

# Research Study Overview

“A Randomized Comparison of NeoCart® to Microfracture for the Repair of Articular Cartilage Injuries in the Knee: a Prospective Phase III Confirmatory Multi-Center Study”

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## **Background**

Drs. Fleischli and Piasecki are participating in a research study investigating the safety and performance of a new biological tissue implant called NeoCart. This product is an investigational treatment designed to replace and repair damaged knee cartilage (elastic tissue found in the joints). The NeoCart tissue is made using the patient’s own cells. The safety and effectiveness of NeoCart will be compared to one of the current treatment options for cartilage defects, called microfracture. During microfracture surgery, the surgeon creates tiny fractures (breaks) in the underlying bone which allows new cartilage to develop from a so-called super-clot.

You are being approached about this study because you have a cartilage lesion in your femoral condyle (rounded end of thigh bone), and you are planning on having an arthroscopic knee procedure. During the arthroscopic examination procedure an instrument called an arthroscope is inserted into your knee through a small incision (cut). This instrument allows the doctor to see inside your knee. This will be done both to complete the diagnostic examination of your injury as well as to determine whether your cartilage injury fully meets the criteria for participation in this study.

## **Randomization**

If your eligibility is confirmed, you will be enrolled in the study and, before the completion of the arthroscopy procedure, you will be assigned to one of the two different treatment groups. You will be randomly selected (like flipping a coin), and neither you nor your physician will be able to choose the group. You have a two out of three chance of being assigned to the NeoCart procedure (Group II) and a one out of three chance of being assigned to the microfracture procedure (Group I). You will not find out which group you are assigned to until after your procedure.

The two groups are:

- **Group I** -you will have a standard microfracture procedure to treat the damaged cartilage in your knee.
- **Group II**- you will have a cartilage biopsy performed during the arthroscopy procedure, then will have a second procedure in about 5-9 weeks to implant the Neocart tissue grown from your own cartilage cells.

**Study Visits will be scheduled to collect information that will be used to evaluate the treatment. The activities associated with each study visit are listed below:**

### **Preop (Before Surgery)\***

- 4 Questionnaires
  - Knee x-rays (3 views)
  - MRI
  - Knee exam performed by physical therapist
  - Blood Work (7 Tubes)
  - Urine Specimen (& pregnancy test if female)
  - Given Patient Diary
  - Meet with the doctor
- Must be collected 7 days prior to your arthroscopy procedure*

*\*Your preop visit may require you to return to the clinic for multiple office visits, however, these study related visits/tests will not be charged to you or your insurance company.*

### 10 days postop (After Surgery)

- Return completed Patient Diary
- Complete Patient Survey
- Given Rehab Plan (Exercises)
- Knee Examination
- Record of Medications taken
- Meet with the doctor

### 6 Weeks

- Return completed Patient Diary
- Given Rehab Plan (Exercises)
- Record of Medications taken
- Blood Work (6 Tubes) & Urine Specimen
- Knee exam performed by physical therapist *therapist is not allowed to know which treatment you received*
- Meet with the doctor

### 3 Months

- Return completed Patient Diary
- Complete Patient Surveys
- Given Rehab Plan (Exercises)
- Record of Medications taken
- Knee exam performed by physical therapist *therapist is not allowed to know which treatment you received*
- Meet with the doctor

### 6 Months

- Return completed Patient Diary
- Complete Patient Surveys
- Given Rehab Plan (Exercises)
- Record of Medications taken
- Knee exam performed by physical therapist *therapist is not allowed to know which treatment you received*
- Meet with the doctor
- MRI \*\*

### 1-3 Years

- Return completed Patient Diary
- Complete Patient Survey
- Knee exam performed by physical therapist *therapist is not allowed to know which treatment you received*
- Record of Medical History (year 1)
- Record of Medications taken
- MRI\*\*
- Meet with the doctor

**After your 3 year visit you may be asked to participate in annual monitoring as determined by the FDA or your physician.**

*\*\*An additional cartilage-specific MRI sequence (which takes about 15 minutes) will be done at six months and annually for three years. All of these MRI evaluations will measure the progress of the cartilage repair. The entire MRI, if performed with the above scans will take about 60 mins.)*

### **Cost/Compensation**

The cost of treatment of your knee cartilage injury will be billed to your medical/hospital insurance plan. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study. OrthoCarolina will pre-certify your surgical procedures as required by your insurance carrier, however, if your insurance carrier denies the surgical claim, the sponsor will reimburse the hospital and/or clinic.

You will not be charged a co-pay and/or will not be required to pay any surgical balance related to your study procedure(s). No charge will be made to you for the NeoCart implant that is used in this study.

**If you are interested in finding out more about the study, or if you have questions, please call Barbara Ann at 704-323-2269 or Caryn Thompson at 704-323-2264.**