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FOX LÁSER MICROSEGUNDO

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WARNING

For your own safety follow all guidelines for handling the equipment and follow the safety instructions in this manual.

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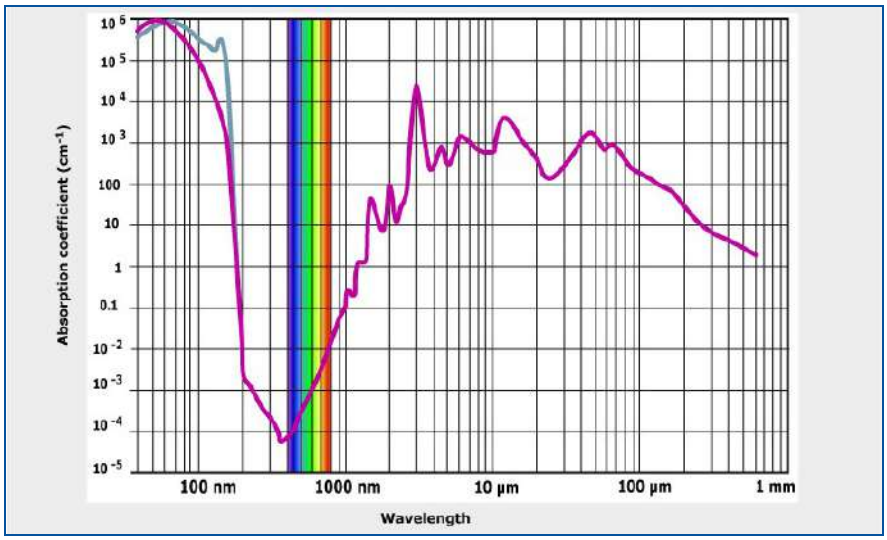
CONTENT

1) Laser safety

Laser radiation emitted by the FOX laser can cause severe damage to the patient as well as to the user and third persons accompanying the laser use. The FOX laser is classified in the laser class IV. This means that the radiation can cause damage when it is directly applied to any tissue and also if the radiation is scattered or reflected.

The FOX laser radiation is intense and efficient to coagulate and evaporate tissue. The most serious injuries occur, when laser radiation is exposed to the eye. Even low laser power is able to damage the retina of the eye, which is not reversible. This may cause permanent blindness. The danger depends on the wavelength of the radiation and on the dose (energy density per time).



Water absorption

Laser radiation in the wavelength range between 400 and 1400 nm is most dangerous for the eye. The cornea as well as the anterior chamber, the lens and the vitreous body of the eye contain mainly water. The other tissue components (mainly collagen) play a minor role for the laser tissue interaction. Between 400 and 1400 nm wavelength water has very low absorption. Therefore the laser radiation is transmitted very well and nearly the full power reaches the retina, where it is absorbed by the blood and the retinal pigment ephithelium.

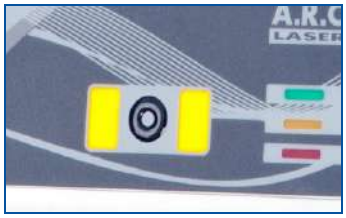
The FOX laser emits infrared laser radiation, therefore it is absolutely necessary to wear eye safety goggles when using the FOX laser system. For the combined use with the microscope, the microscope has to be equipped with an eye protection filter, than the surgeon can work without eye goggles.

With its intensity (e. g. focused beam), the Fox laser radiation can also do harm to skin or other tissue. The radiation can light up inflammable material.

Safety instructions

To avoid any injuries it is important to follow the laser safety instructions:

1. Any user of the Fox laser system has to be trained by A.R.C. Laser authorized personal or by someone trained by A.R.C. Laser authorized personal.
2. The room / the area, where the laser system is used has to be signed with the laser warning symbols in a way that everyone can easily see that there is a laser area, which should not be entered without the adequate protection while the laser is in use.
3. Do not use the system whenever you are not sure that every component works in the dedicated way. Keep an eye on the fiber delivery: The spot shown by the aiming beam should always be round and defined, no scattering should occur. You may test this by using a light paper and holding an endo probe (HS01001 / LL13009s), a hand piece for cyclophotocoagulation (LL11025s), a diopexy probe (LL13012s) or a bare fiber end (e. g. LL13001s) in a distance of about 5 cm (you have to put the laser on Ready mode / laser safety goggles!).
4. Whenever the laser is on Ready mode (2 yellow Ready-LEDs on) every person within the area where radiation from the laser can occur (laser treatment area / laser room) has to wear laser safety goggles which is suitable to protect the eyes from FOX laser radiation.



