



Focal Therapy with MRI guided Focal Laser Ablation (FLA)

MR-g FLA



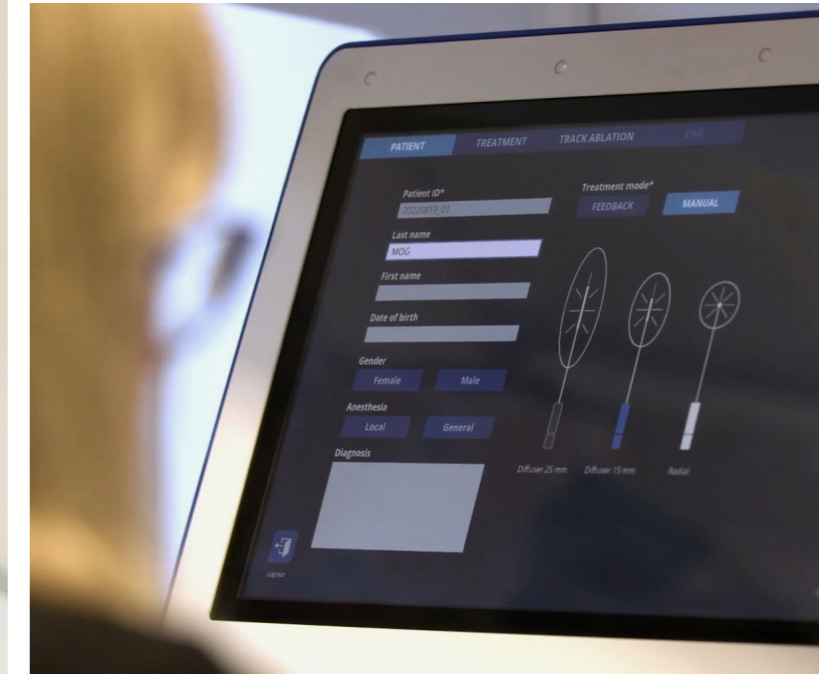
TRANBERG®

THERMAL THERAPY SYSTEM

MRI guided in-bore Focal Laser Ablation in Prostate Cancer

At the forefront of innovation, CLS develops precise and accurate focal therapy systems for image guided minimally invasive laser ablation.

For many patients with localized prostate cancer focal therapy could be an attractive treatment option, overcoming many of the risks associated with traditional treatment modalities.



Focal Laser Ablation in Prostate Cancer

TRANBERG® Thermal Therapy System with Thermoguide™ Workstation is intended for MRI guided in-bore laser ablation of soft tissue, such as the prostate gland. It enables physicians to perform minimally invasive focal therapy in patients with early stage localized prostate cancer, without the need for open surgery. The minimal invasive procedure minimizes the risk of complications that may drastically impact the patient's quality of life.

MR imaging offers precision and control

MR imaging for targeting, monitoring and control of the focal therapy offers significant advantages. Under MRI guidance a laser applicator is inserted and precisely positioned in the defined target area of the prostate. The thermal energy generated

using the TRANBERG® Thermal Therapy System, then destroys the target tissue.

Patient in focus

The Thermoguide™ Workstation provides MRI based tissue temperature mapping and tissue damage prediction, for optimal monitoring and control of the ablation.

The system provides a minimally invasive therapy alternative to conventional care, designed also with challenging cases in mind. Typically the patient can return quickly to normal daily activities.

Potential benefits with MRI guided focal laser ablation:

- Minimally invasive procedure^{1,2}
- Lower risk of surgical complications - including ED and urinary incontinence^{3,4}
- Low risk of infections²
- Low post operative pain^{2,4}
- Sharp ablation zone¹
- Short hospitalization and recovery⁴
- No radiation-associated risks - or dose limitations

Please note that the Thermoguide™ Workstation is not yet approved for use in the U.S. for ablation of prostate tissue.

