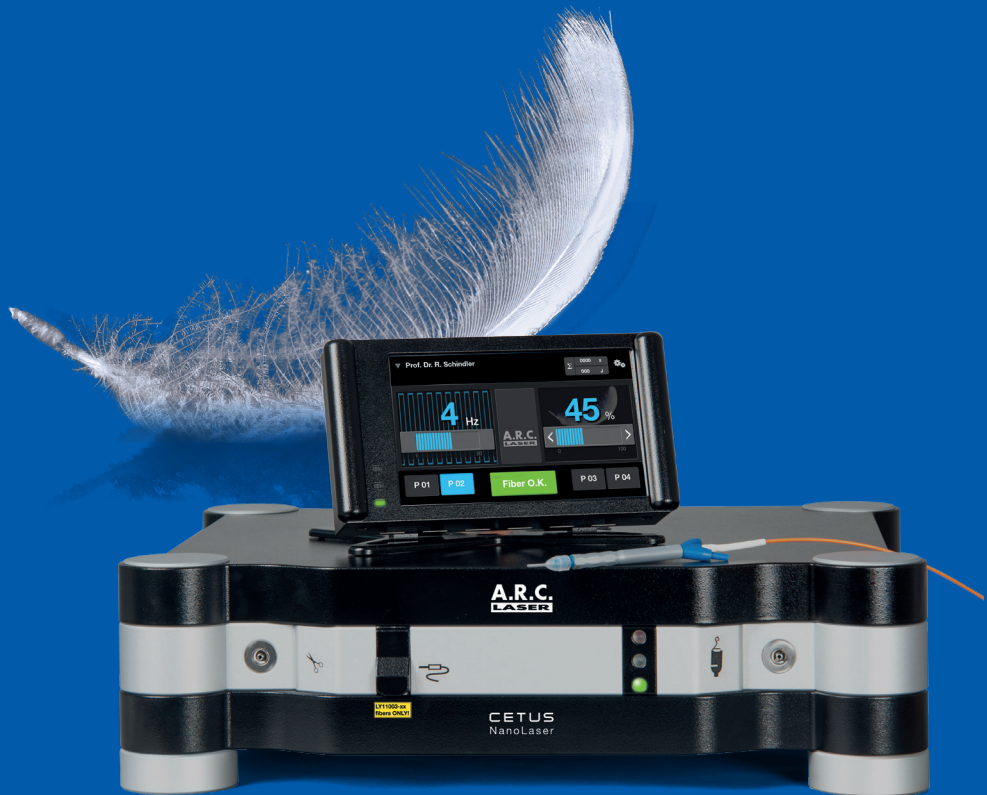


NANO-LASER CETUS



Application Manual

**A.R.C.
LASER**

enlighten your surgery.



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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) Clinical Relevance

Cataract surgery is the most performed procedure in ophthalmology worldwide. Today, due to modern techniques and experienced surgeons, the implantation of an artificial intra ocular lens (IOL) after the removal of the natural lens, is almost free of complications and without any side effects. In addition to traditional ultrasound phaco emulsification quite recently a new laser system was established. The system allows the surgeon the fragmentation and aspiration of the human lens together with his individual existing cataract surgery equipment. Today, it is possible with a Femto laser is also feasible and therefore a complete ultrasound free laser cataract surgery can be offered to the patient.

Risks of infections or thermal complications which can influence surrounding tissue can be avoided.

2) Technique

The system is based on a ultra short pulsed Nd:YAG laser. The centerpiece of the system is the disposable coaxial hand piece. An integrated fiber in the hand piece, ends 1 mm in front of a titanium plate inside the hand piece tip. The radiation of the laser is directed to this plate and a plasma is ignited (optical breakdown) which results in a shock wave exiting the side hole of the hand piece tip. In parallel, the lens material is sucked to the tip and by selective triggering of the laser in contact with the tissue this effect leads to a photo fragmentation of the lens. Simultaneously, the lens, destructed by the shock wave, is removed by the aspiration system through the mentioned side hole. The irrigation fluid (e.g. BSS) or any Viscoelastics are aspirated in the same way. Intraocular pressure can be obtained according to requirements.

