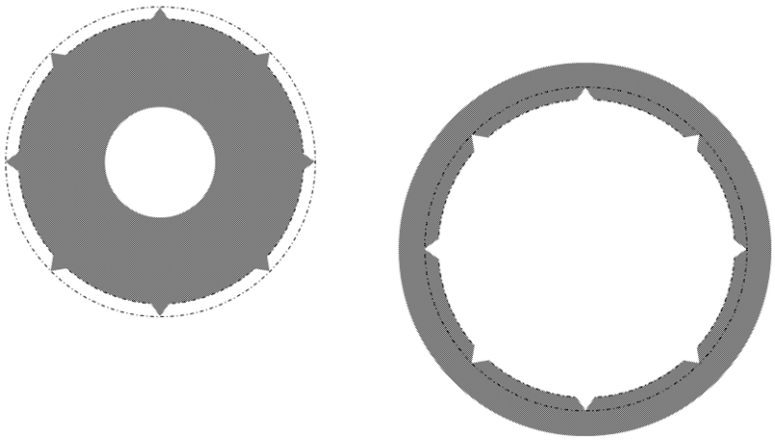
Instruction for Use TREAT

Original version IfU art. no. 2000100-01

Naumann-Rings



CE

SCHWIND eye-tech-solutions GmbH Mainparkstrasse 6-10 · 63801 Kleinostheim GERMANY

General

Dear Customer

Thank you very much for purchasing this medical product and the confidence you have in our company. You have decided on a sophisticated product, which was manufactured and tested under strict quality criteria.

Construction and production fully complies with regulations and requirements which apply to medical products.

Compliance with all effective standards and laws is clearly visible by the CE symbol, which is displayed on the identification label. The CE Symbol stands for conformity with current laws and consequently for security and confidence.

CE

Constant research and development may cause changes in design and scope of supply. Therefore, in individual cases, the figures in this manual might deviate from the delivered product.

If you have any questions or desire further information about your equipment, please do not hesitate to contact us via phone, fax or e-mail. Our team of specialists will be glad to help you. Our address, phone and fax numbers, as well as the e-mail address can be found at the beginning of this manual in chapter GENERAL INFORMATION.

Sincerely,

SCHWIND eye-tech-solutions GmbH

Table of Contents

PART A. REGULATORY REQUIREMENTS

1 GENERAL

1.1 System Identification Data

Product name:	**Naumann-Rings**
Device description:	**Ring masks for laser-assisted perforating keratoplasty**
Device application:	**Corneal surgery in ophthalmology**
Intended purpose:	Refer to chapter 2.1
Medical device class:	**I**
Serial number:	Refer to **identification label** of the device(s).
Accessory to:	**AMARIS** (SP6.1 and higher) **with SCHWIND CAM** (5.2 and higher)
Manufacturer:	**SCHWIND eye-tech-solutions GmbH** **Mainparkstrasse 6-10** **63801 Kleinostheim, GERMANY**
Delivery:	**SCHWIND eye-tech-solutions GmbH** or authorized local SCHWIND representative

1.2 Instruction for Use Identification Data

Description:	**Instruction for Use of Naumann-Rings**
Current document status:	**Version 1.1 dated 2019-12-13**
Other IfU versions:	No
Author:	SCHWIND eye-tech-solutions GmbH

1.3 Explanation of Symbols used

The following conventions are used in this manual:

DANGER

The symbol refers to a hazard with a high risk level that, when not avoided, will result in death or serious injury.

WARNING

The symbol refers to a hazard with a moderate risk level that, when not avoided, could result in death or serious injury.

CAUTION

The symbol refers to a hazard with a low risk level that, when not avoided, could result in moderate or minor injury.

IMPORTANT NOTE

This symbol provides the user with useful or additional information.

1.4 Notes on the Instruction for Use

IMPORTANT NOTE

Read this Instruction for Use carefully and consider all instructions prior to use Naumann-Rings.

Observe all safety and warning notes, and contraindications as described in this manual.

However this Instruction for Use does contain all information necessary for the safe and effective usage of Naumann-Rings.

Please keep the Instruction for Use and all related documents close to the medical device. Allow any user access to the manual(s) at all times, store it readily available.

IMPORTANT NOTE

The present English manual contains the ORIGINAL INSTRUCTIONS, which are legally binding. Translations of these must bear the words **"Translation of the Original Instruction"**.

IMPORTANT NOTE

If you have any questions regarding any matters, contact an authorized local SCHWIND representative or SCHWIND eye-tech-solutions directly for advice.