1. Fütterer et al. World J Urol. (2019) 2. Klotz et al. Curr Opin Urol. (2020) 3. Ghai et al. IMRI abstract (2022) 4. Williams et al. J Vasc Interv Radiol. (2019)



TRANBERG® MRI Guided Workflow for prostate

The TRANBERG® MRI Guided Workflow for prostate optimizes focal therapy:

1. By using MRI guidance for exact positioning of the laser applicator.
2. By continuous treatment monitoring and ablation control.



1 IN-BORE PROCEDURE

- The patient is transported from the preparation room to the MRI facility.



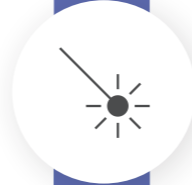
2 LASER APPLICATOR PLACEMENT

- Precise MRI guided navigation is used for placement of the TRANBERG® Laser Applicator. Use preferred navigation system to reach the identified target.
- Verify correct applicator position by acquiring high resolution anatomical images along the device trajectory.



3 INITIATE THERMOGUIDE WORKSTATION

- Activate real time transfer of MR images and data to Thermoguide™ Workstation and acquire MR Thermometry images along desired planes for temperature monitoring.
- Place Region of Interest (ROIs) and set temperature values that can trigger automatic shutdown of the laser ablation.



4 LASER ABLATION

- Apply a test dose to verify correct alignment of the MRI planes for temperature monitoring and the position of the laser applicator.
- Initiate the planned ablation procedure. Numeric and graphic visualization of temperature distribution and resulting tissue damage are super imposed on a high resolution anatomical image and presented in near real time. This allows for safe and effective monitoring and control of the ablation procedure.
- Reposition the laser applicator and repeat the process, if needed.



5 POST-ABLATION PROCEDURE

- Acquire chosen post-ablation images depicting the actual damage zone.

INTRODUCTION

TRANBERG® Thermal Therapy System with Thermo- guide™ Workstation

For controlled laser ablation
TRANBERG® Thermal Therapy System with ThermoGuide™ Workstation enables physicians to perform ablation procedures with near real-time temperature monitoring, thermal mapping and ablation control.

TRANBERG® Thermal Therapy System consists of a desktop mobile laser unit controlled from the workstation and innovative non-cooled laser applicators, easily integrated with preferred navigation option.

The TRANBERG® Thermal Therapy System is intended to be used by trained medical health care professionals to deliver laser energy, resulting in controlled heating and destruction of benign and malignant tumors and diseased soft tissue.

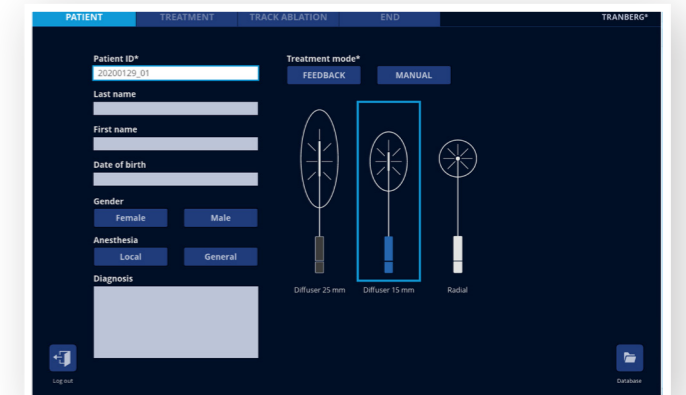
Indicated patient groups and corresponding treatment intent, in adults for the treatment of benign prostate hyperplasia (BPH) and localized prostate cancer.



TRANBERG® Mobile Laser Unit

The TRANBERG® Mobile Laser Unit is the laser source and control component of the TRANBERG® Thermal Therapy System.