Ready-LEDs

5. The laser has to be used only for the defined application; never irradiate any other material / tissue beside the intended use.
6. Special care should be taken to avoid irradiating reflecting materials. Reflected laser radiation can cause the same harm as direct application.
7. Switch off the Ready mode of the laser when the laser is not in use; e. g. during operation breaks or at the end of the surgery.

2) Basics of laser application

The intended effect of the laser application is based on the interaction of the radiation with the tissue components. The laser radiation is absorbed, scattered or reflected by the tissue. Air has only little influence on the FOX radiation and therefore the interaction between air and the FOX radiation can be neglected. Reflection plays a major role with metal, glass and other reflecting surfaces.

When we apply the FOX radiation to tissue the reflection is not dominant. Nevertheless it is not zero! When the radiation is scattered in the tissue, it does not influence the absorption. Absorption is mainly responsible for the efficiency of the laser radiation. Absorption means that the FOX laser radiation is converted mainly into heat, which causes the desired effects (coagulation / vaporisation).

With low energy density (big laser spot or low power) the heat which is achieved in the tissue can cause heating of the tissue. The smaller the spot size is, or the higher the power is set, the warmer it gets. There is a limit, when the tissue does no longer tolerate the heating, tissue proteins denaturate, coagulation occurs. The next limit is achieved when tissue water (intra- and extracellular water) suddenly evaporates (> 300° C). Tissue is fragmented and destroyed. Cutting / evaporation is achieved.

Temperature effect	
Temperature	**Effect**
> 40° C	enzyme induction, membrane disaggregation, edema
45° – 65° C	tissue damage, reversible or irreversible, dependent on the irradiation time
> 65° C	coagulation
> 100° C	dehydration
> 150° C	carbonisation
> 300° C	vaporisation, ablation (removal of tissue)
some 1000° C	ionisation, immediate burn (shock wave formation)

Tissue cutting always needs high energy densities (high power or small spot size). At the cutting edges, respectively beside the evaporation zones the tissue is always affected by the heat (coagulation). The positive effect and advantage of the laser use is that this can stop bleeding from cut vessels (haemostasis). The negative effect is caused directly at the cutting edge where more than 150° C occur. There is a development of carbonization, created by burned carbon, which is toxic and prolongs the healing of the wound.

To avoid extended collateral damage (carbonisation and coagulation) at the cutting edges the application mode of the laser can be modified to a pulsed mode, which causes less damage.

In continuous mode the laser permanently emits radiation. In pulse mode the tissue can cool down between each laser pulse and therefore the side effects of the heating can be reduced.

3) Application

Indications / Contraindications

Retina by endocoagulation	
indications	**contraindications**
· securing pre-exiting retinal breaks · iatrogenically produced retinal breaks · retinotomies · panretinal photocoagulation · coagulation of bleeding retinal surface neovascularization	· existing decreased transparency of the optics (e.g. cataract, cloudy vitreous) · direct application to the macula (beam size too big)

Retinal coagulation with diopexy probe	
indications	**contraindications**
· premature retinal coagulation	· existing decreased transparency of the optics (e.g. cataract, cloudy vitreous)

Glaucoma (Cyclophotocoagulation)	
indications	**contraindications**
· treatment of non responders to medication and pre-surgical failures · non compliance patients with uncontrolled IOP (after ALT/ SLT) · medication allergic patients (after ALT/ SLT) · treatment of non responders to medication and bad surgical prognosis	· initial treatment · medically well controlled IOP · low pressure glaucoma disease

Lacrimal surgery and DCR	
indications	**contraindications**
· endoscopic surgery · surgery with local anaesthetics	· existing scar blocking the lacrimal chanel · anatomy not allowing fiber or endoscope passage

Technique

For the use of the FOX laser, the laser has to be equipped with a laser fiber. The fibers have a fiber plug on one side, which has to be inserted into the fiber coupler of the FOX laser.