Refer to chapter 15 Manufacturer / Technical Assistance / Application Support.

2 INTRODUCTION

2.1 Intended Purpose and Use

The medical device „Naumann-Rings“ are an accessory to the AMARIS excimer laser systems, intended for being used for preparation of corneal grafts as well as the corresponding wound beds by means of providing a mask for laser ablation of the corneal tissue.

The standard surgical procedure for use of the masks is described in an additional clinical document. However, the responsibility for use and the technical realization of the ablation profile is left to the surgeon and the software of the laser system respectively. The device does not provide any functionality besides the shielding of corneal tissue from applied laser energy and is not intended to be used for any other purpose than described herein or the corresponding surgical manual.

The device is to be used exclusively in eye clinics or similar premises with appropriate conditions with respect to sterile conditions. Usage is limited to be in conjunction with the AMARIS excimer laser systems with the software package CAM.

The device is to be used exclusively in eye clinics or similar premises with appropriate conditions with respect to sterile conditions. Usage is limited to be in conjunction with the AMARIS excimer laser systems with the software package CAM.

2.1.1 Intended Users

The intended users of Naumann-Rings are typically ophthalmologists who are focused on therapeutic eye surgery including (perforating) keratoplasty and the personnel of an eye clinic like:

- Surgeon
- Surgery assistant
- Treatment planner
- Application specialists

2.1.2 Indications of Patient Target Group

The human cornea can become damaged by a number of diseases or injuries which may leave scars or opacities that reduce the vision. Sometimes the normal function of the cornea fails, and then it becomes hazy and the eye may become painful and inflamed.

So when the cornea fails to function for any reasons, it may be necessary to replace the diseased cornea with a (full-thickness) graft of healthy corneal tissue transplanted from a human donor. When the entire cornea is replaced it is known as penetrating keratoplasty and when only part of the cornea is replaced it is known as lamellar keratoplasty.

The indication for the use of this application depends on the severity of the corneal disease and the decision of the ophthalmologist.

WARNING

Improper use or failure of function of the Naumann-Rings may result in severe consequences to the patient’s eyesight.

WARNING

Any medical use of the Naumann-Rings outside these specifications is considered to pose severe hazards and is therefore not permitted.

2.2 Normal Use

The Naumann-Rings will be located in eye clinics and private medical practices. The device is designed for sterile use (multiple uses) only and storage outside the operating room. The product is delivered non-sterile and the sterilization is in responsibility of the user. To reprocess the device, the manufacturer provides validated procedures for both manual and automatic reprocessing. Applying any other reprocessing procedure requires prior validation, according to applicable international and/or local standards, by the user. The Naumann-Rings will be used by ophthalmologists and their teams (e.g. surgery assistants, etc.) after having successfully completed specific training with the device and the available techniques. Local regulations in the respective country may impose further requirements to the normal use. The disposal of the Naumann-Rings must be done according to local standards in the respective country.

2.3 Clinical Benefit

The intended clinical benefit of Naumann-Rings - in combination with excimer laser-assisted cornea ablation – is the achievement of a patients' cornea to be relatively homogeneous, with only small amounts of corneal astigmatism, and an improved vision outcome (with best correction). [1]

Further advantages are the very low mechanical pressure and reduced shear-forces in comparison using a trephine for trepanation, which reduces significantly the post-surgery SEQ. [2]

Although the use of a femtosecond laser for perforating keratoplasty became more popular during the last years, the femtosecond procedure also more often includes a mechanical change of the cornea caused by the applanation technique. [3]

[1] PKP for Keratoconus From Hand/Motor Trephine to Excimer Laser and Back to Femtosecond Laser. Seitz B, Szentmáry N, Langenbucher A, Hager T, Viestenz A, Janunts E, El-Husseiny M. Klinische Monatsblätter für Augenheilkunde. 233(6):727-36. June 2016.

[2] Nonmechanical corneal trephination with the excimer laser improves outcome after penetrating keratoplasty. Berthold Seitz, MD, EBOD, Achim Langenbucher, PhD, Murat M. Kus, MD, Michael Küchle, MD, Gottfried O. H. Naumann, MD; Ophthalmology, 1999, 106(6):1156-1165.

[3] Excimer versus Femtosecond Laser assisted penetrating KPL. Moatasem El-Husseiny, Berthold Seitz, Achim Langenbucher , Elena Akhmedova, Nora Szentmary, Tobias Hager, Themistoklis Tsintarakis, Edgar Janunts. Department of Ophthalmology, Saarland University Medical Center UKS, Homburg/Saar, Germany. Journal of Ophthalmology, 2015, Article ID 645830.

