRI suite and making it possible to diagnose the inaccuracies of open surgical biopsy which led to unnecessary mastectomies.

In 2007, the creators of this revolutionary technology entered the neurosurgery space and embarked on a mission to revolutionize neurosurgery by developing breakthrough technologies to improve the standard of care when it comes to accessing and addressing brain abnormalities.

What is the BrainPath Technology? How does it work?

The BrainPath provides atraumatic access to the tumors, cysts and vascular diseases by navigating through the delicate folds and fibers of the brain. The two-piece system consists of a clear plastic sheath around a smooth, cylindrical tool with a specially designed tip. The BrainPath enters the brain through an opening smaller than a dime, allowing the surgeon to then navigate through the brain’s natural folds and fiber tracts, carefully displacing brain tissue. Once at the location of the abnormality, the surgeon removes the cylinder from the sheath, leaving the sheath in place to create a portal or narrow corridor through which the surgeon operates.

Additional FDA clearance was granted for BrainPath in July 2015 for design modifications and revised intended use. Revised intended use includes primary and secondary brain tumors, vascular abnormalities, and secondary bleeds.

How is the BrainPath different from existing minimally invasive brain surgery methods?

While existing minimally invasive approaches also use small openings, surgeons using the BrainPath are not required to cut through the brain’s white matter – tissue responsible for any number of cognitive



and functional responses – to reach the target abnormality. The BrainPath eases through white matter by displacing tissues like a ship’s hull displaces water. When the surgeon removes the BrainPath tool, the brain tissue can return to its previous position.

What differentiates BrainPath from other technology used to conduct brain surgery?

The difference from a surgical standpoint is that surgeons using BrainPath enter the brain through the sulci, the natural folds of the brain, to displace the critical structures in the white matter to reach the abnormality, thereby reducing the potential for tissue damage. This can set BrainPath apart in the field of brain surgery. Techniques with other existing tools are “trans-gyral” and require surgeons to intentionally cut through the white matter.

There is no other technology on the market that allows this type of atraumatic access through the brain – moving brain surgery in a direction much like when knee surgery moved from open surgery to arthroscopic. Today, the trauma and lengthy recovery of open knee surgery is obsolete.

What do the results show?

The new integrated surgical approach that includes BrainPath is the focus of a growing number of professional neurosurgical organizations and national and international patient advocacy organizations. The approach is also gaining clinical credibility with increasing published evidence and data presentations, including:

- 5 clinical articles published in a peer-reviewed publication; two others accepted
- 8 pending papers
- 12 abstracts presented
- 25 presentations at national and international neurosurgical conferences and annual meetings and with society and patient advocacy organization presentations, including the International Stroke Conference, American Brain Tumor Association (ABTA), National Brain Tumor Society (NBTS), Cancer Treatment Options and Management (CTOAM), Pediatric Brain Tumor Foundation (PBTf), Voices Against Brain Cancer (VABC), and Accelerate Brain Cancer Cure (ABC2)

Most recently, multi-center clinical results declared as “statistically significant” were granted a national podium presentation at the American Academy of Neurological Surgeons (AANS) and the International Stroke Conference (ISC). The pilot data was built around a standardized surgical approach that includes using BrainPath.

Each of these venues validates the clinical evidence of the approach and outcomes that have directly impacted the growing adoption of technologies used in the approach. Added interest and growing attendance has also been seen in training courses held throughout the year on the BrainPath Approach™. Currently, more than 300 neurosurgeons have been trained using the BrainPath technology and more than 60 hospitals use the technology regularly and are designated BrainPath Centers.

What kind of impact will this make on the current methods of conducting brain surgery?

The BrainPath technology is a disruptive innovation in the field of neurosurgery. At a time when the entire health care model is transforming towards one of integrated, coordinated care, there is a desire to see the latest in technology, devices and approaches to many facets of medicine. This method will



usher in a new era of brain access and tissue removal, especially subcortical access, and how we approach certain abnormalities.

Collected clinical data of BrainPath procedures demonstrates the possibility that BrainPath may be used in functional neurosurgery, trauma and anywhere access is a key challenge to treatment of brain abnormalities in what is a very complex surgical environment.

