



FIRST U.S. PATIENT TREATED IN SINGLE-LEVEL IDE CLINICAL TRIAL OF BAGUERA® C CERVICAL DISC PROSTHESIS

LAGUNA HILLS, CA, March 2nd, 2021 – Spineart USA Inc. announced today that investigator, Dr. Byron Branch, at Carolina Neurosurgery and Spine Associates in Charlotte NC, performed the first surgery in the single-level U.S. Investigational Device Exemption (IDE) Clinical Trial of the BAGUERA® C Cervical Disc Prosthesis. The BAGUERA® C implant is an investigational device designed to reconstruct the cervical disc following single-level discectomy for symptomatic cervical disc disease.

Surgery to treat cervical degenerative disc disease is generally considered when neurological symptoms are present, such as persistent arm numbness and/or weakness, or when chronic pain is severe and not adequately relieved after at least six months of non-surgical treatments, and daily activities become difficult. Artificial cervical disc replacement involves the removal of the problematic disc and replaces it with an artificial prosthesis. The goal of this surgery is to restore the height and preserve motion at that spinal level.

“The BAGUERA® C cervical disc is an innovative device with a simple yet reliable technique.” said Dr. Byron Branch, Investigator at Carolina Neurosurgery and Spine Associates.

Jerome Trividic, President of Spineart USA Inc., said, “The initiation of the BAGUERA® C single-level trial in the United States is an important milestone for Spineart’s ambitious scientific study program for artificial cervical disc replacement. We are strong believers in the clinical value of conducting, in parallel, our two pivotal IDE studies. Our goal is to gather further solid scientific evidence of safety and effectiveness for the BAGUERA® C artificial disc that can benefit the spine surgeon community and their patients.”

ABOUT THE BAGUERA® C CERVICAL DISC PROSTHESIS:

The BAGUERA® C Cervical Disc Prosthesis, developed by Spineart SA (Geneva, Switzerland), is an investigational device designed to maintain or restore segmental motion and disc height in the cervical region of the spine following single- or two-level discectomy for symptomatic cervical disc disease. The BAGUERA® C is designed to maintain the natural behavior of a functional spinal unit. This design enables the BAGUERA® C nucleus to move in all six degrees of freedom, with independent angular rotations (flexion-extension, lateral bending, and axial rotation) along with independent translational motions (anterior-posterior and lateral translations).

ABOUT THE BAGUERA® C IDE CLINICAL TRIALS:

The BAGUERA® C IDE trials, prospective, multi-center, randomized clinical studies, will evaluate the safety and efficacy of BAGUERA® C compared to the Mobi-C® cervical disc in the treatment of symptomatic cervical disc disease at a single- or two contiguous levels in the cervical spine. Each study will enroll approximately 300 subjects at up to 30 study sites in the U.S. Results of this pivotal clinical trial will be the basis of a premarket approval (PMA) submission to the U. S. Food and Drug Administration.

ABOUT SPINEART

Spineart, a privately held medical device company based in Geneva (Switzerland), is focused on simplifying the surgical act by designing, developing and promoting safe and efficient

solutions to spine surgeons, operating room teams, and patients. Spineart is a pioneer in its field, having introduced unique patented and clinically validated technologies in the fields of Minimally Invasive Surgery, Motion Preservation, Fusion, Biologics, and Fractures Treatment. Spineart markets a complete portfolio combining traceable barcoded sterile packed implants with compact instrument sets, thus proudly promoting greater safety, cost-efficiency, and compliance at the hospital. Its 100% US subsidiary is located in Laguna Hills, California. For more information, visit www.spineart.com.

CAUTION — Investigational device. Limited by United States law to investigational use.