2.4 Contraindications and Side Effects

In the following chapters you find a list of contraindications and possible side effects for refractive surgery.

2.4.1 Contraindications

The following contraindications are determined according to [1,2]

- Uncontrolled intraocular pressure
- Acute corneal hydrops (pain, severe clouding of vision and stromal edema due to leakage of aqueus humor throught a tear in Descement's membrane)
- Untreated vascularized cornea
- Acute ulcerative keratitis

See also contraindications for refractive photo ablation in respective IFU.

[1] *B. Seitz, M. El-Husseiny, A. Langenbucher, Complications and Management in Laser Transplant Surgery, in: S.J. Linke, K. Toam (Eds.), Complicat. Corneal Laser Surg., Springer International Publishing Switzerland 2016, 2016: pp. 199–225.*

[2] *B. Seitz, N. Szentmáry, M. El-Husseiny, A. Viestenz, A. Langenbucher, G.O.H. Naumann, The Penetrating Keratoplasty (PKP): A Century of Success, in: Corneal Transplant., Springer International Publishing, Cham, 2016: pp. 67–92. doi:10.1007/978-3-319-24052-7_6.*

IMPORTANT NOTE

Contraindications are not limited to this list. For a complete list of contraindications, please consult medical literature, associations and current legislation in your particular country.

If surgery is performed for patients with any of these conditions, an additional consent form is recommended to highlight the additional risk or reduced expectations.

2.4.2 Side Effects and Complications

The following **side-effects** relate to perforating keratoplasty according to the existing literature [1,2] but not to the accessory Naumann-Rings itself.

- Tears
- Pain
- "Red eye"
- Slow recovery of visual function over weeks and months / delayed optical rehabilitation
- Temporary blurred vision
- Early postoperative astigmatism with sutures in place
- Late persisting astigmatism after suture removal
- Increase of net astigmatism
- Inhomogeneous wound healing
- Hypesthesia (loss of sensitivity, numbness) of the graft over several years.

- Leakage in donor-recipient junction
- Risk and symptoms of suture loosening
- Risk of epithelial defects with a risk of infection
- Possibility of immunological graft rejection, even after several years
- Loss of the eye due to expulsive haemorrhage

See also side-effects and complications for refractive photo ablation in respective IFU.

The following **complications** relate to the usage of the medical device accessory Naumann-Rings:

- Bleeding
- Inflammation
- Thermal effects
- Treatment abortion, need for manually cutting
- Unintentional deviations from circular recipient openings
- Intraoperative horizontal, vertical and topographical discrepancies between the donor and recipient.
- Over/undersized donor disc
- Deformation of corneal tissue including distortion of the cut edges
- Decentration of mask. Slide of mask during laser action. Step-shaped incision edge of graft due to sliding

[1] *B. Seitz, M. El-Husseiny, A. Langenbucher, Complications and Management in Laser Transplant Surgery, in: S.J. Linke, K. Toam (Eds.), Complicat. Corneal Laser Surg., Springer International Publishing Switzerland 2016, 2016: pp. 199–225.*

[2] *B. Seitz, N. Szentmáry, M. El-Husseiny, A. Viestenz, A. Langenbucher, G.O.H. Naumann, The Penetrating Keratoplasty (PKP): A Century of Success, in: Corneal Transplant., Springer International Publishing, Cham, 2016: pp. 67–92. doi:10.1007/978-3-319-24052-7_6.*

IMPORTANT NOTE

Side effects and complications are not listed in this document. Please inform yourself about side effects and complications from relevant technical literature and medical associations.

2.4.3 Residual Risks

Technical design and safety measures reduce any potential risk to an acceptable level and reduced as far as possible but cannot exclude completely the following residual risks associated with potential harms and complications caused by treatments using Naumann-Rings:

- Customer discontent after surgical intervention
- Incorrect treatment by the surgeon but follow-up treatment possible

3 DEVICE / SYSTEM DESCRIPTION

This section includes the specifications the user requires to use the device appropriately.

3.1 Device Description

The Naumann-Rings are small metal shaped masks to create sharp edges for preparation of corneal grafts and their recipients.

3.1.1 Method for Corneal Grafting

The corneal donor is been fixed in an artificial chamber and get pressurized. Then the donor-masking-ring (Figure 1) is placed on top of the donor cornea. To protect the central corneal tissue from dehydration, it is recommended to put viscoelastic gel on the central part of the masking ring.

