# Manual
## Disposable laser fibers and probes, sterile

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Release version

| | |
|---|---|
| Date of issue | 07.03.2018 |
| Revision | rev14 |
| Date of revision | 07.07.2023 |
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**Content**

# 1. Introduction

This manual is valid for the laser fibers and probes of the A.R.C. Laser product range. These products are packaged disposable products for short-term invasive and non-invasive use. The general notes are listed in Chapter 5, for product-specific notes please see Chapter 7 and Chapter 8.
To ensure safe handling of the laser probe, please read this instruction manual and make sure you have completely understood it. This applies likewise to the instructions for use of the laser device. Please enclose this manual with the manual of the laser unit.
This product may only be used by trained and qualified users and appropriately trained medical staff.

## 1.1 Copyright


We would like to point out that the present manual has been prepared with all the data available to us to the best of our knowledge and belief. We reserve the right to renew or revise any changes to the drawings, pictures or text without additional notice.

## 1.2 Labeling and symbols

 The international symbol for ‘Attention’ can be found at all points of this operating manual which contain particularly important information for the user or for handling the fibers and probes.

## 1.3 General purpose of the laser fibers and probes

### 1.3.1 Indications

The A.R.C Laser GmbH manufactures fibers and probes are accessories for A.R.C. medical laser devices that allow guiding laser radiation from the laser device to the desired treatment area. The application method can be in contact or non-contact-mode. The Fibers can be used with hand pieces, rigid or flexible endoscopes and without any accessories depending on the location of use.
Probes are delivered ready for use and need no accessories. There is no need to adjust the shape of the tip in regards to the application.

Fibers and Probes are intended to be used to guide laser radiation to vaporize, coagulate or stimulate/irradiate tissue and bony structures in surgical and therapeutic applications in ENT (ear, nose and throat), ophthalmology, general surgery, aesthetic and vascular surgery.
One of the probes is intended to convert laser energy in pulsed shock waves to destroy/crush tissue structures mechanically.
The basic material for fibers and probes are optical fibers made of quartz glass. The quartz glass is protected by a coating made of polyimid or HardClad, a plastic which keeps the quarts core flexible and protects it from the breakage. Additionally, there is a second protective layer, the jacket of the fiber which is made of PVC tubing or Nylon.
The product-specific purposes can be found in the sub-chapters of the respective product groups in Chapter 7.

### 1.3.2 Contraindications

The use of fibers and probes in the central circulatory system and central nervous system is not permitted.
These are generally valid contraindications for all product groups; further contraindications can be found in the product-specific notes in Chapter 7

**No reprocessing**
All fibers and probes from A.R.C. Laser are disposable products and may only be used on a single patient. These disposable products have to be disposed after every single application. Reuse and re-sterilization are prohibited.

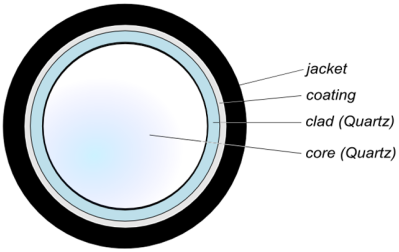
# 2. Theory and technical structure

## 2.1 Optical fiber structure

The basic material for fibers and probes are optical fibers made of quartz glass.

Please note that a sensitive optical fiber made of glass is located behind the sheathing of the fibers and probes.
Please note that the sheathing of the fibers and probes covers a sensitive optical fiber made of glass, which must not be fixed by sharp clamps or loaded with heavy objects.

A cross section illustrates the layered structure and the possible materials



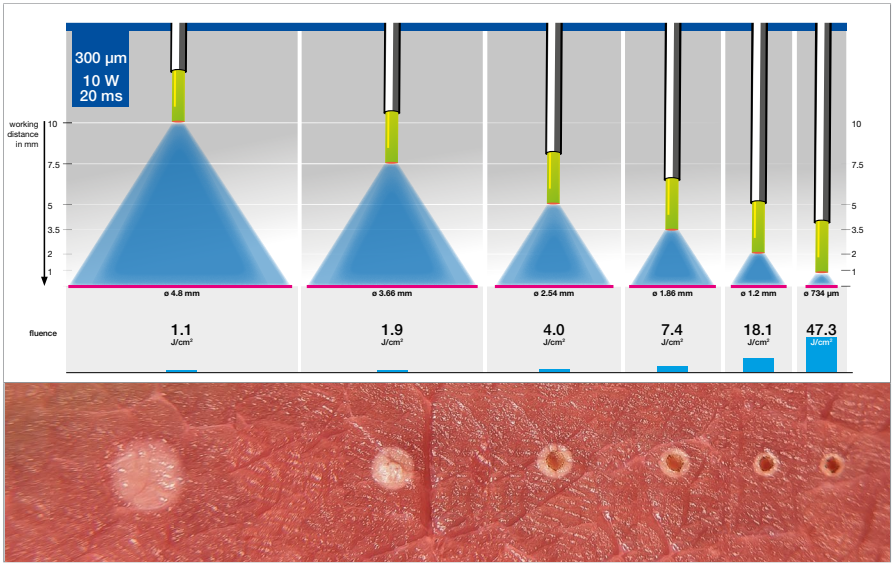

## 2.2 Tissue interactions

| LASER RADIATION & TEMPERATURE EFFECT | |
|---|---|
| TEMPERATURE | EFFECT |
| > 40° C | Enzyme induction, membrane disaggregation, edema |
| 45° – 65° C | Tissue damage, irreversibility depends on irradiation time |
| > 65° C | Coagulation |
| > 100° C | Dehydration, Beginning of vaporization and carbonization |

Interactions in the tissue depend on various parameters:

- Fiber diameter: the larger the diameter the smaller the interaction
- Distance to tissue: the greater the distance the smaller the interaction
- Performance: the higher the power the stronger the interaction
- Irradiation time: the longer the irradiation time, the stronger the interaction
- Wavelength: depending on the wavelength, absorption is achieved in different chromophores

The following illustration shows the effect of different energy densities with the same fiber and laser settings.



## 3. Transport and storage

At A.R.C. Laser, we make sure that both the unit and the accessories are packed and transported with the greatest possible care.
Before unpacking the laser and accessories, please check the packaging for damage and report any damage immediately to the carrier. Make a list of the damaged parts and have this list signed by the carrier‘s agent.

Please note the storage conditions, which can be found on the label on the outer packaging.
The fibers and probes must be stored in a clean, protected place as follows:

- protected against light irradiation
- in a dry place, protected from wet and moisture
- Ideal humidity for storage is between 30 %  and 60 %.
- Storage temperature: between 10°C and 30°C

## 4. Set-up / Installation

Laser fibers and probes may only used with the units intended for this purpose (see Unit-Fiber Matrix Chapter 8). The section on Fiber-Unit-Coupling (cf. Chapter 6.1.5) covers all important information and instructions for connecting the fibers and probes to the A.R.C. Laser systems. Please see also the information about compatible laser systems on the label and refer to the respective operating instructions for the laser for setting up and installing the unit.

