

## **SURGERY**

### **NEUROSURGERY**

#### **🔗 A Prospective, Randomized, Controlled, Multicenter Pivotal Clinical Trial of the Artificial Cervical Disc - LP at Two Levels for Symptomatic Cervical Disc Disease ("Prestige® LP Two Level Trial")**

This study is being conducted to evaluate the safety and effectiveness of a spinal implant called the Artificial Cervical Disc- Low Profile (ACD-LP) for the two level surgical treatment of cervical (neck) degenerative disc disease in your spine. The ACD-LP is made of a titanium ceramic composite. Titanium is a metal used for spinal implants. The ACD-LP designed to replace each disc removed from your neck and is intended to relieve pain while providing the potential for motion in your cervical spine at the treated levels. In this study, the ACD-LP device will be compared to a standard current treatment for cervical disc disease in your spine, which is a fusion utilizing cortical ring allografts (donor bone) and the ATLANTIS- Anterior Cervical Plate System. If you participate in this study, you will be randomly assigned to one of the two treatment groups described below.

1. Artificial Cervical Disc-LP (at 2 spinal levels)
2. Cortical Ring Allografts (donor bone) with the ATLANTIS Anterior Cervical Plate System (at 2 spinal levels)

This clinical trial is being conducted at: Mount Carmel East

For more information on this clinical trial call: 614-261-0402 or 614-868-5872

### **PLASTIC**

#### **🔗 McGhan Medical Corporation Silicone-Filled Breast Implant Adjunct Clinical Study**

This study is designed to collect 5 year data about possible health problems associated with breast implants. This data will be used to help determine if these implants are both safe and effective. If they are proven safe and effective, they will continue to be available. If the data from the studies does not show that they are safe and effective to the satisfaction of the FDA, they may not be available in the future.

This clinical trial is being conducted at: Mount Carmel West  
Mount Carmel East

For more information on this clinical trial call: 614-755-4155 or 614-864-6220

## **🔗 Mentor Adjunct Study for Silicone Gel-Filled Mammary Prosthesis**

Breast implants have been used in nearly two million women since the early 1960's. There are known risks and potential complications from having breast implants. Since 1992 the Food and Drug Administration (FDA) has allowed limited silicone gel implants for clinical studies of breast reconstruction after mastectomy for cancer, correction of deformities, or replacement of damaged implants. The FDA has not formally approved these gel-filled implants as safe and effective because additional scientific evidence needs to be collected. Your participation will help answer the remaining questions.

To receive Mentor silicone gel-filled breast implants participation in this study is required, but there are other kinds of implants available that do not require participation in a clinical trial. Participants may receive one of two different types of silicone gel-filled implants. One implant contains silicone-gel and saline solution and the second contains only silicone.

This clinical trial is being conducted at: Mount Carmel East  
Mount Carmel St. Ann's

For more information on this clinical trial call: 614-898-4595

## **🔗 Memory Gel Implant PAS (Postapproval Study)**

This ten-year postapproval study conducted by Mentor Corporation for women undergoing breast augmentation, augmentation revision, reconstruction, or reconstruction revision with MemoryGel Breast Implants, or patients are being asked to participate as part of the control group. The control group consists of women undergoing breast augmentation, reconstruction, or revision with Saline-filled Breast Implants, for this postapproval study.

The purpose of this study is to address:

- Long-term local complications: What are the complication rates over time, including removal and reoperation rates?
- Connective tissue disease (CTD): What are the types and rates of CTD (a disease such as rheumatoid arthritis, lupus, and scleroderma, which affects connective tissue such as muscles, ligaments, skin and/or the immune system)?
- CTD signs and symptoms
- neurological disease ( such as multiple sclerosis)
- neurological signs and symptoms
- Offspring issues: rates of birth defects, premature birth, low birth weight, neonatal intensive care, and chronic illnesses (such as autoimmune disorders, cancer and neurological disease) in children born to women receiving Mentor MemoryGel™ implants and controls.
- Reproductive issues
- Lactation issues
- Cancer
- Suicide
- Mammography issues (rate of rupture with mammography)
- MRI compliance and results.

This clinical trial is being conducted at: Mount Carmel West  
Mount Carmel East  
Mount Carmel St. Ann's  
Fairfield Medical Center  
The Physician's Office

For more information on this clinical trial call: 614-322-2500 or 614-898-4595 or 614-436-8888  
or 614-890-5565 or 614-864-9547