Finally a UV laser beam controlled by a beam steering system progressively ablate the corneal tissue in a suitable pattern along the masking-ring borders until the cornea perforates (Figure 1: & Image 1).

After first local penetration, anterior chamber water will intrude into the area of laser ablation. In the areas of water ablation the graft is not fully separated. A cornea scissor might be needed to cut residual tissue bonds.

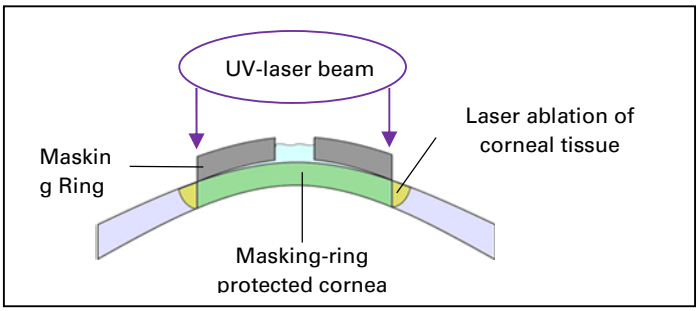
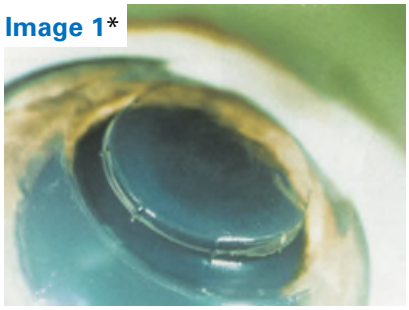


Image 1*



*Source: Book; Theo Seiler, Refraktive Chirurgie der Hornhaut, Enke-Verlag

Figure 1: Schematic principle of operation (donor graft)

3.1.2 Method for Recipient

The patient or at least the patients eye is anesthezised. The eye gets leveled horizontally and the recipient masking-ring (Figure 2) is placed centrally. Finally the UV-laser beam will progressively ablate the corneal tissue along the masking-ring borders until the cornea perforates, analogous to the method described in the previous section. (Figure 2 & Image 2).

After first local penetration, anterior chamber water will intrude into the area of laser ablation. In the areas of water ablation the patients cornea is not fully separated. A cornea scissor might be needed to cut residual tissue bonds.

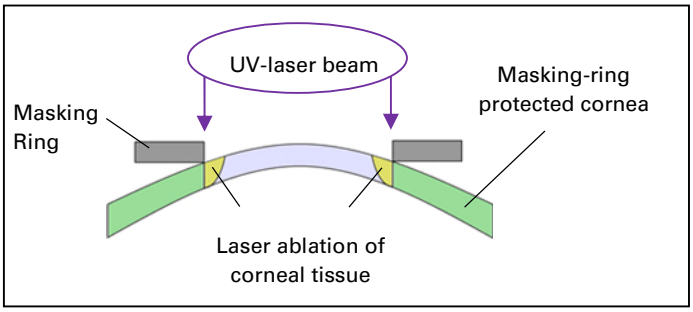
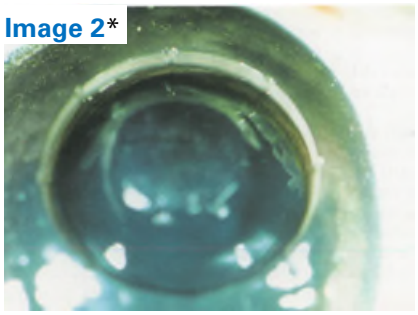


Image 2*



*Source: Book; Theo Seiler, Refraktive Chirurgie der Hornhaut, Enke-Verlag

Figure 2: Schematic principle of operation (recipient cornea)

After trepanation the corneal graft is placed into the recipient eye and finally sutured. (Figure 3 & Image 3)

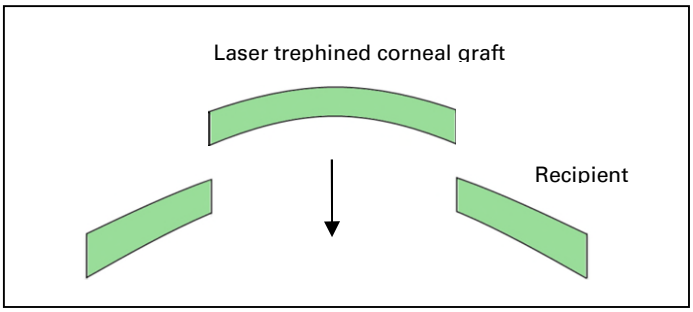
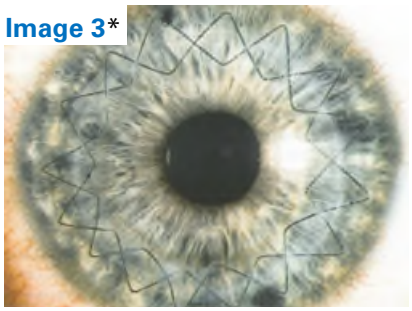