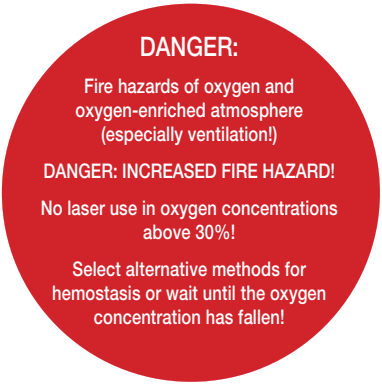
# 5. Safety notes

## 5.1 General information

Please observe the following safety notes

- All Fibers and Probes of A.R.C. Laser GmbH are provided sterile and for single use only. Products delivered in sterile condition do not require reprocessing prior to their first use after delivery.
- Please make a visual inspection of the sterile barrier system before use to rule out any breaches of packaging integrity. The packaging must not have any cracks or holes to guarantee a sterile application of the product. The permitted expiry date must not be exceeded.
- The fibers and probes of A.R.C. Laser may only be used with the corresponding laser units of A.R.C. Laser GmbH.
- Be sure to keep the fiber optic cable sterile during the entire treatment period and observe the valid regulations for handling sterile equipment.
- It is essential to not direct the distal end of the laser fiber to reflective surfaces of other instruments or objects, as there is a risk of uncontrolled scattered radiation and thus a risk of destroying the fiber or tissue damage.
- Before and after removing the fiber optic cable from the packaging, please check it for visible damage, in particular breakage. Should any damage be apparent, do not use the product and return it to the supplier.
- ATTENTION: When using a defective fiber optic cable or when using it improperly, there is a risk of serious eye or tissue damage, unintentional laser irradiation to patients or surgical staff, or even a fire in the treatment area. Observe the detailed safety instructions in the User's Manual for the respective laser unit and the instructions for protection against laser radiation.
- When using fibers and probes, the user manual of the laser device used must be consulted, especially the information contained on indications, contraindications and side effects caused by the laser-tissue interaction.
- When using the fiber optic cable, all persons present must wear safety glasses. The requirements for the protective units depend on the respective application and can be found in the User's Manual for the laser unit used.
- Fibers and Probes must not be fixed by using sharp clamps or loaded with heavy objects/instruments before and during treatment.
- After treatment, the fibers and probes used must be checked with regard to damage/completeness, especially on the application side (e.g., integrity of the tip of fibers or probes, completeness of the product). This check is to ensure that no components of the used fibers or probes would remain in the patient in the event of a defect.
- Warning: In the event of unauthorized reprocessing or reuse, the patient and user are exposed to the following risks:
  - Infection of the patient due to insufficient sterility and biological contamination

- Insufficient treatment success due to impaired performance characteristics
- Laser radiation must not be applied via fibers and probes if the oxygen concentration of the treatment environment is > 30 % (for example during ventilation), there is a fire hazard!




- If an intubation tube is used for treatments in the pharynx/larynx and oral cavity, a laser-safe intubation tube is required.
- All serious incidents relating to the devices must be notified immediately to the manufacturer and the competent authority.
- Fibers and probes must be disposed separately after use on the patient. Disposal in household waste is not permitted.

**In case, that the general information on safety are neglected, the following side effects may occur:**

Infection, tissue damage, bleeding, allergies,burns, encapsulation and rash.

## 5.2 Labeling and symbols of sterile fibers and probes

All sterile fibers and probes from A.R.C. Laser are EO sterilized. Sterilization can be checked using the indications on the packaging and outer packaging.

### 5.2.1 Part number sterile products

All fibers and probes offered as sterile products are marked with the letter '**s**' at the end of the part number.
For example: LLxxxxx**s**

### 5.2.2 Sterile packaging fibers and probes

All sterile products are double-packed in special pouches or blisters with the product label glued or printed on the outer pouch or blister. In addition, these packages are also provided with sterilization indicators (stripes or dot), which changes color and appears yellow after successful EO sterilization.

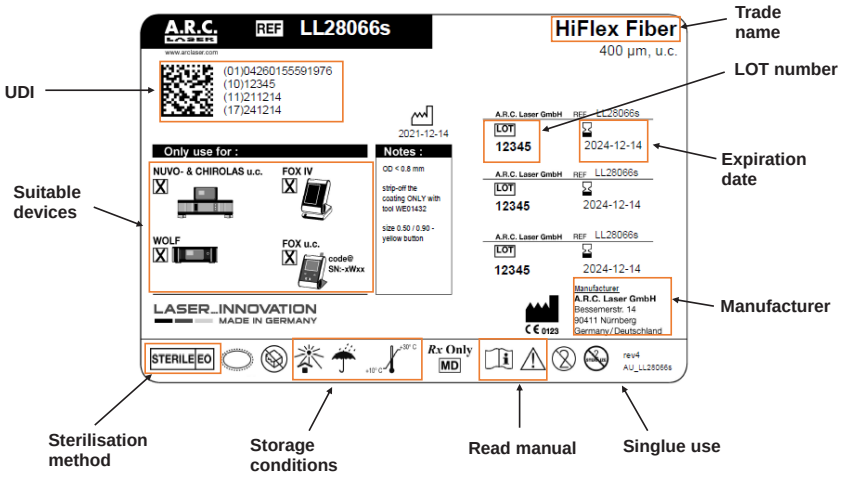

### 5.2.3 Carton / Packaging unit

Each packaging box of the sterile fibers and probes is provided with a sterilization indicator.

| | |
|---|---|
|  |  |
| non-sterile: black dot | sterile product: green dot |

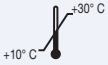
### 5.2.4 Symbols on the product label

The product label shows all relevant product-related information. It is attached to the outer bag of the packaging.




The fibers and probes from A.R.C. Laser must be protected from moisture, light (UV light), ionizing radiation as well as dust, stored at temperatures between +10°C to +30°C and within a humidity range of 30 % to 60 %.

REF, LOT number, expiry date and manufacturer are printed on three sub-labels of the sterile product label and can thus be used for documentation purposes. Please see the explanation of the symbols at the next page.

| Symbol | Meaning |
|---|---|
|  | Consult instructions for use |
|   | Sterilization using ethylene oxide |
|  | Single sterile barrier system with protective packaging outside |
|  | Single use only |
|  | Use by date |
|   | Batch code |
|  | Date of manufacture |
|  | Manufacturer |
|  | Caution |
|  | Protect from light irradiation |
|  | Protect from moisture<br>Acceptable humidity for storage: 30 - 60 % |
|   | Catalogue number |
|  | Do not use if package is damaged |
|   | Storage temperature limit |
|   | Do not re-sterilize |
| *Rx* Only | Only after prescription |
|   | Medical device |

All fibers and probes distributed by A.R.C. Laser GmbH are free of latex. According to valid regulations, only a corresponding label is required as soon as latex is contained.

# 6. User instructions

## 6.1 Technical briefing

The following is a general guide to the detection and specification of A.R.C. fibers and probes.

### 6.1.1 Fiber

The fibers used are all articles from A.R.C. Laser, which are equipped with only one connector and whose distal fiber end remains straight or spherical, but not assembled, or the distal end is provided with a second connector for connecting handpieces.

connector | bending protection | fiber with jacket | fiber without sheathing

### 6.1.2 Probe

All A.R.C. Laser accessories in which a fiber is firmly connected to a handpiece on the production side are called probes.
The shape of the handpieces is designed according to their purpose and can be short, long, straight, curved/angled or flexible.

connector | bending protection | fiber with jacket | handle including fiberguiding cannula

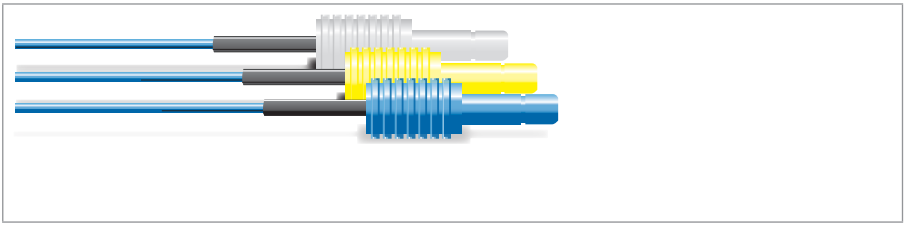
The probes are delivered ready for use. There is no need to adjust the shape of the cannula in regards to the application.

Never touch or clean the fiber end in the connector.

### 6.1.3 Fiber diameter

The available fiber diameters of A.R.C. Laser are:
300 µm / 400 µm / 600 µm.

