



Tranberg Thermal Therapy System - Safety and Performance

CE 0123

**This content is an excerpt from the following IFU applicable for EU:*

INSTRUCTIONS FOR USE

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1. PERFORMANCE

1.1. INTRODUCTION

The TRANBERG®|Thermal Therapy System is indicated for precise soft tissue laser ablation by medical professionals only and consists of a medical laser unit with single use sterile devices. Generated laser light is locally applied within a tumor by means of a single use applicator. The energy within the laser light is absorbed by the tissue resulting in increased tissue temperature. The TRANBERG®|Thermal Therapy System can be used for precise soft tissue laser ablation procedures percutaneously using image guidance or during open surgery procedures in local or general anesthesia. The system is optimized with advanced functionalities for control and monitoring of tissue temperatures within the ablation volume and the surrounding tissue. The heating of tissue and ablation formation can be run in a controlled mode by a tissue temperature feedback system integrated into the TRANBERG®|Thermal Therapy System. Alternatively the system can be run in a manual mode where the output power and the exposure time is manually controlled by the user from the laser unit user interface or through sending parameters from TRANBERG®|Thermoguide Workstation to the laser unit user interface.

2. SAFETY

2.1. MRI SAFETY INFORMATION

TRANBERG®|Mobile Laser Unit is MR Unsafe.

TRANBERG®|Thermoguide Workstation is MR Unsafe

TRANBERG®|Laser Applicator

Non-clinical evidence has demonstrated that TRANBERG®|Laser Applicator is MR Conditional. A patient with this device can be safely scanned in an MR system

TRANBERG®|MR Catheter is MR safe.

TRANBERG®|MR Stylet

Non-clinical testing has demonstrated that TRANBERG®|MR Stylet is MR Conditional.

2.2. WARNINGS AND PRECAUTIONS

During a treatment session with the TRANBERG®|Thermal Therapy System, consider the following list of precautions and warning as well as the safety measures and instructions presented in this IFU.

General safety

WARNING: Every user of the TRANBERG®|Thermal Therapy System must have received adequate training before using the device. Clinical Laserthermia Systems AB is responsible for the training. Using the device without having received adequate training may lead to serious complications or even patient death.

WARNING: Use of controls or adjustments or performance or procedures other than those specified herein may result in hazardous radiation exposure. Disregarding the procedures described in this instruction for use, may lead to blindness or harm to patient or user or equipment damage.

PRECAUTION: The use of the laser unit and its accessories without adequate knowledge or training in laser safety principles and the correct operational procedures may cause accidents and injuries due to uncontrolled exposure to laser light, either from direct or indirect radiation (radiated or reflected beam). Protect the equipment by unauthorized use by always log out from the laser unit when leaving it unattended. **WARNING:** Do not use other treatment accessories or devices than the ones provided by Clinical Laserthermia Systems together with the system. The use of other treatment accessories or



devices may damage the laser unit or the single use devices and may inflict serious injury to the patient or patient death.

WARNING: Do not initiate the procedure/anesthesia before verifying the correct functioning of the devices.

WARNING: Always wear protective goggles appropriate for the absorption of laser light at 1064 nm when the laser unit is being operated. Disregarding this warning may lead to permanent eye injury.

WARNING: Do not activate the laser or the laser applicator if the applicator tip is not correctly placed in the targeted area. Accidental activation of the laser applicator may lead to unintended thermal injury to patient and user.

WARNING: Do not use flammable products, including cleaning products, medical gasses and anesthetics, close to the laser beam.

WARNING: Placement of the laser applicator should be done using sufficient image guidance to ensure a correct position within the targeted tissue.

WARNING: Imaging guidance during treatment is required to ensure the correct device positioning in the targeted area during procedure

WARNING: Prior to treatment, adjacent anatomical structures must be evaluated for susceptibility to collateral optical or thermal damage.

WARNING: To avoid seeding of tumor cells along the puncture track when withdrawing the temperature probes, the temperature probes should be placed outside the tumor border.

