



SECURE[®] -C Cervical Artificial Disc (Sponsored clinical trial listing)

Introduction

It is estimated that 80-85% of the population of the U.S. will experience significant pain as a result of spinal conditions within their lifetime. Diseased conditions related to the



neck, also called the cervical spine, are often associated with neck and/or arm pain.

Your cervical spine is made up of seven bones (vertebrae), with an intervertebral disc between each vertebra. The disc has a thick outer layer (annulus) that surrounds the soft gel-like center (nucleus). Each vertebra also contacts neighboring vertebrae in the back (posterior) portion of the spine at the articulating joints (facets). The natural motion of the spine involves movement between each vertebra, compression of the disc and sliding contact of the facet joints. The disc acts as a shock-absorber between vertebrae.



Neck and/or arm pain is a common ailment of the cervical spine, which may be due to impingement (compression) of the spinal cord or nerve roots. With normal everyday activities and over many years, the soft nucleus may become thinner and more brittle, causing the spaces between the vertebrae to become narrower. This degenerative process may result in compression of the spinal cord or nerve roots, causing pain. Slipped or herniated discs (herniated nucleus pulposus) are conditions in which all or part of the nucleus protrudes through a weakened part of the annulus. This also causes pressure on the spinal cord or nerve roots, resulting in neck and/or arm pain. Such pain may also be caused by excessive growth of bone (osteophyte formation) near the spinal cord.



Spinal fusion remains the treatment of choice for many degenerative conditions; however the results of standard fusion techniques vary significantly. Motion-sparing non-fusion devices such as artificial disc replacements may provide alternatives for treatment of these conditions.

The SECURE[®] -C Cervical Artificial Disc was developed as a potential alternative to spinal fusion. SECURE[®] -C is an artificial disc replacement device inserted anteriorly into the cervical spine, designed to help alleviate pain and retain or improve function.

Study Objectives

The objective of this clinical trial is to evaluate the safety and effectiveness of the SECURE[®] -C Cervical Artificial Disc for the treatment of symptomatic cervical disc disease as compared to anterior cervical discectomy and fusion.

Study Overview

This FDA controlled, prospective, randomized study will involve several hundred randomized subjects at up to 20 sites in the U.S. Patients having met all inclusion/exclusion criteria, having signed the informed consent, and deciding to participate in the study will be included in the trial. Participants will be randomly assigned to either the investigational group (SECURE[®] -C Cervical Artificial Disc) or the control group (anterior cervical discectomy and fusion).

Following surgery, patients return to their study physician for scheduled visits to report on their outcomes, including pain relief and function, etc. These outcomes will be used to evaluate the safety and efficacy of the procedure.

Study sponsor

Globus Medical
www.globusmedical.com

Status



Recruiting

Inclusion criteria

Patients must meet the following criteria in order to be enrolled in the study:

- Symptomatic cervical disc disease (SCDD) in one vertebral level between C3-C7, defined as neck or arm (radicular) pain, or functional or neurological deficit and radiographic confirmation (by CT, MRI, X-ray, etc) of any of the following:
 1. Herniated nucleus pulposus
 2. Radiculopathy or myelopathy
 3. Spondylosis (defined by the presence of osteophytes)
 4. Loss of disc height
- Failed at least 6 weeks of conservative treatment
- Age 18-60 years
- *Additional inclusion criteria as defined in the study protocol*



Click the image for a larger view

Exclusion criteria

Patients having the following criteria are excluded from the study:

- More than one level requiring treatment
- Prior fusion surgery adjacent to the vertebral level being treated
- Prior surgery at the level to be treated
- Severe spondylosis at the level to be treated as characterized by any of the following:
 - Bridging osteophytes
 - A loss of disc height greater than 50%; or
 - Absence of motion ($<2^{\circ}$)
- Pregnancy
- Systematic disease including AIDS, HIV, Hepatitis
- *Additional exclusion criteria as defined in the study protocol*

Participating sites and contact information

Please visit www.globusmedical.com and click on "clinical trials" for more information.

Caution -- Investigational Device, Limited by United States Law to Investigational Use.

The information provided by Spine-Health in this Clinical Trials listing section is designed to help patients find clinical trials that are ongoing in the field of spine medicine, and to provide information to help patients contact the centers conducting the research. Spine-Health is not involved in conducting any of these trials and is not promoting the trials or research.

This is a listing of industry-sponsored clinical trials that are actively recruiting patients. These clinical trial listings are not edited or peer-reviewed by Spine-health.com.