Which types of brain abnormalities will this method apply to?

The BrainPath is abnormality agnostic — it is all about access. However, additional FDA clearance was granted for BrainPath in July 2015 for design modifications and revised intended use. Revised intended use includes primary and secondary brain tumors, vascular abnormalities, and secondary bleeds. The device provides a pathway to deep locations within the brain.

An estimated 500,000 patients in the U.S. each year are diagnosed with brain abnormalities and have limited surgical options available to them. Worldwide, these numbers increase to 2 million. As of April 1, 2014, more than 2,500 BrainPath procedures have been performed using atraumatic access to brain abnormalities and addressing some of the challenges encountered using traditional subcortical surgery methods.

What are the challenges of traditional white matter surgery?

One of the biggest challenges of traditional white matter surgery is access – how to reach brain lesions that are difficult to get to or located deep in the brain. In a clinical paper authored by MD Anderson, they identified the long-standing problem of traditional subcortical surgery: [Subcortical Injury Is an Independent Predictor of Worsening Neurological Deficits Following Awake Craniotomy Procedures](#). This paper indicates a strong need for a solution in the marketplace.

Where is the BrainPath technology used?

The BrainPath technology is currently being used in more than 60 hospitals, with over 300 surgeons currently course trained. The technology is being used in large academic centers, medium-sized and small rural hospitals, indicating an across-the-board need for finding a solution to an unmet need. Among those institutions using BrainPath as a standardized surgical approach include:

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| NorthShore University Health System | Duke Raleigh Hospital |
| University of Arkansas for Medical Sciences | Cancer Treatment Centers of America |
| Houston Methodist Hospital | Stanford University Medical Center |
| Aurora Health Care | Indiana University Health |
| Johns Hopkins Hospital | UC Irvine Medical Center |
| Mayo Clinic Jacksonville | St. Vincent Hospital - Indiana |
| Cleveland Clinic | Phoenix Baptist Hospital |
| Univ of Southern California Medical Center | Delray Medical Center |
| Emory University Hospital | Lafayette General Medical Center |

How many surgeries have been performed?

Over 2,500 surgeries have been performed to date.



What body of physicians is supporting the BrainPath technology?

The Subcortical Surgery Group (SSG) is a group of neurosurgeons who formed a user group to support the awareness and advancement of this technique and other advanced technologies. The group, registered as a 501(c)(6), was formed to help doctors learn and become trained on the surgical approach, share experiences, and help patients find a surgeon in their area who is trained using the BrainPath integrated surgical approach.

The SSG is led by a Board and Executive Committee of 9 neurosurgeons. All are trained in using BrainPath and routinely perform BrainPath procedures. The SSG board is comprised of:

- **Dr. Julian Bailes**, Chairman of Neurosurgery, NorthShore University Health System, and President & Chairman of the Subcortical Surgery Group
- **Dr. JD Day**, Professor and Chair, Department of Neurosurgery, University of Arkansas for Medical Sciences
- **Dr. Amin Kassam**, Vice President of Neurosciences, Aurora Health Care
- **Dr. Richard Rovin**, neurosurgeon, Aurora Health Care, and Vice Chairman, Secretary and Treasurer of the Subcortical Surgery Group
- **Dr. Gary Gallia**, Assistant Professor of Neurosurgery and Oncology and Director of the Neurosurgery Skull Base Center, Johns Hopkins Hospital
- **Dr. Ronald Young**, Chief of Pediatric Neurosurgery, St. Vincent Hospital, Indianapolis
- **Dr. Gustavo Pradilla**, Assistant Professor of Neurosurgery at the Emory University School of Medicine and Chief of Neurosurgery at Grady Memorial Hospital
- **Dr. Lloyd Zucker**, neurosurgeon, Delray Medical Center
- **Dr. Mohamed Labib**, neurosurgeon, Clinical Neurological Sciences, Ontario Canada

Are there similar technologies available right now?

No. Currently, there are no other technologies that provide atraumatic access to deep regions of the brain like BrainPath. Other procedures deemed “minimally invasive” either risk causing trauma to the white matter of the brain during the surgery or utilize tools that emit heat upon resection of the abnormality.