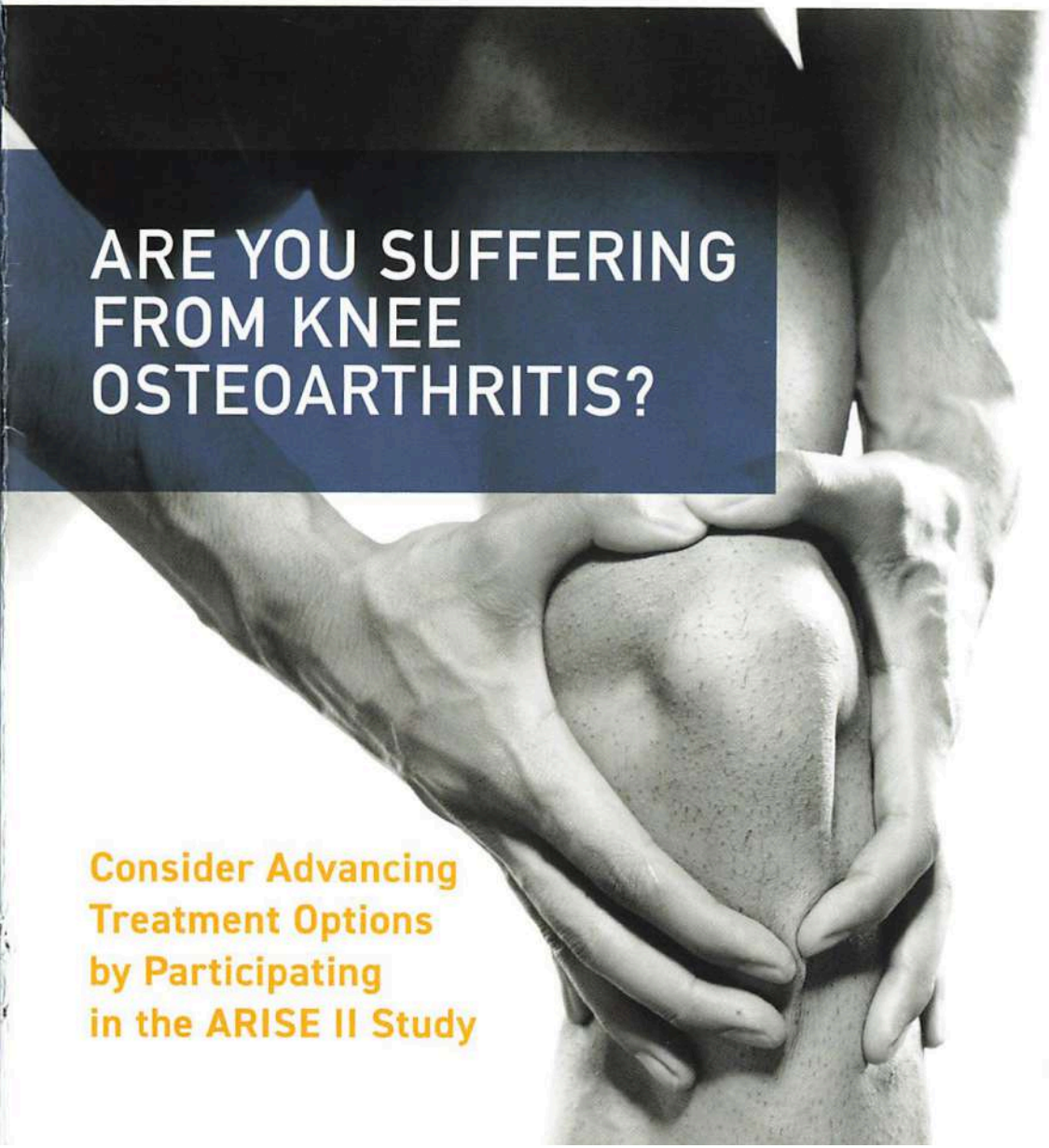
LIPOGEMS ARISE II KNEE OSTEOARTHRITIS FDA IDE STUDY

ARE YOU SUFFERING FROM KNEE OSTEOARTHRITIS?