Pre-treatment tests

The FOX laser does an automatic internal testing on the power output before the device can be used. Keep an eye on the system components. Especially take a look on the fiber delivery: The spot shown by the aiming beam should always be round and defined, no scattering should occur. You may test this by using a light paper and holding an endo probe (HS01001 / LL13009s), a hand piece for cyclophotocoagulation (HS11025s), a diopexy probe (LL13012s) or a bare fiber end (LL13001s or LL13003s) in a distance of about 5 cm (you have to put the laser on Ready mode). When doing this, be aware to wear safety goggles.

Treatments

Therapy indications

This chapter gives detailed information on the laser applications. Of course, this chapter cannot compensate for intensive studies of appropriate literature, personal experiences and critical consideration of facts. Nevertheless, this should help every "beginner" as well as each one who is not working on a regular base with the laser. The following indications are average values – no guidelines! They are based on the fundamental experiences of several medical doctors, who are using our lasers every day. Despite all caution from our side, each medical doctor needs to set their parameters individually, observing the indication and the patient to be treated. Changing the parameters may possibly require a change of other settings. Neither author nor manufacturer is liable for treatment failures.

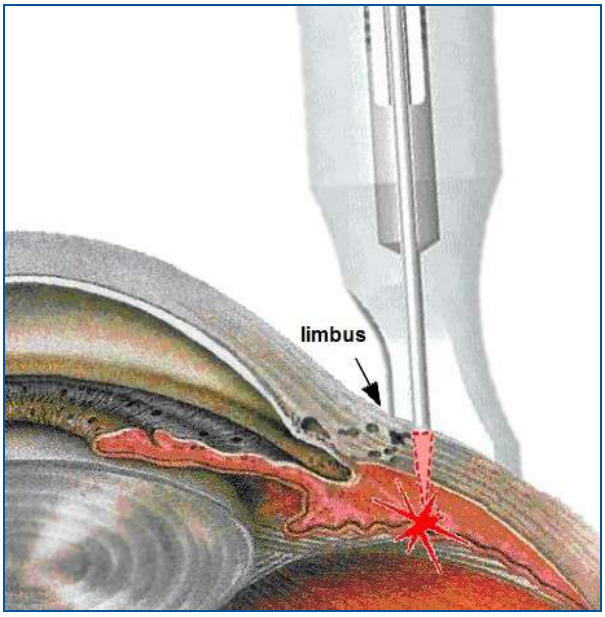
Cyclophotocoagulation

For glaucoma surgery (cyclophotocoagulation), the laser has to be equipped with the hand piece HS11025s.

Cyclophotocoagulation thru the sclera with the Fox aims to the cells of the ciliary body to reduce the production of intra ocular fluid which is achieved by coagulation at a wavelength of 810 nm.

The ciliary body should not be fully coagulated to avoid hypotony.

The temperature for coagulation is delivered by a fiber optic and therefore the spot is sharply focused. To achieve a proper treatment and to reduce the intra ocular pressure, one has to apply multiple coagulation spots. The hand piece needs to be placed properly at the limbus with light pressure to aim and target the cells.



Treatment parameter:

- The max. output power to be chosen is 2.5 Watt at 2 sec. per coagulation spot. [1]
- The average parameter is 2 Watt at 2 sec. [2]
- To reduce the effect, a power lower 2 Watt can be selected, or if the sclera is thinned out at the place of coagulation or a small eye needs to be treated, the power may be reduced to the above mentioned value.
- An average of 20 coagulation spots may be applied (on the total circumference max. 25 spots). A higher number of pulses may even increase the effect of pressure drop in the eye.