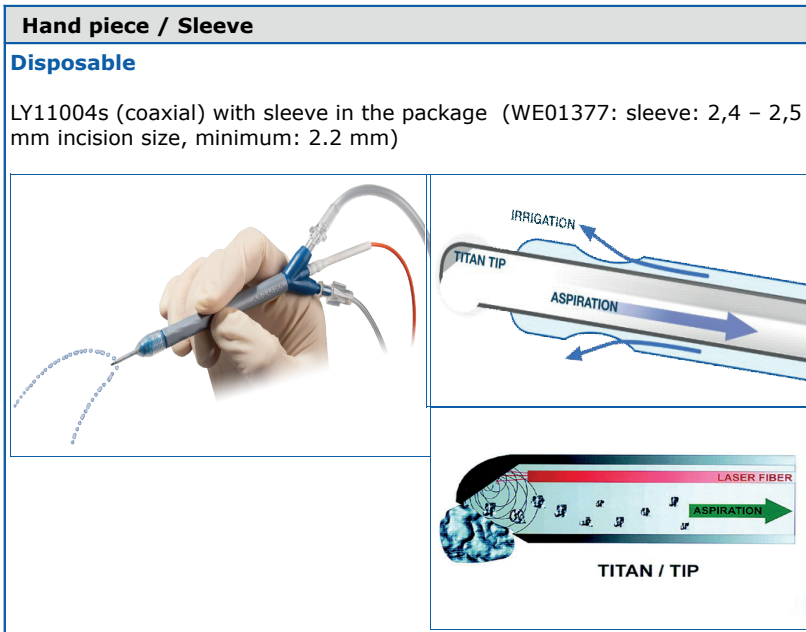
The laser beam does not exit the hand piece and therefore no direct laser tissue interaction occurs. For that reason, the Cetus laser is classified as a laser class I. The laser does not pass through the hand piece directly and thus a danger to users and patients is prevented. Protective eye wear or rooms with particular safety are not necessary.

The Nano Laser can only be used in combination with a phacoemulsification system. All obtainable systems on the market with a pneumatic vitrectomy support can be adapted. A bidirectional foot pedal enhances laser control.

Technical data	
Laser	Nd:YAG, diode pumped
Wavelength	1064nm
Notifications	Digital on display
Repetition rate	1 – 10 Hz
Pulse duration	4 ns
Energy	3 – 8 mJ
Cooling	internal
Electrical data	200 – 240 V,
Weight	12kg
Dimensions	H 16,1 cm / B 47,8 cm / T 42,1 cm

Application

Cataract surgery	
Indications	Contraindications
<ul style="list-style-type: none"> · cataract surgery of the lens via photofragmentation (LOCS 1 - 4) · Fuchs dystrophy · Cornea Guttata · Corneal edema 	<ul style="list-style-type: none"> · mature cataract (LOCS >4) · uveitis



3) Advantages

The advantages of the new system are primarily characterized by the innovative technology:

In general this method does not substitute the traditional ultrasound phacoemulsification in every case, but functions rather as an option and alternative in cataract surgery. The surgeon can maintain his individual surgical technique.

The coaxial hand pieces, are conceived for single use. So for each patient an individual treatment is assured with highest hygienic standards. The hand piece combines irrigation and aspiration and is equivalent to I/A-ports of the ultrasound technique. OR-staff and doctor do not change their routine work and switching of hand pieces is not necessary anymore.

By the use of local anesthesia or with an eye drop anesthesia, the procedure is performed within several minutes and is almost painless for the patient. A general anesthesia is possible, but only done when required or by request of the patient.

