WHY SHOULD I PARTICIPATE?

You will receive treatment from one of the top specialists in the field of orthopaedics. Your doctor will be able to carefully monitor your treatment using the most advanced diagnostic techniques available and to prescribe the best therapy available. This personalized and intensive approach should give you the best chance of gaining relief from your symptoms, regardless of which therapy you undergo in the study.

Upon completion of the study, your doctor will also remain available to you to monitor your knee condition in case of any further progression of your OA condition, which might require subsequent treatment. Your surgeon will also be among the first to have access to the NUsurface® Meniscus Implant once it is approved for use in the U.S.

By participating in this clinical trial, you have the opportunity to make a major contribution to the understanding of osteoarthritis and to increase the scientific knowledge of the best therapies with which to treat it. You will also play a crucial role in the introduction of a new therapeutic alternative for patients suffering from persistent knee pain, should the NUsurface® Meniscus Implant be approved for use in the U.S.

The same or the next day after the operation you will be allowed to go home.

If you have any questions about the study or if you are interested in participating in the study, you will need to read and sign a detailed Informed Consent Form that thoroughly explains the potential risks. For more information please visit: www.venus-trial.com

More details about the study, including statement references, can be found on the website. A more detailed Informed Consent Form will need to be signed before you can be considered eligible to enter this study.

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INTRODUCTION
After meniscus surgery, many patients still suffer from persisting knee pain that can seriously affect their daily lives. Non-surgical treatment can be helpful in addressing these symptoms. It represents the current standard of care for those who still have pain or other symptoms after their surgery. The NUsurface® Meniscus Implant has been developed as a new treatment alternative for patients with persistent knee pain following meniscus surgery.

The NUsurface® Meniscus Implant mimics the function of the natural meniscus and is made from medical grade polymers. It has been used in Europe and Israel since 2008 and is now undergoing a clinical trial in the U.S. Before a new treatment can be offered to patients, evidence is needed to evaluate its benefit. This clinical study has been designed to provide that evidence. While the NUsurface® Meniscus Implant and non-surgical treatments have been shown in separate studies to have a beneficial effect for persistent pain, only a study that compares the two directly, one treatment to the other, can prove that the NUsurface® Meniscus Implant works as well as the current standard of care.

The meniscus is a fibrous structure that stabilizes your knee and distributes load from your upper leg to your lower leg. If your meniscus is degenerated or was damaged or torn, the loose ends may have caused pain and limited your range of motion. When your surgeon removed these torn or loose ends, this may have temporarily resolved your symptoms. But this resulted in a meniscus that is smaller and thinner and this puts your knee at risk of being overloaded. Overloading can damage the cartilage that covers the bones, a process called osteoarthritis or OA.

OA involves degradation of the joints, including damage to the cartilage and the bone underneath the cartilage. Symptoms may include joint pain, a limited range of motion, tenderness, stiffness, locking and sometimes swelling of the knee. If you still have persistent pain and other symptoms following your meniscus surgery, it is likely that OA is the cause, not your meniscus.

WHAT ARE THE TREATMENTS?
The goal of both treatments is to improve your quality of life by relieving pain from your knee and helping you to improve your knee function.

HOW DOES THE STUDY WORK?
Once selected, you will be randomly assigned, like through the flip of a coin into one of two groups. You have an even chance of getting either the non-surgical standard of care or the NUsurface® Meniscus Implant. Neither you nor your doctor can decide which treatment you will receive.

The study lasts for 24-months following your initial treatment. During this period you will be seen or contacted frequently by your doctor. At each study visit (1½, 3, 6, 12, 24 months) you will be asked to complete questionnaires describing how you feel about your knee and the quality of your life. Your doctor will also examine your knee. A MRI (magnetic resonance imaging) scan of your knee will be taken three times or more. During the study, you will be fully supported and monitored by your doctor.

The study will last for a minimum of six weeks.

Non-Surgical Care
The best standard of care will be tailored to your specific needs and condition in close cooperation with your surgeon and a physiotherapist. Besides extra examinations (surgeon visits, MRIs) your treatment may include an array of non-surgical treatments, including state-of-the-art physiotherapy programs, strengthening, low-impact aerobic exercises, and weight-loss programs, if required.

Braces, compression sleeves, crutches, canes and/or shoe inserts may also be prescribed for you. Your doctor will also explain which activities are recommended and which should be avoided.

Your doctor may also prescribe drug treatments such as oral pain medication or knee injections.
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Contact the nearest study site at:
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