Image 3*



*Source: Book; Theo Seiler, Refraktive Chirurgie der Hornhaut, Enke-Verlag

Figure 3: Schematic principle of operation (placement and suturing of corneal graft)

The masking ring diameters are depending from diagnosed disease.

Masking rings with or without so called "Erlanger Orientierungszähnchen" are used. The common used "Erlanger Orientierungszähnchen" are small teeth (Figure 4) or small notches (Figure 5) in each masking ring.

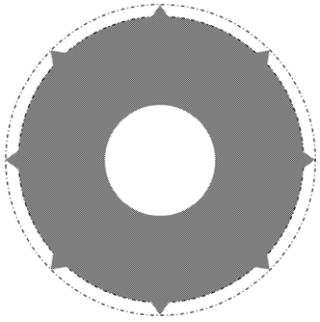


Figure 4: Masking ring for graft

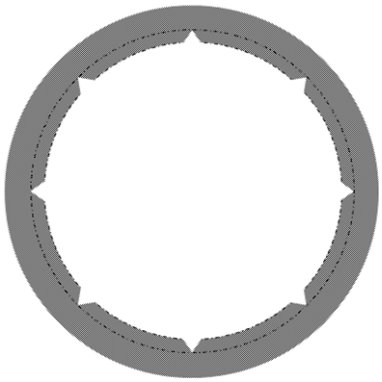


Figure 5: Masking ring for recipient

Image 4 of Figure 6 shows a good centered recipient eye with transplant graft after laser trepanation using masking rings with so called “Erlanger Orientierungszähnchen” (meanwhile also known as “Homburger Zähnchen”)

*Source: Book; Theo Seiler, Refraktive Chirurgie der Hornhaut, Enke-Verlag

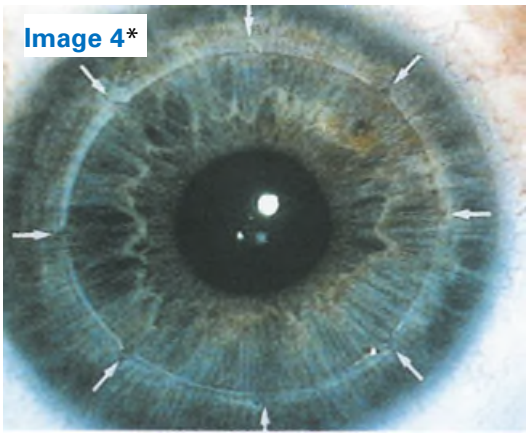


Figure 6: Example of transplant graft after laser trepanation with masking rings

3.1.3 Software Modules and Accessories

For Naumann-Rings itself there are no existing software.

Naumann-Rings application is used for perforating keratoplasty in conjunction with SCHWIND PTK-CAM software module for treatment planning:

- **KPL is selected within PTK-CAM module for planning perforating keratoplasty treatments with use of masking rings**
  Instead of mechanical trepanation by using a surgical blade for penetrating corneal transplant this technique is using an excimer laser and masking rings for cutting full-thickness human corneal tissue.

No accessories are available.

4 REQUIREMENTS

4.1 Qualification and Training

Naumann-Rings will be used by ophthalmic surgeons and their teams which may consist of treatment planner, surgeon and surgery assistants. The usage of Naumann-Rings requires specific training, instructions and abilities of every user. SCHWIND eye-tech-solutions or authorized local SCHWIND representative will instruct and train the user personnel in accordance with this Instruction for Use.

The completion of training for the responsible operators and users involved in operation and maintenance should be documented in the Medical Appartus Book. The maintenance of the Medical Appartus Book is an obligation of the operating company.

IMPORTANT NOTE

The usage of Naumann-Rings is only allowed by trained medical personnel.

IMPORTANT NOTE

Naumann-Rings may only be used by specially trained medical doctor, physicians or surgeons who possess the necessary skills to use it in accordance with Instructions for Use. Each surgeon has ultimate responsibility for the treatment, postoperative measures and follow-ups.

