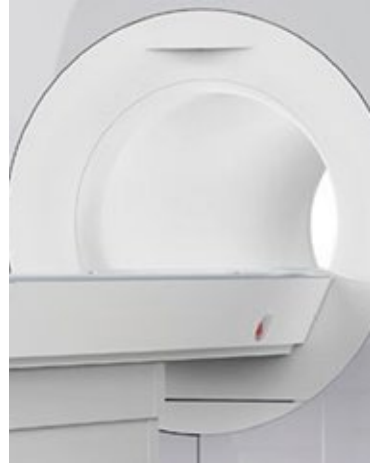




When precision matters



TRANBERG® Thermal Therapy System

Laser technology - also for MR guided interventions





TRANBERG® | Thermal Therapy System

The TRANBERG® | Thermal Therapy System has been developed for image guided high precision thermal therapy procedures within interventional oncology and is approved for ablation of benign and malignant tumors and diseased soft tissue. Laser light and optical fiber applicators allow use with MR-guidance and MR-thermometry, without creating disturbing artifacts. For CT/US-guided procedures the TRANBERG® | Thermal Therapy System is equipped with an integrated comprehensive tissue temperature feedback system for precise monitoring and control of the thermal therapy.”

The system includes a computer controlled mobile laser unit with touch screen graphical user interface, non-cooled laser applicators, external tissue temperature probe sensors and indication specific accessories.

Features and benefits

- Light weight compact mobile laser unit
- Two integrated 19 inch touch screens with graphical user interface
- Multiple options to control treatment power and time
- Storage of procedure data and patient information
- Robust non-cooled laser applicators for faster procedure
- Radial and diffusing fiber technology for optimized heat distribution in tissue
- 3 and 12 m MR-compatible 15 Gauge laser applicators
- Tissue temperature real-time feedback system with external 17 Gauge probes

The TRANBERG® | Thermal Therapy System is intended for use by medical professionals only.



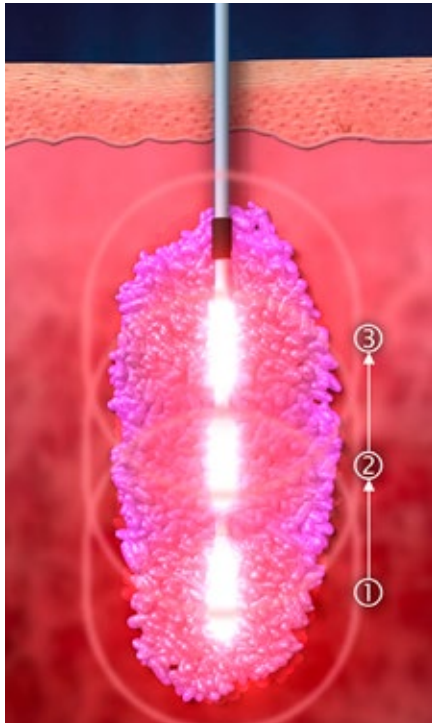
TRANBERG® | Laser applicators and accessories

The applicator portfolio includes 3 m and 12 m non-cooled 15 Gauge laser applicators allowing adaptation to any type of image guidance, including MRI. With the unique diffusing fiber technology by CLS, heat distribution in tissue is optimized and the need for external cooling has been made obsolete, both features saving significant procedure time.

The radiopaque introducers allow precise positioning of the laser applicator by means of image guided percutaneous access technique alternatively in open surgery. When using the integrated real-time tissue temperature feedback system, up to 6 sensors can be applied simultaneously for enhanced temperature mapping of the targeted area and monitoring of surrounding sensitive structures.