Not all products are available in all fiber diameters, as the installed sizes of the basic fibers are selected according to application. The user can identify the fiber diameter by the connector color:



| Connector color | Fiber diameter |
|---|---|
| White | 300 µm |
| Yellow | 400 µm |
| Blue | 600 µm |

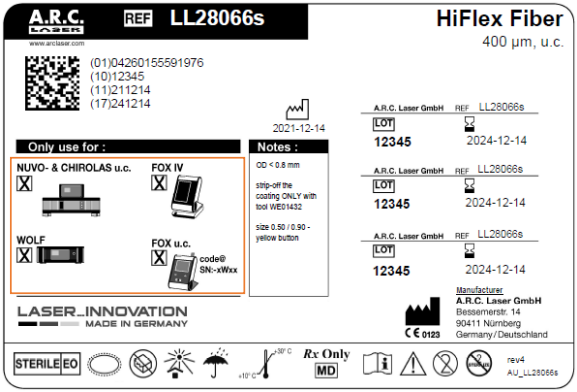
### 6.1.4 Permissible bending radius of fibers and probes

The permissible bending radius of the fibers and probes describes how much the laser fiber may be bent (winding or kinking) without suffering performance problems (higher losses or burn-through). We recommend not to exhaust the long-term bending radius during treatment (e.g. by arrangement of device, fiber, physician, patient and other instruments used).

| Fiber diameter [µm] | Bending radius [mm] – Short term (max. 10 min) | Bending radius [mm] Long term |
|---|---|---|
| 300 | 15 | 90 |
| 400 | 20 | 120 |
| 600 | 30 | 185 |

### 6.1.5 Fiber unit coupling

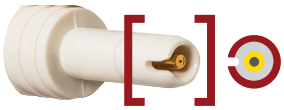
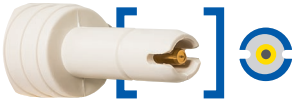
The A.R.C. Laser fibers and probes are used on approved surgical laser units of A.R.C. Laser with a special quick-release connector. The product label is certified for compatibility with the A.R.C. Laser devices.




If laser fibers and probes made by A.R.C. Laser are coupled to an incompatible device, this may cause a defect to the fiber as well as the connected unit. Problems in power transmission may occur.

**Anti-twist protection**

All A.R.C. Laser fibers and probes have a quick-release connector. The connectors are equipped with an anti-twist protection, recognizable by small notches in the connector (see illustration).

| | | |
|---|---|---|
|  |  | **Standard-coupling and U.C. 1.0**<br><br>identifiable through a single notch |
|  |  | **Coupling U.C. 2.0**<br><br>identifiable through a double notch |

This ensures an optimal fit in the fiber coupling, which results in a reproducible power transmission. Insert the connector plug into the connecting socket of the A.R.C. Laser until it clicks into place.

**Coupling systems**

The laser units of A.R.C. Laser GmbH have 4 different coupling systems

- 300 µm standard coupling, single anti-twist protection (suitable for red connectors, white connectors and green connectors with white bending protection)
- 400 µm standard coupling, single anti-twist protection (suitable for yellow connectors and green connectors with white bending protection)
- U.C. 1.0 coupling - Universal Centering, single anti-twist protection (suitable for all connector colors with black bending protection) - produced until 11/2019
- U.C. 2.0 coupling - Universal Centering, double anti-twist protection (suitable for all connector colors with black bending protection) - produced from 12/2019

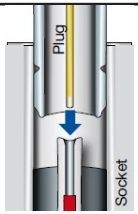
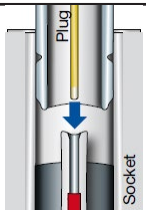
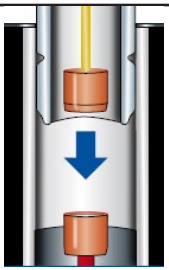
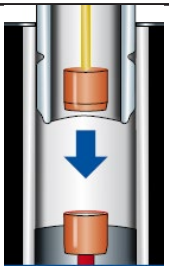
When using the fibers and probes, check the compatibility of the unit on the packaging label before each use. The fiber or probe can be connected only if the corresponding unit is shown in a schematic diagram.

Never connect an incompatible fiber, this will destroy the laser coupling and leads to service costs for you.

## Identification of the coupling

The socket of the unit is colored, which indicates the coupling variant. The connectors of the fibers and probes can also be identified by the color of the bending protection.

The identification characteristics of the coupling are assigned as follows:

| Coupling | Coupling scheme | Color of the socket | Identification based on the fiber |
|---|---|---|---|
| 300 µm<br>standard coupling<br><br>Units:<br>FOX 300 µm<br>NuvoLas 300 µm |  |  <br>silver |  <br>Bending protection: white<br>Connector color: white<br>Bare fiber is visible in the connector<br>REF HS11xxxs, LL11xxx, LL13xxxs |
| 400 µm<br>standard coupling<br><br>Units:<br>FOX 400 µm<br>ChiroLas 400 µm |  |  <br>yellow |  <br>Bending protection: white<br>Connector color: yellow<br>Bare fiber is visible in the connector<br>REF LL11xxx, LL13xxxs |
| U.C. coupling<br><br>Units:<br>FOX IV<br>WOLF<br>Nuvolas U.C.<br>Chirolas U.C. |  |  <br>black |  <br>Bending protection: black<br>Connector color: white, yellow or blue<br>Metal ferrule is visible in the fiber connector<br>REF LL28xxxs |
| U.C. 2.0<br>coupling<br><br>Geräte:<br>FOX U.C.<br>FOX IV<br>WOLF<br>Nuvolas U.C.<br>Chirolas U.C. |  |  <br>black, 2 Pins |  <br>Bending protection: black<br>Connector color: white, yellow or blue<br>Metal ferrule is visible in the fiber connector<br>REF LL28xxxs<br>Double anti twist protection |

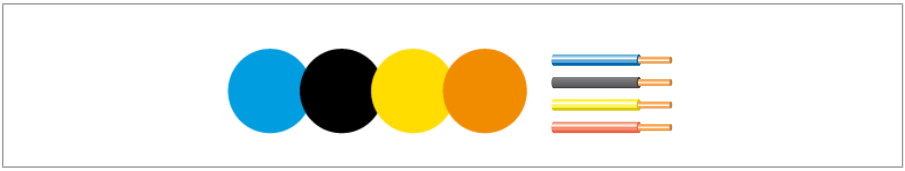
The serial numbers of the FOX and WOLF laser units are also coded in such a way that the coupling variant can be derived from the letter code. In this case, the second letter of the serial number determines the type of coupling:

SN: 6xxxxx-xAxx: A ≙ 300 µm coupling
SN: 6xxxxx-xCxx: C ≙ 400 µm coupling
SN: 6xxxxx-xUxx: U ≙ U.C. 1.0 coupling
SN: 6xxxxx-xWxx: W ≙ U.C. 2.0 coupling


**Fiber jacket**

The fibers and probes from A.R.C. Laser are sheathed by the fiber jacket to protect them from external influences.

The coloring is based on material properties and has no relation to the size or coupling variant.

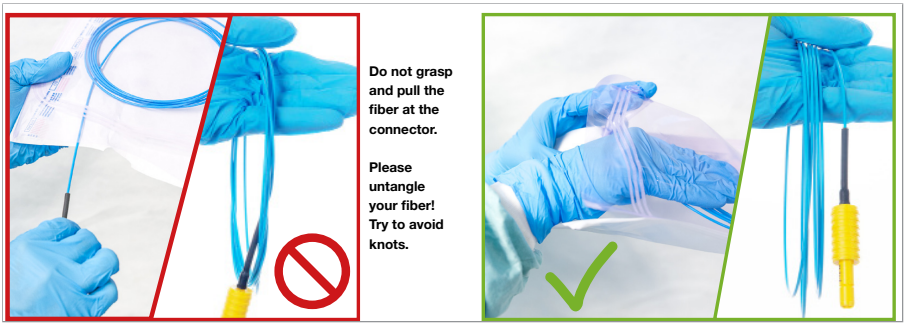


## 6.2 Unpacking the fibers and probes

The most important steps for opening the sterile packaging are explained in more detail below.
It is important to open the corners first. This makes it easy to open the packaging without the risk of the outer surface of the bag touching the fiber.