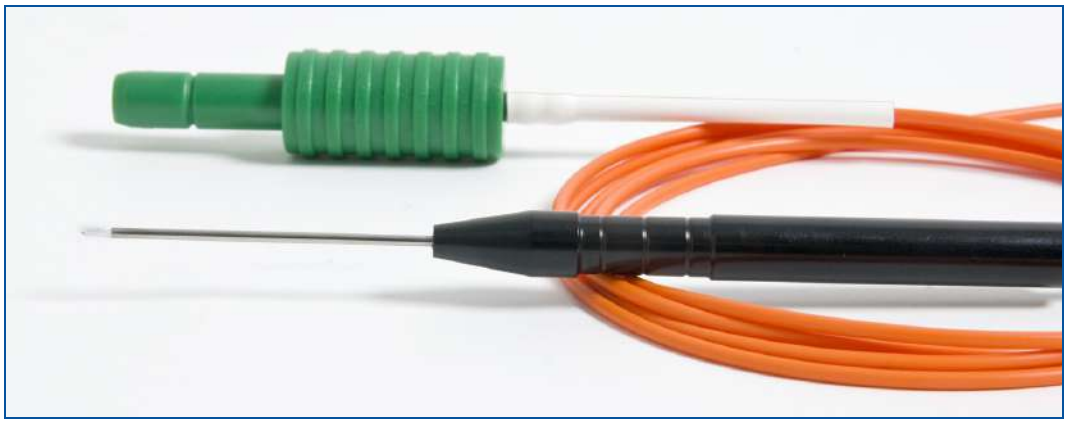
Never aim for hypotonic intra ocular pressure! A hypotony due to ciliary body destruction causes serious trouble and should be avoided.

(1) Chang SH, Chen YC, Li CY, Wu SC, Contact diode laser transscleral cyclophotocoagulation for refractory glaucoma: comparison of two treatment protocols, Can J Ophthalmol. 2004 Aug; 39(5):511-6

(2) Hauber FA, Scherer WJ, Influence of total energy delivery on success rate after contact diode laser transscleral cyclophotocoagulation: a retrospective case review and meta-analysis, J Glaucoma. 2002 Aug; 11(4):329-33

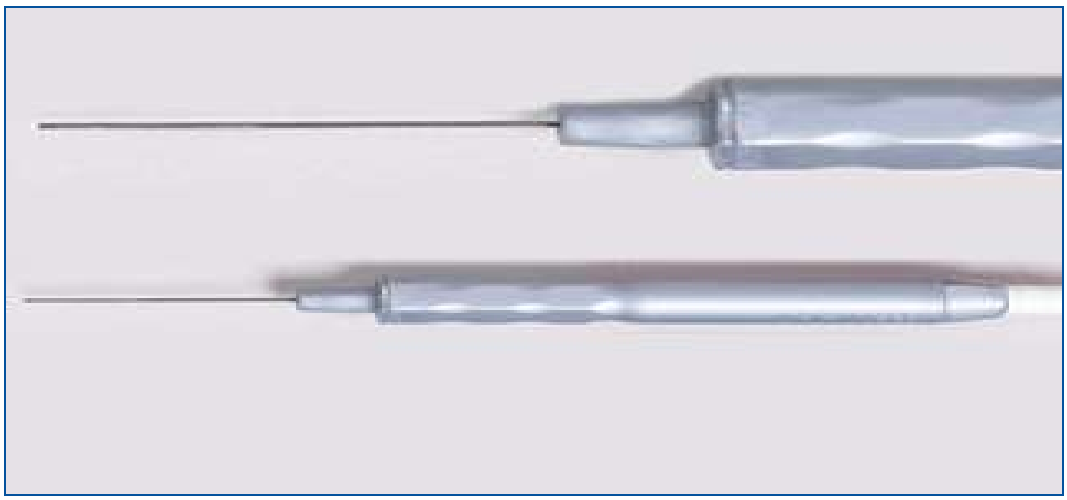
Retinal coagulation with diopexy probe

Retinal coagulation with the diopexy probe (LL13012s) is mostly done in premature cases. The laser emission is directed sideways to the probe tip. This allows retinal coagulation with this special hand piece in the periphery of the retina through the sclera. The parameters used are higher than for endo coagulation, because the laser radiation must pass the sclera first before it can be absorbed in the retina to cause coagulation.



