ELESTA
Beyond Laser

EchoLaser®: *First, Unique, Micro-invasive, Integrated System* Offering Diagnostic Ultrasound and Laser Ablation Treatments.

ECHO · LASER®

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PHYSICS OF LASER ABLATION

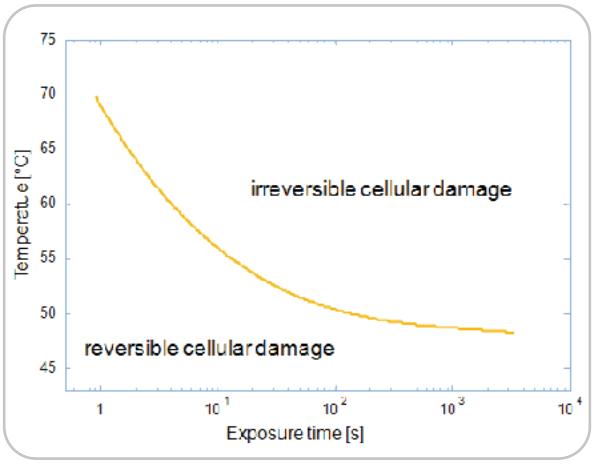
What is Laser Ablation (LA)?

Laser Ablation is an image-guided micro-invasive procedure for the tumour treatment in the oncology field. The procedure exploits the Light Amplification by Stimulated Emission of Radiation (L.A.S.E.R.) process to produce a local rise in tissue temperature which leads to a coagulative necrosis of the cells.

The temperature effects on tissue are as follows:

>300°C	**Fusion, sublimation**
>100°C	**Charring, carbonization**
100°C	**Vapour-bubble formation, mechanical rupturing**
60°C	**Denaturation of protein and collagen, coagulation**
>50°C	**Decreased enzymatic activity, loss of the cellular recovery mechanism**
42°C - 50°C	**Hyperthermia, bond destruction, modification of the cell membrane**

Irreversible necrosis of cells occurs due to the combined action of the local temperature and the exposure time.



At T>60°C, almost instantaneous cell death occurs

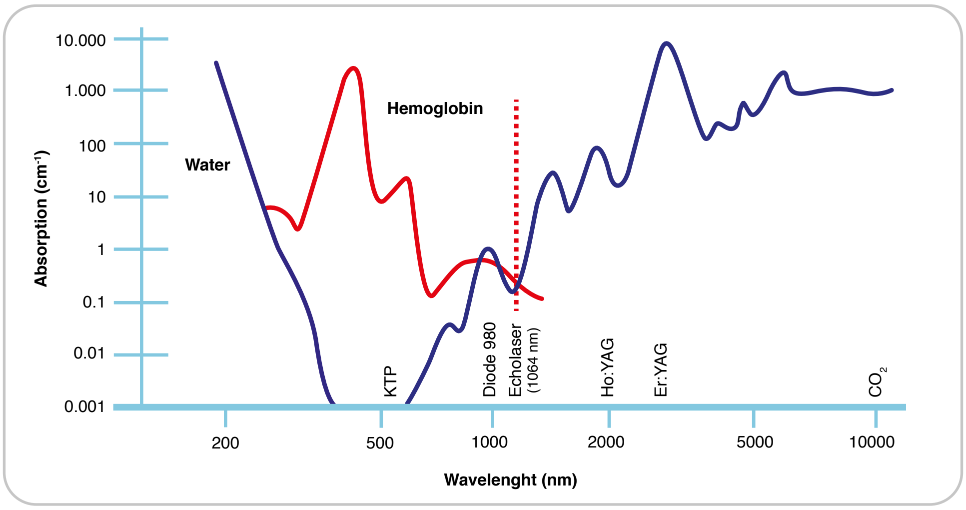
At lower temperatures the same effect is achieved with longer exposures

Advantages of Laser Ablation:

- Thermal destruction of the lesion "in situ"
- Image-guided minimally invasive approach
- Suitable for malignant and benign tumours
- Conscious sedation
- Lower morbidity
- Outpatient setting
- Cost-saving compared to surgery

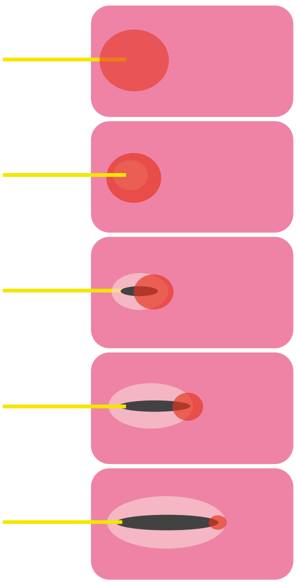
Choice of Wavelength

Laser radiation is monochromatic: this means it has one single wavelength (colour), allowing specific and selective interaction with tissue chromophores. The interaction of the laser radiation with biological tissue depends on wavelength, power, exposure time of the laser radiation and the optical properties (scattering and absorption) of the biological tissue.



1064 nm wavelenght of EchoLaser diode laser represents the optimal choice to perform Laser Ablation, since differently from other wavelenghts typically used in the thermal ablation field (532 nm, 980 nm, 1480 nm, 2140 nm, etc.) it has the lower absorption coefficient, which allow the best light penetration into tissues.

Thermal damage dynamics during Laser irradiation



Start lasing

Initial spherical coagulation of tissue occurs around the fiber tip (changing its optical properties from native to coagulated tissue)

Water starts to boil, vapour is formed and a cavity starts to grow

The tissue is coagulated, dehydrated and vaporized in a cyclic pattern giving rise to a well defined cavity in the centre

Due to divergency of fiber optic emission, moving front velocity decreases with cavity enlargement leading to an asymptomatic limit of treated volume

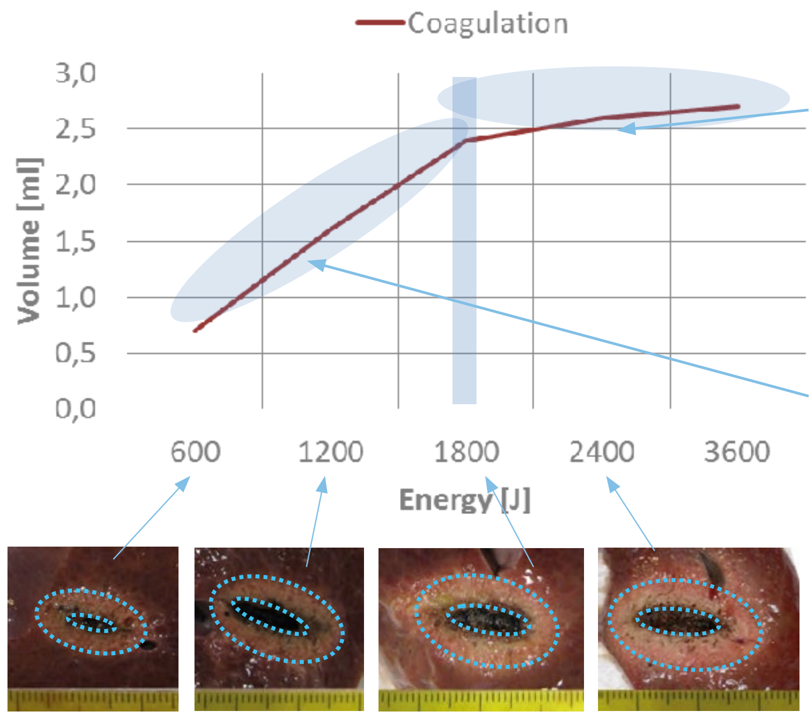
Coagulation area

The volume of the thermal damage produced depends on:

- Energy delivered per fiber;
- Number of fibers (applicators);
- Fibers mutual distance;
- Number of pull-backs during the same session (pulling back the applicator from the initial position along the needle and fiber axis by 1.0-1.2 cm so as to treat the tissue volume not yet treated in the previous energy application).

Coagulation volume in relation with delivered energy dose

The relationship between coagulation volume and the delivered energy dose is described by an almost linear progression for small energy doses, up to almost 1800 J, while it evolves in a saturation phenomenon with a volume increase plateau for doses higher than 1800 J.