To remove the laser fibers and probes, it is necessary to grasp the fiber by hand and remove it from the bag. Make sure that the connector does not get between the windings of the fiber.

The following illustrations compare incorrect and correct handling:

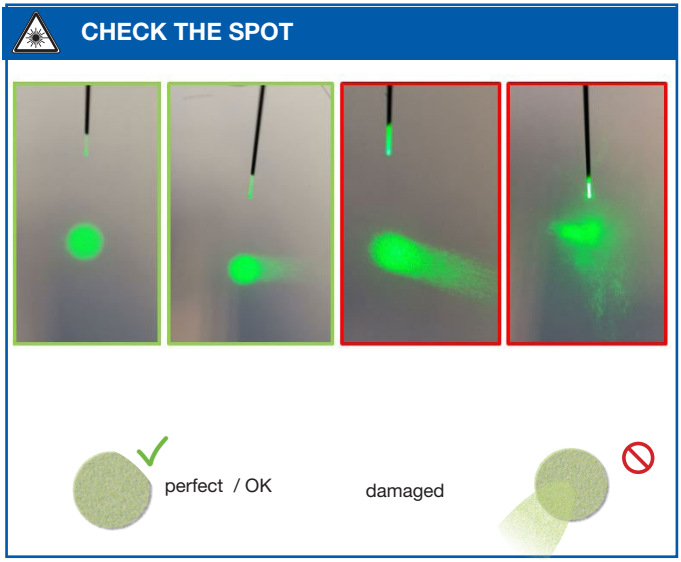



Never pull laser fibers and probes out of their packaging at the connectors.

After removing them from the sterile packaging, check the end faces of the connector and the distal fiber end for contamination or foreign particles. Damaged or soiled front surfaces may damage or destroy the product and/or damage the laser system used.

## 6.3 Preparation - Checking the fibers and probes for damage

After connecting the fiber or probe, check again for excessive bending, breaks and other defects. Pay particular attention to the radiation exit of the aiming beam outside the distal end surface. To do this, set the laser to Ready Mode after connecting the fiber / probe.
Direct the distal end towards a non-reflecting surface. The aiming beam must form a sharply defined, homogeneously illuminated circle. If a lateral reflection can be detected or the circle is not complete, the fiber or the probe is damaged and must not be used for treatment. This also applies to all other visible damages.




The image of the aiming beam as a sharply limited, homogeneously illuminated circle does not apply to the products Bulb Fiber, Side Emission Fiber (Donut Fiber), Glaucoma Probes (Cyclo Probe, µCPC Probe) and Shockwave Emission Probes (Cetus Probe and Coaxial Probe).

# 7. Sterile fibers and probes

**Intended purpose**
Guiding laser radiation from the device to the desired treatment area.

Below please find a detailed description of the structure of the fibers and probes for each product group, their intended purpose and possible variants.

## 7.1 Bare Fiber, sterile (HiFlex Fiber)

### 7.1.1 HiFlex Fiber, sterile

HiFlex Fibers are used to guide the laser radiation of A.R.C. Laser devices to the treatment area. The fiber end can be used in contact with the tissue or at a distance from the tissue. The HiFlex Fibers can be used with handpieces (e.g. surgery handpiece REF: HS11018), rigid or flexible endoscopes or without any accessories depending on the location of use

**Indications**
HiFlex Fibers are intended to be used to guide laser radiation to vaporize, coagulate or stimulate/irradiate tissue
in surgical and therapeutical applications in ENT and general surgery, for example:
ENT: rhinology (e.g. for rhinosinusitis), otology (e.g. stapedotomy), laryngology (e.g. papilloma, stenosis, carcinoma)
General Surgery: ablation (vaporization) and coagulation of tissue
Phlebology: endovascular coagulation

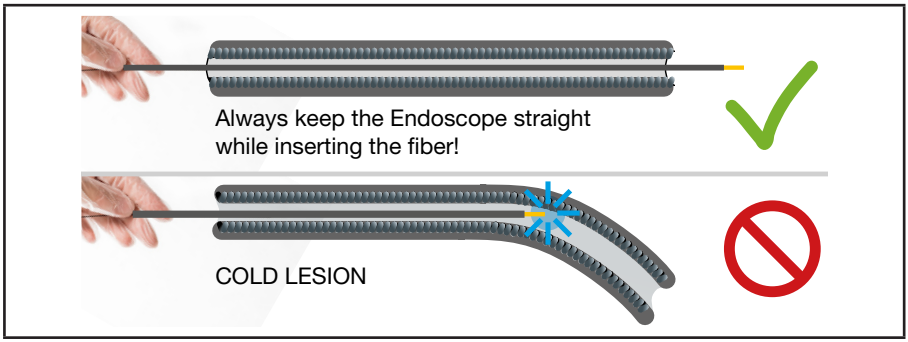
**Contraindications**
HiFlex Fibers are not intended for treatments at the eye surface or inside the eye

**Side effects**
Pain, Scar formation

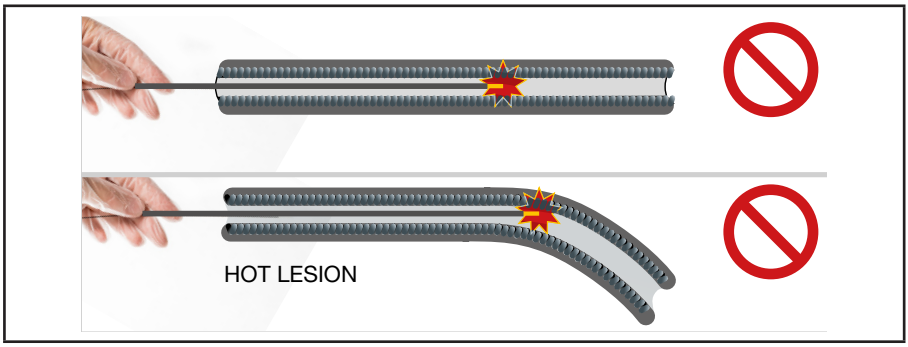
HiFlex Fibers increase the surgical application spectrum of Bare Fibers to include indications that are performed using flexible endoscopes or in conjunction with handpieces or cannula longer than 120 mm.

**For the use of the HiFlex Fiber in flexible endoscopes the following is to note:**

**Avoid a „Cold lesion“**
– Insert the HiFlex Fiber only into the stretched endoscope. If the fiber is inserted into the already bent endoscope, the fiber tip may damage the endoscope. There also entails a risk of damaging the fiber tip and altering the beam image.




**Avoid a „Hot lesion“**
Apply laser power only when the fiber tip protrudes sufficiently far from the endoscope. If the fiber is inside the endoscope during power output, the working channel will be damaged.




When using endoscopes, position the probe approximately 1 cm outside the distal end of the endoscope.

| REF | Description | matching handpiece |
|---|---|---|
| LL13062s | HiFlex Fiber 300 µm | HS11018 / Endoscope (working channel min. 0.6 mm) |
| LL13066s | HiFlex Fiber 400 µm | HS11018 / Endoscope (working channelmin. 0.8 mm) |
| LL28062s | HiFlex Fiber 300 µm, U.C. | HS11018 / Endoscope (working channel min. 0.6 mm) |
| LL28066s | HiFlex Fiber 400 µm, U.C. | HS11018 / Endoscope (working channel min. 0.8 mm) |
| LL28068s | HiFlex Fiber 600 µm, U.C. | HS11018 / Endoscope (working channel min. 0.9 mm) |

### 7.1.2 Guiding and fixing the Bare Fiber for the application

The Bare Fibers are fixed in the surgery handpiece (e.g. HS11018) and guided by blunt end needles.