Endocoagulation

Endo coagulation should never be done in contact to the retina. Keep a small distance to the retinal surface.



hand piece	
single use	**reusable**
LL13009s (19 G, straight)	HS01001 (19 G, straight)
LL13011s (20 G, straight)	HS01002 (19 G, curved 60°)
LL13006s (23 G, straight)	HS01003 (19 G, curved 45°)
LL13010s (25 G, straight)	HS01004 (23 G, straight)
LL13014s (20 G, curved 30°)	
LL13015s (25 G, curved 30°)	

Retina coagulation by indirect ophthalmoscope

The photocoagulation for the retina with indirect ophthalmoscope mainly is used for the Retinopathy of prematurity (ROP) treatment.

Converging lens can be used for the treatment with 20-40 dpt. The below parameters are generating with 28 dpt converging lens:

Power: 150 – 400 mW, Pulse length: 200 – 300 ms*

Power: 300 – 500 mW, Pulse length: 100 ms**

*M. J. Banach, P. J. Ferrone, M.T. Trese, A Comparison of Dense versus Less Dense Diode Laser Photocoagulation Patterns for Threshold Retinopathy of Prematurity, Ophthalmology 2000;107:324–328 © 2000 by the American Academy of Ophthalmology.

**K. A. Rezai, D. E. Eliott, P. J. Ferrone, R. W. Kim, Near Confluent Laser Photocoagulation for the Treatment of Threshold Retinopathy of Prematurity, (REPRINTED) ARCH OPHTHALMOL/VOL 123, MAY 2005 WWW.ARCHOPHTHALMOL.COM

Lacrimal surgery and DCR

For lacrimal surgical use the laser Fox 810 nm (alternative 980 nm), it has to be equipped with a bare fiber LL13017s (400 µm diameter with 300 µm fiber plug) or LL13003s (200 µm diameter). Also a 600 µm fiber (LL13008s) is available. To hold the fiber, the surgery hand piece (HS11013) can be used with the fiber. For the 600 µm fiber, the surgery hand piece (HS11013) should not be used. We suggest to hold the fiber without hand piece. The bare fibers LL13001s (300 µm diameter) or LL13003s (200 µm diameter) also endoscopic use is possible. As alternative the 400 µm of the Fox can be used with bare fiber LL11052s (400 µm diameter).

The DCR set ZU11026 contains two cannulas (ZU01031) which can be used for the lacrimal channel.

How to prepare the bare fiber and surgery hand piece + cannula for lacrimal surgery and how to use it:

The surgery hand piece (HS11013) consists of 4 parts: the long part which has a connector for the hand piece tips (luer connector). The short part, which is screwed in the long part and two plastic cones which trap the fiber when the two metal parts are screwed tightly together.

During usage of the surgery hand piece, the hand piece parts do not have to be disassembled; there is always the risk of loosing the small plastic cones. For removing and entering the fiber in the surgery hand piece, the tight fixation only has to be opened by 2 to 3 turns.

After assembling the hand piece (HS11013) with the hand piece tip, the bare fiber can be inserted in the hand piece. Be sure that the hand piece fixation is open! The end of the bare fiber should be at least 3 mm longer than the end of the cannula. In case of long surgery times, increase this distance to 5 mm or more.

If the fiber end gets in contact to the cannula during surgery, the cannula warms up and after some time the cannula end may melt!! Be cautious, a hot cannula tip can cause thermal damage to the tear duct!!!

To start lacrimal surgery, the cannula should be inserted without the fiber first. After placement of the cannula, the fiber can be inserted and the hand piece can be connected with the cannula.

For the laser tissue interaction with the FOX laser, emitting infrared laser radiation, the penetration depth is 2 – 4 mm and vaporisation can hardly be achieved without a special absorber. Any dark structure (pigment / little carbonisation / color) can enhance absorption and increase efficiency.

Therefore it is advised to make the fiber tip "black" before starting surgery. This can be done by firing on a piece of wood or color paper for a short time. This process is called initiation of the laser tissue interaction. The fiber end now absorbs the laser radiation much better and the surgery is efficient.

For surgery with the diode laser FOX, the bare fiber end has to be in contact with the tissue. For this reason, the fiber tip should have slight pressure to achieve successful canalostomy in the tear duct or even more pressure for the DCR treatment.

