



For Immediate Release

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**NICO Receives Additional FDA Clearance for Specific BrainPath Indications
for Subcortical Access to Brain Tumors, Cysts and Vascular Disease**

Decision opens door for new surgical option to once inoperable tumors and blood clots

INDIANAPOLIS, July 27, 2015 — Brain and spine medical device manufacturer NICO Corporation received additional clearance from the U.S. Food and Drug Administration (FDA) for specific indications on its patented BrainPath technology. The additional clearances provide specific disease state approval for: primary and secondary brain tumors, vascular abnormalities, and secondary bleeds. The addition of these indications by the FDA are a critical milestone for NICO's BrainPath technology, which is helping to redefine the notion of "inoperable" brain surgery through non-invasive subcortical access to the brain. More than 2,000 BrainPath procedures have been completed at over 60 institutions throughout the United States since the device became commercially available two years ago.

"It is very encouraging that all of the clinical evidence and careful surgeon proctoring using the BrainPath has led the FDA to clear specific indications for a technology that is a true breakthrough, as measured by the clinical outcomes," said Jim Baumgardt, chairman of the Board of Directors for NICO Corporation. "We have fought against significant odds to prove this. The subcortical space is the last part of the human body to have a true minimally invasive option for surgery, which is the gold standard of treatment for primary and secondary tumors due to its demonstrated ability to lengthen life.¹ We are positive that our growing clinical evidence demonstrates that we have earned the more specific cleared indications."

BrainPath is used to access and navigate through the delicate folds and fiber tracks of the brain by displacing brain tissue as it creates a corridor to the abnormality, all through an opening the size of a dime. There is no other technology on the market that allows for atraumatic access within the brain using a trans-sulcal surgical approach. Clinical data for BrainPath procedures demonstrates it is not only safe, but can also be used anywhere that access is a challenge to the treatment of brain abnormalities.

The technology has also been included in five peer-reviewed publications, with 8 pending papers, at least 25 presentations at national and international neurosurgical conferences, and 12 abstracts.

Clearance for the specific indications was based on the evaluation of the clinical effectiveness and documented patient outcomes when using BrainPath. The device gets very high scores for these criteria, said Jim Pearson, president and CEO of NICO Corporation.

"For intracerebral hemorrhages or hemorrhagic stroke in particular, surgeons were taking a watch-and-wait approach and were not being called to administer immediate treatment because it was deemed surgery would be a greater risk to the patient with little clinical benefit," he said. "We feel it has been proven now that our technology, approach and results – when standardized in the hospital

– show we create better outcomes for patients, and presentations on study results at the recent International Stroke Conference also conclude this.”

Through closely managed courses, more than 230 neurosurgeons, residents and fellows have been trained on BrainPath and 200 more are expected to participate in training courses scheduled this year across the country. The training includes a trans-sulcal surgical approach using BrainPath to access primary and secondary brain tumors, intraventricular tumors and cysts, and vascular abnormalities that cause intracerebral hemorrhage (ICH), including primary bleeds (better known as a hemorrhagic stroke) and secondary bleeds from other causes such as arteriovenous malformation, and trauma.

The hemorrhagic stroke and brain tumor market in the U.S. numbers nearly 500,000 patients. More than 50 percent of those patients have few, if any, effective surgical treatment options due to location of the abnormality in this very complex area of the body. Hemorrhagic stroke is considered the deadliest class of stroke with an early mortality rate of 32-50 percent, while many brain tumor patients are at risk of additional damage to brain fiber tracts using current surgical techniques.

The [results](#)² of a multi-center study on the safety and efficacy of hematoma evacuation using a trans-sulcal surgical approach with BrainPath showed “statistically significant” improvement in patients’ neurological state associated with early intervention. This improvement was reported in 35 patients at 10 centers with 89 percent clot evacuation, as well as no new deficits or mortalities. The results were cited as a breakthrough in hemorrhagic stroke by the National Stroke Association.

“No matter where the tumor, cyst or ICH is located in the brain’s white matter, chances are we can now access and remove it with the goal of greatly improving clinical and functional outcomes as measured by the standards hospitals now look at critically – reduced length of stay, improved functional recovery, and faster recovery,” Pearson said. “Neurosurgeons can now consider BrainPath a true minimally invasive option for a wide group of patients who had no surgical options before.”

There are currently 20 designated BrainPath Center hospitals using BrainPath as a standardized surgical approach, including Cleveland Clinic, Emory University Hospital, Johns Hopkins Hospital, Aurora Health Care, NorthShore University Health, Delray Medical Center, Mayo Clinic Jacksonville, UC Irvine Medical Center, Stanford University Medical Center, Methodist Houston Hospital, University of Arkansas for Medical Sciences, Duke Raleigh Hospital, Indiana University Health, St. Vincent Hospital Indianapolis, and Phoenix Baptist Hospital.

Learn more about the NICO BrainPath by visiting the website at www.NICOneuro.com. Procedure videos showing atraumatic access with BrainPath can be found on YouTube at NICOneuroCorp.

¹Patchell RA, Tibbes PA, Walsh JW. A randomized trial of surgery in the treatment of single metastases to the brain. *N Engl J Med*. 1990 Feb 22;322(8):494-500. doi: 10.1056/NEJM199002223220802.

²Labib M, et al. The safety and efficacy of image-guided trans-sulcal radial corridors for hematoma evacuation: a multicenter study. Late breaking oral presentation LB12 at: 2015 International Stroke Conference; February 11-13, 2015; Nashville, TN.