Arthrex®

**ACP Double Syringe System** Clinical Trial

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# Does this sound like you?

- Have you been suffering with knee pain for at least six weeks?
- Have you been told you have osteoarthritis in your knee?

If you answered “yes” to these questions, you may be eligible to participate in the Autologous Conditioned Plasma (ACP) clinical trial.

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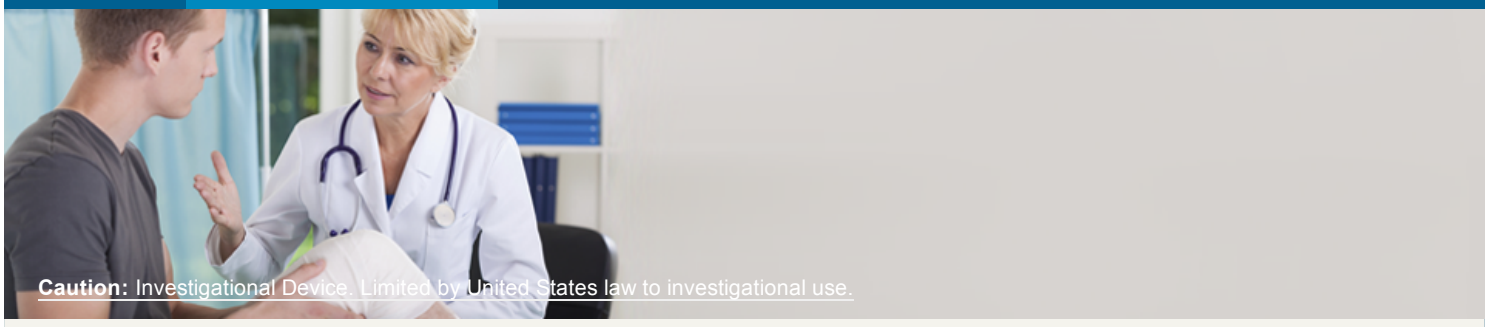
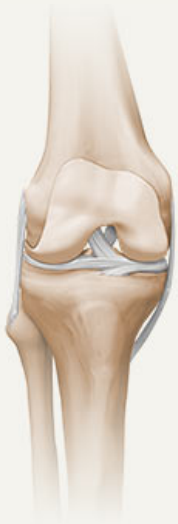



# Knee Osteoarthritis

**What is knee osteoarthritis?**



Knee osteoarthritis (OA) is the condition in which the natural cushioning between joints, called the cartilage, wears away. As this happens, bones of the joints rub one another without the shock-absorbing benefits of cartilage. This rubbing causes pain, swelling and stiffness in the joint. The pain can lead to decreased mobility and inability to function.

**What causes knee osteoarthritis?**

The most common cause of knee osteoarthritis is age, however, several other factors increase the risk of developing arthritis at an earlier age. Weight plays a role as it increases pressure on all joints, especially the knees. Other factors include heredity, repetitive stress, injuries, athletics and other illnesses.

**What are the symptoms?**

People suffering from knee osteoarthritis will experience pain, stiffness and loss of strength. A ‘grinding’, ‘clicking’ or ‘locking’ sensation may be felt in the affected joint.

**How is knee osteoarthritis diagnosed?**

Knee osteoarthritis is diagnosed by physical exam and X-ray. Your orthopaedic surgeon will examine your knee, noting range of motion, strength and pain with motion. Your surgeon will obtain X-rays to evaluate the arthritis.

**How is it treated?**

Common treatments for knee osteoarthritis include weight management, healthy

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diet and exercise, non-drug pain relief techniques, medications, alternative therapies and/or surgery.

For more information, please visit our surgeon finder.

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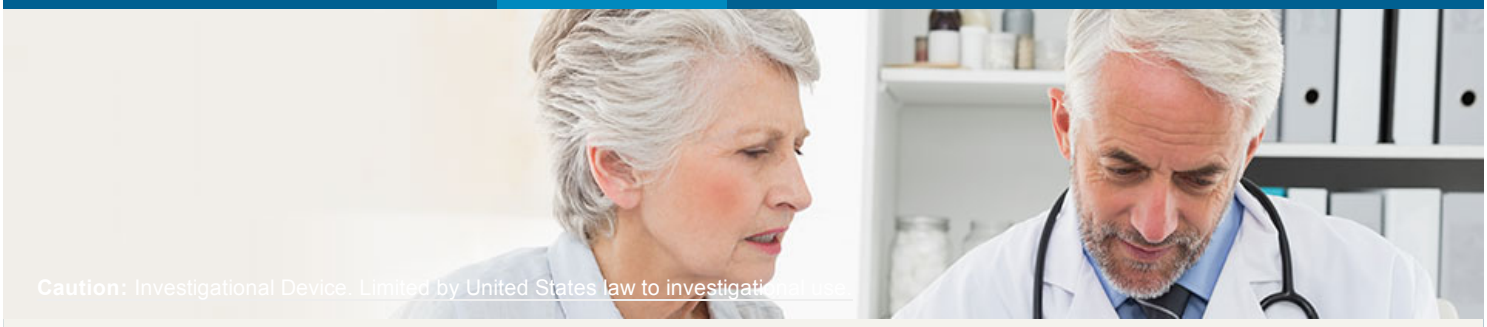