The saturation phenomenon showed for enery doses higher than 1800 J allows to obtain high treatment repeatability, regardless of the tissue response to energy deposition

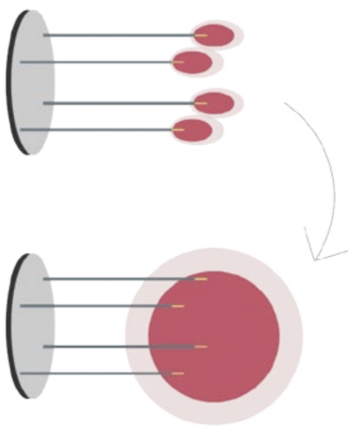
Almost linear relation up to 1800 J allows:

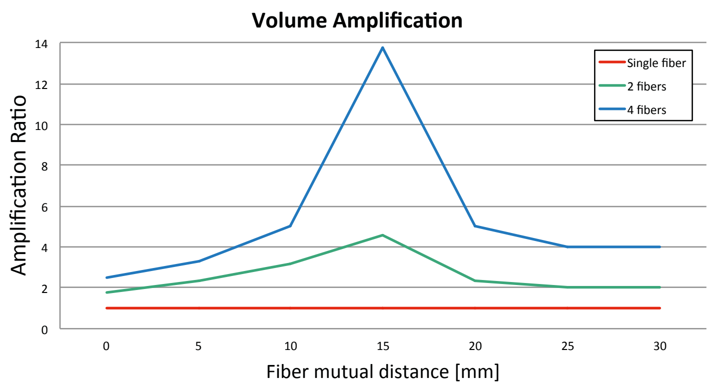
- Excellent behaviour in treating small lesions in small organs (i.e. thyroid)
- Treatment tailoring in relation to lesion dimensions
- Uniqueness of LA versus other thermal ablation modalities which shows lack of precision for small amount of energy delivery

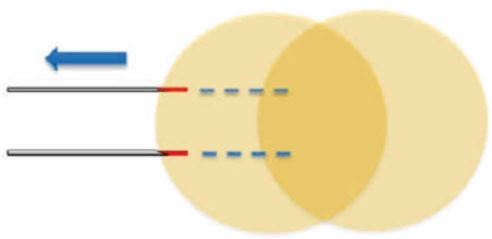
- Experimental Set-Up (ex vivo)
- Tissue: porcine liver
- Basal Tissue Temperature: 20°C
- Power:5W
- Energy: 1800J
- Plane-cut fiber: 300μm
- 1 plane-cut fiber used

Amplification of coagulation volume: Multi-fiber approach & pullback technique

Laser source allows the use of multi-fiber approach. The transmission of the laser energy by the fibers takes place simultaneously and thanks to a synergic coalescence action, large volumes of coagulative necrosis can be obtained with perfect control of the borders, even in larger lesions. Not only the fiber number but also the mutual distance within them are important in the amplification of cogulation volume.



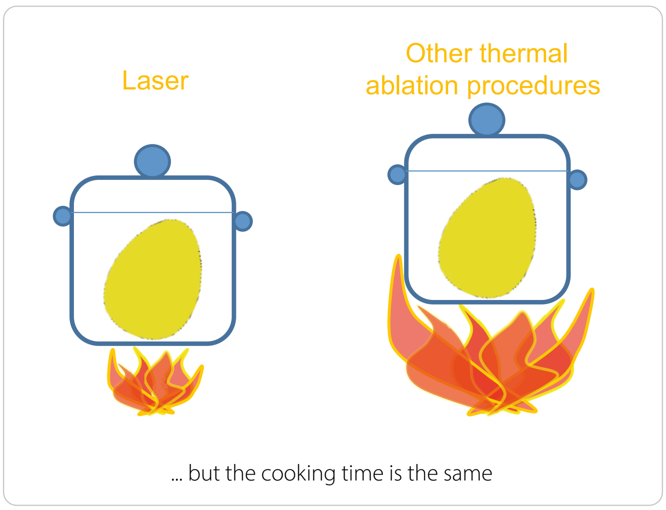




The so called "pullback technique", performed by withdrawing the applicators for 1 cm after the release of the first energy dose, allows to enlarge the volume of ablation in the longitudinal plane to address big lesions.

Power and Energy dose

Laser Ablation exploits lowest energy dose and power to achieve the same coagulation volume compared to other thermal ablation procedures due to a very effective mechanism of energy conversion.



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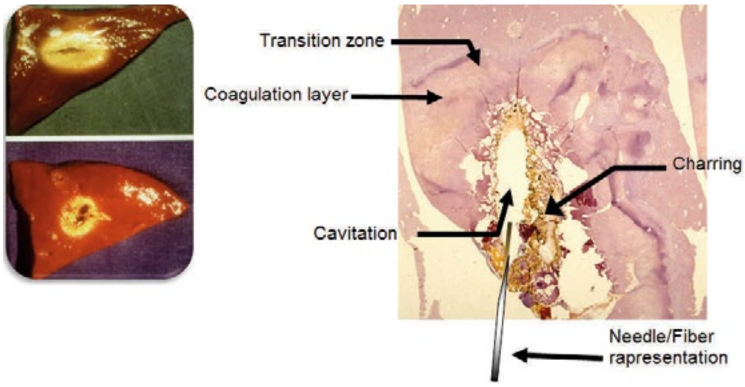
Laser Ablation: biological effects

Histological specimen of treated animal tissue (longitudinal section)



In a central zone surrounding the insertion of the applicator the gross tissue structure is well preserved, whereas cellular build up is characterized by acidophilic cytoplasm and elongated nuclei. This zone is surrounded by a broad area, containing dilated sinusoids and cells with vacuolated cytoplasm. The outer, macroscopically detectable, hemorrhaged zone consists of cells with less vacuolated cytoplasm and hyperaemic sinusoids.

Although heat from laser light absorption is the primary mechanism of cell death, there is some evidence that laser ablation may cause coagulation of microvessels and progressive ischemic injury as long as 72 hours after the ablation procedure. (Courtesy of Prof. C.M. Pacella).

Laser-tissue interaction and the penetration depth of the laser into the tissue (depending on the wavelength) make laser ablation a successful choice.

Consequently:

- laser can deliver a great deal of energy to a very small area;
- laser produces predictable, precise and controlled thermal ablation;
- laser exploits high effective energy conversion;
- laser uses low power and low energy dose;
- the laser energy dispersion in tissues other than the ablation target is minimal (allowing treatment of selected volumes and in critical zones);
- laser energy is well-tolerated by the organism (very low risk of complications).

ECHOLASER

What is EchoLaser?

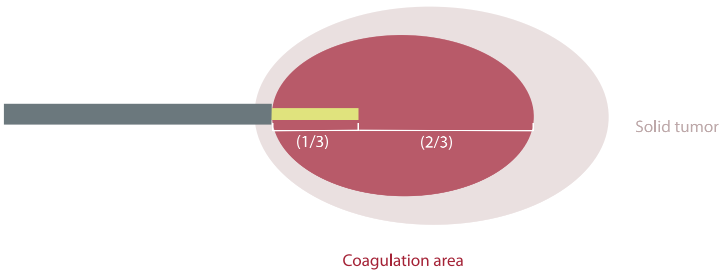
EchoLaser is the first and only laser system integrated with an ultrasound module and a dedicated planning and simulation system allowing ultrasound-guided micro-invasive Laser Ablation (LA) treatments for multiple clinical applications.

Laser Ablation (LA) is a micro-invasive procedure that uses the laser light for a few minutes to heat the tissue to be treated until irreversible in-situ damage occurs.

LA can be performed under ultrasound guidance for real-time monitoring of the correct positioning of the laser light applicators and the effective extension of damage generated in the tumour.

The laser light is conveyed from the source to the tissue through extremely flexible, small-gauge (300 µm in diameter) flat-tipped quartz optical fibers, introduced percutaneously by thin needles (21 gauge).

Laser emission through a flat-tipped fiber produces a lesion (coagulation area) with an ellipsoidal shape, located beyond the tip of the introducer needle.



EchoLaser allows:

Micro-invasive technique with fine needles

The technique with very fine needles (<0.8mm) is completely a-traumatic and very well tolerated by the patient, ensuring fewer complications and side effects, less risk of infection and bleeding, rapid recovery times and excellent aesthetic results without the need for anesthesia.

Real-time monitoring of the treatment

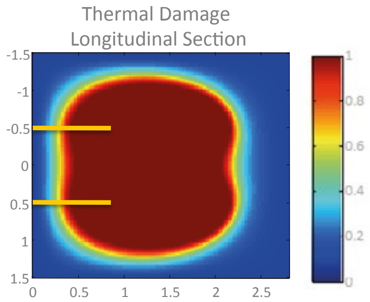
Ultrasound guidance enables real-time positioning of several needles in a safe and rapid manner, thereby reducing the operating times (with less stress for the patient, more economical treatments, and a greater number of treated patients).

Planning of the treatment

A dedicated pre-treatment Planning Software developed by Elesta allows the operator to choose, between the different treatment options, the most suitable and the safest one for each specific case and to check the correct position of the needle once inserted into the lesion.
A closed, oval shaped line representing the the safety distances to be maintained in order to spare anatomical structures which need to be preserved from the effect of thermal treatment aid the operator in the correct applicators positioning in the target tissue. Treatment parameters (number and spacing of fibers, energy dose to be delivered, number of pull-backs, etc.) are manually adjusted in order to obtain the best match between the volume of tissue to be treated and the safety distances to be assured. Once the match is achieved we obtain a set of parameters which help in performing an effective and safe treatment.

