

A therapy by CLS

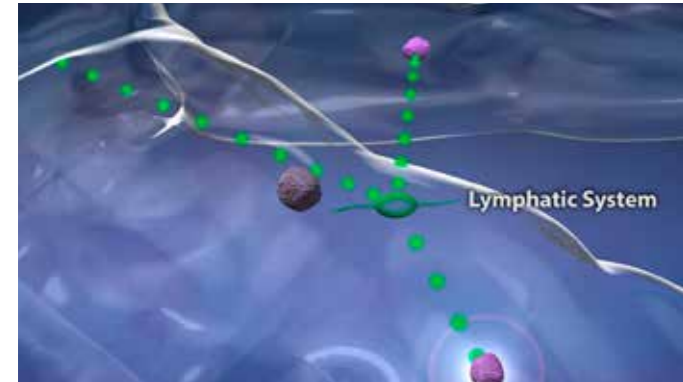
Immunostimulating interstitial laser thermotherapy or imILT® is a safe, promising treatment in the growing field of cancer immunotherapy². The minimally invasive, thermal treatment is performed using the TRANBERG® Thermal Therapy System, developed for high precision thermotherapy and ablation procedures.

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 to stimulate a tumor specific systemic immune response.

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

The typically 30 min long imILT®-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.

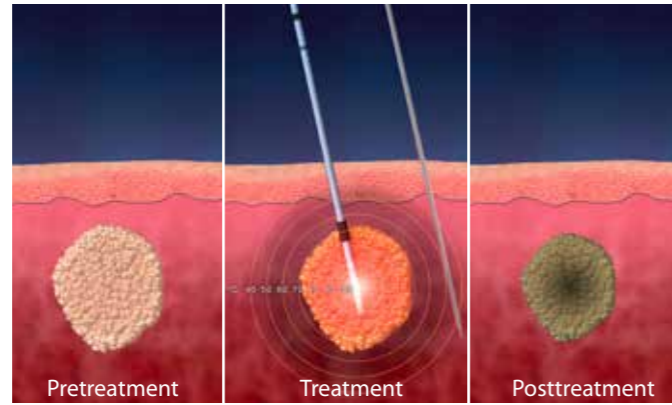


Anti-tumor immunity

During and after imILT® intact, non-coagulated tumor antigens are released and exposed to the immune system. The treatment enables a beneficial tumor immune micro-environment. Antigen presenting cells (APCs), such as dendritic cells (DCs) and macrophages, present the tumor antigens to T cells, which are activated and becomes cytotoxic. The result is systemic immune activation against remaining tumor.

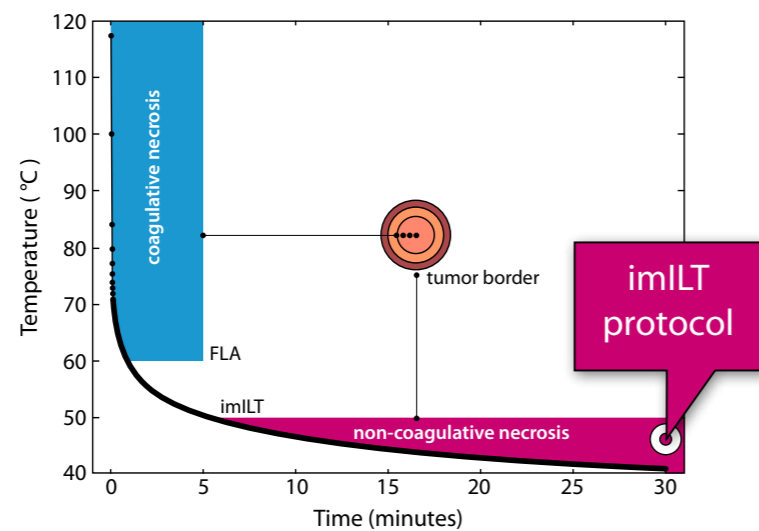
imILT®

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 treatment of targeted tumor

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 (FLA) while by increasing time and maintaining lower temperatures at the tumor border, a non-coagulative necrosis can be obtained, optimized for immune activation.

Cell death is tissue dependent and should always be estimated with a safety margin.