Consider Advancing Treatment Options by Participating in the ARISE II Study

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LIPOGEMS

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DON'T LET **KNEE OSTEOARTHRITIS** STOP YOU FROM ENJOYING YOUR LIFE

Knee osteoarthritis (OA) is typically the result of progressive wear and tear on the joint as we age and is one of the leading causes of disability. It can be hard when the pain, swelling and stiffness from your knee osteoarthritis impacts you from enjoying your life

Patients suffering from knee OA oftentimes have a hard time performing daily activities such as:

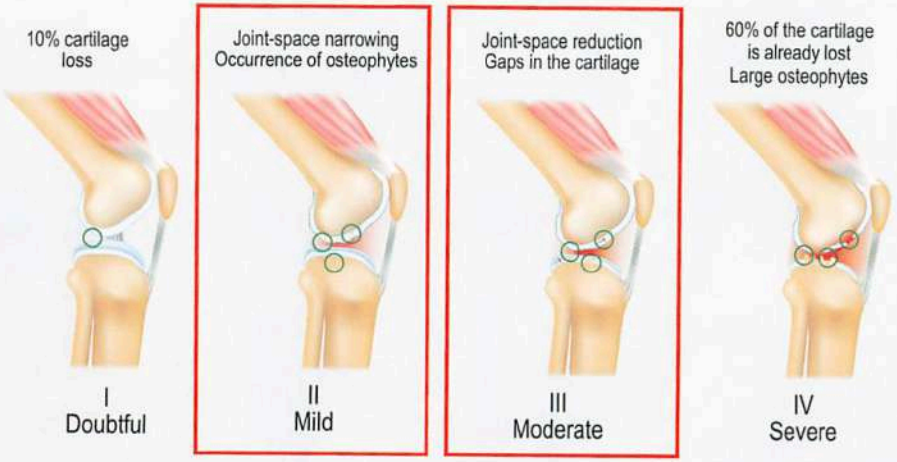
HAVE YOU TRIED **CONSERVATIVE OPTIONS** WITH LIMITED RELIEF AND ARE **NOT READY FOR MAJOR SURGERY**?

Surgery is not the first step. Many patients try conservative options first (ex. physical therapy, corticosteroids, other injections, activity modification). Over a period of time, these interventions may provide limited relief. There are not many effective treatment options available to patients that have tried conservative options but are not ready for major surgery.

ABOUT THE **ARISE II STUDY**

This study will look at how well an investigational therapy using MicroFat helps treat pain and function for patients that have mild to moderate knee osteoarthritis.