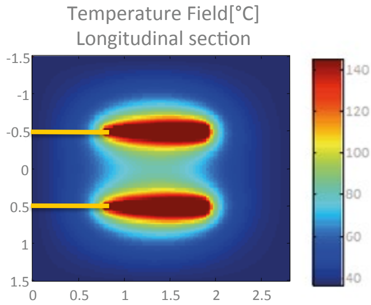
Mathematical model of the thermal lesion prediction

Elesta owns a mathematical model that allows to simulate both the thermal field and the thermal damage of the tissue according to the Arrhenius model. The model takes into account the optical (scattering and absorption coefficient) and thermal characteristics of tissue, the perfusion of the tissues and the formation of the vapor and cavity. Moreover, this allows to obtain the simulation of coagulation volume in presence of multi-fiber approach and pull-back.

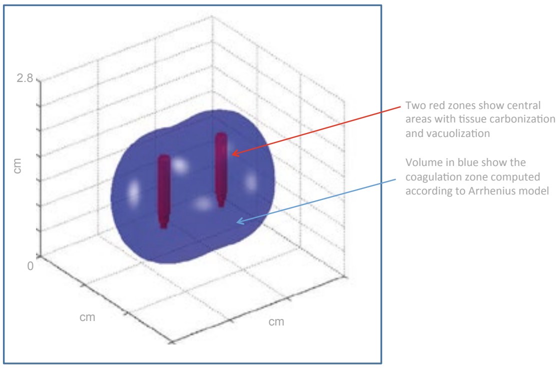


Evaluation of coagulation area in percentage of damaged tissue according to Arrhenius model (yellow lines represented fiber position).

Simulation Parameters
Tissue: liver
Tissue Temperature: 37°C
Perfusion: yes
Power: 3W
Energy: 1200J from each fiber



Temperature field in the longitudinal plane, which contains two fibers.



Versatility of the treatment

If required by the size or shape of the lesion to be treated, the multi-fiber approach, thanks to the multi-source laser, and the pull-back maneuver can be used giving versatility to EchoLaser treatment, in particular:

- Option of treating lesions with a very wide size range (<1 cm with one fiber and up to 5 cm with four fibers);
- Option of adapting the treatment to the shape and position of the lesion;
- Option of treating lesions in high risk position (due to close vicinity to vital structures);
- Positioning of the needles with less trauma for the organ, also with the possibility of multiple repositioning actions.

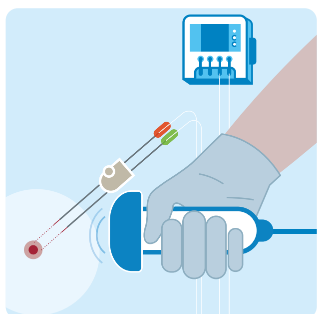
Advantages of EchoLaser

Thanks to these features, EchoLaser allows to carry out thermal ablation treatments in the field of the micro-invasive methods offering the possibility of treating lesions with a much broader size range.

- Thermal destruction of the lesion "in situ";
- Preservation of the organ and the healthy tissue;
- Micro-invasive approach (thanks to the extremely fine needles);
- No need for a general anaesthesia;
- Brief duration of treatment (few minutes);
- No or reduced post-op pain;
- No or reduced hospitalisation;
- Fast recovery times.

Compared to other ablative techniques, EchoLaser offers greater safety and effectiveness thanks to:

- The availability of a pre-treatment planning software;
- The use of finer needles;
- A lower dose of energy;
- A localised effect on the treated area with clearly defined borders.



MAIN APPLICATIONS

What are the applications of EchoLaser?

EchoLaser is suitable for echo-guided percutaneous laser ablation of soft tissues such as benign and malignant lesions in various organs.

The main applications of EchoLaser Thermal Ablation currently involve:
- Benign Thyroid Nodules (BTN) (ModìLite) and enlarged prostate volume due to BPH (SoracteLite), with the aim of producing a reduction in volume of the tissue due to the Laser Induced CytoReduction (LICR) process;
- Primary and secondary malignant liver lesions (PBLite) and localised low risk prostate and kidney cancer (SoracteLite) and papillary thyroid carcinoma (Modìlite) with the aim of tumour complete ablation with a sufficient safety margin.

Elesta is developing other EchoLaser Thermal Ablation applications on soft tissue lesions such as breast, lung and pancreas.

Elesta gives to each application procedure a dedicated name to differentiate the procedure performed with EchoLaser (micro-invasiveness and multi-fiber approach in a single system) from the other thermal ablation techniques.
Depending on the tissue, anatomical district, size and nature (benign or malignant) of the mass to be treated, the objectives of laser ablation treatment with EchoLaser can be the following:

- Determine a volumetric reduction of the target ablation tissue due to the cytoreduction process induced by laser ablation (LICR, acronym for Laser Induced CytoReduction) with consequent improvement or disappearance of the symptomatology. The ablation is carried out in an internal area of the mass in order to obtain an area of necrosis inside it that the body's natural process will eliminate in the weeks following the treatment. This objective is generally pursued in the case of benign pathology, such as benign thyroid nodule or prostate adenoma, but sometimes also in malignant pathologies when the ablation treatment is performed for palliative purposes;
- Produce a complete ablation of the mass with a sufficient safety margin in order to achieve its total destruction. This objective is pursued in case of malignant or even benign pathology when the anatomical conditions allow it.

MODÌLite

ModìLite is Elesta EchoLaser Thermal Ablation for treating lesions of the neck. Depending on the type of tumor, the performances of ModìLite are:
- Determine a volumetric reduction of benign thyroid nodules, due to the cytoreduction process induced by laser ablation (LICR, acronym for Laser Induced CytoReduction), with consequent improvement or disappearance of the symptomatology
- Produce a complete ablation of malignant neck tumours, with a sufficient safety margin in order to achieve its total destruction.


No scars

In the first case **ModìLite** is indicated for those who have one or more benign solid thyroid nodules which are large enough to create aesthetic damage or local compression symptoms, or for those who prefer not to undergo surgery or for those who, due to critical medical conditions, are not able to undergo surgery. **A single ModìLite treatment gives rise to a significant and persistent reduction in the volume of the benign thyroid nodule and reduces the local symptoms without any changes to the thyroid function.**

ADVANTAGES

- a reduction in the compressive symptoms and/or aesthetic damage - for benign applications
- "in situ" thermal destruction with a consequent reduction of nodule volume - for benign applications
- preservation of the healthy tissue and the organ function
- highly predictable and repeatable coagulation volume, as required in the small organs
- use of fine, a-traumatic needles for the neck structures
- possibility of treating patients with pace-makers (excellent electromagnetic compatibility)
- absence of general anaesthesia (thanks to the very fine needles not even local anaesthetic is necessary)
- short duration of the treatment (few minutes)
- absence of scars on the neck
- rapid recovery times
- life-long hormone replacement therapy not necessary
- no or insignificant post-treatment pain

