

## CERVICAL DISC DISEASE

Spinal discs work like shock absorbers for the bones of the spine and help people be flexible. These discs are made up mostly of water, and as people age, the discs dry out making them less effective at absorbing shock. This can lead to degenerative disc disease, including cervical disc disease—when damaged discs are in the cervical spine.

## SYMPTOMS

Some major symptoms of disc disease can include pain as well as reduced flexibility and mobility. With cervical disc disease, individuals can experience neck and arm pain, as well as nerve or spinal cord irritation.

## TREATMENT

The good news is that there are options to help treat cervical disc disease. When patients have not had success in alleviating the symptoms through exercise, pain management or acupuncture, they may become candidates for surgical options. Spinal disc fusion surgery immobilizes the spine, but the goal of cervical disc replacement surgery is to help preserve motion. This can provide patients with improved quality of life after treatment.

The BAGUERA® C Cervical Disc Prosthesis may help patients with degenerative cervical disc disease maintain or restore neck motion and spinal disc height. The BAGUERA C artificial disc may offer patients the opportunity to maintain the natural behavior and mobility in their spine.

**Talk to your spine specialist about the BAGUERA C Cervical Disc Prosthesis clinical trials to learn if you are eligible to participate.**

To find a clinical trial site near you, visit:



For more information about participating in the BAGUERA C Clinical Trials, contact:

IRB Approval Number:

**CAUTION:**  
Investigational Device. Limited by US law to investigational use only.  
Participation in the BAGUERA C clinical trial is completely voluntary.

<sup>1</sup> Teraguchi M, Yoshimura N, Hashizume H, et al. Prevalence and distribution of intervertebral disc degeneration over the entire spine in a population-based cohort: the Wakayama Spine Study. *Osteoarthritis Cartilage*. 2014;22(1):104-10.



SPINEART USA INC.

23332 Mill Creek Dr. Suite 150 Laguna Hills, CA 92653

USA



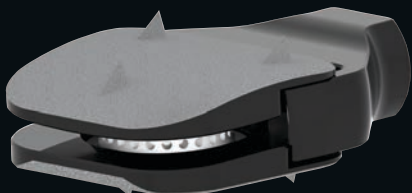
# BAGUERA® C CERVICAL DISC PROSTHESIS CLINICAL TRIALS

For patients with  
degenerative cervical disc disease





## CERVICAL DISC REPLACEMENT



The BAGUERA® C Cervical Disc Prosthesis, or artificial disc, is intended to help maintain the natural behavior and mobility of a functional cervical spine. BAGUERA C benefits may include, but are not guaranteed:

Diminish neck/arm pain	Improve patient function
------------------------	--------------------------

Improve overall quality of life

The unique design of the BAGUERA C makes it different from other available artificial discs. The BAGUERA C is designed to enable full mobility and move in all six degrees of freedom.

The BAGUERA C Cervical Disc Prosthesis is designed and manufactured by Spineart.



90% of people over age 50 have some level of degenerative disc disease.<sup>1</sup>



While the BAGUERA C is new in the U.S. and only available in clinical trials, more than **35,000 BAGUERA C disc prostheses** have been implanted in patients in more than **40 countries** outside the U.S. since 2007. The BAGUERA C has been clinically supported with five years of follow up data post surgeries.

## CLINICAL TRIALS

Two clinical trials are now enrolling patients to evaluate the BAGUERA C as a new cervical disc replacement option for patients with degenerative cervical disc disease. Each trial will enroll approximately 300 patients at up to 30 study sites in the U.S. The clinical trials will compare the Spineart BAGUERA C to the Zimmer Biomet Mobi-C® Cervical Disc at a single level or at two contiguous levels in the cervical spine.

## CLINICAL TRIAL ELIGIBILITY

Patients suffering from symptomatic cervical disc disease affecting one level or two adjacent levels between C3 and C7, and who experience the following signs and symptoms may be candidates:

- Neck or arm pain, and/or
- Functional and/or neurological deficit accompanied by at least one of the following conditions confirmed by MRI or X-Ray:
  - Herniated nucleus pulposus; and/ or
  - Spondylarthrosis defined by the presence of osteophytes; and/ or
  - Reduction of disc height
- Age between 22 to 69
- No response to non-surgical treatment for a period of at least six weeks, or symptoms or signs of progressive root compression despite conservative treatment.