# The Clinical Trial

Arthrex is sponsoring a clinical trial to study a non-surgical alternative treatment for osteoarthritis. The clinical trial will include 90 patients treated by a group of knee specialists considered experts in the field of therapeutic biologics. Each specialist and the associated medical facility have been approved by Arthrex and the facility's Institutional Review Board.

If you take part in the trial, you will be randomly assigned to receive one of two treatments described below.

- ACP treatment injections
- Normal saline injections

To skip ahead to a particular question, click the questions below:

What are clinical trials?

Why would someone want to take part in a clinical trial?

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# Investigational Device

ACP is an investigational treatment option for knee osteoarthritis. The purpose of the clinical trial is to investigate the safety and effectiveness of ACP in treating pain in subjects with knee osteoarthritis. The current non-surgical standard of care for osteoarthritis is treatment with substances that provide pain relief.

**Autologous Conditioned Plasma (ACP) Double Syringe System**

- Investigational device
- Rapid prep of autologous PRP from a small sample of blood
- Convenient and safe handling under a closed system


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# Frequently Asked Questions



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## What are the symptoms of knee osteoarthritis?

People suffering from knee osteoarthritis may experience pain, stiffness and loss of strength. A ‘grinding’, ‘clicking’ or ‘locking’ sensation may be felt in the affected joint. The patient may experience difficulty bending and straightening the knee.

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## Why is ACP being investigated?

This clinical trial is a standard FDA requirement before this treatment can be available to the general population in the U.S.

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## What are the possible benefits of participating in the clinical trial?

If the procedure is successful, it may result in a decrease in your knee pain, improve your knee function and improve your knee range of motion compared to how you are now. However, it cannot be guaranteed that your condition will improve as a result of your participation in this study and you may receive no direct benefit at all. This study may generate information that leads to the development of improved devices and procedures for the treatment of osteoarthritis. Future patients may benefit from these new improvements.

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### Will I be financially compensated for participating in the study?

Yes; complete follow-up is very important to the outcome of the study. You will be reimbursed for visits completed within the required window dates for each treatment and follow-up visit in the form of cash, check or cash card. The reimbursement amount is to offset the cost of meals, transportation and parking.

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### How does the clinical trial operate?

If you take part in this research study, you must first sign a study-specific consent form. You must also meet all the requirements for the study. Your study doctor or other study personnel will ask about your medical history, your symptoms, and the medicine you take to determine if you qualify for this study. Additional tests will be done to see if you can participate, which include a physical examination to measure the present motion and strength in your affected knee. If you are female with child-bearing potential, a pregnancy test will be performed. Your medical history records and any X-rays that have been taken before the study that are used to determine whether you meet the study requirements will become part of your study file. You will be asked to complete questionnaires that will be used to determine the amount of pain in your affected knee and your current activities of daily living.

If you meet all of the requirements of participation, you will be scheduled for a treatment visit to receive your first intra-articular injection.

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### How do I know if I am eligible for the clinical study?

Inclusion criteria includes:
Osteoarthritis for six weeks or more
X-rays confirming osteoarthritis
Continued osteoarthritis in the knee

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### What are the time commitments required to participate in the study?

If you agree to take part in this study, your participation is expected to be for a period of 6 months with a continuation up to 12 months. You will have a total of 8 study visits. The screening visit will be approximately 1-2 weeks before your first injection and your three injections will be scheduled one week apart. Your follow-up visits will be 2, 3, 6 and 12 months after your first injection. You will be asked

questions about medications you are taking and to to determine the amount of pain in your affected knee and your current activities of daily living. You will have a physical exam performed during each study visit.

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## Where can I get more detailed information about the clinical study?