PRECAUTION: Laser fume and/or plume and/or gases emitted during laser therapy may contain viable tissue particulates and may be hazardous.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TRANBERG®|Thermoguide Therapy System, including

Laser unit

WARNING: To avoid the risk of electric shock, the laser unit must only be connected to a supply mains with protective earth (grounded mains sockets only). The appliance inlet is the mean for isolation from mains.

WARNING: Keep the ventilation panels of the laser unit clear from dust and any object that could obstruct the air flow.

PRECAUTION: The user must follow the instructions described in the installation chapter, to ensure proper operation of the laser unit and safety for the user and the patient.



WARNING: The laser unit should only be used at a temperature higher than 18°C (65°F). Acclimatization of the laser unit at a temperature higher than 18°C (65°F) must be performed without connecting the mains power cable to the mains wall socket.

PRECAUTION: The laser system must always be stored in switched off condition. The log in credentials must only be in the possession of authorized personnel.

WARNING: Service shall only be performed by individuals authorized by Clinical Laserthermia Systems AB and having adequate training. Performing service without being authorized by Clinical Laserthermia Systems AB may lead to serious complications or even patient death.

WARNING: The service to the laser unit must be done according to the instructions in these instructions for use. Improper or lack of service may cause serious injury to the patient or patient death.

WARNING: The expected service life of the laser unit is 10 years. Using the unit for a longer period than its expected service life may cause serious injury to the patient or patient death.

WARNING: No modifications to the system are allowed if not authorized by Clinical Laserthermia Systems AB.

WARNING: If the laser unit is not placed in the transport case correctly, it may be damaged during transportation.

WARNING: Exported data may contain sensitive patient information and should be treated as such.

WARNING: For a safe usage and maintenance of the laser output:

- Never leave the laser output uncovered. Use the protective cap attached to the unit.
- Keep the environment around the laser output clean.
- Clean the laser output regularly, using a bottle of compressed air.

It is recommended to clean the laser output and its protective cap every time they are exposed to air. Damage and power loss caused by the contamination of the laser output are not covered in the product warranty.

WARNING: Always disconnect the laser unit from the mains before cleaning it.

WARNING: Do not use solvents or abrasives when cleaning the laser unit. This may cause damage.

WARNING: Always clean the laser unit between treatments to avoid cross-contamination between patients.

WARNING: TRANBERG® Mobile Laser Unit and supporting hardware must at any time be kept in the MR control room and outside of the 5 Gauss line of the MRI magnet.

Single use devices

WARNING: Excessive heating can cause charring of the tissue which may damage the tip of the laser applicator. There is a slight risk that the tip may break and remain in the tissue under these conditions. Inspect the tip of the laser applicator after treatment. If the tip of the laser applicator is damaged and part of it is left in the tissue, there is a small risk of infection and abscess formation. The best way to handle this situation is active observation of the patient. Do not try to remove the part left behind.

WARNING: Handle the laser applicator carefully to avoid breakage and/or loss of radiation. Avoid hitting, pulling or torsion of any kind. Avoid excessive pressure at insertion. Do not bend it with a bending radius smaller than 15 cm. Severe bending or mechanical deformation of the laser applicator tip can result in uneven power distribution or complete tip failure during therapy.

WARNING: Always connect and inspect the laser applicator using the built in red aiming beam in the laser prior to use. Disregarding this warning may lead to patient injury and/or permanent compromised vision for patient, user or third party.



WARNING: To avoid damage to the optical fiber resulting in uncontrolled light emission, avoid any contact of metallic instruments to the tip of the optical fiber.

WARNING: Make sure that the laser applicator tip is uncovered when the laser light is emitted. If the laser applicator tip is inside the introducer while the laser is on, the laser light can cause the plastic material to melt or the metallic material to overheat. This may cause post-treatment infection.

WARNING: To avoid damage to the tip of the laser applicator, do not place the temperature probes closer than 7mm from the laser applicator tip.

WARNING: The fiber connector should never be touched or exposed to dust or particles without the protective cap on. Failure to comply with these precautions can reduce the light dose delivered to the tissue (under-treatment) and induce damage to the laser unit and laser applicator.

WARNING: Check the sterile pouch for disposable products visually before use:

- Look for any signs of damage before use. Do not use if the sterile pouch is damaged.
- Look for the ETO indicator, it must be yellow. Do not use if the indicator is not yellow.