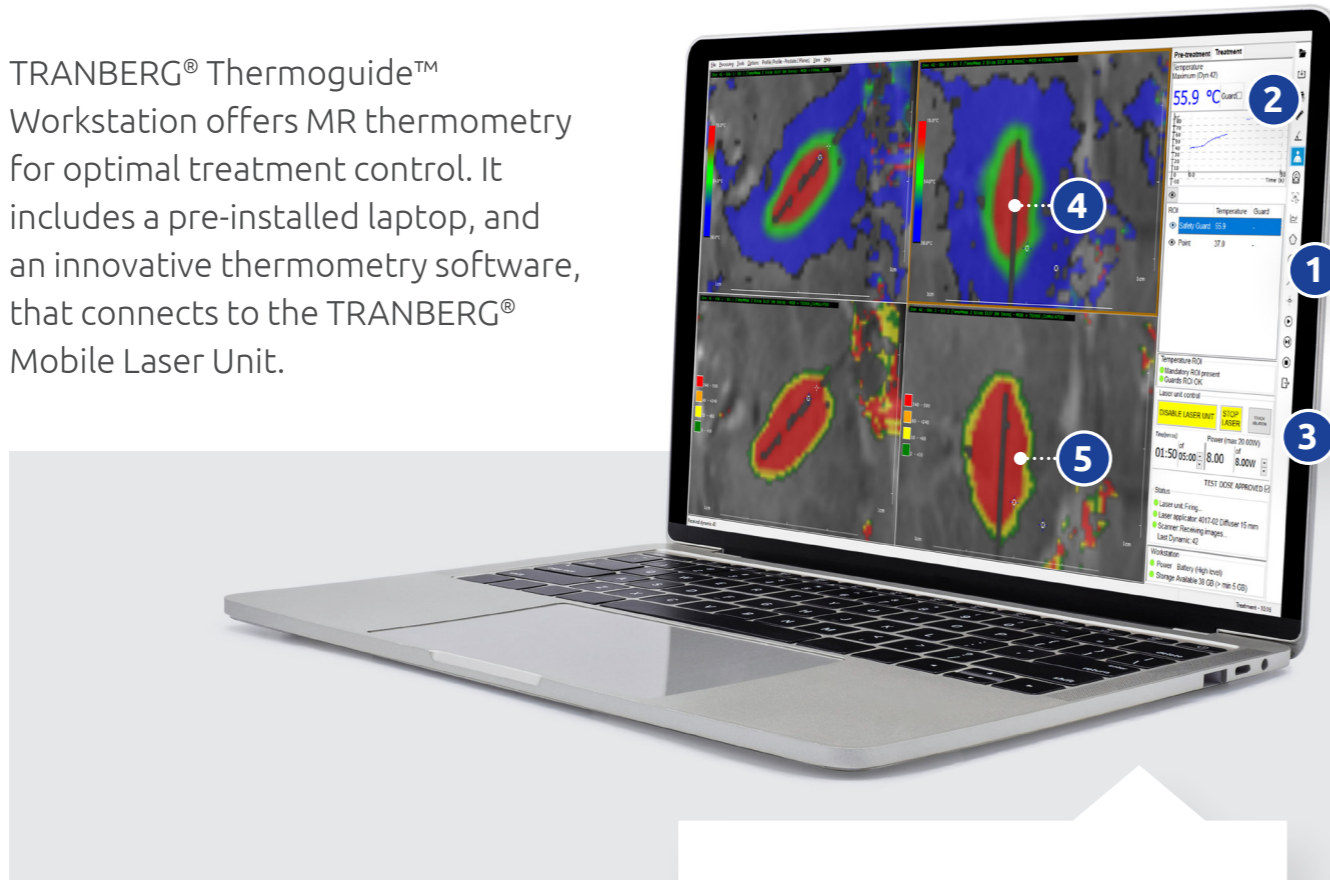
- Medical laser, wavelength 1064 nm
- Multiple options to control ablation by treatment power and time
- Small footprint
- Two touch screens with step by step instructing software



Easy to use interface for good overview and precise monitoring of the procedure.