A description of this clinical trial will be available on www.ClinicalTrials.gov. Federal law in the U.S. requires information for this type of clinical trial to be submitted to this data bank. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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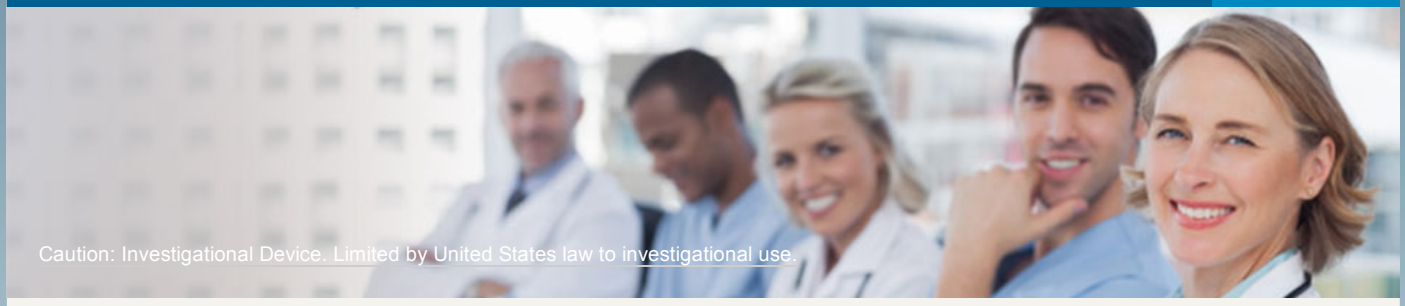
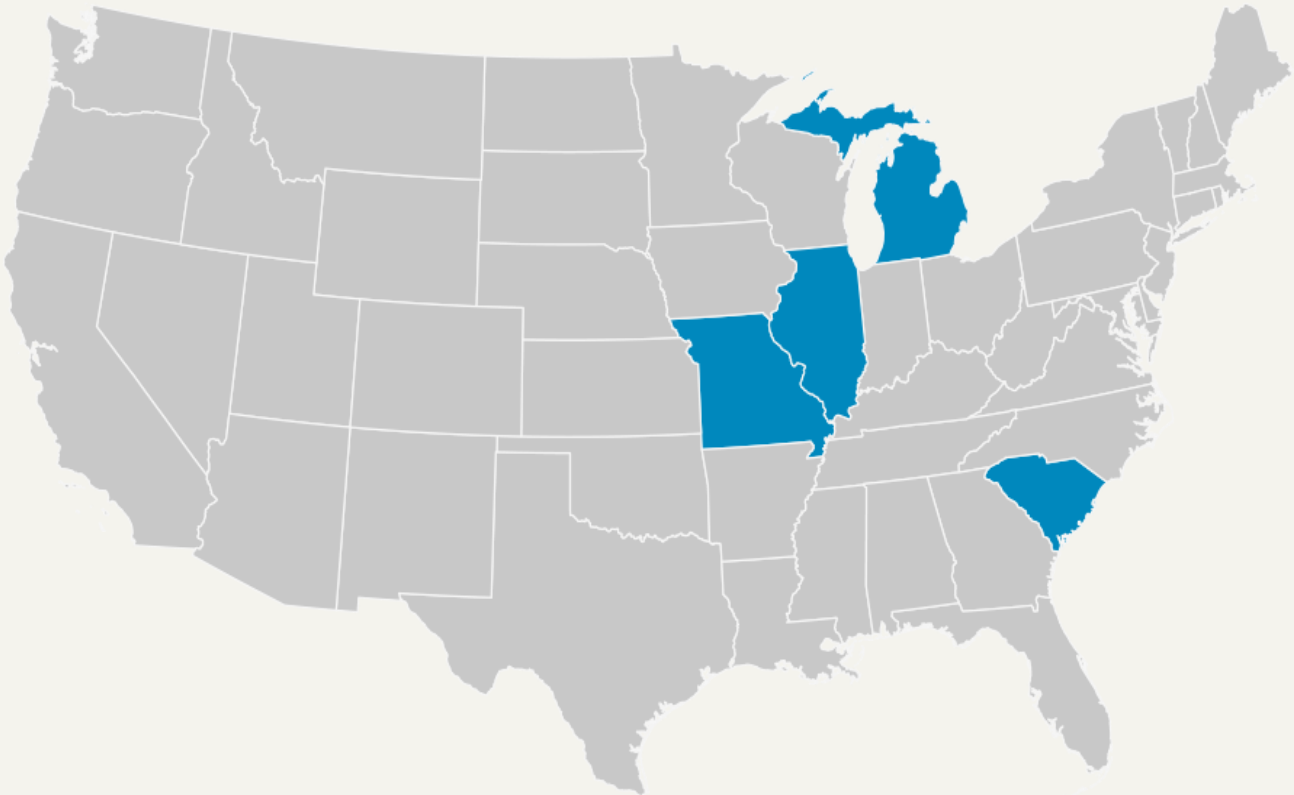



# Find a Doctor

This section lists the site locations for the Arthrex Autologous Conditioned Plasma Double Syringe System U.S. clinical trial. Sites participating in the study will be located within the U.S.

Institution and doctor contact information will be added to the list below as sites are added to the trial.
For more information please visit ClinicalTrials.gov.

Please check back soon to learn more about which institutions near you may be participating in this important study.



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