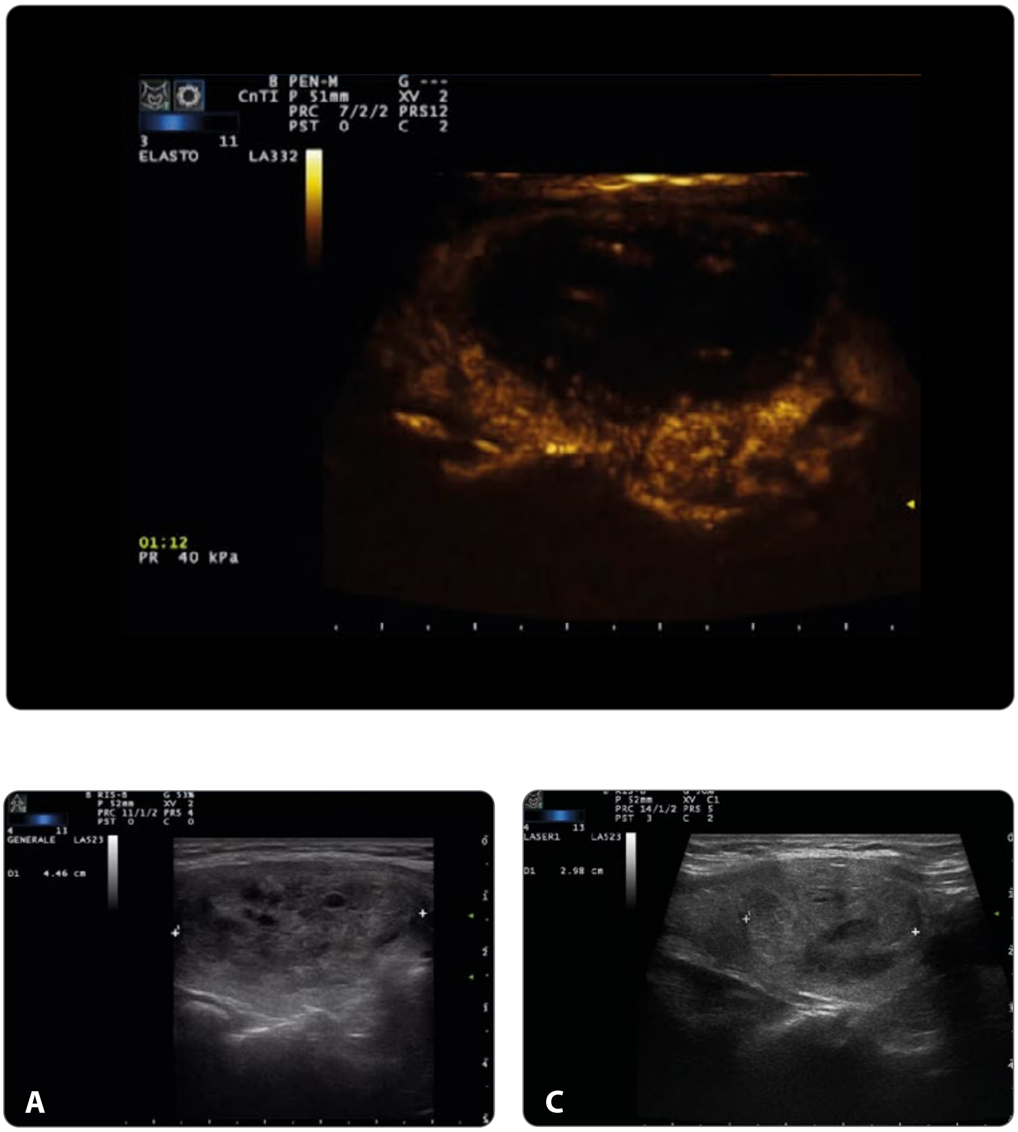


Figure 1: a) A solid isoechoic nodule (volume 20ml) in the right thyroid lobe before the treatment; b) Contrast-enhanced US images after the treatment shows the hypoechoic zone of the coagulation area; c) US image the two-year follow-up showed a reduction in the nodule volume equal to 70% compared to the basal volume. *Images by courtesy of Dr. Rago (Cisanello Hospital, Pisa).*

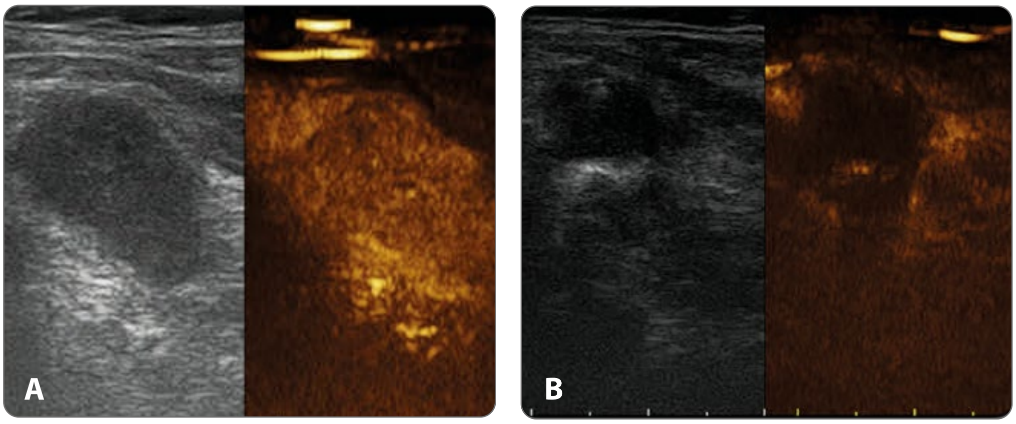
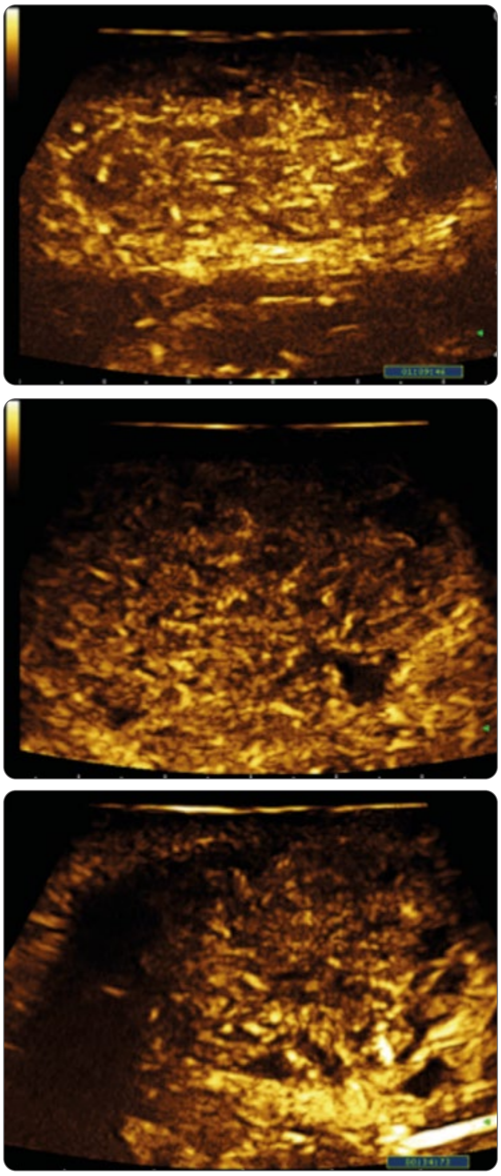


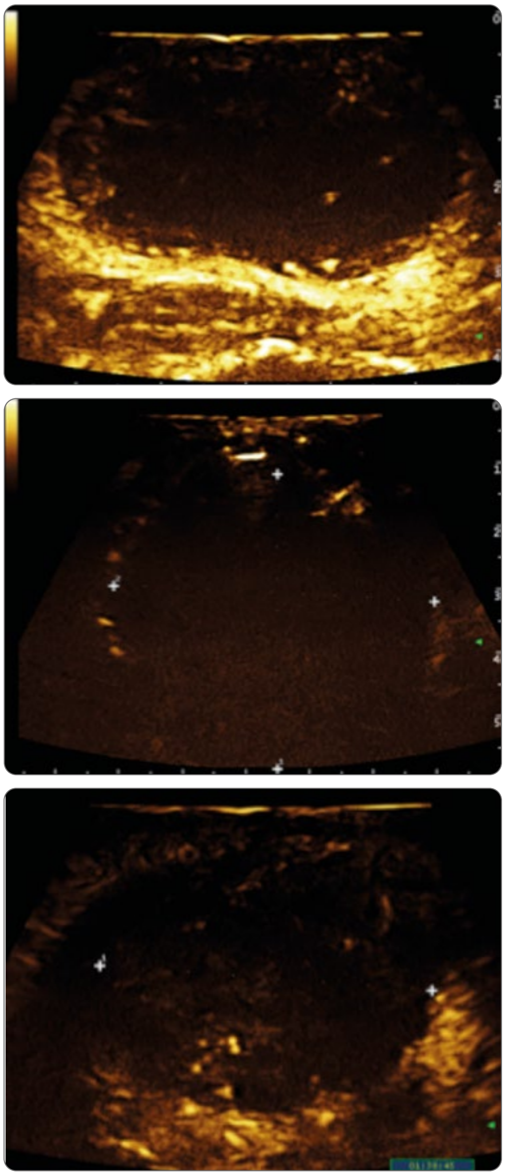
Figure 2: A metastatic lymph node from papillary thyroid carcinoma has been treated with EchoLaser Thermal Ablation with two fibers; a) CEUS image before the treatment showing the high absorption of the contrast of the pathological lymph node; b) CEUS image after the treatment showing the absence of enhancement. *Images by courtesy of Dr. Mauri (IEO, Milan).*

ModìLite, thanks to multi-fiber approach and pull-back maneuver, allows to treat big nodules (Volume >30 ml) in a relative fast time.

CEUS Image Pre-treatment



CEUS Image Post-treatment



A publication about this consideration on big nodules is "A comparison of laser with radiofrequency ablation for the treatment of benign thyroid nodules: a propensity score matching analysis", Pacella CM et al, International Journal of Hyperthermia, 2017.