TRANBERG® Thermoguide™ Workstation

TRANBERG® Thermoguide™ Workstation offers MR thermometry for optimal treatment control. It includes a pre-installed laptop, and an innovative thermometry software, that connects to the TRANBERG® Mobile Laser Unit.



Thermoguide™ Workstation receives and utilizes detailed MR images in near real-time, allowing the user to define and monitor the ablation area. The images are displayed in multiple planes, giving a complete overview and control of the procedure.

The physician can set temperature guarding checkpoints in any plane, to reach optimal treatment effect and simultaneously avoid damaging nearby critical structures. Whenever a checkpoint threshold is reached, the laser immediately shuts off.

Using the TRANBERG® system for MRI guided laser ablation with

1. **Define Region of Interest (ROIs)**
2. **Set temperature control guard(s)**
3. **Select laser applicator, apply test dose and after confirming position, initiate laser power**
4. **Monitor temperature change**
5. **Choose and stop when target is reached**

MR Thermometry thus adds targeting confirmation as well as ablation monitoring, and damage confirmation capabilities also to challenging procedures.

TRANBERG® Thermoguide Workstation is intended to retrieve, store, process, and display temporally dynamic magnetic resonance (MR) data from scanners to monitor temperature changes. When used to monitor thermal ablation, the software can also calculate thermal damage induced by ablation devices.



Benefits with MR guided laser ablation and MR thermometry:

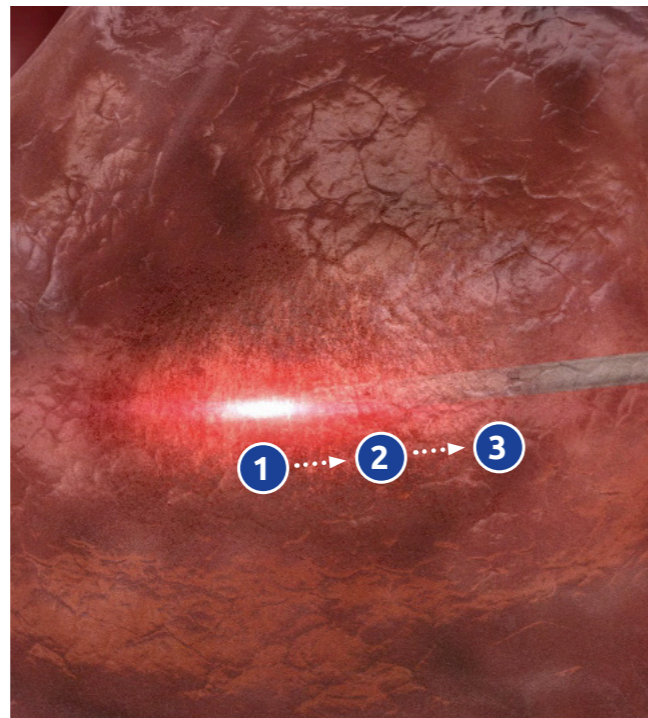
- Utilizes MR images to define the ablation area
- 2D/3D graphic thermal mapping in near real-time
- Allows for temperature monitoring and control
- Provides tissue damage prediction
- Optional safety guards to protect surrounding, sensitive structures

TRANBERG® Sterile Disposable Devices

The TRANBERG® portfolio includes three different 12 m long non-cooled 15 Gauge sterile laser applicators, allowing a multitude of ablation shapes and sizes.

The laser applicators can typically create single ablations in the size of 10/10-20/25 mm (D/L). When larger ablations are needed the laser applicator can be repositioned and the procedure repeated.

With the unique diffusing fiber technology of CLS, heat distribution in tissue is optimized and the need for external cooling has been made obsolete. The laser applicator is introduced using an introducer (MR Catheter and MR Stylet).