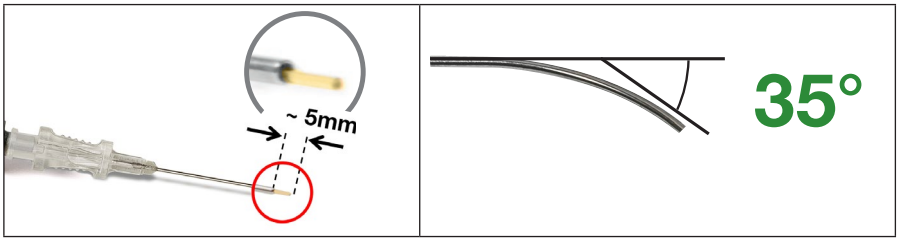
| REF | Description | matching fiber |
|---|---|---|
| ZU01156s | Blunt end needle 22 G, length 40 mm | HiFlex Fiber 300 µm |
| ZU01157s | Blunt end needle 22 G, length 70 mm | HiFlex Fiber 300 µm |
| ZU01158s | Blunt end needle 19 G, length 50 mm | HiFlex Fiber 400 µm |
| ZU01160s | Blunt end needle 18 G, length 100 mm | HiFlex Fiber 400 µm |
| ZU01162s | Blunt end needle 18 G, length 250 mm | HiFlex Fiber 300 µm and HiFlex Fiber 400 µm |

HiFlex Fibers 600 µm can be used without a blunt end needle due to their stability.

**Please note that:**

a) the protrusion of the bare fiber from the cannula/instrument is set to at least 5 mm

b) the bending of the cannulas must not exceed 35°



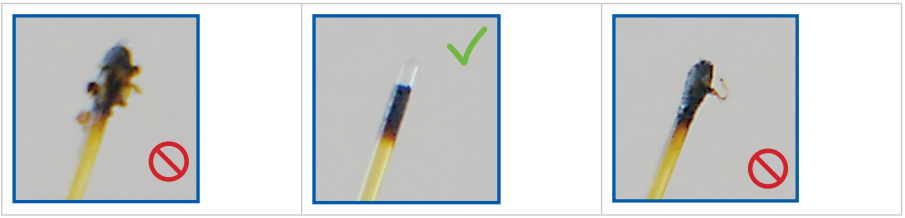

c) Only bend the blunt end needle after the fiber is inserted.

The HiFlex Fibers can be used with short and long cannulas as well as endoscopes. Due to the protective nylon layer, there is no restriction in terms of instrument length as long as the unprotected fiber end (unsheathed part) protrudes from the tip of needle or instrument completely.
But it is important that the stripped fiber end protrudes from the tip of needle / instrument completely.

Do not use any cannulas, whose lumen has not been deburred and grinded. Uncleanly processed cannulas may damage the fiber and cause it to break.

### 7.1.3 Keep fiber tip clean

To ensure that the desired interaction is always achieved, the fiber tip must be free of tissue adhesions. This is why you should carefully clean the fiber tip with a damp swab or cloth during the treatment, especially during vaporization / cutting.



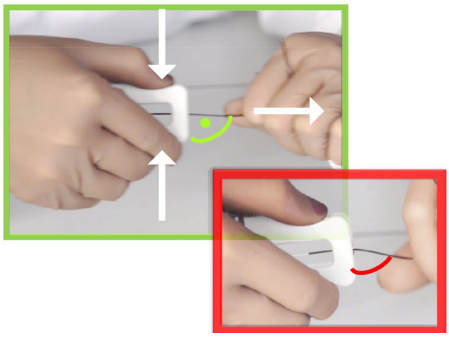
You may continue to use the fiber after cleaning when the quartz becomes clearly visible again at the fiber tip. Use a new fiber to continue the treatment if the tissue could not be wiped off. Where the laser is only used for a short time, you can also trim the fiber.

### 7.1.4 Trim the tip

- **HiFlex Fiber stripping**

For the HiFlex Fibers, special strippers adapted to the fiber diameters are available (see table at next page), which can be sterilized.
Insert the fiber into the stripper and cut the sheathing by pressing the handles simultaneously and smoothly. It is particularly important to pay attention to the smooth operation of the handles and a straight fiber position.

recommended strip length 1-2 cm



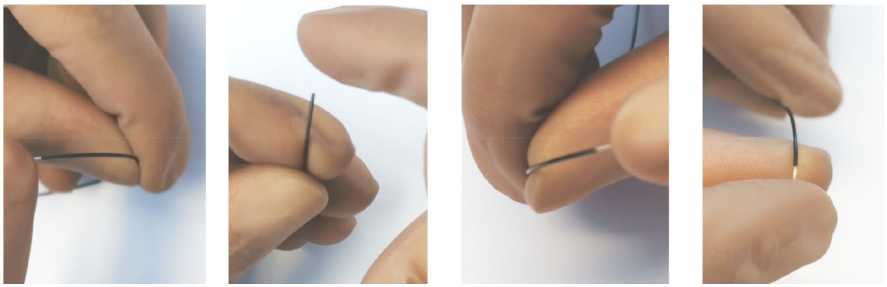
WE014xx

| REF | Description | Suitable stripper |
|---|---|---|
| WE01432 | HiFlex Fiber Stripper 400 µm | with yellow buttons |
| WE01440 | HiFlex Fiber Stripper 300 µm | with grey buttons |
| WE01441 | HiFlex Fiber Stripper 600 µm | with blue buttons |

It is not necessary to strip a Bare Fiber before trimming the tip, as the protective tube (jacket) has already been stripped 130 mm on the production side.

- **Fiber testing**

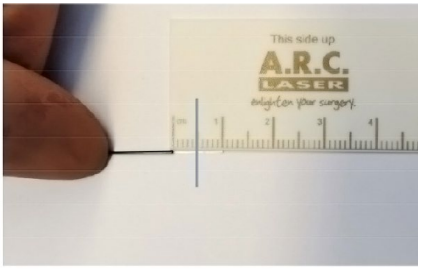
Test the fiber for brittleness after stripping as these processes may damage the protective coating on the fiber by repeatedly brushing along the exposed fiber. Apply moderate pressure under bending load.

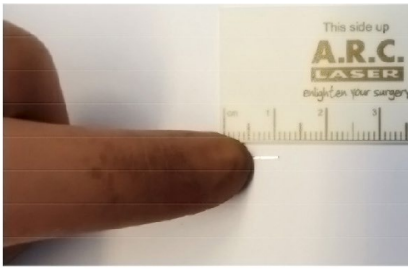


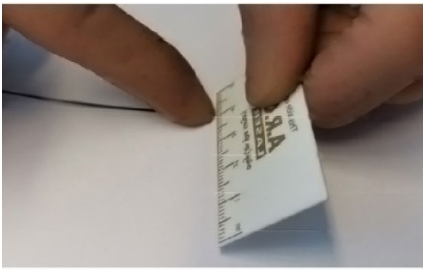
Repeat the procedure 2 - 3 times.

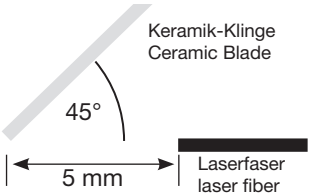
- **Trim the Fiber**

The ceramic cutter (WE01436s) is sterile and is therefore suitable for shortening the Fibers during treatment.



