

## ENT

Application manual for the FOX laser



980 nm wavelength



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**WARNING**

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

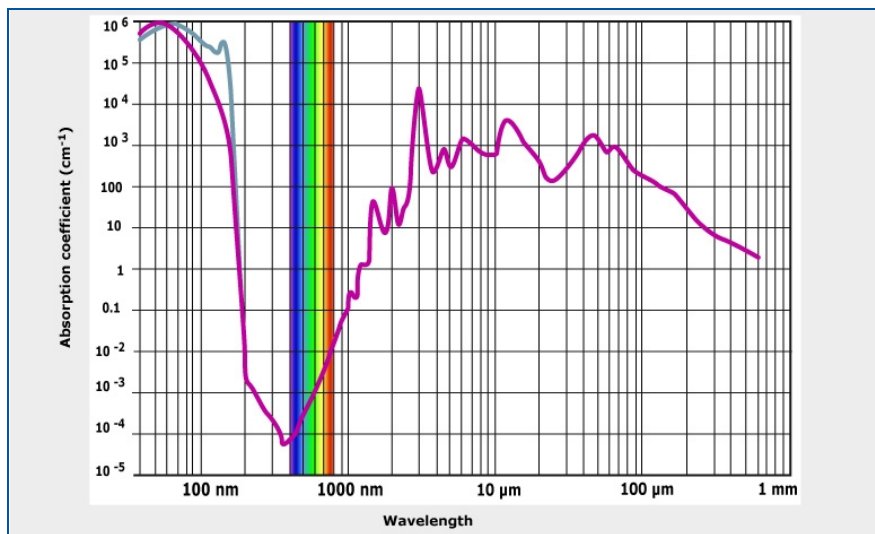
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## 1) Laser safety

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 epithelium.

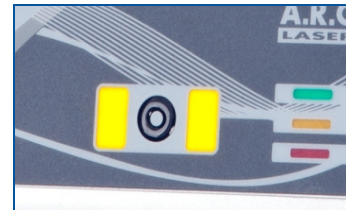
The FOX laser emits infrared laser radiation, therefore it is absolutely necessary to wear eye safety goggles when using the FOX laser system. With its intensity (e. g. focused beam), the Fox laser radiation can also do harm to skin or other tissue. The radiation can light up inflammable material.



## 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 a bare fiber end (e. g. LL13001) 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.
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.



Ready-LEDs

## 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 denature, coagulation occurs. The next limit is achieved when tissue water (intra- and extracellular water) suddenly evaporates ( $> 300^{\circ}\text{C}$ ). Tissue is fragmented and destroyed. Cutting / evaporation is achieved.

Temperature effect	
Temperature	Effect
$> 40^{\circ}\text{C}$	enzyme induction, membrane disaggregation, edema
$45^{\circ} - 65^{\circ}\text{C}$	tissue damage, reversible or irreversible, dependent on the irradiation time
$> 65^{\circ}\text{C}$	coagulation
$> 100^{\circ}\text{C}$	dehydration
$> 150^{\circ}\text{C}$	carbonisation
$> 300^{\circ}\text{C}$	vaporisation, ablation (removal of tissue)
some $1000^{\circ}\text{C}$	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.

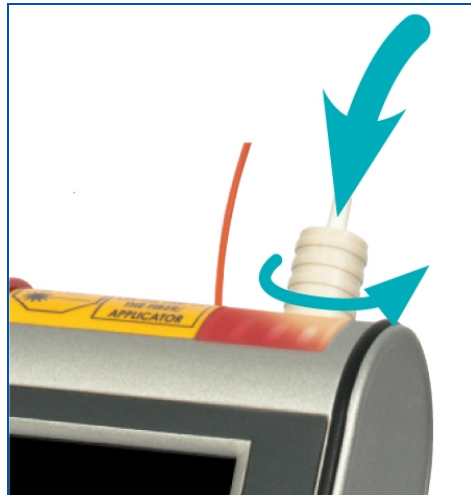
To avoid extended collateral damage (carbonisation and coagulation) at the cutting edges the application mode of the laser can be modified to a pulsed mode, which causes less damage.

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

#### Technique

For the use of the FOX laser, the laser has to be equipped with a bare fiber, preferably LL13003 (200  $\mu\text{m}$  diameter), LL13001 (300  $\mu\text{m}$  diameter) or LL13008-s (600  $\mu\text{m}$  diameter). The fiber has a fiber plug on one side, which has to be inserted into the fiber coupler of the FOX laser.



