Amendment ID:IRB15-1732-AM007 Date Approved: 5/2/2017 Expiration Date: 4/23/2018

BACKGROUND OF STUDY

MRI-guided Transurethral Ultrasound Ablation (MRI-TULSA) technology was developed at Sunnybrook Research Institute (Toronto, Canada), after several years of research and testing. The early feasibility testing in humans was conducted at Sunnybrook Research Institute by Dr. Laurence Klotz. Early studies have shown that MRI-TULSA can precisely ablate prostate tissue[1]. Profound Medical Inc. has licensed exclusively the MRI-TULSA technology from Sunnybrook Research Institute and has developed it into a medical device named the TULSA-PRO®.

Recently, 30 patients went through this procedure in a Phase I clinical trial in the United States, Canada, and Germany. The purpose of the study was to assess safety of the TULSA-PRO system. Patients were all treated successfully and the study end points were met. The study data was published in European Urology[2].

References

1. Chopra et. al. Radiology 2012, Volume 265, Number 1, pages 303-313.
2. Chin et al, European Urology, Sept 2016

Participating in this study is completely voluntary.

IF YOU ARE INTERESTED IN **JOINING** THIS STUDY, PLEASE CONTACT THE **RESEARCH TEAM** BELOW

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Information for Patients

TACT Clinical Trial for Prostate Ablation in **Patients with Localized Prostate Cancer**

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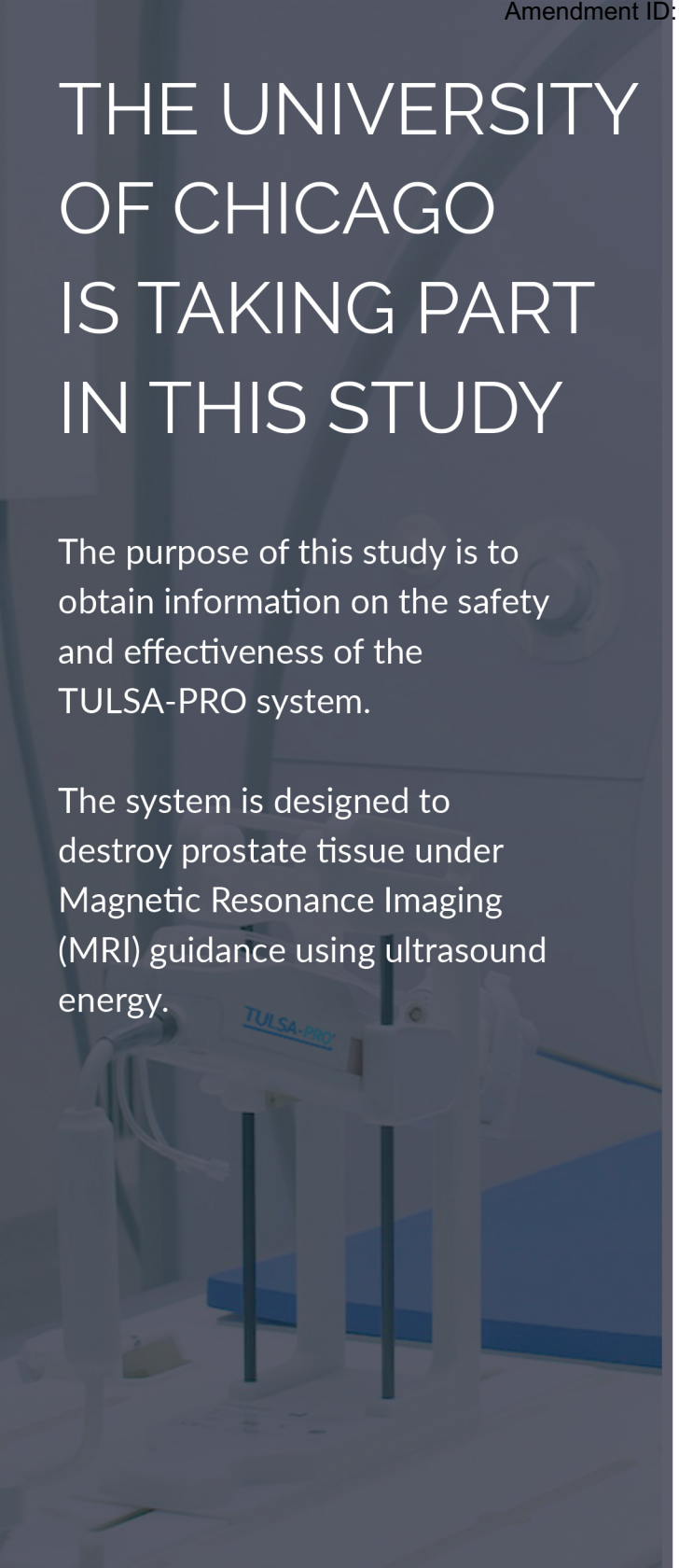
THE UNIVERSITY OF CHICAGO IS TAKING PART IN THIS STUDY

The purpose of this study is to obtain information on the safety and effectiveness of the TULSA-PRO system.

The system is designed to destroy prostate tissue under Magnetic Resonance Imaging (MRI) guidance using ultrasound energy.



What Is A Clinical Study?

A clinical study is a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. If you have any questions, you can ask your doctor for more explanation.

What Is The Procedure?

The TULSA procedure is designed to destroy prostate tissue under Magnetic Resonance Imaging (MRI) guidance using ultrasound energy. This device is not approved for clinical use except within this investigational study.

Who Can Join This Study?

You can take part in this study if you are between the age of 45-80 years, and have been diagnosed with prostate cancer that is low to intermediate risk and is confined to your prostate gland. There are also additional criteria for participating in this study. Your doctor will review the full list with you. Approximately 110 men will participate in this study from Canada, US and Europe.

How Often Will I Be Seen?

After the procedure, within a few weeks you will be seen by your doctor for the removal of the urinary catheter. After that your follow-up visits will be at 1 month, 3 months, 6 months, 1 year, 2 years, 3 years, 4 years, and 5 years post procedure.

Are There Any Risks?

As with many procedures, there are risks associated with TULSA which can include: pain and inflammation in the treatment area, blood in urine, increased urinary frequency, urinary tract infection, penile discharge, retrograde ejaculations, and erectile dysfunction. Your doctor will review with you all the risks associated with the procedure.

How Much Will It Cost?

There will be no costs incurred by you directly related to participation in this study. Clinical services provided during a clinical trial are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are responsibility of the sponsor of the study. Usual medical care (standard of care) costs include any and all services that are considered medically necessary for your disease and will be billed to your insurance carrier/health plan.