Visualase®

Visualase® provides advanced Magnetic resonance guided laser induced thermal therapy in neurosurgery.

Laser energy is delivered to the target area using a laser applicator. As light is delivered through the laser applicator, temperatures in the target area begin to rise, destroying the unwanted tissue.

Advantages

Because Visualase procedures are guided by MRI images, the procedure can provide precise ablation. Due to the minimally invasive nature of the procedure, hospital stays have been reported to be reduced compared to open procedures.

Because Visualase procedures are guided by MRI images, precise anatomical targeting is possible

Because the Visualase procedure does not deliver ionizing radiation: There are no dose number limitations (the procedure can be repeated to ablate the targeted tissue, if necessary);

There are none of the toxicities typically associated with ionizing radiation.

Requires no skull flap.

Does not limit use of other treatment options.

Provides real-time imaging of the procedure to the surgeon.

Most procedures are completed in less time as compared to open procedures

Most patients have little or no hair removed

Minimal sutures required, typically a 1-stitch suture

Most patients are discharged after a shorter stay as compared to open procedures

Reduced scarring compared to open procedures.

Technique

A small flexible laser applicator is guided to the intended target area.

The patient is transported to an MRI unit. The MRI allows a physician to precisely monitor treatment using special software to measure temperature changes.

Laser light heats and destroys target area. Temperature maps show the physician the extent of the tissue being destroyed, minimizing risk of potential damage to surrounding healthy tissue.

The laser applicator is removed and the small incision is closed with minimal sutures (typically one stitch).

Technology

Visualase uses light energy to destroy soft tissue.

Stereotactic laser ablation (SLA) is one of the most recent developments in laser technology.

Visualase utilizes minimally-invasive laser ablation in combination with a powerful image-guided system (MR, MRI) to localize heat to a target and to visualize thermal ablation in real-time. Laser light is delivered through the applicator which raises the temperature of the target tissue, irreversibly destroying the targeted tissue.

A minimally invasive procedure: the laser applicator is 1.65mm in diameter.

Contraindications

The following contraindication is from the Visualase Cooled Laser Applicator System manual:

The Visualase Cooled Laser Applicator System should not be used if thermal therapy or interstitial laser therapy are contraindicated.

The following contraindications are from the PhoTex Laser User Manual:

We strongly recommend physicians weigh advantages and disadvantages of using a diode laser. Other modalities or wavelengths may be more appropriate due to any of the following:

Depth of penetration

Volume of necrosis

Propensity of scarring

This product should not be used if thermal therapy or interstitial laser therapy are contraindicated.

Use only in specialties listed in the Indications for Use.

For those whom the physician determines the laser is not the surgical tool of choice.

Patients who are unable to be treated by surgical means or who are intolerant to anesthesia.

Do not use endoscopically in any procedure where endoscopes are contraindicated.

Warnings

The Visualase System should NOT be used with an extension cord.

DO NOT connect items to the Visualase System which are not specified as part of the System.

Use the Visualase System only in an appropriate, dry area with proper power and grounding connections.

Read all cautions and procedures in the accompanying PHOTEX LASER USER MANUAL before operating the laser.

Read all cautions and procedures in the accompanying Visualase Cooled Laser Applicator System INSTRUCTIONS FOR USE before using any Visualase laser applicator.

Read all cautions and procedures in the accompanying Visualase ENVISION Image Analysis Workstation USER MANUAL before using the Visualase Thermal Therapy System.

DO NOT connect any equipment which has not been supplied as part of the System to the multi-socket outlets supplied with the system.

The multi-socket outlet strip provided with the Visualase system is ONLY to be used for components supplied with the Visualase system. DO NOT connect other electrical devices to the multi-socket strip.

DO NOT connect any equipment which has not been supplied as part of the System to the multi-socket outlets supplied with the system.

DO NOT take any component other than the Visualase Cooled Laser Applicator into the high-field region of the MRI magnet.

The following Warnings are from the Visualase Cooled Laser Applicator System manual:

Permanent injury to the eyes can occur if persons in the surgical area fail to wear laser safety eyewear specifically for the wavelengths being used.

Proper use of the LDF requires an adequate knowledge of laser-tissue interaction and the physiologic process associated with it.

The user should be well acquainted with the laser being used with the LDF and its wavelength’s interaction with the target tissue.

Prior to treatment, adjacent anatomical structures within the target tissue must be evaluated for susceptibility to collateral optical or thermal damage.

Excessive heating can cause char and tip destruction within the tissue. Though remote, the possibility exists for a portion of the tip to remain in the tissue under these conditions.

Debris on the face of the SMA inserted into the laser coupler can preferentially absorb the laser energy resulting in significant heating at the laser connection point. This can cause damage to both the LDF and the laser itself.

The catheter and fiber are MR compatible up to 1.5T, however the SMA connector on the proximal end of the LDF is not. Damage to imaging equipment or patients can occur if appropriate precautions are not taken.

Severe bending or mechanical deformation of the tip will result in uneven power distribution and possible tip failure during therapy.

Core diameter and numerical aperture incompatibility with the laser will result in improper coupling and could lead to damage to the laser and decreased power output from the diffusing tip.

The LDF and CCS are designated as single-use devices and should not be re-sterilized.

The following Warnings are from the PhoTex Laser User Manual:

IMPROPER USE OF SYSTEM CONTROLS or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.

FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation.

NEVER direct the laser beam at anything other than the area to be treated.

NEVER allow the eyes of any living being to look directly into the distal end of the optical fiber connected to an active laser device – WITH or WITHOUT wearing appropriate laser-emission protective eyewear.

DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes and skin. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device.

THERE ARE NO USER SERVICEABLE COMPONENTS inside this laser device. Therefore, do not attempt to gain access to any internal device component. Doing so may cause serious and/or irreversible injury.

DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. To do this, the operator releases the foot switch, touches the Ready screen button on the display panel, and visually observes the laser device returning to Standby.

DO NOT insert foot switch while in External Modulation Mode.

DO NOT insert DB-9M connector into Remote Control Port while using foot switch.

THE LASER PLUME may contain viable tissue particulate matter.

AVOID THE USE of flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen. High temperatures produced in normal use of the laser equipment may ignite some materials, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solution used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should be drawn to the danger of ignition of endogenous gases.

The following Warnings are from the Visualase ENVISION+ User Manual:

The Visualase System and Components should ONLY be connected to equipment and devices which conform to IEC Standards.

Multi-socket outlet taps or extension cords should NOT be connected to the Visualase System.

The Visualase System should NOT be used with an extension cord.

DO NOT connect items to the Visualase System which are not specified as part of the System.

Use the Visualase System only in an appropriate, dry area with proper power and grounding connections.

DO NOT connect any equipment which has not been supplied as part of the System to the multi-

socket outlets supplied with the system.

DO NOT place the multi-socket power strip supplied with the system on the floor.

DO NOT place any additional multiple portable socket outlets on the floor.

The multi-socket outlet strip provided with the Visualase system is ONLY to be used for components supplied with the Visualase system. DO NOT connect other electrical devices to the multi-socket strip.

Precautions

The following Cautions are from the Visualase Cooled Laser Applicator System manual:

The device should be stored at within the following temperature range: 40˚F - 120 ˚F.

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Read all instructions prior to use. Observe all warnings and precautions noted throughout the instructions. Failure to do so may result in complications.

All fibers and catheters are ethylene oxide sterilized for single use in a sterile surgical environment.

Do not use if package integrity has been compromised.

Lasers should only be operated by qualified personnel and in appropriate areas.

DO NOT bend the fiber or the CCS sharply. This can cause fiber breakage, kinking of the catheter, and/or energy loss. In the event of excessive bending, the aiming beam is visible at the bend.

DO NOT cut the jacketing around the fiber or the wall of the CCS. This creates a weak point that will lead to failure of the fiber or the catheter.

All persons in the surgical area must wear laser safety eyewear specifically for the wavelengths being used to prevent eye injury.

The dust cover installed on the SMA of the LDF should remain installed until the fiber is coupled to the laser.

Ensure the face of the SMA is free of debris prior to connection to the laser.

Care should be exercised when inserting the fiber into any device, specifically intravenous introducers, cooling jackets, or other insertion device to avoid mechanical deformation.

The coolant outlet tubing should have a minimum inner diameter (ID) of 1/8” (0.125”) Use of smaller diameter tubing will created an increase in pressure in the outlet chamber potentially resulting in coolant leakage from said chamber into the surgical field greater than one milliliter over ten minutes (0.1 ml/min).

Core diameter and numerical aperture compatibility with the laser must be verified prior to use.

Comply with all safety precautions defined by the imaging modality that will be used. For example, be aware of laser apparatus and syringe pumpincompatibilities with MRI environments.

Care should be taken when using the printed cm marks on the catheter to make accurate

measurements. Misreading the measurement could result in improper depth placement of the applicator.

The following Cautions are from the PhoTex Laser User Manual:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Read all instructions prior to use. Observe all warnings and precautions noted throughout the manual. Failure to do so may result in complications.

Never allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.

DO NOT remove protective eyewear until the operator returns the laser device to “Standby mode”. To do this, the operator must release the foot switch, touch the READY screen button on the display panel, and visually observe the laser device returning to “Standby mode”.

Place Laser Warning Signs at each entrance to the location where the laser device will be operated.

This laser device produces infrared laser energy that is invisible and can be an extreme hazard to the eyes of any living being. Irreparable corneal and/or retinal damage may occur if a person exposes one or both eyes to direct or indirect (reflected) laser energy.

The protective eyewear used should have an optical density rating greater than 5 for the appropriate wavelength range and meet ANSI Z 136.1 and Z 136.3. All personnel present during device operation must wear this eyewear.

Select a secure, properly equipped, and well- ventilated location in which to install and operate the laser.

Always put the laser in Standby mode or switch the device off prior to adjusting or preparing the delivery system.

Never leave this device in the READY mode unattended. See Section 6.2.1 in the Operations section of the manual for instruction on toggling between STANDBY and READY Modes.

Remove the key from the device’s key switch when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions.

Turn the device off before relocating equipment in the same vicinity.

Never press the foot switch without first verifying the safe orientation and proper positioning of the delivery system and ensuring compliance to all safety precautions.

During any laser procedure, do not allow any nonessential personnel into the treatment area.

ALWAYS clean the SMA connector of the delivery system before inserting into the SMA emission port. Debris on the connector could result in damage to both the delivery system and laser unit.

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