Features and benefits

- Introducers and laser applicators compatible with MR 3T
- 3 m and 12 m 15 Gauge laser applicators
- Applicator length allows for treatments in any MR-suite
- Laser diffusing technology tailored heat distribution in tissue
- Applicators tailored for both smaller spherical ablations and larger ablations
- Robust non-cooled laser applicators for faster procedure
- Portfolio include accessories allowing also for transrectal and transperineal applicator access
- Tissue temperature real-time feedback system with external 17 Gauge probes
- Allows use of optional 2D/3D real time thermal mapping by MR scanners



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



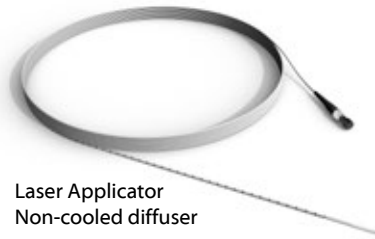
MRI-guided laser ablation offers advantages now and in the future

- No dose limitation or radiation risk
- Superior tumor detection and capacity to confirm ablation
- Optional 2D/3D real time thermal mapping in MR scanners allows improved precision

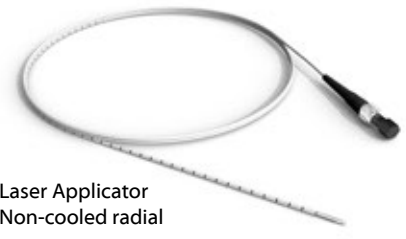
TRANBERG® | Laser applicators and accessories



Tissue Temp Probe



Laser Applicator
Non-cooled diffuser



Laser Applicator
Non-cooled radial



Tissue Temp Introducer
(not for US)



Standard Introducer

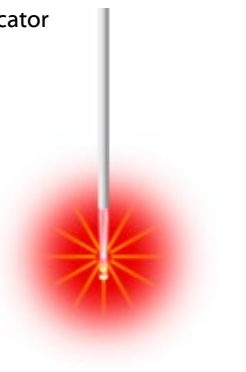


MR Introducer

Diffuser laser applicator



Radial laser applicator



Reference ablation sizes

Exposure time	Diffuser 25 mm 20W	Diffuser 25 mm 15W	Diffuser 25 mm 10W	Diffuser 25 mm 5W	Diffuser 15 mm 15W	Diffuser 15 mm 10W	Diffuser 15 mm 5W	Radial 8W	Radial 5W
1 min	26x14	22x11			22x14	15x9		12x12	7x8
2 min	33x19	30x16	23x13		28x18	22x14		19x16	13x12
3 min	35x23	33x20	27x16	18x10	30x21	26x17	15x11		
4 min		36x22	31x19	20x13	34x25	28x20	18x13		

Ex vivo, bovine myocardium at 37°C. 1064nm, CW.

Size in mm, HxW.

N≥10, SD≤ 2.1mm

A therapy by CLS

The TRANBERG®|Thermal Therapy System can be used in a feedback mode in which the system can control the temperature in e.g. the tumor border for a prolonged time, this technique can be used for applying the imILT® Immunostimulating Interstitial Laser Thermotherapy treatment protocol*.

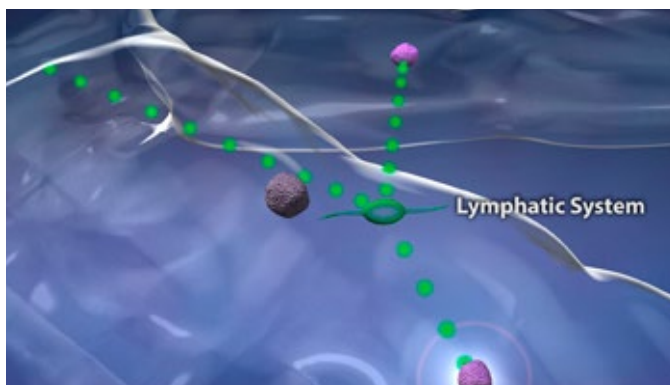
imILT® - a treatment protocol with potential

TRANBERG®|Thermal Therapy System can also be used in Feedback mode, enabling procedure protocols as imILT®.