Features and benefits

- Medical grade Class 4 laser, wavelength 1064 nm, 1– 25 W output
- Feedback controlled laser power or manual mode
- 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

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 Introducer	2.1mm / 14G	230mm	-	-	-	4013-04
MR Cannula	2.1mm / 14G	230mm	-	-	-	4013-05
MR Stylet	1.8mm / 15G	230mm	-	-	-	4013-06
MR Adapter	-	-	Transrectal	-	-	4013-07
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
2. Initial findings of Interstitial Laser Thermotherapy Treatment of Patients with Solid Tumors. Axelsson. J et al, JCS 2017

Clinical Laserthermia Systems AB

Scheelevägen 2 | 223 81 Lund, Sweden | Phone: +46 46-15 21 00
E-mail: info@clinicallaser.com

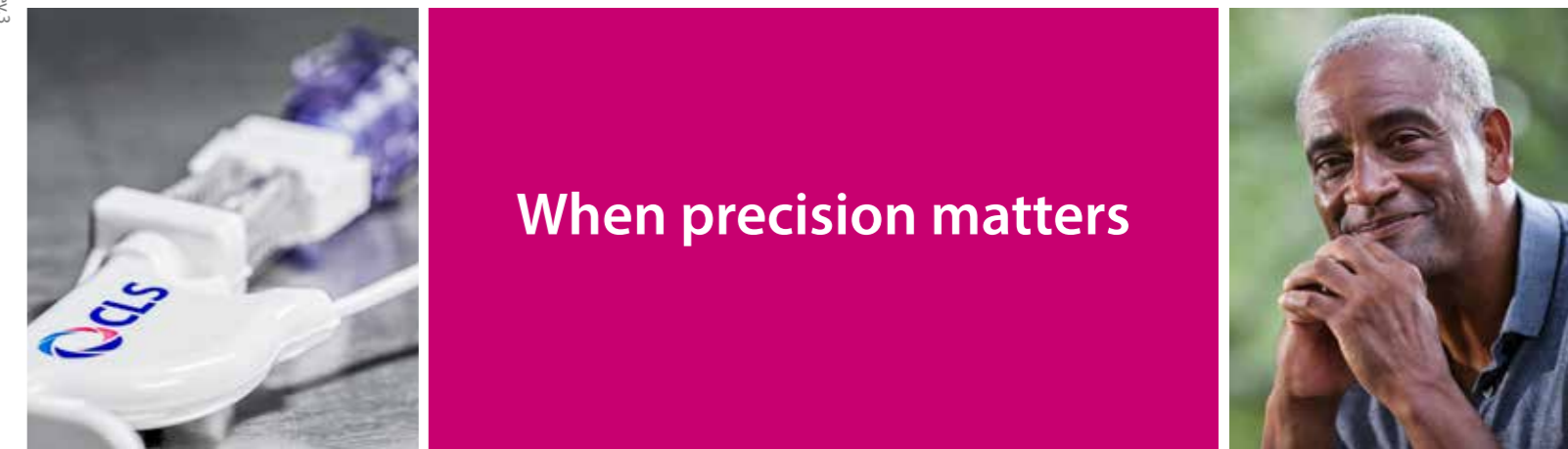
Clinical Laserthermia Systems Americas Inc.

945 Concord St. Framingham | MA 01701 | Phone: +1 (508) 620-4521
E-mail: sales@clinicallaser.com

www.clinicallaser.com

TRANBERG®

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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 soft tissue ablation. Laser light and optical fiber applicators allow for 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 interventions.

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 18 kg 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.



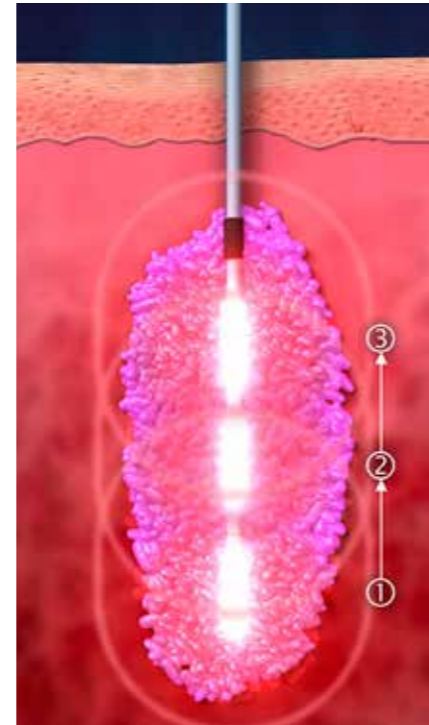
TRANBERG® |Laser applicators and accessories

