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Contact Information
Debbie Davis
(o) 317.595.0820
(c) 317.508.2179

Karen Busse
(o) 502.384.5434
(c) 502.417.9171

CERVICAL ARTIFICIAL DISC RECEIVES FDA APPROVAL
Indianapolis Spine Surgeons Are Only Ones to Offer Procedure in Indiana

INDIANAPOLIS, Ind., – A new option is available for people with a form of neck and arm pain. The Bryan™ Cervical Disc, a surgical device manufactured by Medtronic to treat cervical degenerative disc disease has now received FDA approval. At this time, it is only available at the 30 investigational sites which participated in the clinical trials including the Indiana Spine Group, based in Indianapolis.

Cervical degenerative disc disease, a common cause of neck and arm pain is a result of the natural aging process or trauma. The current standard surgical treatment when medical management is ineffective is a spinal fusion.

The Bryan Cervical Disc is a good option for many patients who meet the criteria for cervical arthroplasty, a surgical alternative to spinal fusion. With cervical arthroplasty the damaged cervical (neck area) disc is removed, and replaced with an artificial disc. "This newer procedure allows patients to continue an active lifestyle and maintain their natural neck motion," said Rick Sasso, M.D., Indiana Spine Group.

Dr. Sasso has been a principal investigator in the clinical trials of the Bryan Cervical Disc. Additionally, he implanted the first one in the United States at St.Vincent Hospital (Indianapolis) in May 2002 with neurosurgical spine surgeon Kenneth Renkens, M.D.

The cervical spine, consisting of seven bones called vertebra are separated from one another by intervertebral discs. These discs allow neck motion; rotation and bending, and as a result of aging the discs can deteriorate or be damaged by trauma – resulting in neck and arm pain that can sometimes be debilitating. When medical management of this pain is ineffective, the standard surgical treatment option has historically been spinal fusion. Industry analysts project

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that there are approximately 200,000 cervical spinal fusions annually in the United States. With the standard fusion surgery, a bone is grafted into place between the vertebral bodies where the damaged disc is removed. This bone is from either the patient (creating a second surgical site) or donor bone. If the entire disc was removed, typically plate and screws will be used to hold the bone graft into place. Following fusion surgery, the patient must to wear a cervical collar for up to six weeks to immobilize the neck. Once the collar is no longer needed, neck motion is still limited, and there is an increased risk for post-operative pain and infection at the surgical sites.

The state-of-the-art alternative to a typical spinal fusion is cervical arthroplasty. This is the surgical procedure that utilizes the artificial disc. During this procedure, the damaged disc is removed and the Bryan Cervical Disc is implanted. With a shorter length of stay in the hospital and less post-operative restrictions, patients are able to return to their normal activities and work faster than with a fusion. “The ideal patient for the Bryan Cervical Disc is someone who is younger, an individual that is in their 20’s to 50’s that leads an active lifestyle and who is not affected by spinal arthritis,” said Sasso.

The Bryan Cervical Disc was developed by Vince Bryan in the early 1990’s. Constructed out of a polyurethane nucleus surrounded by titanium endplates, it is designed to preserve the normal, physiologic motion of the cervical spine. “The Bryan Cervical Disc more closely mimics natural spine disc movement with shock absorbing characteristics than a previously approved device,” said Sasso.

Indiana Spine Group spine surgeons’ have been involved with the Bryan Cervical Disc clinical trials since they launched in 2002; beginning with the implant of the first artificial disc in the United States on May 28, 2002. Dr. Rick Sasso testified at the FDA hearings in July 2007 leading up to the disc receiving preliminary FDA approval.

Dr. Sasso also co-authored a two-year follow-up clinical study on the Bryan Cervical Disc. In this study, patients that received the Bryan Cervical Disc and those that underwent spinal fusion were evaluated at regular intervals following surgery. This study concluded that patients in both groups – the Bryan Cervical Disc and spinal fusion – showed significant improvement in their outcomes at each post-operative evaluation when compared to their pre-operative state, but the patients in the artificial disc group had statistically better

outcomes at each post-operative evaluation as compared to those that had a standard fusion. “A four-year study recently submitted for publication concluded the same results,” said Sasso.

“Additional biomechanical studies indicate that disc replacement creates less adjacent level strain than a spinal fusion.”

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Rick C. Sasso, M.D., is a board-certified spine surgeon with Indiana Spine Group and co-director of the St. Vincent Spine Center. Specializing in adult and pediatric spine surgery, Dr. Sasso has dedicated his medical career to the comprehensive treatment and surgery of spinal disorders and abnormalities. Actively involved in spine surgery research, Dr. Sasso is a pioneer in the development of minimally invasive spine surgery techniques. He is actively involved in many research studies, as well as the development of instrumentation technology used to treat spinal disorders.

Kenneth L. Renkens, M.D., is a board-certified neurosurgeon specializing in spinal surgery with Indiana Spine Group. Additionally, he is a clinical instructor for neurosurgery and orthopaedic surgery at Indiana University School of Medicine. Dr. Renkens has dedicated his career to the comprehensive treatment and surgery of spinal disorders and abnormalities.

Indiana Spine Group is a Center of Excellence for comprehensive spine care. Providing comprehensive diagnosis and treatment for all spinal disorders, our spine specialists are experts in using the most advanced diagnostic and treatment tools, with a focus on minimally invasive non-operative spine treatments. The comprehensive patient care team includes board-certified minimally invasive spine specialists and spine surgeons. For more information, call 317.228.7000 or visit www.indianaspinegroup.com.

Bryan Cervical Disc Patients - Available for Interviews

The following patients were involved in the clinical trials, and received Bryan Cervical Discs in 2002. Today, they have active lifestyles and enjoy many of their hobbies including golf, waterskiing, bowling and hiking.

Mike Rudicle, a consultant, was injured in a waterskiing accident when he was 17. While in his 40's he started to lose function on his left side and was no longer able to treat the pain with medicine and physical therapy. A father of two, with an active lifestyle, and love of golfing and water skiing he did not want the spinal fusion procedure because of its limitations. He sought a surgeon that was participating in the Bryan Cervical Disc trials, and if he had not been accepted into the study he would have gone to Europe for the procedure. Today, Mike enjoys golfing and waterskiing. He also testified at the FDA hearings for the Bryan Cervical Disc.

Kevin Wacasey is the first patient to have received the Bryan Cervical Disc in the United States. Suffering from a neck injury from an automobile accident, he had minimal movement in his left arm and neck prior to surgery. A father of an active teenage boy, today he is in the home remodeling business and enjoys golfing, bowling and fishing.

Nazli Kahn is an owner and operator of two day care centers and mother of three boys. She was sidelined after a neck injury. Today, she exercises daily, loves to walk and play volleyball and “she does not hold back from anything.”

Bryan™ Cervical Disc Timeline

Early 1990's	Developed by neurosurgeon Dr. Vincent Bryan
January 2000	First Bryan Cervical Disc implant, Leuven Belgium by Dr. Jan Goffin
May 28, 2002	First Bryan Cervical Disc implant in the United States by Dr. Rick Sasso and Dr. Kenneth Renkens
July 2007	Preliminary FDA hearings for Bryan Cervical Disc, Dr. Rick Sasso testifies. Patient Mike Rudicle also testifies. Bryan Cervical Disc receives preliminary FDA approval
October 2007	Publication of clinical outcomes of Bryan Cervical Disc study, a 24-month follow-up of patients; Dr. Rick Sasso co-author
May 2009	Bryan Cervical Disc receives FDA approval