By selective triggering of the laser and the inflexible tip no thermal damages at the cornea or other ocular tissues occur compared to the vibrating ultrasound needle¹. The very short pulses allow no heating of cells on large areas². There are published data describing morphology and cell damages after surgery in several studies, presented on international conferences (ESCRS 2013, DOC 2014). The gentle effect of this technology to the corneal endothelium could be confirmed³.

1. "Relationship between endothelial cell loss and microcoaxial phacoemulsification parameters in noncomplicated cataract surgery", M. AE Soliman Mahdy et.al., Clin Ophthalmol. 2012; 6: 503–510
2. Fluid temperature at the corneal endothelium during phacoemulsification: comparison of an ophthalmic viscosurgical device and balanced salt solution using the finite element method, Reepolmaha S ;2010; Ophthalmic Res.43(4):173-8
3. „Nanosecond laser–assisted cataract surgery: Endothelial cell study“, Ivan Tanev, PhD, Vesselin Tanev, DMSc, Anastasios John Kanellopoulos, PhD; JCRS 2016; 42:725–730

4) Therapy Indications

The following chapter gives detailed information about the laser application. 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 a study carried out by several medical doctors, who shared their experiences using the Nano Laser system every day. Despite all caution from our side, each medical doctor needs to set all pa-

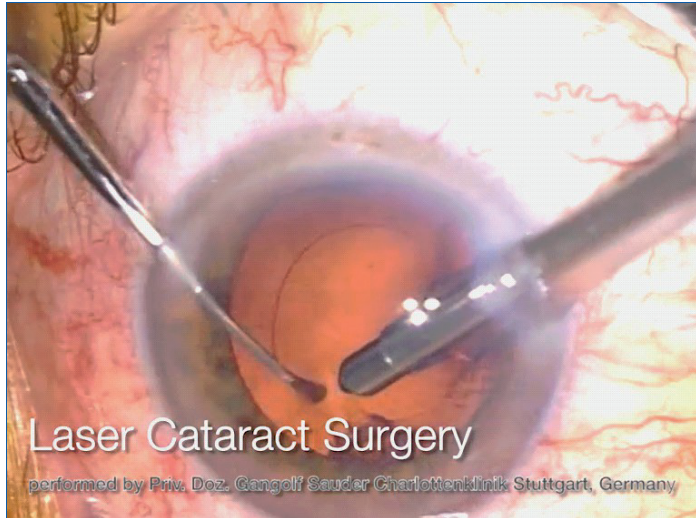
rameters individually, observing the indication and the patient to be treated. Changing the parameters may possibly require a change of other settings. Neither author nor manufacturer are liable for treatment failures.

Working Technique

The CETUS Nano Laser is used with hand pieces and silica fibers (300 μ m), having on one side a fiber plug to connect into the fiber port of the laser. The light up of the yellow LED indicates the standby mode of the laser. After the fiber is connected, the laser switches to READY mode and the green LED lights up. The laser is activated in the vitrectomy mode by pressing the foot pedal of the coupled phaco device. The hand pieces can be used parallel for irrigation and aspiration like in standard phacoemulsification.

The laser offers variable power settings, which can be set individually by the physician depending on the performance. The user can choose between different energy parameters between 30 and 100%, which equals 3 to 8 mJ. Normal values are 4 to 5 mJ. The CETUS provides pulse rates from 1 Hz up to 10 Hz. Thus the physician is able to adapt the procedure due to the level of lens hardness.

Before surgery, the function of the hand piece can be checked by activating the laser one or two times. The plasma should be visible and an acoustic effect clearly noticed. The surgeon uses a manipulator in his second hand as he is used to from conventional ultrasound phaco emulsification (stop and chop technique!).



Sleeve

For sealing incisions a silicone sleeve for the tip is given with every hand piece.