For more details about the ModìLite procedure, LICR of benign thyroid nodules, please visit the website: **www.modilite.info.**

ModìLite is also effective for malignant neck lesions such as metastatic lymph nodes. With this application, the treatment is radical, obtaining complete ablation of the lesion (Figure 2).

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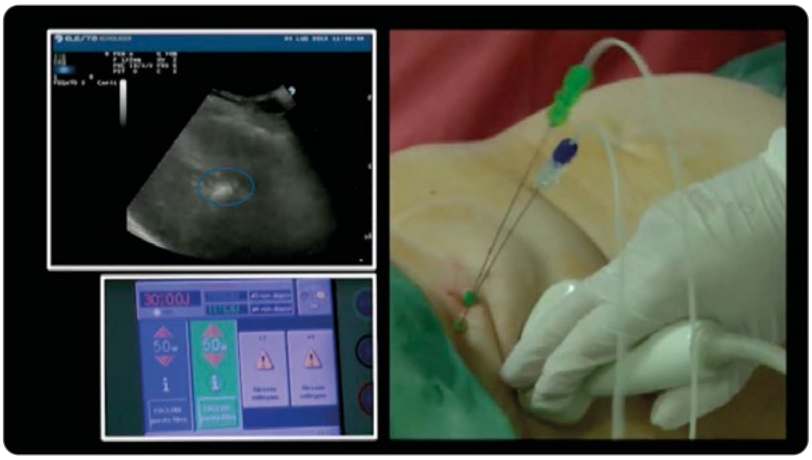
PBLite

PBLite is Elesta EchoLaser Thermal Ablation to treat primary and secondary malignant liver tumors in the form of focal lesions. **PBLite** is also a safe and effective treatment of those who, due to critical medical conditions, are not able to undergo surgery. **With just one PBLite session it is possible to treat liver lesions with a very wide size range and diameters of up to 5 cm thanks to the versatility offered by the multi-fiber approach. The localised thermal effect of PBLite makes it the gold standard for liver lesions close to structures at risk.**

ADVANTAGES

- complete ablation with a sufficient safety margin
- "in situ" thermal destruction
- preservation of the healthy tissue and the organ function
- highly predictable and repeatable coagulation volume as required for the safety margin
- localized thermal effect in the target volume only, which makes the treatment possible close to sites at risk
- use of fine, a-traumatic needles for liver organ
- possibility of treating patients with pace-makers (excellent electromagnetic compatibility)
- absence of general anesthesia
- short duration of the treatment (few minutes)
- rapid recovery times
- no or insignificant post-treatment pain
- brief hospitalization
- bridging therapy for organ transplants



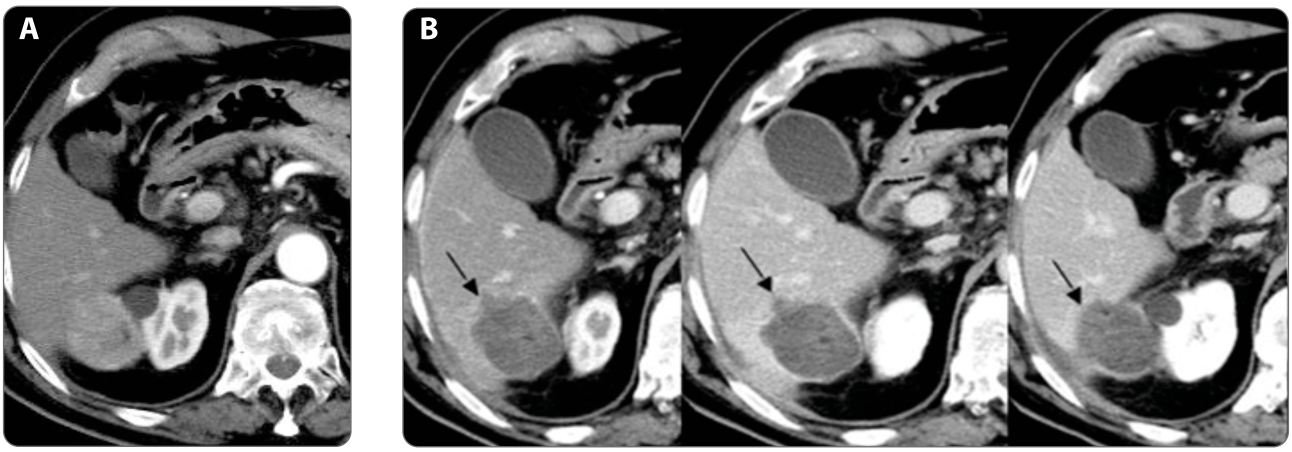


Figure 3: a) Hepatocellular nodule adjacent to the right kidney with extrahepatic growth in lesion (4.5-cm-diameter) was completely destroyed in a single session with four fibers, two pull-back and three applications. b) Post-treatment CT images show a large hypo attenuating coagulation zone.

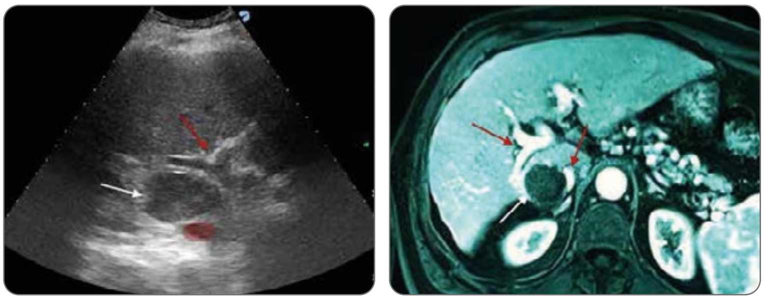


Figure 4: a) a partially exophytic HCC (white arrow), located between a branch of the portal vein and the vena cava, was completely ablated without any alterations to the surrounding vascular structures; b) MR image at one-month follow-up showing complete ablation (white arrow). *Images by courtesy of Dr. Giovan Giuseppe Di Costanzo (Cardarelli Hospital, Naples).*

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SORACTELite

SoracteLite is Elesta EchoLaser Thermal Ablation for treating benign and malignant urological pathologies, namely **Benign Prostatic Hyperplasia** (BPH), low-risk localized **Prostate Cancer** (PCa) and **Kidney Cancer**.

Depending on the type of lesion, the performances of SoracteLite are:

- Determine a volumetric reduction of the enlarged prostate, due to the cytoreduction process induced by laser ablation (LICR, acronym for Laser Induced CytoReduction), with consequent improvement or disappearance of the symptomatology;
- Produce a complete ablation of malignant tumours (Prostate Cancer or Kidney Cancer), with a sufficient safety margin in order to achieve its total destruction.

Benign Prostatic Hyperplasia

If addressed to benign clinical applications (BPH), SoracteLite allows in a single treatment session, a significant and persistent reduction of the prostatic gland volume and a gradual and steady relief from local symptoms, without changing the prostate physiology.

Moreover, **SoracteLite** represents true innovation for BPH treatment. Its mode of action is completely different from other laser used in urology (mostly surgical ones); in facts, it differs in wavelength and power (EchoLaser employs 1064 nm wavelength and extremely low powers, 3-5 W), its mode of action, and lastly and most importantly **SoracteLite** is performed in a truly micro-invasive approach (transperineal vs transurethral) with extremely thin introducer needles (21G).

SoracteLite treatment for BPH consists in the percutaneous insertion of optical fibres (one or two fibres per lobe, depending on the basal volume of the prostate gland) via transperineal access, and the delivery of laser energy for few minutes, which heats the tissues until they are destroyed. This causes a progressive reduction in the volume of the prostate lobe and the subsequent disappearance of the symptoms. The planning of the treatment, the insertion of the needles and the monitoring are all carried out under ultrasound guidance.