To hold the fiber the surgery hand piece (HS11018) can be used. For the 600  $\mu\text{m}$  fiber the surgery hand piece (HS11018) should not be used. We suggest to hold the fiber without hand piece for coagulation only. With the bare fibers LL13001 (300  $\mu\text{m}$  diameter) or LL13003 (200  $\mu\text{m}$  diameter) a hand piece tip (e. g. ZU01024) allows easier application and guides the fiber to the desired application area.



Bare fiber LL13003 (200 micron diameter)



## **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.

## **Treatments**

In most of the surgical procedures 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  $\mu\text{m}$  fiber can be also used for surgical procedures, the power necessary for cutting is less than for the 300  $\mu\text{m}$  fiber due to the higher power density (smaller fiber diameter!).

## **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 the bare fiber end (LL13001 or LL13003) 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.

## Surgery / Cutting

To hold the fiber the surgery hand piece (HS11018) can be used and can be equipped with different hand piece tips. The standard tip is the 2 cm long bend tip (ZU01024 / not in combination with the 600  $\mu\text{m}$  fiber). The tip can be connected to the hand piece by the luer connection and allows easier application and guide the fiber to the desired application area.

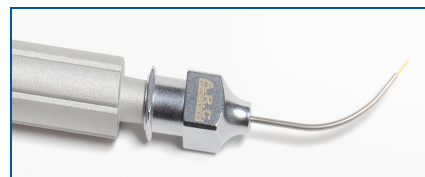


### How to prepare the bare fiber and surgery hand piece for surgery and how to use it:

For removing and entering the fiber in the surgery hand piece, the knob at the end of the hand piece has to be pressed. Please be sure that there is still silicon protection over the fiber; the fiber fixation stops the fiber by pressing on the silicon tube. When the silicon tube is removed the fiber cannot be fixed!



After assembling the hand piece 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 hand piece tip.



In case of high power surgery, or long surgery times, increase this distance to 5 mm or more. If the fiber end gets in contact to the hand piece tip during surgery, the hand piece tip warms up and after some time the tip may melt! Be cautious, a hot hand piece tip can cause thermal damage to any tissue!!! To avoid extended heating of the fiber tip, or even more dangerous, heating of the hand piece tip, the fiber end has to be cleaned during surgery if it gets covered by burned blood or coagulated tissue or any carbonization.

To start surgery now, the fiber end can be placed directly on the tissue to be cut (vaporized). If the tissue is light (blond skin), the interaction of the FOX laser light with the tissue is not efficient. The penetration depth is 2 – 4 mm and vaporisation can hardly be achieved. Any dark structure (pigment / little carbonisation / color) can enhance absorption and increase efficiency.

It is advised in this case 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 decontamination the fiber end has not be be initiated.

For surgery with the diode laser FOX, the bare fiber end has to be in contact with the tissue! The cutting procedure is nearly similar to a knife cutting, except that the bare fiber end should only be moved over the tissue in one direction with an angle of less than 90°.



Cutting with FOX Laser

## **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 filter 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.

## Nose

### Turbinoplasty / Conchotomie

The desired effect is to coagulate the tissue. With the small fiber diameter (300 µm, LL13001) it is advised not to put any pressure on the tip, as this can lead to cutting instead of coagulation. The fiber end has to be directed along the area and to be treated in a way that the angle between the fiber and the surface is small (about 10° to 20°). A big angle may result in a cutting effect and a nearly parallel direction leads to energy loss which decreases efficiency.

<b>Laser settings for mucosa hyperplasia treatment</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Л [ms]</b>
600 (LL13008-s)	4 – 6	1000 or cw	1000 or no
300 (LL13001)	4 – 6	1000 or cw	1000 or no

### Polyps resection

For polyp resection it is advised to work with the surgical hand piece and a bare fiber (contact application surgery).

<b>Laser settings for resection of polyps</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Л [ms]</b>
300 (LL13001)	5 – 8	cw	–
300 (LL13001)	6 – 9	20 – 30	4 – 6

### Epistaxis treatment

For the epistaxis treatment the main idea is to coagulate, but not to cut with the laser. The advice therefore is to use a 600 µm fiber. The fiber end must not contact the tissue; the treatment is a non-contact coagulation. If the 300 µm fiber is used, the fiber end should have a greater distance to the tissue than in case of the 600 µm fiber (min. ca. 1 mm).

<b>Laser settings for epistaxis treatment</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Л [ms]</b>
600 (LL13008-s)	5 – 7	1000 or cw	1000 or no
300 (LL13001)	4 – 6	1000 or cw	1000 or no

## Larynx

### Papilloma resection

For papilloma removal it is advised to work with the surgical hand piece and a bare fiber (contact application surgery).