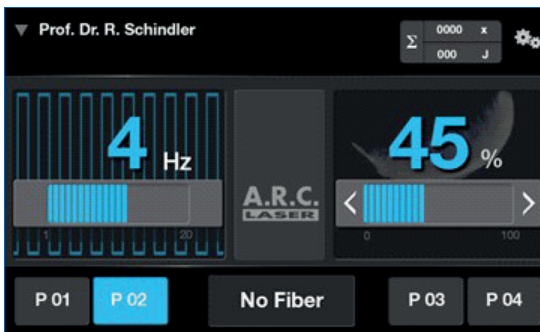
The sleeve is designed for incision sizes from 2.4 to 2.5 mm (minimum 2.2). For larger incision sizes there are larger sleeves available. The sleeve is fixed on the tip by a thread. Two openings are arranged at the tip at an angle of 180° which provide the inflow of irrigation solution into the anterior chamber. The

surgeon may adjust the exact sleeve position according to his personal experience. However, the aspiration opening has to stay clearly open of course.



The display

The adjustment of the power can be done via touch-screen. Additionally the number of applied pulses and the total energy are displayed.



5) Treatment related issues

The surgeon needs to familiarize with the new laser and align his individual technique. The characteristic "impaling effect" of an oscillating phaco needle into the nucleus is not given similar to the ultrasound tip. In order to work efficiently, for photofragmentation the opening of the tip has to be targeted downwards to the lens. The nucleus can also be pre-treated by femto laser fragmentation or pre-chopping etc. to reduce energy to a minimum for lens fragmentation.

It has to be taken into account that this technique is recommended for lenses with a LOCS grade up to 4. The fragmentation of mature cataracts (>4) can be difficult and takes longer time because of the low intensity of the shock waves⁴, which result in less energy deposited to the eye. Repetition rates for treatment are recommended from 5 to 8 Hz and to be decreased during surgery. The rate should be reduced during the procedure, because experience has shown, that hard nuclei fragments at the second half of the surgery when the capsular bag is not completely filled with nucleus material any more, can be treated better with lower rates. To avoid capsular rupture and increase working efficiency, the aspiration opening of the laser hand piece should be targeted towards the equator whenever the capsular bag is no more completely filled with nucleus material. This avoids aspirating the capsule and increases efficiency when working on the nucleus material in between the manipulator/chopper and the hand piece tip. A harder nucleus implies the application of more laser pulses and therefore an extension of the operating time and increasing of energy. Higher repetitive rates lead to an uncontrollable movements of lens particles within the

capsule (“tumbling parts”), which cannot be captured by the aspiration and due to the repulsing effect of the shock waves may harm surrounding tissue or even result in a capsule rupture. For that reason a selection of patients and previous determination of the cataract grade are necessary. Hard cataracts should be still treated with conventional ultrasound. In case of a false diagnose of cataract categorization, the surgeon should switch to ultrasound phaco emulsification to sustain surgery in a tolerable time and to prevent any damage to the eye. A pulse number of 1000 should normally not be exceeded. Power settings of 40 – 50 % are normally enough and can be increased to 60% in case of hard nuclei. Moreover high energy levels should be avoided, to prevent early damage of the fiber or the reduction of the hand piece efficiency.

The dimension of irreversible damage to the tissue depends on the intensity of aspiration and activation of the laser. If the aspiration level is set too high, aspiration of the posterior capsule can occur and by triggering the laser simultaneously a capsule rupture can be the consequence. A continuation of the procedure has to be stopped immediately.

Furthermore, it has to be taken into account that this method of lens fragmentation may take more time compared to an ultrasound procedure in case nucleus fragmentation requires a lot of energy application. Experienced surgeons are able to compensate this discrepancy in the course of routine. In case of clear lens extraction, the procedure may be quicker. Soft nuclei can take up the same time as using ultrasound phaco.

4. Eye World, Jan 2014, Back to the future: Ultrasound gets replaced by laser, again, Matt Young (Contributing Writer).

6) Behavior in case of a system error

A restart of the laser 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.

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 results in less effect. When this occurs, the user can check for the hand piece first and then for the laser. Any damage to the fiber results in an absence of the plasma which is not noticeable anymore. The user should not continue the procedure and change the fiber.

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.

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