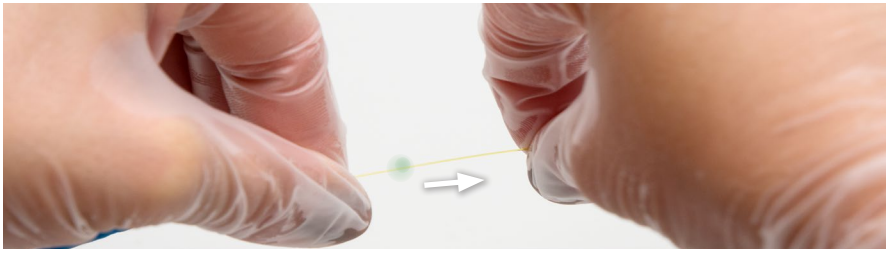






Only scribe the fiber, never cut it through!

Fix the fiber tip with your fingers. Guide the ceramic cutter to the fiber at an angle of 45° and scribe the fiber using some slight pressure. When the aiming beam is switched on, the scribed area becomes visible.
Then grasp the fiber tip between your thumb and index finger and pull it off forwards with a jerk. Then check the spot as described in chapter 6.3 and repeat the trimming process if necessary.

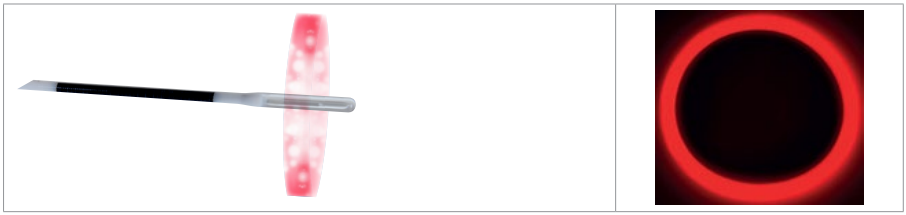


The fiber tip of the HiFlex Fiber must protrude at least 5 mm from the nylon jacket.

Each time the fiber tip is trimmed, the fiber shall be checked for breakage and the spot test (see. Chapter 6.3) shall be carried out.

## 7.2 Side Emission Fibers (Donut Fiber)

The Side Emission Fibers are used to guide the laser radiation from A.R.C. laser devices to the desired treatment area for coagulation and vaporization of tissue. These fibers emit the laser radiation laterally/radial from the fiber tip.



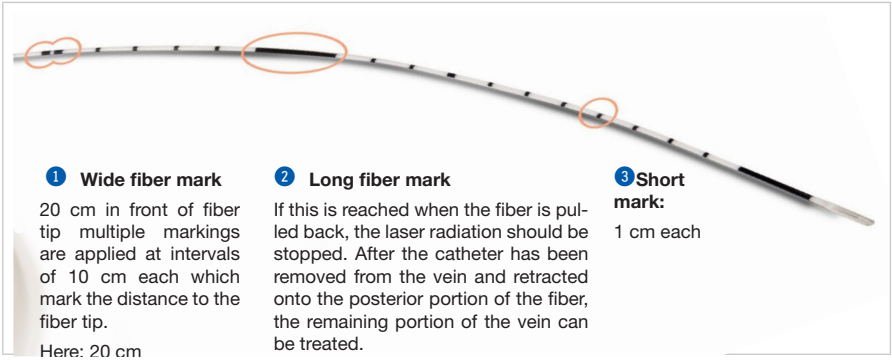
**Donut Fiber**
The rounded (atraumatic) fiber tip with 360° radial radiation pattern has no frontal radiation. Due to the radially emitted laser energy, the Donut Fiber is suitable for coagulation of vein tissue in case of varicose veins.

**Indications**
The Side Emission Fibers are intended to be used for laser coagulation of vascular tissue in varicose veins (e.g. insufficient vena saphena magna, vena saphena parva or vena saphena accessoria).

**Contraindications**
Side Emission Fibers cannot be used if acute phlebothrombosis is present, if there is an elevated risk for a thrombosis or hemodynamically relevant collateral function of vein segments exists.
The Side Emission Fibers are not intended for treatments at the eye surface or inside the eye.

**Side effects**
Infection, edema, ecchymosis/hematoma, discomfort and pain may occur during use of the Donut Fiber. Rare side effects associated with the use of the Donut Fiber with the appropriate laser device include phlebitis, paresthesia, hyperpigmentation, and embolism.

The two long markings close to the fiber tip indicate the retraction of a possibly used introducer (e.g. ZU01067s) to avoid melting of the introducer itself.
The compatibility of the markers with another introducer must be checked before use.




Characteristics of a donut fiber

| REF | Description | Matching Introducer |
|---|---|---|
| LL28060s | Donut fiber standard, 600 µm, U.C. AD: 1,8 mm | 6 F |
| LL28061s | Donut fiber slim, 400 µm, U.C. AD: 1,0 mm | 16 G |

A check of the aiming beam according to Chapter 6.3 is not necessary, as the radiation pattern is different. The fiber must nevertheless be checked for damage. The image of the aiming beam can be examined with a small distance to a mat light surface and must have a radiation pattern as shown in the image above.

## 7.3 Endo Probes

Endo Probes are probes used in ophthalmology for guiding laser radiation of A.R.C. Laser devices to the treatment area (vitreo-retinal surgery) for coagulation purposes. They are used to apply either visible (green) or near infrared (810 nm) laser radiation is used in the treatment area, mainly the retina. It is important to ensure that the Endo Probe is not applied in direct contact with the retina to avoid mechanically provoked damage.
Endo Probes are inserted into the eye, an application at the eye surface is not intended for this. Endo Probes from A.R.C. Laser can be used with or without trocar. When using trocars, compatibility must be checked before use.

**Indications**

- retinal detachment
- retinopathy
- retinal breaks
- retinal bleedings
- retinal tears
- neovascularization

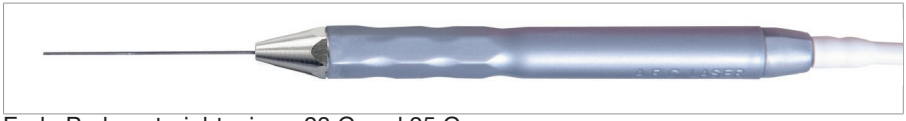
**Contraindications**

The Endo Probes are not intended for treatments of the human tissue except the eye. Endo Probes are inserted into the eye only, application on the eye surface is not intended.
Endo Probes cannot be used if posterior segment surgery is not feasible. For example in case of non transparent media (e.g. non transparent lens nucleus due to advanced cataract or non-transparent cornea, or other reasons for decreased transparency) when the retina is not visible.

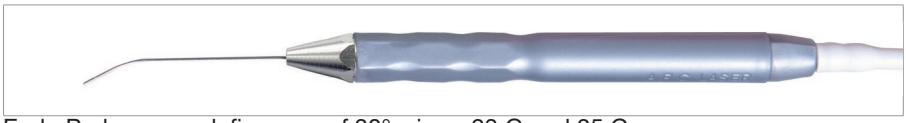
**Side effects**

The following side effects were identifeid for the Endo Probe itself: Infection (e.g. endophthalmitis), discomfort and pain.

The hand pieces length is 120 mm, the stainless steel cannulas is 34 mm.
The probe may only be used if it can be easily adjusted between the straight and bent positions.



Endo Probe, straight, sizes: 23 G and 25 G



Endo Probe, curved, fix curve of 30°, sizes: 23 G and 25 G

| REF | Description | Material |
|---|---|---|
| LL13006s | Endo Probe, 23 G, straight | Stainless medical grade steel, quartz fiber, plastic (acrylonitrile butadiene styrene – ABS), Aluminum |
| LL13010s | Endo Probe, 25 G, straight | |
| LL13015s | Endo Probe, 25 G, curved | |
| LL13025s | Endo Probe, 23 G, curved | |

## 7.4 Glaucoma Probes (Cyclo Probe / µCPC Probe)

Guiding laser radiation from the device to the desired treatment area. (As Sanchez et al.* demonstrated, the total amount of the applied energy should be in the range of 112-150 J. This range provides good pressure reduction with the least regression and fewer complications.)