STAGES OF KNEE OSTEOARTHRITIS



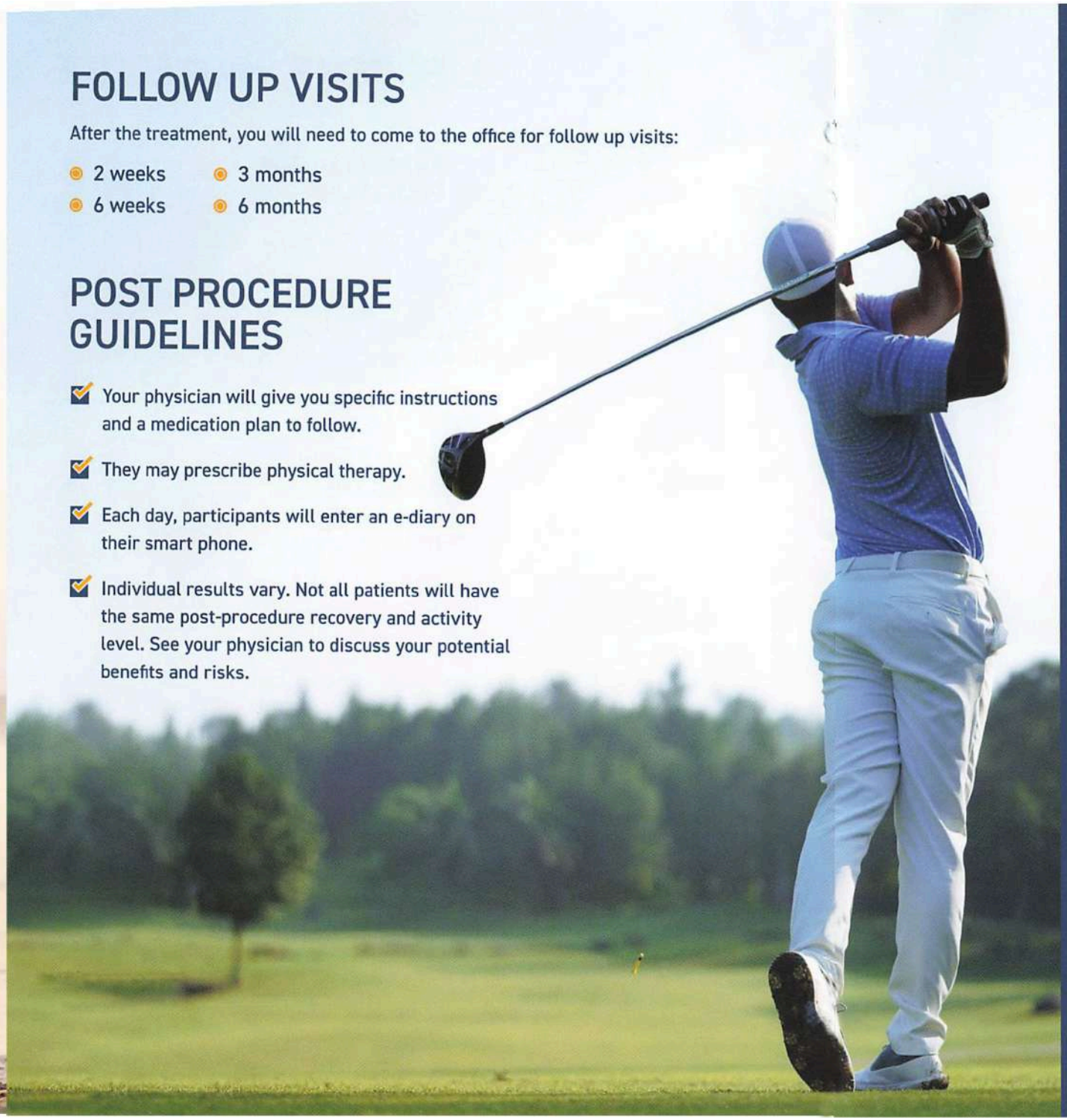
FOLLOW UP VISITS

After the treatment, you will need to come to the office for follow up visits:

- 2 weeks
- 6 weeks
- 3 months
- 6 months

POST PROCEDURE GUIDELINES

- Your physician will give you specific instructions and a medication plan to follow.
- They may prescribe physical therapy.
- Each day, participants will enter an e-diary on their smart phone.
- Individual results vary. Not all patients will have the same post-procedure recovery and activity level. See your physician to discuss your potential benefits and risks.



FREQUENTLY ASKED QUESTIONS

How many research participants and centers are involved?

The ARISE study will enroll 173 participants across 20 well-respected orthopaedic institutions across the United States.

Will I need to pay for the procedure?

If you qualify for the study and choose to participate in the study, you will sign an informed consent and you will receive all study related care by a trained physician and team at no cost.

Will I receive compensation?

If you choose to participate in the study, compensation may be provided for travel and expenses for each study visit you complete.

Is participation voluntary?

