BRYAN Cervical Disc

<html><iframe width="560" height="315" src="https://www.youtube.com/embed/X4D0jbiyjM4" frameborder="0" allow="accelerometer; autoplay; encrypted-media; gyroscope; picture-in-picture" allowfullscreen></iframe> </html>

The BRYAN® Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The BRYAN® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT, and/or magnetic resonance imaging (MRI). Patients receiving the BRYAN® Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation of the BRYAN® Cervical Disc.

The BRYAN® Cervical Disc should not be implanted in patients with an active infection or with an allergy to titanium, polyurethane or ethylene oxide residues, active systemic infection or infection at the operating site; osteoporosis defined as a DEXA bone mineral density T-score equal to or worse than -2.5; moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of greater than 50% of its normal height; marked cervical instability on radiographs (e.g., radiographic signs of subluxation greater than 3.5mm or angulation of the disc space more than 11 degrees greater than adjacent segments); significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma); significant kyphotic deformity or significant reversal of lordosis; or symptoms necessitating surgical treatment at more than one cervical level.

The BRYAN® Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, such as neurological complications.

The safety and effectiveness of this device has not been established in patients with the following conditions: axial neck pain as solitary symptom; not skeletally mature; prior cervical spine surgery, including prior surgery at the index level; facet joint pathology of involved vertebral bodies; active malignancy; Paget’s disease, osteomalacia, or other metabolic bone disease; chronic or acute renal failure or history of renal disease; taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids); pregnant; unstable cardiac disease; diabetes mellitus requiring daily insulin management; and extreme obesity as defined by the NIH Clinical Guidelines Body Mass Index (i.e., BMI ≥40); less than 21 years of age and were not refractory to at least six weeks of unsuccessful conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care.