**Indications:** The Glaucoma Probes are accessories for A.R.C. medical laser device FOX 810 nm which are connected to the laser device via a fiber coupler. The Probes allow guiding laser radiation from the laser device to the desired treatment area at the human eye. Glaucoma Probes are intended for coagulation or irradiation of the ciliary body in forms of glaucoma due to increased intraocular pressure (IOP) as for example open-angle glaucoma. The laser application with Glaucoma Probes enables the reduction of IOP values. For information regarding restrictions to the intended medical conditions and medical indications when using the Glaucoma Probes in combination with a compatible laser device, please, refer also to the documentation of the laser device FOX.

**Contraindications:** The Glaucoma Probes are not intended for treatments of the human tissue except the eye.The Glaucoma Probes are not intended to be used on the central circulatory system (arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior). Glaucoma Probes are intended to be applied at the eyes surface, application inside the eye is not intended. Cyclo Probe (HS11025s) should not be used for Cyclophotocoagulation using micro pulses (µCPC) where the probe is moved in continuous motion over the eyes surface as it is done with µCPC Probe (HS11036s). Further contraindications are: Inflammation or infection of the eye, forms of glaucoma that are not associated with increased intraocular pressure (low-pressure glaucoma,...), and treatment of the 3 and 9 o'clock position or areas with implanted filtering or drainage devices as well as any area of thinned sclera or if there is an existing superficial bleeding, which might absorb the laser radiation.

**Side effects:** Rare side-effects associated to the use of the Glaucoma Probes itself are:
pain, discomfort, inflammation (this risk increases in µCPC treatment when a swiping motion is not given), abrasion/ lacerated conjunctival or scleral tissue, subconjunctival hemorrhage and swelling.
Side-effects associated to the use of the Glaucoma Probe with the corresponding laser device include:
hypotony, (anterior) uveitis, loss or decrease of vision, conjunctival or scleral burns, atrophy or phthisis bulbi, conjunctival hyphema, pop-effect'-tissue disruption, corneal and (cystoid)-macular edema, long lasting anterior chamber inflammation, necrotizing scleritis, scleral thinning, hyposphagma, choroidal hemorrhge, choroidal detachment, anterior chamber flare reaction, subconjunctival hemorrhage, hemorrhage of anterior chamber or vitreous body , pupillary distortion, mydriasis, Iritis.

For information regarding other side-effects when using the Glaucoma Probes in combination with a compatible laser device, please, refer to the documentation of the laser device.

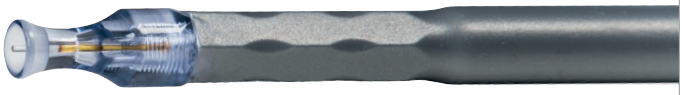
* Micropulse Transscleral Cyclophotocoagulation: A Hypothesis for the Ideal Parameters - Med Hypothesis Discov Innov Ophthalmol. 2018 Fall; 7(3): 94-100

**Principles of operation and mode of action**
There are two treatment option in Glaucoma treatment where laser radiation of a diode laser 810 nm is guided via Glaucoma Probes to the eye.

**Cyclo Probe** The cyclo probe is placed on the sclera at certain points using the wedge-shaped attachment. The spherical radiation pattern of the 600 µm fiber, which is embedded in the attachment, is particularly well suited for the transcleral coagulation of ciliary body cells (e.g. induced reduction of intraocular fluid in glaucoma).


**µCPC Probe**

The µCPC Probe is the further development of the CycloProbe, which is particularly suitable for cyclophotocoagulation by means of micropulses due to its bell-shaped attachment. It is recommended to fill the cavity with methyl cellulose (Methocel) to improve the sliding properties on the eye surface during the movement of the probes along the hemispheres required for application. This treatment is conducted in a chopped laser emission mode so the tissue can cool down between each laser pulse and therefore the side effects of the heating can be reduced.



| REF | Description | Material |
|---|---|---|
| HS11025s | Cyclo Probe | Quartz fiber, plastic (Acrylonitrile Butadiene Styrene – ABS), Makrolon Rx 1805, Polycarbonate |
| HS11036s | µCPC Probe | |

Never insert the Cyclophoto probe into the eye or use it in areas outside the cilliary body.

## 7.5 Shockwave Emission Probe (Cetus Probe)

The Shockwave Emission Probes are used to guide and convert the laser radiation of A.R.C. Laser device Cetus for ophthalmic applications.


**Indications**

Shockwave Emission Probes are intended to be inserted into the eye to perform photofragmentation of tissue. The Laser energy is converted into shock wave pulses which mechanically destroy/crush tissue structures e.g. lens nucleus material and lens epithelial cells in cataract surgery.

**Contraindications**

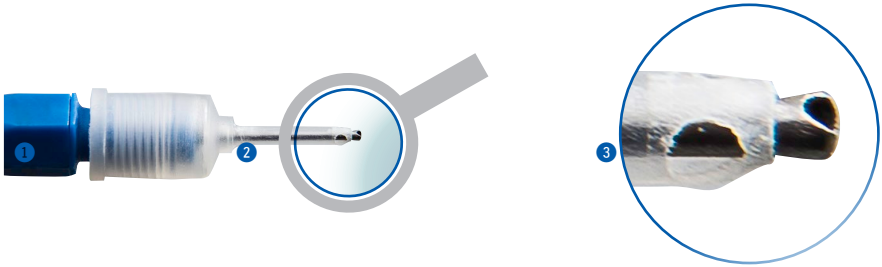
The Shockwave Emission Probes are not intended for treatments of the human tissue except the eye. Shockwave Emission Probes are inserted into the eye only, application on the eye surface is not intended.
Shockwave Emission Probes cannot be used if the tissue cannot be fragmented because of hardness (e.g. in case the lens nucleus is quite mature and hard).
In case of cloudy cornea or non-transparency of the cornea due to other reasons no surgery is indicated as the surgeon cannot see the treatment area well. Intraocular or extraocular inflammation right at the places of eye access are contraindications to perform the surgery.

**Side effects**

Side and adverse effects when using the Shockwave Emission Probes can be infection, discomfort and pain.
The eye of the patient is opened with a small parazenthesis which serves as a entrance to access the target tissue. The treatment takes place inside the eye. E.g. by unindented manipulation, the capsular bag maybe opened posterior which then requires vitrectomy. Side effects which may occur from cataract surgery in general are also macular edema, inflammation and corneal edema or folds.

| REF | Description | Material |
|---|---|---|
| LY11004s | Cetus Probe | Medical grade stainless steel, quartz fiber, plastic (Acrylonitrile Butadiene Styrene – ABS), Silicone, titanium |

Sleeves are placed on the tip of the probes. The Cataract Surgery Sleeve (WE01377s) is included in the standard scope of delivery.




The position of the sleeves on the tip of the shockwave emission probe does not differ from the sleeve position on the ultrasound phaco handpiece:
the irrigation openings should point to the side (90° to the aspiration opening);
if necessary, the position of the irrigation openings can be varied, since the aspiration opening in the eye may point to the equatorial plane and therefore the irrigation openings can then be placed in such a way that the irrigation fluid is not discharged in the endothelial direction.
The Shockwave emission probe does not require testing;
however, if a functional test is to be carried out, it should be conducted in a container with rinsing solution before insertion into the eye, never in air and never after a test in rinsing solution outside the container in air.