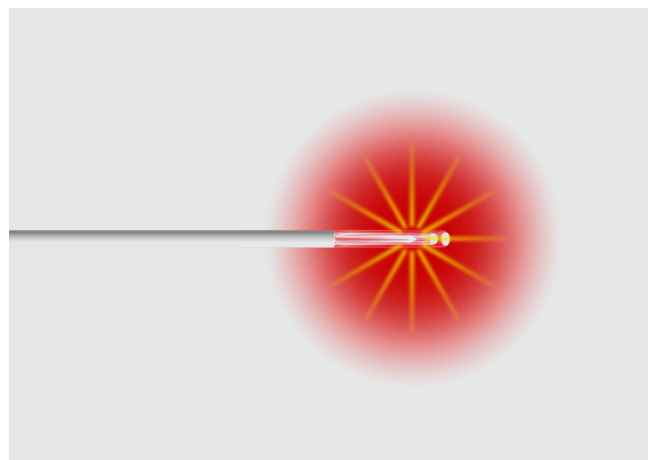


Pull back technique can be used to create and shape larger ablation zones.

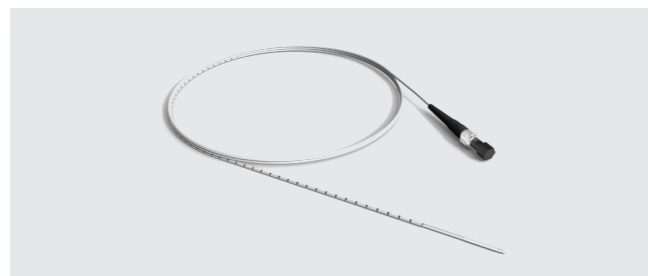


Benefits with TRANBERG® disposables:

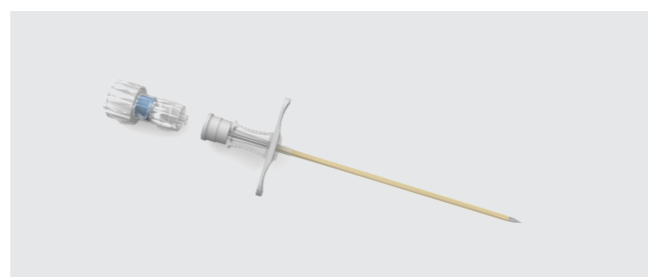
- Portfolio of MR safe/conditional devices
- Selection of laser applicators for various ablation sizes
- No need for external cooling of laser applicators



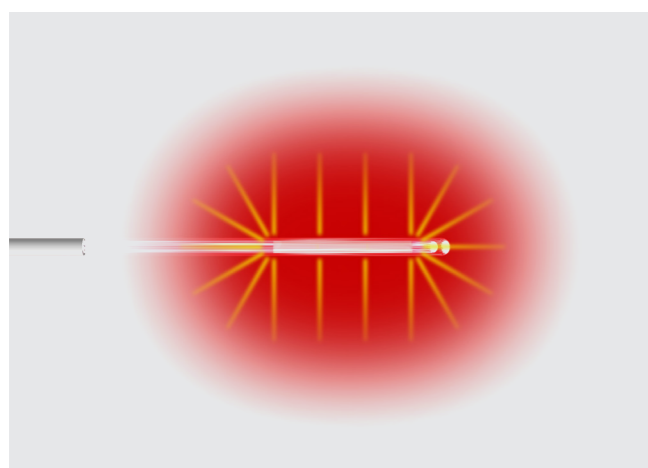
Radial laser applicator



Laser Applicator Non-cooled radial



MR Introducer



Diffuser laser applicator



Laser Applicator Non-cooled diffuser



About CLS

CLS is an innovative company within healthcare technology and therapy. With people in mind, we are at the forefront of developing more precise, more effective interventional healthcare solutions. Our products are approved and marketed in the US and Europe, providing minimally invasive alternatives to traditional treatments.



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Carefully precise