The principle behind imILT® is simple, but the procedure requires great precision and control. Tumor thermal ablation with lower non-coagulating temperatures at the surface of the tumor allows intact tumor antigens to be released and potentially stimulate a tumor specific immune response.

There is data from pre-clinical studies suggesting that imILT®, in addition to local ablation, also may evoke an immune-mediated abscopal anti-tumor effect as a result of its specific heating properties.

The typically 30 min long procedure can be controlled and monitored by the integrated tissue temperature feedback system of the TRANBERG®|Thermal Therapy System or for MR guided treatments, with further support of MR-thermometry.

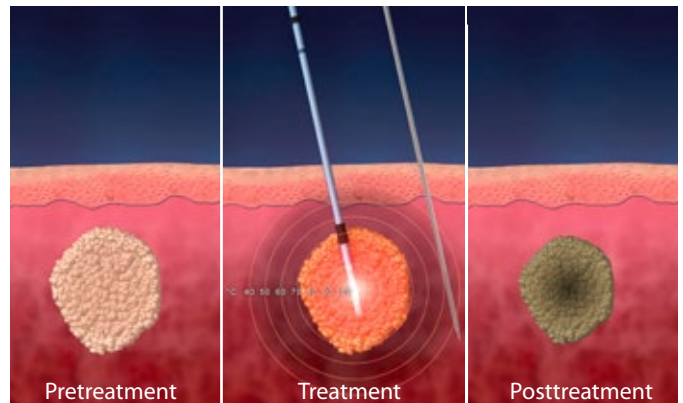


Anti-tumor immunity

During a successful imILT® intact, non-coagulated tumor antigens may be released and exposed to the immune system. The treatment may hence enable a beneficial tumor immune microenvironment. Antigen presenting cells (APCs), such as dendritic cells (DCs) and macrophages, can present the tumor antigens to T cells, which are activated and becomes cytotoxic. These results as shown in preclinical studies can trigger a systemic immune activation against remaining tumor.

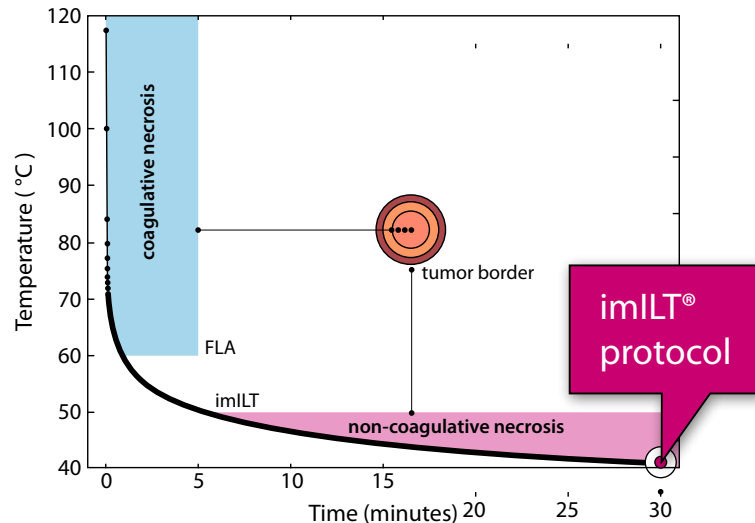
imILT®

The TRANBERG®|Thermal Therapy System has not yet a market clearance for Immune stimulating interstitial laser thermotherapy (imILT®) by the Food and Drug Administration (FDA) in the United States of America (USA).



imILT® by using feedback mode

The laser-generated heat induces destruction of the targeted tumor. The treatment process is controlled by tissue temperature feedback, enabling control of ablation size and maintaining optimal non-coagulating temperatures at the tumor border.



Thermal injury in tissue described using Arrhenius equation¹.