## 7.6 Otology Probes

Otology probes are used to guide laser radiation of A.R.C. Laser devices to coagulate or vaporize tissue in the target treatment area, the middle ear. Besides the usage on tissue, Otology Probes are also intended to expose laser radiation to middle ear implants, if they require laser radiation for activation.
The fiber end can be used in contact with the tissue or at a distance from the tissue, depending on the desired effect.

**Indications**

Vaporization or coagulation of tissue and bony structures in Otology, for example:

- Stapedotomy / Stapedectomy
- Paracenthesis / Myringotomy
- Tumor / Glomus tumor
- Cholesteatoma
- Coagulation of blood vessels

**Contraindication**
Otology Probes are not intended for treatments at the eye surface or inside the eye.

**Side effects**
Infection, discomfort, pain, refixation of footplate, stapes luxation, floating footplate, fracture of footplate, bleeding, inner ear lesions, saccular injury, misdirected beam, heating of labyrinth fluid, sensorineural hearing loss, vertigo, damage to distal structures, damage to facial nerve.

| REF | Description | Material |
|---|---|---|
| LL11058s | Otology Probe long | Stainless medical grade steel, quartz fiber, plastic (acrylonitrile butadiene styrene – ABS), Aluminum |
| LL11059s | Otology Probe, curved tip | |
| LL28058s | Otology Probe long, U.C. | |
| LL28059s | Otology Probe, curved tip, U.C. | |

**Otology Probe, short**


Standard otology probe - curved tip 20°

**Otology Probe, long**


curved 20° - alternative otology probe

The fiber protrusion from the distal cannula of 3 mm allows the user a good view to the treatment area.

## 7.7 DCR Probe


DCR Probes are used to guide laser radiation with the A.R.C. Laser devices to the desired treatment area (tear duct) for vaporization of tissue and bony structures. Due to the curved cannula design and the small cannula diameter of 0.7 mm, the DCR probe is particularly suitable for use in the area of rhinology (e.g. tear duct surgery).
Laser parameters in the range (> 7 W and at pulse length > 10 s) are not intended for DCR Probes.

**Indications**
Vaporization or coagulation of tissue and bony structures for tear duct surgery.

**Contraindications**
DCR Probes are not intended for treatments at the eye surface or inside the eye.

**Side effects**
Carbonization, insufficient osteotomies, ecchymosis, swellings, scarring

| REF | Beschreibung | Material |
|---|---|---|
| LL13069s | DCR Probe, 300 µm | Stainless medical grade steel, quartz fiber, plastic (acrylonitrile butadiene styrene – ABS), Aluminum |
| LL28067s | DCR Probe, U.C. | |

## 7.8 Lipolysis Probe

The Lipolysis Probes* are used to guide the laser radiation from A.R.C. laser devices to the desired treatment area for subcutaneous minimally invasive dissolution of fatty tissue in regions: face, chin, neck, upper arms, abdomen, back hips, inner thighs, outer thighs, knees, calves and ankles.

The Lipolysis Probes must be moved continuously during the entire duration of treatment, selective use is not recommended.

**Contraindication**

Lipolysis Probes are not suitable for the use in the human eye.

**Side effects**

Common: Swelling, hematoma, bruising, numbness or tenderness, itching, pain, redness
Uncommon: Postoperative pain, minor scarring
Rare: Infection, oedema
Very rare: Abscess formation

Cannula length 120 mm, outer diameter of cannula:
1.2 mm, specially rounded cannula end.

| REF | Description | Material |
|---|---|---|
| LL13032s** | Lipolysis Probe 400 µm, U.C. | Stainless medical grade steel, quartz fiber, plastic (acrylonitrile butadiene styrene – ABS), Aluminum |

* According to the regulation (EU) 2017/745 of the European Parliament and Council on medical devices, a device for reduction or removal of fatty tissue has no medical benefit.
** Only for existing clients

# 8. Overview of fiber/sensor unit compatibility

| | | FOX 300[1] | FOX 400[2] | FOX U.C.[3] | FOX IV | WOLF | Nuvolas 300[4] | Nuvolas U.C.[5] | Chirolas 400[6] | Chirolas U.C.[7] | Classic 532 | Cetus |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Bare Fibers** | | | | | | | | | | | | |
| LL13062s | HiFlex Fiber, 300 µm | x | | | | | x | | | | | |
| LL13066s | HiFlex Fiber, 400 µm | | x | | | | | | x | | | |
| LL28062s | HiFlex Fiber, 300µm, u.c. | | | x | x | x | | x | | x | | |
| LL28066s | HiFlex Fiber, 400µm, u.c. | | | x | x | x | | x | | x | | |
| LL28068s | HiFlex Fiber, 600µm, u.c. | | | x | x | x | | x | | x | | |
| **Side Emission Fibers** | | | | | | | | | | | | |
| LL28060s | Donut Fiber EVLT 600 µm, u.c. | | | | | x | | | | | | |
| LL28061s | Donut Fiber EVLT 400 µm, u.c. | | | | | x | | | | | | |
| LL28080s | Donut Fiber EVLT 600 µm, u.c. | | | | | x | | | | | | |
| LL28081s | Donut Fiber EVLT 400 µm, u.c. | | | | | x | | | | | | |
| **Glaucoma Probes** | | | | | | | | | | | | |
| HS11025s | Cyclo Probe | x | | | | | | | | | | |
| HS11036s | µCPC Probe | x | | | | | | | | | | |
| **Endo Probes** | | | | | | | | | | | | |
| LL13006s | Endo Probe 23G, straight, 300 µm | x | | | | | | | | | x | |
| LL13010s | Endo Probe 25G, straight, 200 µm | x | | | | | | | | | x | |
| LL13015s | Endo Probe 25G, curved, 200 µm | x | | | | | | | | | x | |
| LL13025s | Endo Probe 23G, curved, 300 µm | x | | | | | | | | | x | |
| **Shockwave Emission Probes** | | | | | | | | | | | | |
| LY11004s | Cetus Probe | | | | | | | | | | | x |
| **Otology Probes** | | | | | | | | | | | | |
| LL11058s | Otology Probe long | x | | | | | x | | | | | |
| LL11059s | Otology Probe, curved tip | x | | | | | x | | | | | |
| LL28058s | Otology Probe long, u.c. | | | x | x | x | | x | | x | | |
| LL28059s | Otology Probe, curved tip, u.c. | | | x | x | x | | x | | x | | |
| **DCR Probes** | | | | | | | | | | | | |
| LL13069s | DCR Probe, 300 µm | x | | | | | x | | | | | |
| LL28067s | DCR Probe, u.c. | | | x | x | x | | x | | x | | |
| **Lipolysis Probes** | | | | | | | | | | | | |
| LL28032s | Lipolysis Probe 400 µm, u.c. | | | x | x | x | | | | x | | |

[1] Einkopplung: 300 µm, λ= 810 nm
[2] Einkopplung: 400 µm, λ= 980 nm
[3] Einkopplung: U.C., λ= 980 nm
[4] Einkopplung: 300 µm, λ= 514 nm
[5] Einkopplung: U.C., λ= 514 nm
[6] Einkopplung: 400 µm, λ= 980 nm
[7] Einkopplung: U.C., λ= 980 nm

## 9. Maintenance

Consumables are exempt from regular maintenance. Please ensure that the checking and inspection instructions in this User's Manual are observed.

## 10. Service

### 10.1 Warranty information

All consumables are excluded from the warranty.

### 10.2 Sales and service information

For sales and service information, please contact A.R.C. Laser GmbH.

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Bessemerstr. 14
90411 Nürnberg
Germany
Tel: +49(0)911- 21779-0
Mail: info@arclaser.de

A.R.C.
LASER
made in Germany

Manual Fibers and Probes

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 28.01.20