Either cw (continuous mode) or a pulse mode can be selected. Continuous mode causes more haemostasis and more extended collateral damage (higher effective power, faster, more efficient cutting), pulsed mode reduces collateral damage (less effective power, slower, less efficient cutting). The 200 µm fiber can be also used, the power necessary for cutting is less than for the 300 µm fiber due to the higher power density (smaller fiber diameter!).

Methods in case of unwanted effects

The application of laser radiation can cause vaporisation if the energy density is high enough. This may result in unwanted tissue fragmentation (cutting). Tissue fragmentation instead of coagulation can occur if the surgeon applies laser radiation at the same position for a too long time, the same as with too much power.

In case bleeding occurs due to tissue fragmentation, immediately enhance the distance between the hand piece tip and the area irradiated, this reduces the energy density (bigger spot size) and helps to stop the bleeding through low power heating.

Treatment related issues

The amount of irreversible damaged tissue depends on the time and extend of the radiation. Discomfort from the heating which is generated by the laser may occur. All personal, including the patient have to wear eye protection goggles, this may lead to decreased vision regarding contrast and color by the personal and surgeon. For endo coagulation, the eye protection filter for the microscope has to be mounted and the interlock cable from the filter to the laser has to be connected. The eye protection filer in the microscope protects the surgeon, who is not wearing goggles in this case.

In case of any eye injury due to disregard of the eye protection by safety goggles, a clinical center specialized on eye care has to be consulted.

Behavior in case of a system error

In case of any failure in the power generation of the laser, the power which is delivered to the patient decreases. Overpower cannot occur as the current for the laser diode is limited by a fuse. Less power than expected results in less effect. When this occurs, the user can check for the fiber delivery first and then for the laser. Any damage to the fiber results in a decrease of the power. A broken fiber shows reflections of the aiming beam at the breakage. The user should not continue the use of the laser and change the fiber.

When he checks the laser a restart results in a new check of the system at the beginning. When the laser measures too low or too high power, the system does not start.

Any error message displayed by the system can be checked in the operation manual. In case of any insecurity or questions please contact your local A.R.C. Laser representative.

Treatment parameters

Endocoagulation			
hand piece	**power [W]**	**pulse on ⎍ [ms]**	**pulse off ⎎ [ms]**
LL13006s	0.5 to 1	300 to 500	SP
LL13009s	0.5 to 1	300 to 500	SP
LL13010s	0.5 to 1	300 to 500	SP
LL13011s	0.5 to 1	300 to 500	SP
LL13014s	0.5 to 1	300 to 500	SP
LL13015s	0.5 to 1	300 to 500	SP
HS01001	0.5 to 1	300 to 500	SP
HS01002	0.5 to 1	300 to 500	SP
HS01003	0.5 to 1	300 to 500	SP
HS01004	0.5 to 1	300 to 500	SP

For repeat mode operation, a pulse off time of 300 to 400 ms can be used.

Retina coagulation with diopexy probe			
hand piece	**power [W]**	**pulse on ⎍ [ms]**	**pulse off ⎎ [ms]**
LL13012s	Adults: 2 to 2.5 children: < 2	800 to 1000	SP

Cyclophotocoagulation			
hand piece	**power [W]**	**pulse on ⎍ [ms]**	**pulse off ⎎ [ms]**
HS11025s	1.75 to 2.5	2000	SP

DCR treatment / lacrimal surgery			
hand piece	**power [W]**	**pulse on ⎍ [ms]**	**pulse off ⊔ [ms]**
LL13008s	8	cw	–
LL13008s	8	400 to 500	600 to 700
LL13001s or LL13003s	4 to 6	cw	–
LL13001s or LL13003s	5 to 7	20 to 30	4 to 6

In case of pain at cw mode use pulse mode!!! The 600 µm fiber can only be used without endoscope or cannula!!

Removal of obstructions in the lacrimal channel			
hand piece	**power [W]**	**pulse on ⎍ [ms]**	**pulse off ⊔ [ms]**
LL13001s or LL13003s	4 to 7	20 to 30	4 to 6

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