SOPHIA2 Study

Study to assess the safety and effectiveness of the UroActive® artificial urinary sphincter In the treatment of Stress Urinary Incontinence in Men

This study is sponsored by

UroMems implantable solutions

WHY IS THIS RESEARCH BEING DONE?

Stress Urinary Incontinence (SUI) is a common type of urinary incontinence (urine leakage) and has been reported with varying frequency among men. It has been reported more commonly in men who have undergone prostate surgery including prostatectomy or radical prostatectomy.

WHERE IS THIS RESEARCH BEING DONE?

The study is being conducted at multiple locations in the United States and France. A total of up to 140 participants may be enrolled.

WHAT IS BEING EVALUATED?

The purpose of the SOPHIA2 study is to demonstrate the safety and effectiveness of a new Artificial Urinary Sphincter (AUS), UroActive®, in adult male patients with Stress Urinary Incontinence (SUI).

WHY SHOULD I PARTICIPATE IN A RESEARCH STUDY?

The treatment you will receive in this study is intended to relieve your SUI symptoms. Your participation may also benefit other people, as information learned from this study may help further advance the development of the device.

Common Questions

IS THIS AN EXPERIMENTAL PROCEDURE?

Yes.

ARE THERE RISKS?

As with any procedure and anesthesia, there are risks. Your study doctor will discuss these risks with you.

WHEN CAN I RESUME REGULAR ACTIVITIES AND RETURN TO WORK?

You may take a few days to heal from the procedure, and you may be asked to restrict certain activities. Your study doctor will provide instructions on your care.

HOW MUCH WILL IT COST ME?

You will receive the investigational device at no cost to you. You and/or your health plan will need to pay for all tests and procedures that you would normally have as part of your medical care, that are not associated with this study.

WILL I BE COMPENSATED?

You may receive a stipend for your study participation based on your completed study visits. Actual amount may vary.

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Participating in SOPHIA2

AM I ELIGIBLE?

- Age ≥ 22 years
- Been diagnosed with Stress Urinary Incontinence for over 6 months
- Failed approved non-invasive therapies for the treatment of SUI

Your doctor will review your eligibility with you to see if you can participate in the SOPHIA2 study.

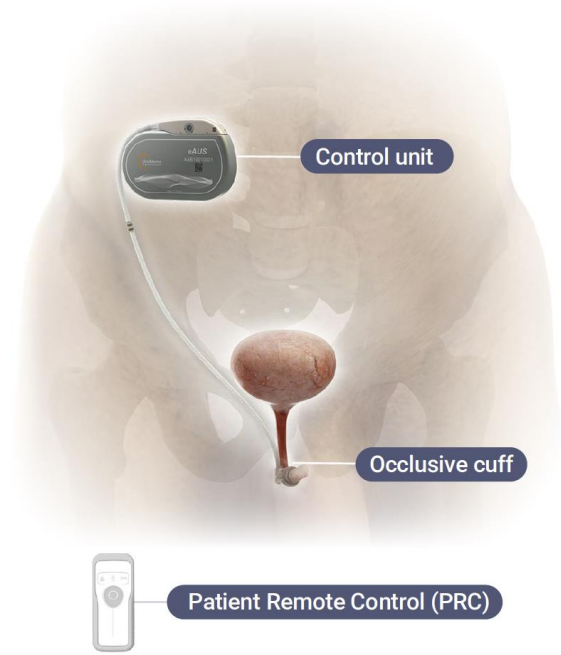
If you are a candidate, you will be scheduled to complete a series of tests to further confirm your eligibility to participate.

WHAT IS UROACTIVE® THERAPY?

UroActive® is designed to provide an experimental solution to patients who suffer from Stress Urinary Incontinence. The device aims to reduce the rate of urinary leaks and the number of additional surgeries that you may need due to atrophy or damage to the tissues.

The UroActive® device consists of 3 main components: An Occlusive Cuff, a Control Unit and a Patient Remote Control.

The Occlusive Cuff and Control Unit are implanted in your body and the Patient Remote Control is a hand-held device used to adjust settings to allow you to urinate (or void) as you choose.



Patient Journey Map

You will be followed for a period of 5 years after device activation in the SOPHIA2 clinical study.

1. SCREENING

If you are interested in the study, you will sign an Informed Consent Form at this visit after you have discussed the study in detail with your study doctor and/or study team. Your study team will review your medical history records and may conduct a series of medical tests to check if you are eligible for the study. You will be provided with incontinence pads and a 3-day Bladder diary to complete before your next visit. This visit may take up to 2 hours.

2. BASELINE

Your study team will review your completed 3-day Bladder diary and weigh your used incontinence pads to confirm if you are still eligible for the study. You will be asked questions about your current SUI symptoms, daily activities and quality of life. This visit may take up to 2 hours. If you are approved for surgery, you will receive instructions on how to prepare.

3. PROCEDURE DAY

Your UroActive® device will be implanted in an operating room under general anesthesia. Once implanted, your device will be tested, then deactivated during your healing period, which may take up to 6 weeks.

4. DEVICE ACTIVATION

Your device will be activated, tested and programmed based on your SUI symptoms and health status. You will receive your Patient Remote Controls (2 in quantity) and detailed instructions on how to use them. This visit may take up to 1.5 hours.

SCHEDULE OF VISITS FOLLOWING DEVICE ACTIVATION:

- **2 and 4 weeks** (30-minute office visits)
- **8, 21, and 47 weeks** (15-minute phone calls)
- **12 and 26 weeks** (1.5-hour office visits)
- **39 weeks** (15-minute phone call or 30-minute office visit)
- **1, 2, 3, 4, and 5 years** (1.5 hour office visits)

Your study team will ask questions during each follow-up to assess your overall health and the performance of your device. You will be asked to bring completed 3-day Bladder diaries and used incontinence pads to some follow up visits. Additional testing and training may be performed if needed.