



150 U.S. PATIENTS TREATED IN EACH OF THE ONE AND TWO-LEVEL IDE CLINICAL TRIALS OF THE SPINEART BAGUERA® C CERVICAL DISC PROSTHESIS

LAGUNA HILLS, CA, December 13th, 2022 – Spineart USA Inc. announced today that surgery has been performed on 150 patients in both the one and two-level for a total of over 300 patients to date in the U.S. Investigational Device Exemption (IDE) Clinical Trials of the BAGUERA® C Cervical Disc Prosthesis. The BAGUERA® C implant is an investigational device in the U.S. designed to reconstruct the cervical disc following discectomy for symptomatic cervical disc disease.

Just over one year after the start of the two studies in more than 25 sites, this milestone surpasses our enrollment midpoint.

“It’s exciting to have both arms, 1- and 2-level, of the BAGUERA® C study reach this significant enrollment milestone. It’s one step closer to making this innovative cervical artificial disc available to patients in the US.” said Dr Dom Coric, of the Jerry and Audrey Petty Endowed Professor of Spine Surgery at Atrium Health (NC) and one of the lead Principal Investigators on the studies.

“I would like to acknowledge our surgeon clinical investigators, their research, clinical and surgical teams and the Spineart team for their relentless efforts and this wonderful milestone after this first full year of enrollment. We are witnessing a growing interest throughout the U.S. for artificial cervical disc replacement as an alternative to fusion for the adequate candidates. We look forward to completing enrollment of both studies and contribute the clinical data to the growing body of level II evidence supporting cervical arthroplasty” said Jerome Trivodic, CEO of Spineart.

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.

ABOUT THE BAGUERA® C CERVICAL DISC PROSTHESIS:

The BAGUERA® C Cervical Disc Prosthesis, developed by Spineart SA (Geneva, Switzerland), is an investigational device in the U.S. 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).

To find a clinical study site near you, or to learn more about the IDE, visit:

<https://www.spineart.com/us/ide-clinical-investigation/>

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