WARNING: To avoid contamination, sterile products must be handled according to sterile protocol.

WARNING: Do not use disposable products after the expiration date indicated on the package.

WARNING: Do not re-use disposable products.

WARNING: Optically effective debris such as tissue residues or blood may remain on the laser applicator after use. Re-use of the laser applicator can lead to massive heating up and to possible destruction of the laser applicator in the tissue.

WARNING: Single use products must be properly disposed. Disregarding this warning may lead to infection to the patient or to the user.

WARNING: Do not introduce MR unsafe devices or accessories in MR environment.

WARNING: Metallic or conductive objects can appear larger than their real dimensions during MR ("blooming effect").


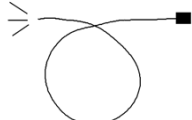



WARNING: The laser applicator is MR conditional. Please keep all metallic and/or conductive parts of the laser applicator, such as the SMA connector on the proximal end, outside the 5 Gauss line during scanning. If proximity of the metallic parts to the MR bore is required, ensure that a distance of at least 1.5m between the bore and the metallic or conductive part is kept at all times and that the part is securely attached to avoid interaction with the conductive part in MR environment. Damage to imaging equipment or injury to patients or users may occur if appropriate precautions are not taken.

WARNING: The MR introducer (MR Stylet and MR Catheter), contains metallic parts in nickel titanium and is MR conditional in 1.5T and 3.0T.



2.3. SAFETY LABELS















2.3.1. Warning signs






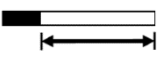
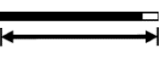





The warning sign placed on the laser system must remain perfectly legible and should be replaced if necessary. Avoid exposing the laser unit to UV light, including sunlight. Exposure to UV light can cause important safety labels to be unreadable.

Label	Description
	<p>Label indicating the maximum values and the classification of the laser according to the regulations of standard EN 60825-1.</p>
	<p>Label indicating the laser output. It indicates that the radiation is emitted at the end of the laser applicator.</p>
	<p>Laser emission warning sign to be placed outside the room where the laser unit is operated.</p>
	<p>Emergency stop.</p>
	<p>Read Operator's Manual (IFU).</p>

2.3.2. Symbols on labeling

Symbol	Explanation
	<p>Caution. Please read the accompanying documents carefully before using the device.</p>
	<p>Mains OFF, the unit is switched off.</p>

Symbol	Explanation
	Mains ON, the unit is switched on
UNIT CLASS I	Protection against electric shock does not only depend on the insulation: also, all the conducting parts are grounded (in accordance with EN 60601-1)
	This symbol refers to the type of isolation, TYPE BF, for the laser unit.
 YYYY-MM	Manufacturer / Date of manufacture
 0123	CE mark
 SN	Show the singular serial number for the equipment.
 	Do not use ordinary dustbin
	Date of manufacture
 REF	Catalogue Number (i.e. article number)
	Consult instruction for use
 LOT	LOT Number
	Do not use if package is damaged.
	Single use only.
	Double sterile barrier system. Sterilized with Ethylene Oxide.
	Temperature Limit

Symbol	Explanation
	Humidity limitations
	Expiration date
	Keep dry
	Keep away from sunlight
 <p data-bbox="343 862 582 940">(01)XXXXXXXXXXXXXXXXXX (11)YYMMDD (21)XXXXXXXXXX</p>	UDI data matrix: (01)UDI (11)Expiration date (21)Serial number or LOT number
<p data-bbox="359 974 454 1052">Rx ONLY</p>	Prescription only
	Needle/tip length
	Total/cable length
<p data-bbox="391 1299 422 1355">∅</p>	Maximum outer diameter
	Quantity
	MR Unsafe - item is NOT MRI compatible and is known to pose a hazard in MR environments. This equipment should not be taken into the MRI room within the 5 Gauss perimeter line.
	MR Conditional - the item poses NO known hazards in a specified MRI Environment (e.g. 1.5T to 3.0 T)
	MR Safe - the item poses NO known hazards in ALL MR environments.
	Medical Device