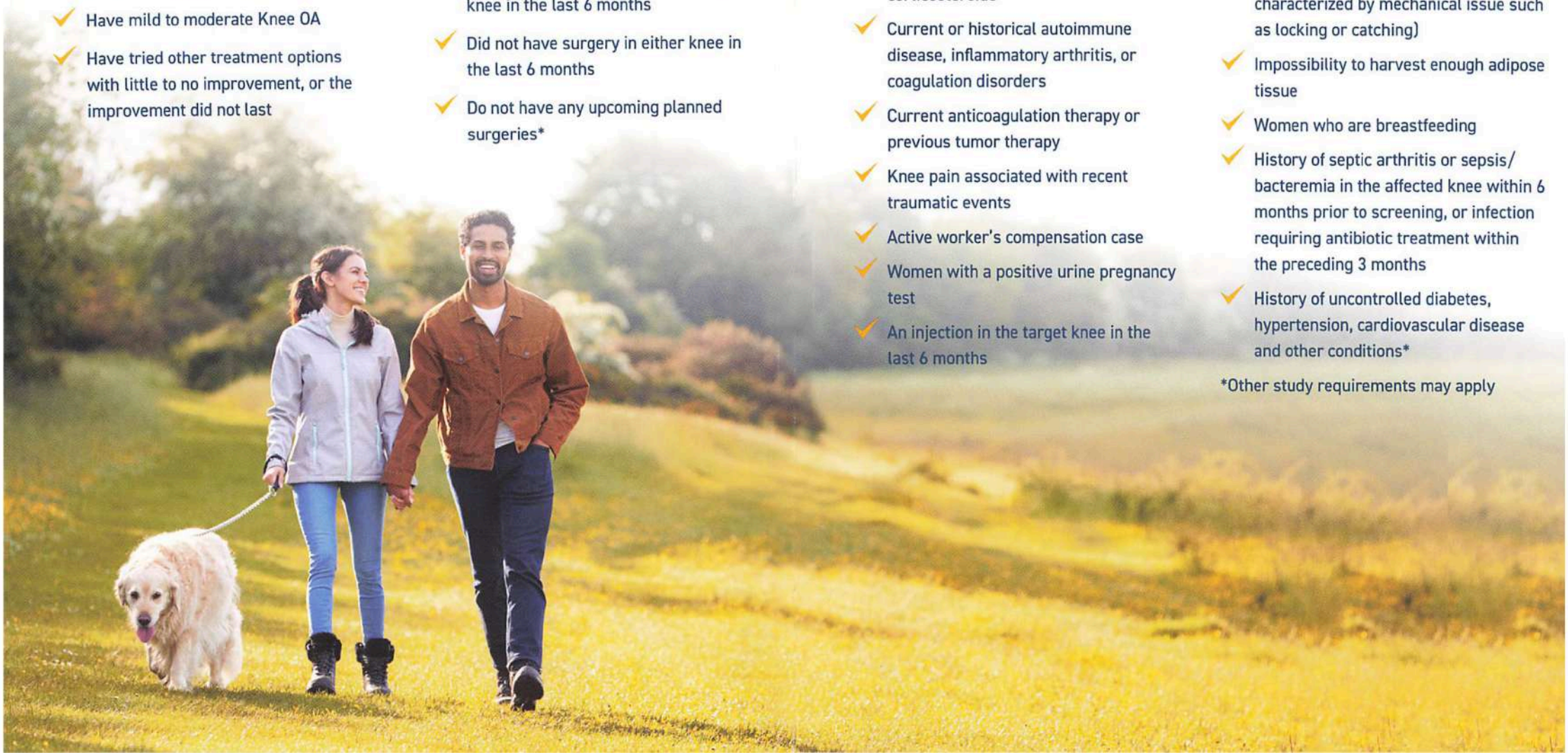
Your participation is voluntary. You may withdraw from the study at any time and for any reason. Please inform your study research team of your decision.

STUDY PARTICIPANTS

Participation is entirely voluntary. Clinical studies oftentimes have firm inclusion and exclusion criteria. Patients in the study will be screened to determine if they meet the criteria below to see if they are eligible to participate in the study.

You may be able to participate, if you:

- Are aged 18 years or older
- Have mild to moderate Knee OA
- Have tried other treatment options with little to no improvement, or the improvement did not last
- Did not have an injection in the target knee in the last 6 months
- Did not have surgery in either knee in the last 6 months
- Do not have any upcoming planned surgeries*



You may not be able to participate if:

- X-ray findings of Knee OA that is K/L Grade 1 (doubtful) or 4 (severe)
- BMI greater than 35 kg/m^2
- Any local or systemic active infection
- Allergies to anesthetics or corticosteroids
- Current or historical autoimmune disease, inflammatory arthritis, or coagulation disorders
- Current anticoagulation therapy or previous tumor therapy
- Knee pain associated with recent traumatic events
- Active worker's compensation case
- Women with a positive urine pregnancy test
- An injection in the target knee in the last 6 months
- Surgery in either knee in the last 6 months
- Untreated symptomatic injury of the index knee (e.g., acute traumatic injury, anterior cruciate ligament injury, clinically symptomatic meniscus injury characterized by mechanical issue such as locking or catching)
- Impossibility to harvest enough adipose tissue
- Women who are breastfeeding
- History of septic arthritis or sepsis/ bacteremia in the affected knee within 6 months prior to screening, or infection requiring antibiotic treatment within the preceding 3 months
- History of uncontrolled diabetes, hypertension, cardiovascular disease and other conditions*

*Other study requirements may apply

THE POWER OF FAT

Fun Fact: Adipose tissue is the medical term for your body fat!

