II. Device Description

A. Description of Device and Properties Relevant to Indications for Use

The BRYAN® Cervical Disc is a spinal arthroplasty system intended for use in the cervical spine to treat degenerative disc disease. The device is intended to maintain motion at the treated level.

The BRYAN® Cervical Disc prosthesis is made up of the following components: two titanium shells, two titanium retaining wires, a polyurethane nucleus, a polyurethane sheath, and two titanium seal plugs.

The polycarbonate polyurethane nucleus is designed to fit between the two titanium shells. The nucleus-contacting side of each shell has a center pin which interacts with a central hole in the nucleus to allow a normal range of motion (see Table 1 below which shows, for four different types of motion, the minimum range allowed by any prosthesis within the spectrum of device sizes), to provide a soft stop at the extremes of motion, and to limit the possibility of traumatic nucleus expulsion. The bone-contacting side of each shell includes a sintered titanium porous coating designed to allow for biologic ingrowth and provide long-term device stability.

Table 1. Minimum range of motion for all prosthesis sizes

Flexion/Extension (degrees)	Lateral Bending (degrees)	Rotation (degrees)	Translation (mm)
±10	±11	±7	±1

The polyurethane sheath surrounds the nucleus and attaches to each shell with one retaining wire. The two wires are placed around the sheath and seated in a circumferential groove at the

edge of the shell. [redacted] thus forming a closed compartment. [redacted]

Holes are located on the apex of each shell, pass through the post, and allow for injection of sterile saline into the compartment prior to implantation. The saline functions as an initial lubricant for the prosthesis, minimizing friction and wear. The titanium seal plugs screw into the holes used for saline introduction and function to retain the saline in the compartment.

The prosthesis is held in the intervertebral disc space by the fit of the shells' outside diameter and convex outer surfaces into the precision milled concavity of the vertebral endplates. This fit is such that device expulsion or migration is restricted in the anterior/posterior and lateral directions. [redacted] A stop or wing, which extends superiorly on the cephalad shell and inferiorly on the caudal shell, is intended to prevent migration into the spinal canal.

The prosthesis is implanted using a surgical procedure that is an extension of current anterior cervical discectomy (ACD) procedures. [redacted]

o [redacted]

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The prosthesis is currently available in five diameters - 14, 15, 16, 17, and 18 mm. The available components are listed in Table 2 below.

Table 2. BRYAN® Cervical Disc sizes.

Catalog Number	Size (mm)
6470314	14
6470315	15
6470316	16
6470317	17
6470318	18

B. Pictorial Representation

Unimplanted and implanted views of the BRYAN® Cervical Disc device are provided below.

Figure 1. Photograph of device shells and nucleus prior to assembly.

Figure 4. Photograph of assembled device.

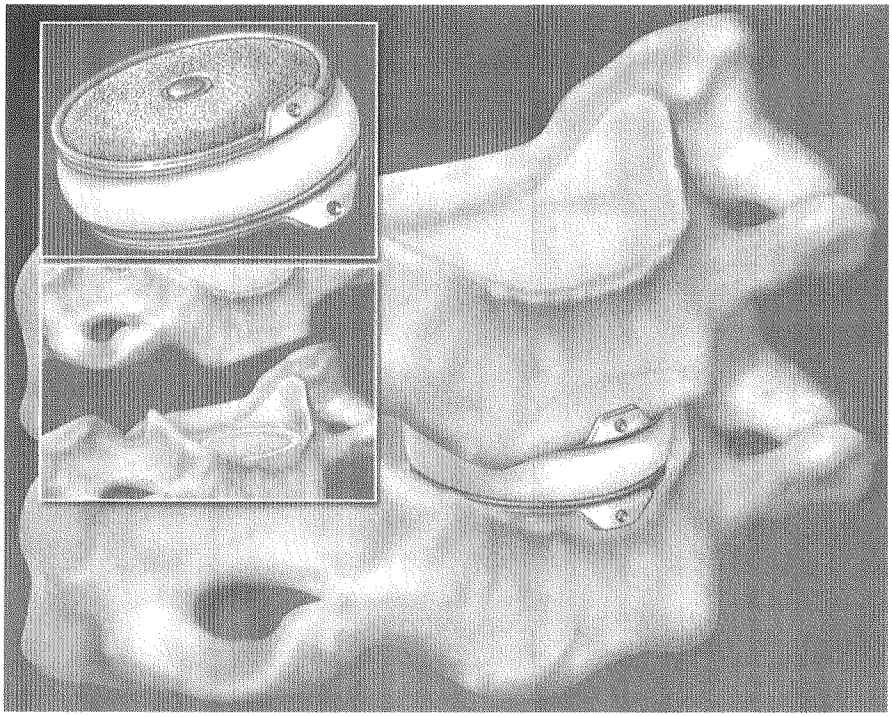

Figure 5. Artist's rendering of disc space preparation and implantation.

C. Mechanism of Action / Principle of Operation

The BRYAN® Cervical Disc is a cervical intervertebral disc prosthesis designed to provide for motion similar to the normal cervical functional spinal unit. The intent is to treat stable degenerative disc disease by reducing or eliminating the signs and symptoms, including pain, without fusing the vertebrae. The prosthesis is designed to act as an intervertebral body spacer while allowing for spinal movement.