ADVANTAGES

- gradual and steady relief from symptoms
- "in situ" thermal damage with consequent reduction of the prostatic lobe
- use of fine, a-traumatic needles with transperineal approach
- preservation of the healthy tissue and the organ function
- highly predictable and repeatable coagulation volumes
- absence of general anaesthesia
- short duration of the treatment (few minutes)
- rapid recovery times
- no or insignificant post-treatment pain
- absence of erectile dysfunction or complications linked to the reproductive organs

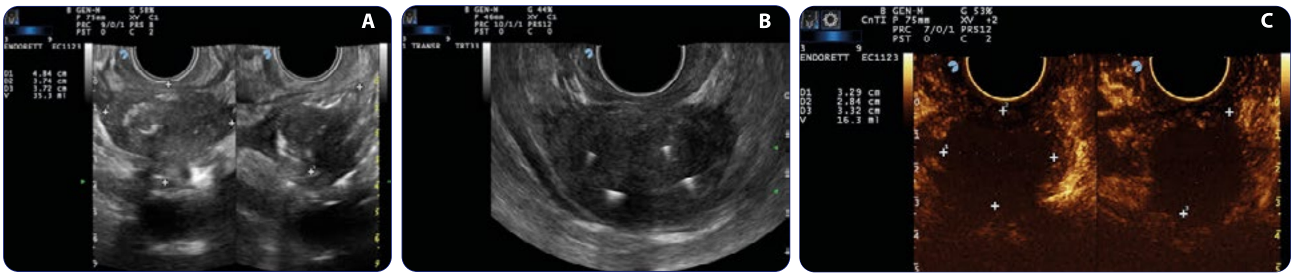

Figure 5: a) Basal transrectal ultrasound. The prostate has a volume of approximately 35 cc with an inhomogeneous echostructure in the adenomatous base; b) The transversal scan of the prostate shows the optical fibres inserted; c) Final transrectal ultrasound with echo-amplifying contrast medium (SonoVue). The avascularised hypoechogenic area measures approximately 16 cc (about 46% of the initial prostatic volume).
Images by courtesy of Dr Gianluigi Patelli (Pesenti Fenaroli Hospital, Alzano Lombardo).

For more details about the SoracteLite procedure, please visit the website: **www.soractelite.info.**

ELESTA
Beyond Laser

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Prostate Cancer

The gold standard treatments for patients with low/Intermediate risk tumours prostate cancer are surgery or radiotherapy, but the side effects of the treatment and possible patient comorbidities might hamper patients to allow these kind of approaches. In such cases, as stated by the Guidelines on Prostate Cancer issued by medical associations in the USA and Europe, Focal Therapy may be a therapeutic option to offer to those patients, preferably recommended within a clinical trial setting. Among the available Focal Therapies, SoracteLite Transperineal Laser Ablation (TPLA) is a new Focal Laser Ablation (FLA) method that can destroy the lesion without causing the undesired side effects of radical therapies.

The treatment consists in the percutaneous insertion of optical fibres via transperineal access under MRI-US Fusion Imaging guidance, and the delivery of laser energy for few minutes to heat the tissues until they are completely destroyed with a sufficient safety margin. The treatment is carried out with the use of needle guiding systems for the positioning of the applicators in the lesion, allowing to treat only the cancerous tissue, thus sparing the remaining healthy prostate.

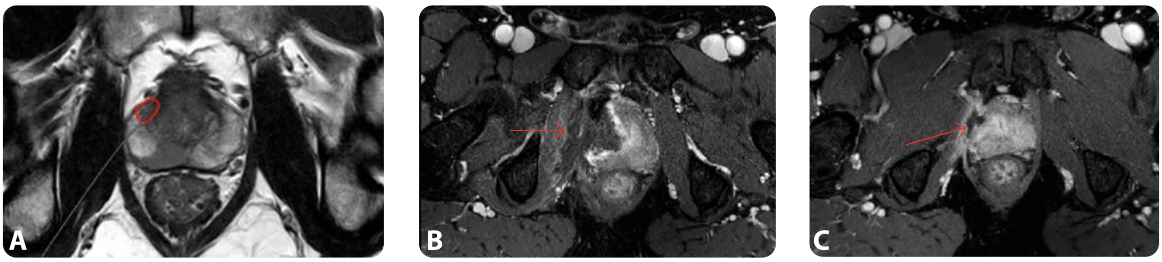

Figure 6: Patient with a non-advanced localized tumor (3 + 3 Gleason score) in the upper right aspect of the prostate with a dimension of 17.5x8.5x4.8 mm was treated with focal laser ablation. a) Target areas with altered MRI signal with suspicion for localized tumor before biopsy. Biopsy confirmed the cancerous lesion and the patient was treated with laser ablation. b) The axial MRI scan shows a large area of coagulative necrosis surrounded by a ring of hyperaemia 24 hours after laser ablation without complications. c) The axial MRI scan at 8 months after ablation shows a marked reduction of the induced necrotic area. Biopsies at 8 months after treatment were negative. *Images by courtesy of Dr. Stefano Regusci and Dr. Martina Martins (ImageRive La Colline, Geneva)*

ADVANTAGES

- gradual and steady relief from symptoms
- “in situ” thermal damage
- use of fine, a-traumatic needles with transperineal approach
- absence of general anaesthesia
- short duration of the treatment (few minutes)
- rapid recovery times
- no or insignificant post-treatment pain
- absence of erectile dysfunction or complications linked to the reproductive organs

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Kidney Cancer

As reported in the Guidelines issued by US and European urological associations, thermal ablative therapies have already been investigated as a possible alternative to surgery for the treatment of small and localized renal tumors (<4cm), with promising clinical results. This kind of approach is particularly suitable for patients at high surgical risk or with impaired renal function. In the field of minimally invasive therapies, SoracteLite applicators are considerably thinner than those used for radiofrequency ablation (RFA), microwave ablation (MWA) and cryoablation (CRA) devices currently on the market, ensuring an even less invasive approach, a key feature for patients at high risk of complications due to the presence of comorbidity (e.g. high risk of bleeding) or difficulty in technical access.

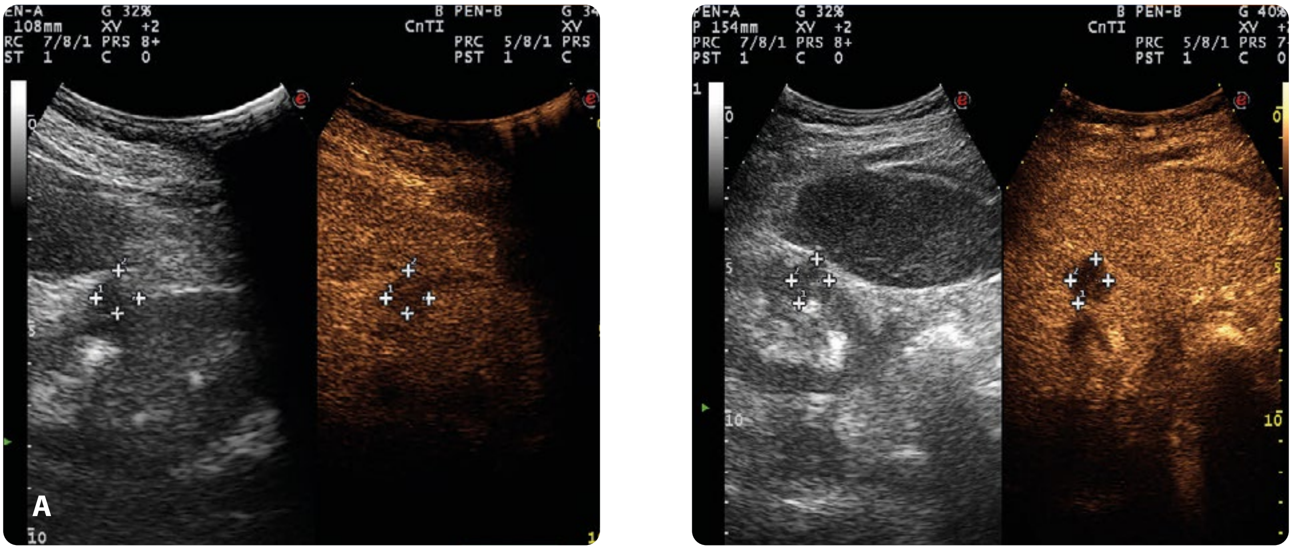

Figure 7: a) patient with 10 mm tumor treated with two fibres b) 1 day follow-up showed that the nodule was perfectly ablated

Images by courtesy of Dr. Sartori (Ospedale S.Anna, Ferrara).

ADVANTAGES

- "in situ" thermal damage
- preservation of the healthy tissue and the organ function
- use of fine, a-traumatic needles with transperineal approach
- absence of general anaesthesia
- short duration of the treatment (few minutes)
- rapid recovery times
- no or insignificant post-treatment pain

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OTHER APPLICATIONS

1. Breast

Malignant breast cancer has been the subject of many studies of the minimally invasive ablative techniques since the 90s (there are reviews about laser ablation, RF ablation, microwave ablation, cryoablation and HIFU on the breast).
AgathaLite is Elesta EchoLaser Thermal Ablation for treating breast lesions. By the time the application is only adopted in Reference Centres. AgathaLite has not yet been commercially launched.

