

100 U.S. PATIENTS TREATED IN THE TWO-LEVEL IDE CLINICAL TRIAL OF THE SPINEART BAGUERA[®] C CERVICAL DISC PROSTHESIS

LAGUNA HILLS, CA, May 13, 2022 – Spineart USA Inc. announced today that surgery has been performed on 100 patients in the two-level U.S. Investigational Device Exemption (IDE) Clinical Trial 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.

Spineart is currently conducting, in parallel, a single-level and two-level IDE Clinical Trials of the BAGUERA® C Cervical Disc Prosthesis at more than 20 sites in the U.S. This milestone comes on the heels of the single-level IDE Clinical Trial reaching 100 patients last month, bringing the total number of patients treated so far to more than 200.

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.