

# Scott & White Hospital & Clinics

## Clinical Research at Scott & White

**Study Title:** A Prospective, Randomized Clinical Investigation of the Cervitech, Inc. Porous Coated Motion (PCM) Artificial Disc for Stabilization of the Cervical Spine

**Project ID#:** 060450

**Department:** Orthopaedics

**Sponsor:** Cervitech, Inc.

### Brief Synopsis of the Study

Condition(s):	Treatment(s):
Degenerative joint disease.	Porous Coated Motion (PCM) Artificial Disc <b>or</b> cervical fusion, the current standard of treatment.

The purpose of this research study is to evaluate the Porous Coated Motion (PCM) Artificial Disc (an investigational device – not approved by the Food and Drug Administration) to determine its safety and effectiveness in the treatment of degenerative joint disease in comparison to cervical fusion, the standard treatment currently available.

### Who is eligible to participate in the study?

**Age:** 18 -65 years of age

**Gender:** M/F

All subjects ages 18 to 65 at the time of surgery and are scheduled for cervical (neck) surgery. Subjects who have had neck, shoulder and/or arm pain for six weeks with no relief from conservative (non-surgical) treatments. There will be a screening process to verify that you qualify for the study.

### What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)

Your participation will require you to follow up with your surgeon and the study coordinator for a minimum of two years after your surgery. You will be scheduled to have x-rays and a CT scan or MRI of your neck prior to your surgery along with the study physician performing physical and neurological exams as part of the screening process. You will be required to complete study questionnaires and exams at every study visit. All subjects will be randomized (like the flip of a coin) to receive either the PCM artificial disc or the cervical fusion.

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**For More Information Contact:**

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