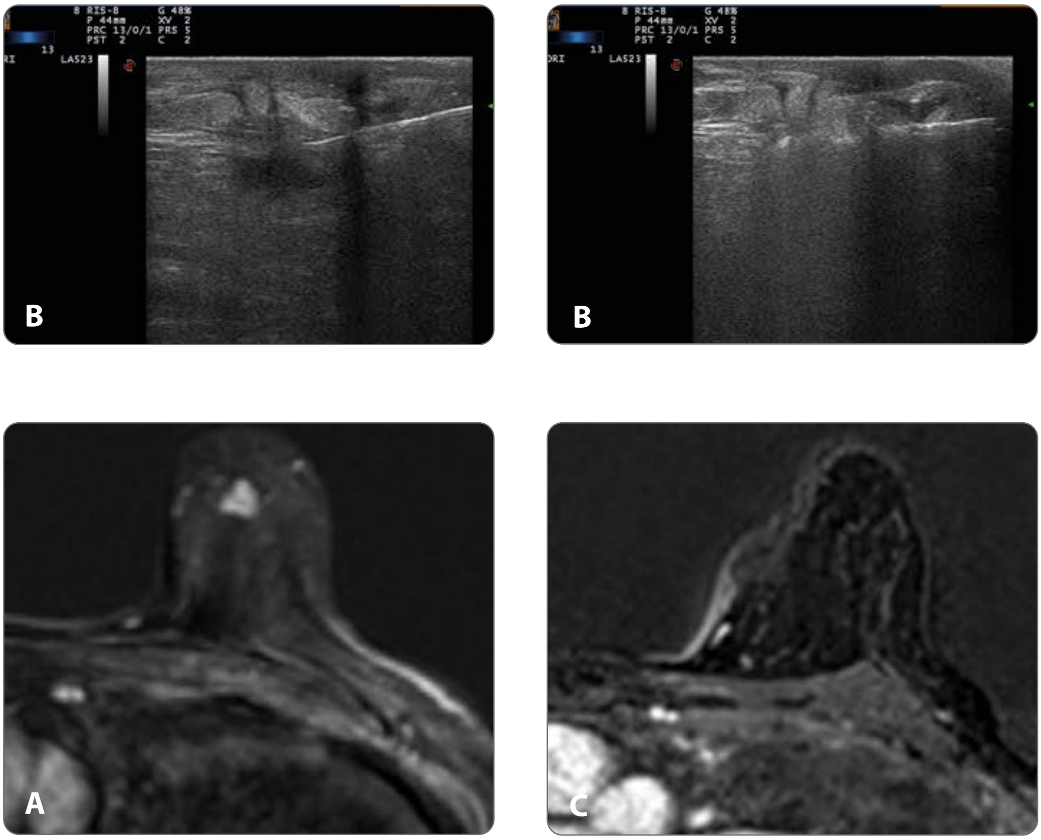

Figure 8 a) MRI image of a infiltrant tumour in the Upper Outer quadrant of right breast that was treated with EchoLaser Thermal Ablation; b) Us image of needle insertion in the breast tumour and end of laser treatment; c) MRI image performed 12 months after the treatment showed no impregnation in treated area corresponding to complete ablation.
Images by courtesy of Dr. Jacopo Nori (Careggi Hospital, Florence).

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2. Lung

Percutaneous laser ablation may be useful for treating patients with primary or secondary lung tumors and its endpoint is the complete ablation of the lesion with a sufficient safety margin. Only the superficial lesion in the lung can be treated under ultrasound guidance, so the best image guidance for this application is Computed Tomography.

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3. Endoscopic application

In this case the approach is not percutaneous but endoscopic: the optical fiber reaches the tumour from an echo endoscope and a flexible needle is introduced. This approach allows to treat lesions in a critical position (i.e., lesions in the posterior part of the liver near the stomach), which are difficult to reach by conventional methods.

Figure 9 Laser ablation of an HCC lesion in liver through an Endoscopic access and ultrasound guidance. (Courtesy of Dr. Francesco Di Matteo, Campus Biomedico, Rome)

The endoscopic approach can be used also for ablating primary pancreatic tumours. For this application, ex-vivo experiments have been performed on porcine pancreas, followed by chronic animal testing in order to assess the survival of the animal, and a study protocol on humans has been approved by the Ethics Committee (EC). The endpoint is to evaluate the feasibility of laser ablation in unresectable pancreatic tumours. Five patients have already been treated with excellent results.

Another endoscopic application is biliopancreatic-tract cancer. With the current practice, stents are inserted to remove or prevent the obstruction of the bile ducts, however this does not stop the tumour from growing and it progresses and finally incorporates the stent itself. With Endoscopic laser ablation it would be possible to reduce or destroy the tumour causing the obstruction and then insert the stent to stop or delay re-growth of the tumour.

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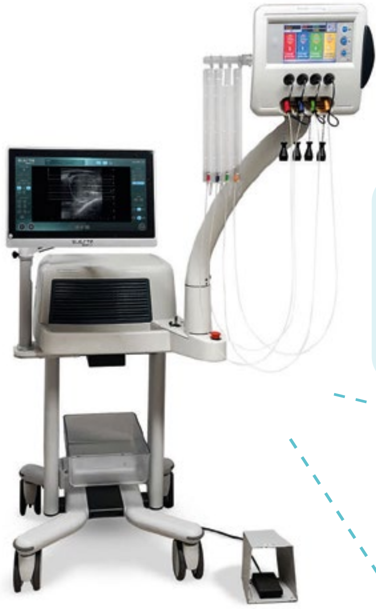
Products offering to perform EchoLaser thermal ablation treatments on soft tissues

ECHO·LASER > EVO

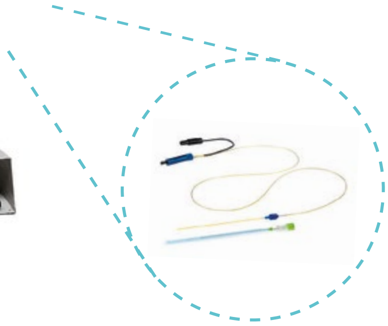
EchoLaser EVO offers options for integrating in a single system all the components needed to perform Laser Thermal Ablation procedures on soft tissues in a safe, predictable and reproducible way. It is in fact a system composed by a multi-source laser module for the delivering of laser radiation and a dedicated smart interface which can be paired with the majority of ultrasound (US) systems available on the market for the planning, realtime guidance and verification of the treatment.



ECHOLASER X4 – a 1064 nm solid state 4-channels laser module for the delivery of laser radiation.

Echolaser Smart Interface (ESI) a dedicated device connected with the video output of the US system, for real-time user assistance in performing the procedure.

ESI Licenses – Dedicated software licenses for the planning and monitoring of the treatment in different clinical applications.



Disposable fiber optics kit (fiber optic + introducer needle) for laser light transmission from the laser source to the tissue to be treated.

Dedicated multi-needle guiding systems that can be mounted on the US probes to aid the user in the fine positioning of the introducer needles.

With the Echolaser Smart Interface (ESI) we redefined the approach to soft tissue ablation

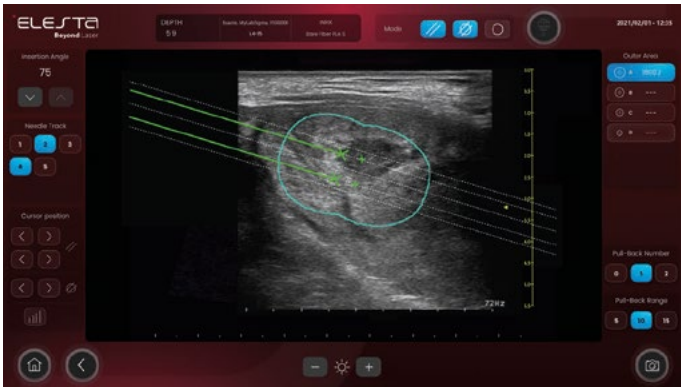
ESI is a medical device which provide a real-time reproduction of the video image supplied by selected ultrasound devices, overlapping on the US image graphic signs, indicating the trajectory of the introducer needles and the safety distances to maintain from the anatomical structures not intended to be treated, which can be used to improve needle positioning for the laser treatment procedure.

Pre-treatment planning with enhanced lesion targeting

Dedicated pre-treatment planning software aids the operator in determining the most suitable treatment options for each specific clinical case and treatment endpoint: Laser Induced Cyto Reduction (LICR) to address benign lesions or complete necrosis for the treatment of malignant lesions.