RESEARCH

Many studies have shown that fat has been used to support the healing process of damaged or injured tissue.[1,2,3]

STRUCTURAL TISSUE

Fat is a structural tissue that contains a variety of reparative cells and tissue. It provides cushioning and support to help with the healing environment in response to a tissue injury.[4,5,6]

AGE MAY NOT BE A FACTOR

Research has shown that as a person ages, their adipose tissue maintains the reparative properties, unlike other similar tissue, which may lose healing capacity with age.[7,8,9]

MINIMALLY INVASIVE

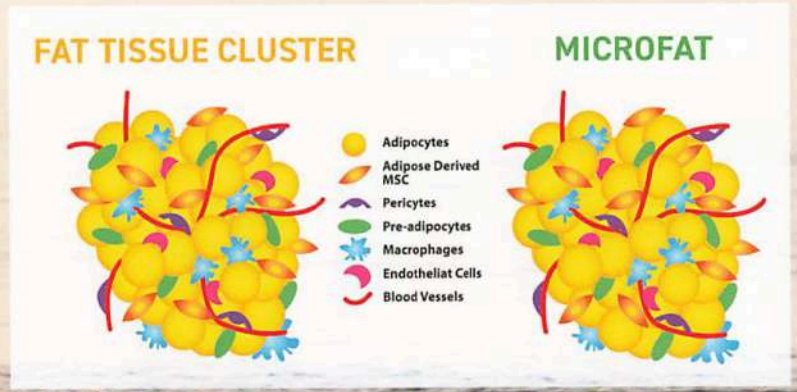
Fat can be easily collected using a minimally invasive procedure using local anesthesia in an outpatient setting.

VOLUME OF TISSUE

Fat may be collected in a plentiful volume.

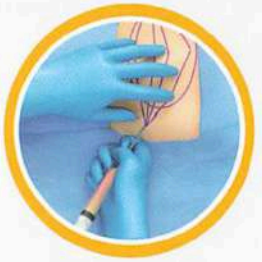
MINIMIZED RISK OF INFECTION

Because the doctor is using your own tissue, there is a minimal risk of rejection or infection.



LIPOGEMS PROCEDURE

1 FAT COLLECTION PROCEDURE

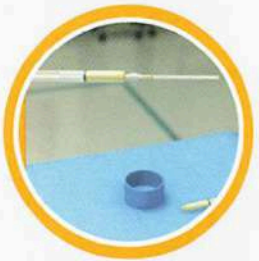


In a minimally invasive procedure, your physician will make a tiny puncture through your skin and collect a small amount of fat from either your midsection or "love handles".

2 GENTLE PROCESSING USING THE LIPOGEMS™ DEVICE

The collected fat will then be processed in the patented Lipogems device using only sterile saline to wash away any impurities, including blood and oil residues. During this process, your fat is resized and concentrated into smaller clusters, called MicroFat.

3 MICROFAT



MicroFat is an optimal size for injecting into the knee to potentially help treat pain and function for patients that have mild to moderate knee osteoarthritis.

WHAT ARE THE NEXT STEPS?

If you would like to participate in the study, the physician and research team will screen you to see if you meet the inclusion and exclusion criteria. The study will be thoroughly explained by the team, and you will have the ability to ask any questions.

If you qualify and choose to participate in the study, you will sign an informed consent and be scheduled for treatment. On the day of treatment, we will need to re-confirm your eligibility by checking vitals, urine pregnancy test*, and questionnaires. If you meet the criteria on treatment day, you will have a 2:1 chance of receiving the Lipogems MicroFat (aka MFat) versus a saline injection. You will receive all study related care at no cost. Compensation may be provided for travel and expenses for each study visit you complete.

Screening may include checking:

- Medical History
- Physical Exam
- Vitals
- Blood Test
- Urine Pregnancy Test*
- EKG
- X-Rays
- Questionnaires

** If applicable*

PAIN MEDICATION

The study requires a specific pain medication protocol. Study participants should be willing to stop usage of:

Prescription pain medication for a condition other than your knee

Over-the-counter pain medication (e.g., Acetaminophen or NSAID), "Rescue Analgesics", for 7 days prior to any follow-up visit, with the exception of one "baby aspirin" per day for cardiovascular therapy or prophylaxis

Prescription pain or prescription anti-inflammatory medication for the duration of the study, with the exception of Tramadol during the immediate post-procedure period noted below

NSAIDS for 7 days pre-injection and 2 weeks post-injection. Tramadol is allowed during the 72 hours immediately post-injection, with e-diary documentation of usage

Contraception for 3 months post-procedure unless postmenopausal (for at least 2 years) or surgically sterilized (bilateral tubal ligation, bilateral oophorectomy, or hysterectomy)