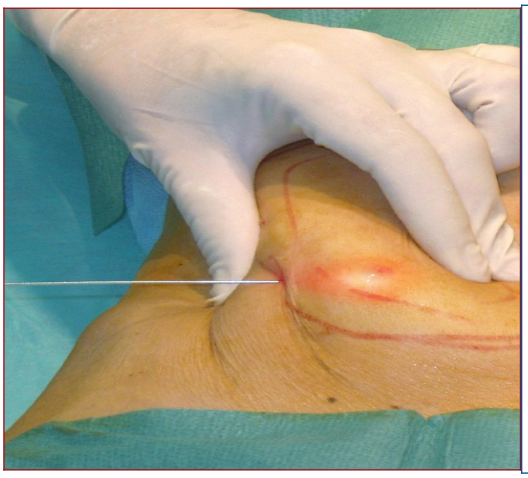
Lipolysis

Application manual for the WOLF 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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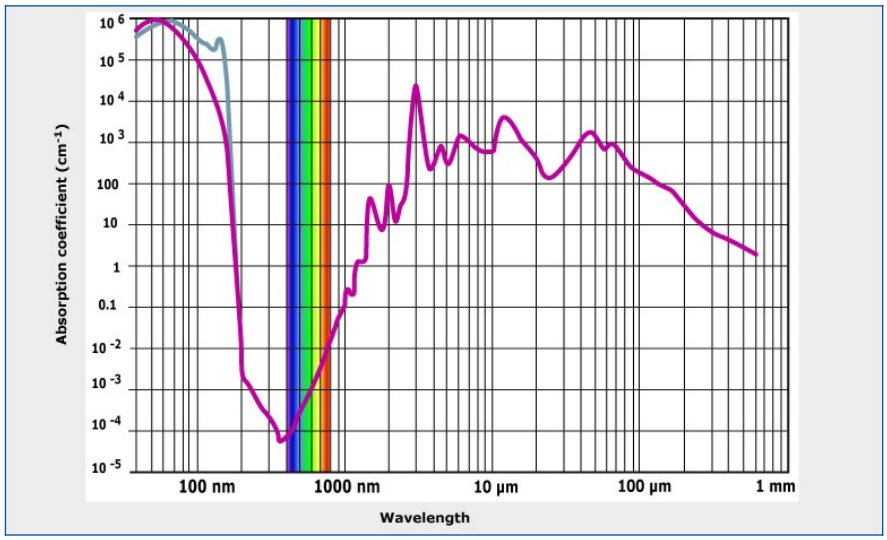
Content

1) Laser safety

Laser radiation emitted by the Wolf laser can cause severe damage to the patient as well as to the user and third persons accompanying the laser use. The Wolf 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 Wolf 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

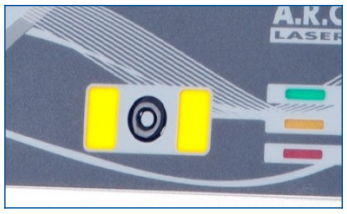
Laser radiation in the wavelength range between 400 and 1400 nm is most dangerous for the eye. The cornea as well as the anterior chamber, the lens and the vitreous body of the eye contain mainly water. The other tissue components (mainly collagen) play a minor role for the laser tissue interaction. 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 Wolf laser emits infrared laser radiation, therefore it is absolutely necessary to wear eye safety goggles when using the Wolf laser system. With its intensity (e. g. focused beam), the Wolf 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 Wolf 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 the distal end of HiFlex Fiber or Lipolysis Probe LL280xx-s in a distance of about 5 cm (you have to put the laser on Ready mode / laser safety goggle!).
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 Wolf 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 Wolf radiation and therefore the interaction between air and the Wolf radiation can be neglected. Reflection plays a major role with metal, glass and other reflecting surfaces.

When we apply the Wolf 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 Wolf 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	carbonization
> 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 (carbonization 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.

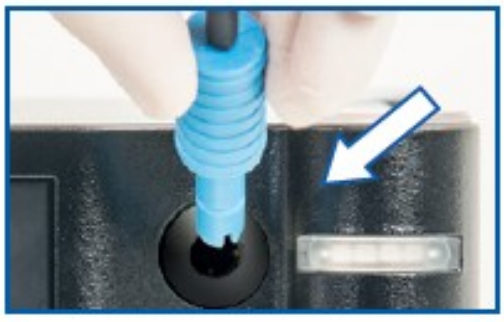
3) Application

Therapy indication

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.

Pre-treatment tests

The Wolf 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 Lipolysis Probes (LL28031s/ LL280032s) or HiFlex Fiber (LL28066s) 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.



What is laser assisted lipolysis?

Destruction of the adipose deposits by a controlled thermal effect caused by interaction of laser irradiation on the adipose tissue: A subcutaneous laser treatment in fat.

What can laser assisted lipolysis do?

Destruction of the fat cells without damaging the surrounding tissue, second tightening of the tissue:

- Smoothing the skin
- Skin tightening
- Reduction of fat deposits
- Contouring of the treatment area

Indications

- Treatment of small areas
- In addition to liposuction
- Areas of laxity
- Lipoma

Treatment areas

- Abdomen
- Knee
- Hips
- Waist
- Arms
- Trochanter
- Cerival

Laser assisted lipolysis in addition to liposuction

Laser assisted lipolysis in addition to liposuction is beneficial because the thermal rising in the dermis leads to:

- Stimulation of fibroblasts
- Production of collagen
- Tightening of the tissue

General advantages

The method is beneficial for patient and surgeon because:

- Only one treatment session
- Ambulant procedure
- Local anesthesia
- No cuttings or scars
- Low risk of haematoma

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.