LICR applications – Benign lesions

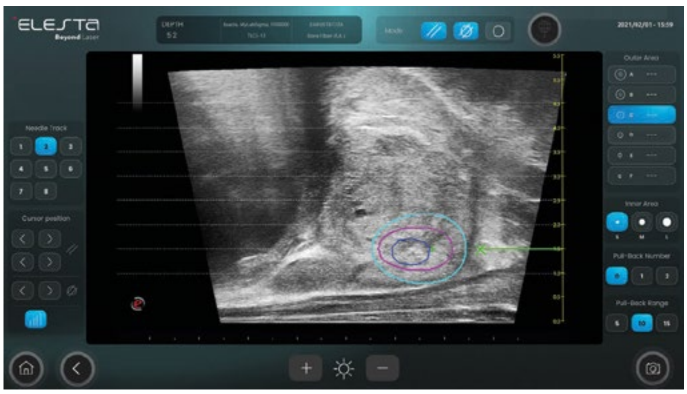
The aim of the treatment is to reduce the amount of excess tissue in benign lesions, i.e. Benign Thyroid Nodules (BTN) or Benign Prostatic Hyperplasia (BPH). In such applications ESI software allows the operator to set treatment parameters (needle insertion angle, number and spacing of fibers, pullback etc.), reproducing in real-time needles insertion trajectories and a closed perimeter, representing the safety distances to be maintained in order to spare anatomical structures which need to be preserved from the effect of thermal treatment. The correct treatment planning is achieved by enlarging the displayed perimeter as much as possible, without exiting the lump or including anatomical structures not intended to be treated.



Example of correct pre-treatment planning for benign lesions (e.g. BTN)

Complete necrosis applications – Malignant lesions

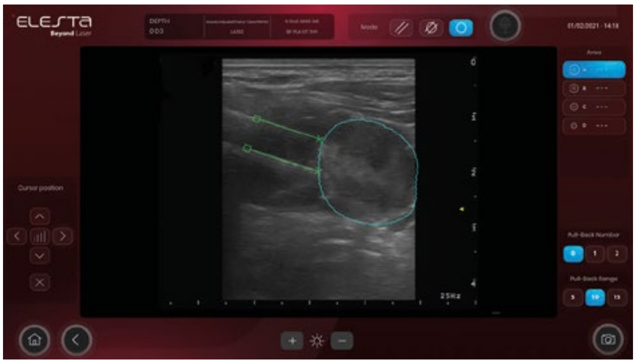
The aim of the treatment is the complete necrosis of the tissue.
In such applications ESI software adds to the tools provided for the planning of LICR treatments, an additional inner area useful to center the target lesion as a viewfinder for the fine positioning of the introducer needles.
The correct treatment planning is achieved by including in the inner area the targeted tumour itself plus the desired extra ablation area (safety margin), while respecting the distances from critical anatomical structures. If one of these conditions is not satisfied, needle repositioning should be considered.



Example of correct pre-treatment planning for malignant lesions (e.g. low-risk localized PCa)

Planning verification

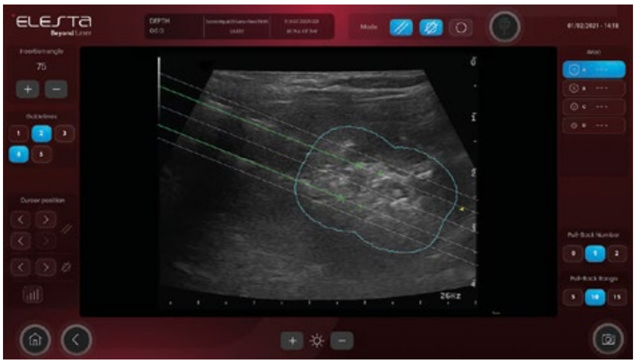
This feature allows the physician to verify needles placement in the target tissue. It is a useful tool to double check the real applicators positioning before starting the ablation procedures.



Verification of needle positioning for the treatment of a BTN

Real-time visual support

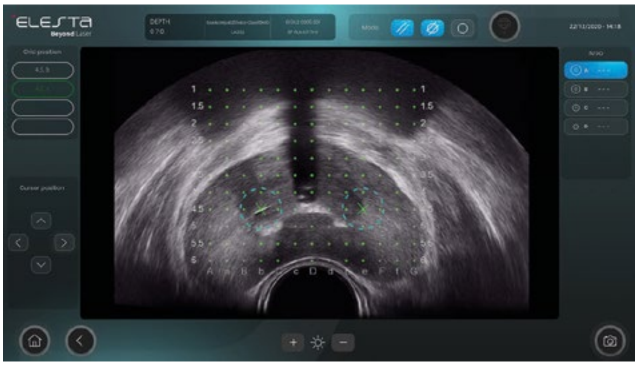
The US image provided by the monitoring system is replicated in real-time on ESI, allowing the user to have a visual feedback throughout the treatment.



Treatment area monitoring during energy delivery

Template grid coupling

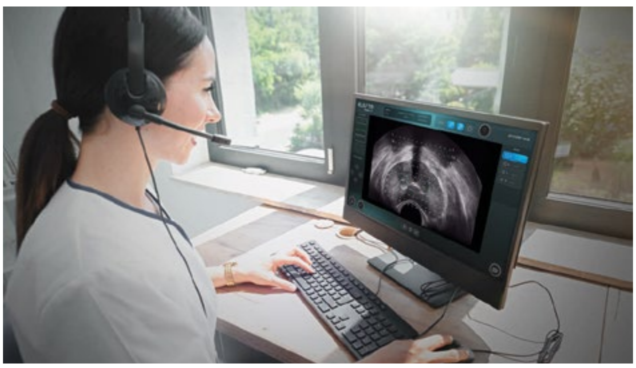
Dedicated software for BPH and PCa procedures shows needles insertion points available using biplanar ultrasound probes template grids. The operator can thus place multiple applicators inside the prostate lobes, easily reaching the optimal position to perform the thermal treatment.



Needle positioning in the prostate lobes using the template grid

Remote assistance

The operator can activate the remote control modality to share in real-time the Echolaser Smart Interface screen with experienced colleagues, to share and discuss the planning of the thermal ablation procedure during new users' learning phase or to seek expert advice for complex clinical cases. This modality can also be used for technical remote support from Elesta application specialists.



Remote support in performing planning phases of the thermal ablation treatment

ECHO·LASER > EVO

Sigma & Omega Systems

EchoLaser EVO is also available for the integration with Esaote MyLab Sigma and Omega US devices. This configuration allow the option of having an integrated and compact system which couple US and ESI features to perform Laser Ablation (LA) procedures.

EchoLaser EVO OMEGA/SIGMA System

ECHO·LASER Systems

EchoLaser Systems are available thanks to the integration of the laser module with customized Esaote US machines, providing a fully operational system to perform real-time monitoring, planning and execution of Laser Thermal Ablation treatments through dedicated planning software embedded in the US machine*.

EchoLaser 9/9eXP

*Pre-treatment planning for malignant lesions and Remote Assistance functionalities are not supported on EchoLaser Systems embedded planning software. The availability of these functionalities is provided by coupling the EchoLaser Smart Interface with EchoLaser Systems.

Select the system configuration which better fits your needs

A wide range of available system configurations allow the selection of different possible combinations, depending on the clinical application the user wish to address.

MODÌLite

- Benign Thyroid Nodules (BTNs)
- Papillary Thyroid Carcinoma (PTC)

SORACTELite

- Benign Prostatic Hyperplasia (BPH)
- Prostate Cancer (PCa)
- Kidney Cancer (RCC)

PBLite

- Hepatocellular Carcinoma (HCC)
- Liver Metastases (LM)

Clinical application / EchoLaser configuration	BTNs	PTC	BPH	PCa	RCC	HCC	LM
Echolaser 9 eXP with fusion imaging + ESI (supporting pre-treatment planning for malignant lesions)	●	●	●	★	★	★	★
EchoLaser 9 eXP + ESI (supporting pre-tratment planning for malignant lesions)	●	●	●	●	★	●	●
EchoLaser 9 + ESI (supporting pre-tratment planning for malignant lesions)	●	★	●	●	●	●	●
EchoLaser 9 System	★	●	★	●	●	●	●
EchoLaser EVO (to be coupled with US system)	★	★	★	●	●	●	●
EchoLaser EVO (to be coupled with US system supporting fusion imaging)	●	●	●	●	●	●	●
EchoLaser EVO Omega System	●	★	●	●	●	●	●
EchoLaser EVO Sigma System	★	●	★	●	●	●	●

★ Suggested configuration

● Available configuration

ELESTA
Beyond Laser

Follow us on

Elesta SpA

Via Baldanzese,17
50041 Calenzano (FI) Italy

T +39 055 8826807
F +39 055 7766698
E info@elesta-echolaser.com
W www.elesta-echolaser.com

Organization with a certified Quality Management System Certificate Nr. 50 100 15712

Exclusive Distributor for Lombardia and Triveneto

sunmedical

SUNMEDICAL S.r.l.
Via Modigliani, 45
20054 Segrate (MI) - Italy
T +39 02 87282900
F +39 02 87282910
E info@sunmedical.it
W www.sunmedical.it

Specifications subject to change without notice.

ECHOLASER X4 is FDA approved for Soft Tissue Ablation
This brochure is not intended for USA.