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

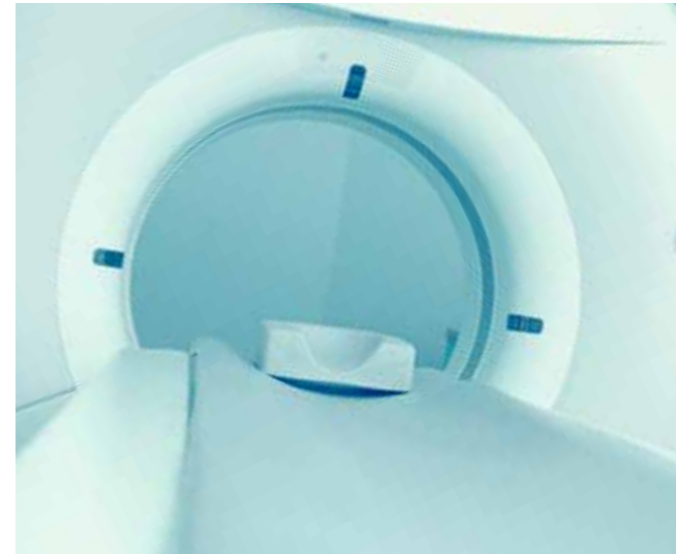
The radiopaque introducers allow for precise positioning of the laser applicator by means of image guided percutaneous access technique alternatively in open surgery. When using the integrated real-time tissue temperature feedback system, up to 6 sensors can be applied simultaneously for enhanced temperature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

Features and benefits

- MR compatible introducers and laser applicators up to 3 T
- 3 m and 12 m 15 Gauge laser applicators
- 12 m applicator fiber length allows for MR In-bore treatments
- Laser diffusing technology for 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 for use of optional 2D/3D real time thermal mapping by MR scanners



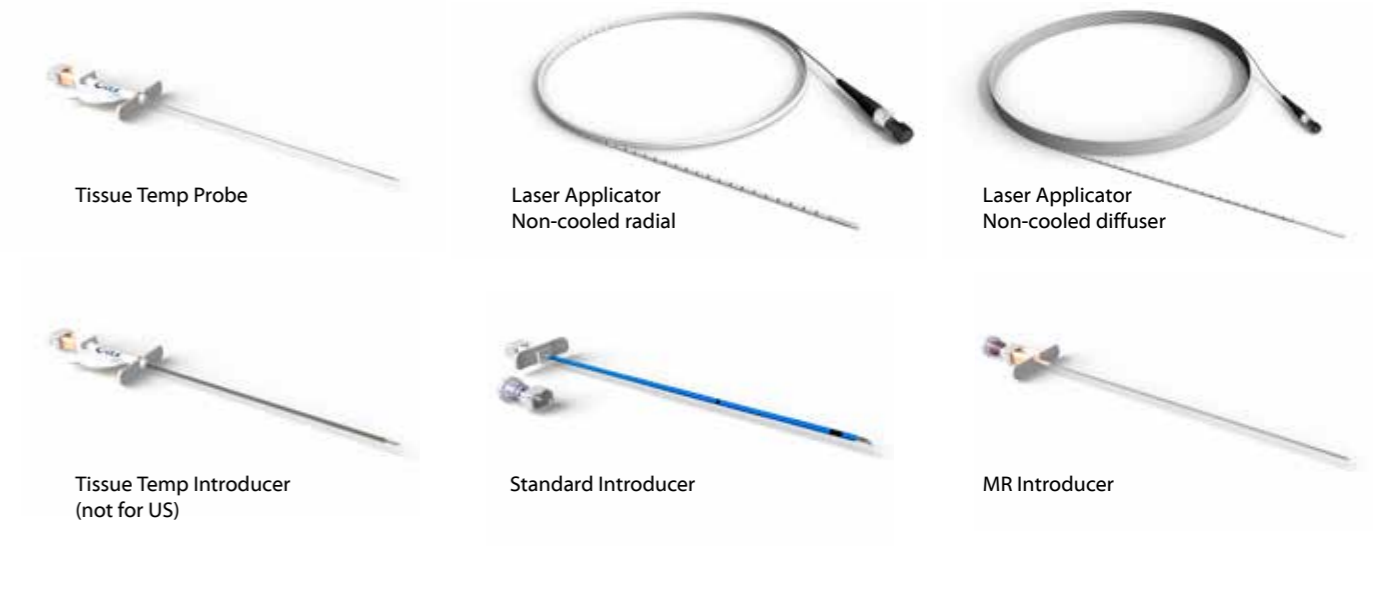
Pull back technique can be used to create and shape larger ablation zones by means of appropriate image technique



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

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

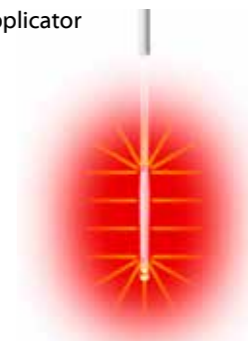
TRANBERG® |Laser applicators and accessories



Radial fiber applicator



Diffuser 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
1 min	26x14	22x11			22x14	15x9		12x12
2 min	33x19	30x16	23x13		28x18	22x14		19x16
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