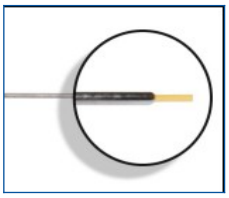
4) Technique

For the application the connector of the Lipolysis Probes or HiFlex Fiber has to be inserted into the fiber coupler of the Wolf laser 980 nm, 18 Watt output power.

Lipolysis Probes, single use:

The Lipolysis Probes (LL28031s/ LL28032s) is already pre-assembled and is delivered sterile. There is 600 µm or 400 µm version for this application.

The Lipolysis Probe should be cleaned during surgery to avoid overheating of the tip is strongly advised. Any carbonization/ burned fat / coagulation at the end of the hand piece may block or absorb the radiation. This leads to a decrease of the efficiency, overheating and destruction of the fiber tip.



5) Pre-surgical preparations

Application

Before using the laser system on the patient, all the pre-surgical preparations (anesthesia, etc.) should be completed.

To avoid damage and overheating of the fiber tip, it is advised to mobilize the application area before using the laser hand piece the first time by a standard small liposuction cannula.

Tumescent anesthesia sterile table

Important steps

- Selection of patients
- Clinical history
- Patient letter of agreement
- Picture (preoperative)

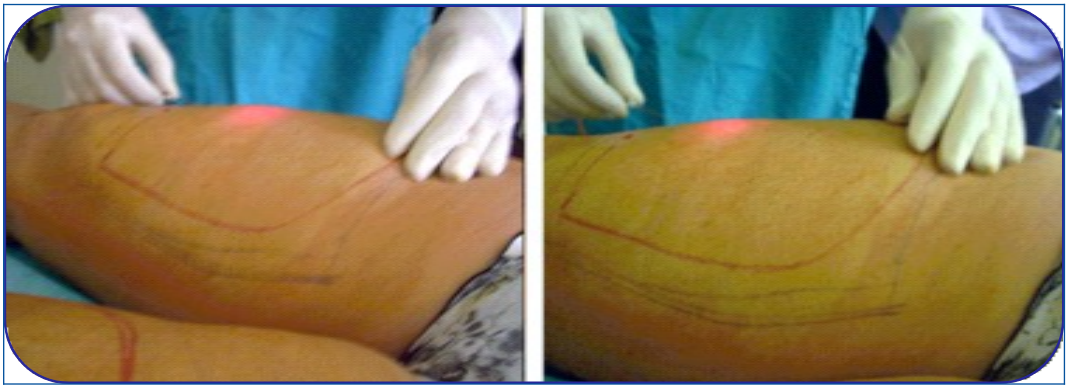
Pre-treatment

- Marking the area
- Preparing the sterile table
- Preparing the sterile area
- Moderate tumescent: *Kleinsche* infusion solution:

  150 cc. to 250 cc. for a size of 10 x 10 cm
- Several access points

6) Treatment procedure

The Lipolysis Probe has to be moved continuously parallel to the skin surface in the fat layer underneath the dermis, in a range of about 0.8 to 2.5 cm depth.



Laser settings	
area	**Power [W]**
abdomen	up to 18
arms, knee	8 – 10
chin	6 – 8
other areas	around 8

Treatment of small lipoma		
4 – 5 W	**100 – 150 J**	**Introduction of HiFlex Fiber, 400 µm, u.c. (LL28066s) with PVC**

Speed of treatment		
treatment	**pulse on M**	**pulse off U**
slow	10 ms	10 ms
fast	1.5 - 2.0 s	300 ms
fastest	cw (max. 18 Watt)	-

The faster the treatment the more risk of possible burns in case the user stops moving the hand piece.

As and when required it´s possible to increase the power to achieve better results of the melting process.

- Make a continuous movement until the total input energy reaches minimum 2500 to 3500 J (minimal total energy for an area of 10 x 10 cm). The total energy varies from 2200 J (hips) up to 51000 J (abdomen). (1)
- To control the surface temperature, the second hand can be used as a temperature sensor. The surface temperature rises slightly from about 32° to 35° - 36°

(1) J. P. Reynaud et. al., Lipolysis using a 980 nm diode laser: a retrospective analysis of 534 procedures, Aesth Plast Surg (2009) 33: 28 – 36

Laser times (10 x 10 cm area, pulse mode 10 ms/10 ms)			
Power	**2500 J**	**3000 J**	**3500 J**
6 W	14 min	16 min	20 min
7 W	12 min	14 min	16 min
8 W	10 min	12 min	14 min
9 W	9 min	11 min	12 min
10 W	8 min	10 min	11 min
11 W	7.5 min	9 min	10.5 min
12 W	7 min	8 min	10 min
13 W	6.5 min	7.7 min	9 min
14 W	6 min	7 min	8.3 min
15 W	5.5 min	6.5 min	7.7 min
16 W	5.2 min	6 min	7.2 min
17 W	5 min	5.7 min	7 min
18 W	4.6 min	5.5 min	6.5 min

Post-operative

- Adequate anesthesia (if necessary)
- Compression
- Medication: antibiotic (Gemfibrozil)
- Protein diet for 3 days
- 1.5 – 2 liter fluid increase

7) Remarks

Advice / Remarks

Additional liposuction can improve the aesthetic result. It offers immediate volume removal which is not possible with laser assisted lipolysis without suction. The final aesthetic result will be reached after a minimum of 3 months.


A.R.C.
LASER