

## Frequently Asked Questions

### Q: What is the purpose of the study?

**A:** To determine if the SECURE®-C Cervical Artificial Disc is effective for treating symptomatic cervical disc disease in the cervical spine (neck).

### Q: Can I participate in this study?

**A:** Talk to your doctor about whether your medical condition is appropriate for this study. If your condition qualifies and you are interested in participating, you will be asked to read and sign an informed consent document.

### Q: What if I have had previous surgery?

**A:** Previous surgery does not exclude you from the study, however some types of previous spinal surgery may exclude a patient from the study.

### Q: What are the risks of participating in this study?

**A:** There are known and unknown risks associated with any clinical trial. Such risks may include serious or life-threatening side effects as a result of the treatment. Possible risks are detailed and included in the informed consent document.

### Q: How much does it cost to participate?

**A:** Participation in the study does not require any additional costs to the current standard treatment of care. The study does not require examinations that differ from those normally required for non-investigational spine surgical fixation.

This information has been provided to you by:

\_\_\_\_\_  
DOCTOR

\_\_\_\_\_  
ADDRESS

\_\_\_\_\_  
STUDY COORDINATOR

\_\_\_\_\_  
CONTACT INFORMATION



Patient  
Information



Globus Medical  
Valley Forge Business Center  
2560 General Armistead Avenue  
Audubon, PA 19403  
www.globusmedical.com

©2007 Globus Medical. All rights reserved. Patents pending.  
SECURE is a registered trademark of Globus Medical.

GMCA102

SECURE®-C  
Cervical Artificial Disc

## Cervical Disc Disease

The cervical spine has seven vertebrae and between each of those vertebrae is a disc. Age, genetics, and everyday wear and tear caused by routine activities can contribute to damage and degeneration of cervical discs. Degeneration of discs commonly causes neck pain that radiates toward the shoulders and arms causing pain, weakness, and numbness. Non-surgical treatment, such as physical therapy, injections, and neck braces are usually prescribed first by a doctor. However, some patients do not respond well to non-surgical care and may be candidates for spine surgery.

## Standard Treatment

The current standard of care for the treatment of cervical disc disease is anterior cervical discectomy and fusion (ACDF). An ACDF consists of removing the disc and then replacing it with a bone graft, and inserting a cervical plate with screws. The procedure attempts to permanently fuse two or more vertebrae together so they cannot move except as a single unit. This may alleviate pain but has potential disadvantages, including loss of motion and flexibility, and possible further degeneration of adjacent discs.



## SECURE®-C Cervical Artificial Disc

The SECURE®-C Cervical Artificial Disc has been developed to potentially provide the relief of pain while preserving motion of the cervical spine. The device is designed to provide support for the vertebrae while permitting motion in backwards and forward bending, side to side bending, and turning. The implant is composed of two endplates and a core. The metallic endplates are designed to move and slide on a central core made of polymer material often used in artificial hips and knees.



The surgeon accesses the spine from the front of the neck (anterior), and removes the diseased or damaged disc (discectomy). The SECURE®-C Cervical Artificial Disc is then inserted into the disc space. The surgery lasts approximately one to two hours.

## Clinical Study

The Food and Drug Administration has determined that the SECURE®-C Cervical Artificial Disc is an investigational device in the United States. The FDA has approved an Investigational Device Exemption (IDE) study for 20 clinical sites to use the SECURE®-C device in a limited number of patients that meet certain criteria. Over 200 patients have been enrolled in the study.

The SECURE®-C Cervical Artificial Disc is being investigated in the U.S. for the treatment of symptomatic cervical disc disease in the cervical spine (neck). Eligible patients must be between 18-60 years of age, have degeneration or herniation at only one spinal level, symptoms of nerve compression, at least six weeks of conservative treatment, ability to attend all follow-up exams at enrollment site, and meet further eligibility criteria.

Patients that meet the criteria will randomly receive either the SECURE®-C Cervical Artificial Disc or an anterior cervical discectomy and fusion with graft bone and a cervical plate with screws. Following treatment, patients are asked to see their doctor at specified intervals.

## Your Decision

In order to make the most informed treatment decision for your care, please discuss any questions you may have with your doctor. While discussing the SECURE®-C Cervical Artificial Disc as a possible treatment option for your symptoms, discuss other possible treatment options for your medical condition. With investigational devices there is always the possibility that you may have a reaction or side effect that is currently unknown and unexpected, in addition to the normal risks of spine surgery. It is not known whether you will benefit from this treatment or not. What is learned in this study may benefit other patients suffering from symptomatic cervical disc disease.