Multiple treatment modalities

The figure graphically illustrates the importance of the "time-temperature relationship" for creating thermal damage. High temperatures create a classical ablative necrosis within minutes by using manual mode while, by increasing time and maintaining lower temperatures at the tumor border, a non-coagulative necrosis optimized for immune activation may be obtained by using feedback mode. Cell death is tissue dependent and should always be estimated with a safety margin.

* The use of the imILT® protocol is restricted to clinical studies.

Features and benefits

- Medical grade Class 4 laser, wavelength 1064 nm, 1– 25 W output
- Feedback controlled laser power or manual control
- Continuous tissue monitoring for protection of sensitive structures
- 3-12 m non-cooled radial and diffusing laser applicators
- MR compatible instruments
- Small and user friendly system with touch screens
- Compact footprint, 18 kg
- Minimal set up time
- CE marked, FDA cleared

TRANBERG®

Order information

Product Name	Diameter	Length	Description	Specification	Markets	Part Number
Mobile Laser Unit	-	-	-	-	-	1001-01
Laser Applicator Non-cooled	1.7mm / 15G	1mm; 3m	Radial	-	-	4012-01
Laser Applicator Non-cooled	1.7mm / 15G	1mm; 12m	Radial	-	-	4012-05
Laser Applicator Non-cooled	1.7mm / 15G	15mm; 3m	Diffuser	-	-	4017-01
Laser Applicator Non-cooled	1.7mm / 15G	15mm; 12m	Diffuser	-	-	4017-02
Laser Applicator Non-cooled	1.7mm / 15G	25mm; 3m	Diffuser	-	-	4017-03
Laser Applicator Non-cooled	1.7mm / 15G	25mm; 12m	Diffuser	-	-	4017-04
MR Stylet	2.1mm / 14G	230mm	Pencil tip	-	-	4013-08
MR Catheter	2.1mm / 14G	230mm	PEEK	-	-	4013-10
MR Stylet	2.1mm / 14G	230mm	Trocar tip	-	-	4013-13
MR Stylet	2.1mm / 14G	100mm	Trocar tip	-	-	4013-11
MR Catheter	2.1mm / 14G	100mm	PEEK	-	-	4013-12
Standard Introducer	2.6mm / 12G	100mm	-	-	-	4013-01
Standard Introducer	2.6mm / 12G	200mm	-	-	-	4013-02
Standard Introducer	2.6mm / 12G	350mm	-	-	-	4013-03
Tissue Temp Introducer	3.0mm / 11G	100mm	Blue	Sensors: 1	not for US	4016-01
Tissue Temp Introducer	3.0mm / 11G	200mm	Blue	Sensors: 1	not for US	4016-02
Tissue Temp Introducer	3.0mm / 11G	350mm	Blue	Sensors: 1	not for US	4016-03
Tissue Temp Probe	1.3mm / 17G	100mm	Blue	Sensors: 1	-	3101-01
Tissue Temp Probe	1.3mm / 17G	100mm	White	Sensors: 1	-	3101-02
Tissue Temp Probe	1.3mm / 17G	100mm	Green	Sensors: 4	-	3201-01
Tissue Temp Probe	1.3mm / 17G	200mm	Blue	Sensors: 1	-	3102-01
Tissue Temp Probe	1.3mm / 17G	200mm	White	Sensors: 1	-	3102-02
Tissue Temp Probe	1.3mm / 17G	200mm	Green	Sensors: 4	-	3202-01
Tissue Temp Probe	1.3mm / 17G	350mm	Blue	Sensors: 1	-	3103-01
Tissue Temp Probe	1.3mm / 17G	350mm	White	Sensors: 1	-	3103-02
Tissue Temp Probe	1.3mm / 17G	350mm	Green	Sensors: 4	-	3203-01

References:

1. Welch AJ and van Gemert MJC book editors: Optical-Thermal Response of Laser-Irradiated Tissue, Thomsen S and Pearce JA, Chap. 13 530-537; 2011. Rates of accumulation of damage in tissue based on the rate coefficients of Henriques/1947

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