<b>Laser settings for papilloma resection</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Ъ [ms]</b>
300 (LL13001)	5 – 8	cw	–
300 (LL13001)	6 – 9	20 – 30	4 – 6

## Oral

### Tumor resection

For tumor resection it is advised to work with the surgical hand piece and a bare fiber (contact application- surgery).

<b>Laser settings for tumor resection</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Ъ [ms]</b>
300 (LL13001)	6 – 9	cw	–

## Otology

### Granuloma resection

For granuloma removal in otology it is advised to work with the surgical hand piece and a bare fiber.

<b>Laser settings for granuloma resection</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Л [ms]</b>
300 (LL13001)	3 – 5	cw	–
300 (LL13001)	3 – 6	20 – 30	4 – 6

### Mucosa coagulation in the middle ear

<b>Laser settings for mucosa coagulation in the middle ear</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Л [ms]</b>
300 (LL13001)	1 – 1.5	cw	–

### Stapedotomy

For the stapedotomy or stapedectomy the 200 µm bare fiber is advised (contact application and pre-blackening of the fiber end is recommended).

<b>Laser settings for stapedotomy or stapedectomy</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Л [ms]</b>
200 (LL13003)	1 – 1.5	60 – 150	500 – 750
200 (LL13003)	1 – 1.5	60 – 90	80 – 120

### Paracentesis

For a paracentesis the bare fiber has to be placed in contact to the tissue. As soon as the opening is created the treatment has to be stopped!!

<b>Laser settings for paracentesis</b>			
<b>fiber-Ø [µm]</b>	<b>power [W]</b>	<b>pulse on П [ms]</b>	<b>pulse off Л [ms]</b>
200 (LL13003)	2	cw	–

## Lacrimal surgery and DCR

For lacrimal surgical use the laser FOX 980 nm (alternative 810 nm), it has to be equipped with a bare fiber LL13017-s (400 µm diameter with 300 µm fiber plug) or LL13003 (200 µm diameter). Also a 600 µm fiber (LL13008-s) 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 LL13001 (300 µm diameter) or LL13003 (200 µm diameter) also endoscopic use is possible. As alternative the 400 µm of the Fox can be used with bare fiber LL11052 (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.

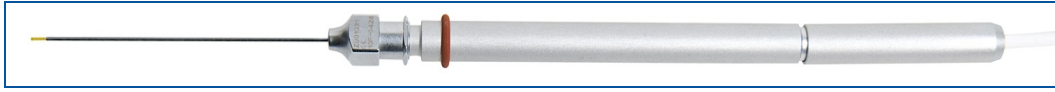


During usage of the surgery hand piece, the hand piece parts do not have to be disassembled; there is always the risk of losing the small plastic cones. For removing and entering the fiber in the surgery hand piece, the tight fixation only has to be opened by 2 to 3 turns.

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  $\mu\text{m}$  fiber can be also used, the power necessary for cutting is less than for the 300  $\mu\text{m}$  fiber due to the higher power density (smaller fiber diameter!).

In case of pain at cw mode use pulse mode!!! The 600  $\mu\text{m}$  fiber can only be used without endoscope or cannula!!

<b>DCR treatment / lacrimal surgery</b>			
<b>hand piece</b>	<b>power [W]</b>	<b>pulse on <math>\sqcap</math> [ms]</b>	<b>pulse off <math>\sqcup</math> [ms]</b>
LL13008-s	8	cw	-
LL13008-s	8	400 – 500	600 – 700
LL13001 or LL13003	4 – 6	cw	-
LL13001 or LL13003	5 – 7	20 – 30	4 – 6

<b>Removal of obstructions in the lacrimal channel</b>			
<b>hand piece</b>	<b>power [W]</b>	<b>pulse on <math>\sqcap</math> [ms]</b>	<b>pulse off <math>\sqcup</math> [ms]</b>
LL13001 or LL13003	4 – 7	20 – 30	4 – 6

## **Other treatment**

### **Granuloma resection (beyond the ear)**

Granuloma removal (e. g. pulmonal) is a contact application (surgery). For this application the power settings are higher than in the ear.

<b>Laser settings for granuloma resection</b>			
<b>fiber-<math>\emptyset</math> [<math>\mu\text{m}</math>]</b>	<b>power [W]</b>	<b>pulse on <math>\sqcap</math> [ms]</b>	<b>pulse off <math>\sqcup</math> [ms]</b>
300 (LL13001)	6 – 8	cw	-
300 (LL13001)	6 – 9	20 – 30	4 – 6



**A.R.C.**  
**LASER**