WARNING

Insufficient training of the user can give rise to human errors when using the Naumann-Rings with the consequent risk of injury to the patient. Demand or agree regular training upgrades, whenever you feel that you or your team need further support.

4.2 Room Conditions

The conditions of the operating room are in accordance to the used of the SCHWIND AMARIS laser system.

IMPORTANT NOTE

Please refer to the SCHWIND AMARIS documentation or get in contact with your authorized local SCHWIND representative or SCHWIND eye-tech-solutions directly in case of questions.

4.2.1 Device and Room Dimensions

The dimensions of the operating room are in accordance to the used of the SCHWIND AMARIS laser system.

5 SAFETY

5.1 General Safety Notes

WARNING

The reuse of the Naumann-Rings is limited to 10 reuses.

WARNING

Check if you use the right mask size prior preparation graft or patient, use the microscope of the laser system as described in the laser system manual for reading the labelled mask size on the mask itself.

WARNING

Prior using the masks it is necessary to make a visual inspection of the masks. No damage, deterioration or corrosion allowed.

WARNING

Only use the masks cleanly and sterile.

WARNING

In order to detect a slide of the masks, it is necessary to observe the mask through the microscope of the laser system during treatment.

WARNING

Only use the masks with the label positioned away from the eye.

WARNING

If there is a treatment abortion due to the laser it may be necessary to complete the cut manually by the surgeon.

WARNING

Before the patient cornea is treated, the graft should be prepared usable.

5.2 Consumable Components and Replacement

If it is necessary to replace the Naumann-Rings, a complete set will be delievered. Single masks are not replaced by the manufacturer.

IMPORTANT NOTE

The Naumann-Ring is designed and intended to be re-used 10 times, inclusive cleaning and sterilisation cylces.

IMPORTANT NOTE

SCHWIND eye-tech-solutions delivers sets of Naumann-Rings 7.5 mm, 8.0 mm, and 8.5 mm (nominal mask sizes for the recipient) as standard size recommendation.

IMPORTANT NOTE

Due to superficial material alterations (hardening due to laser energy applied) the metal surface will become darkened during the first re-uses. This is not a damage but a consequence of the normal use.

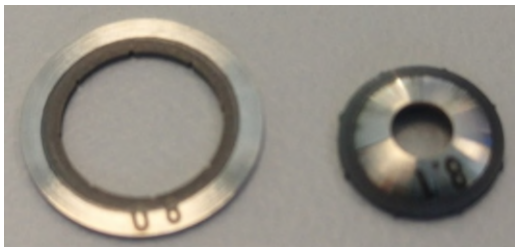


Figure 7: Naumann-Rings after multiple use (example)

6 INSTRUCTIONS FOR STERILISATION

IMPORTANT NOTE

Only use the masks cleanly and sterile.

An clinic internal process for cleaning and sterilisation is applicable.

The manufacturer recommended a validated cleaning and sterilisation process described in the instruction for re-sterilisable SCHWIND products.

7 PROCESS FOR REUSE

IMPORTANT NOTE

Only use the masks cleanly and sterile.

IMPORTANT NOTE

Due to superficial material alterations (hardening due to laser energy applied) the metal surface will become darkened during the first re-uses. This is not a damage but a consequence of the normal use, see Figure 7.

The manufacturer recommended a validated cleaning and sterilisation process described in the instruction for re-sterilisable SCHWIND products

8 COMBINATION WITH OTHER DEVICES OR EQUIPMENT

This part informs you about the possible use of the intended product with other devices and/or general purpose equipment in order to inform on any known restrictions to the combinations for a safe use:

There are no approved system combinations.

The packaging of the manufacturer are a disposable package. The Naumann-Rings itself can be disposed after lifecycle in order to the clinic disposable procedure.

9 OBLIGATION TO REGISTER INCIDENTS/ ACCIDENTS

9.1 Protective Measures of the Manufacturer

The necessity for personal protection measures of the user against dangerous effects from Naumann-Rings are reduced to a minimum through various measures undertaken by SCHWIND during the manufacturing process. Most important measures are listed below.

Organizational Measures, such as:

- Classification of Naumann-Rings.
- Training courses for user.
- Support of operator and user by the application department of SCHWIND or of the authorized local SCHWIND representatives.
- Providing of equipment documentation as listed in chapter Scope of Documentation with Safety Notes in the Instruction for Use.

9.2 Regulations for Medical Devices

IMPORTANT NOTE

For safe use of the SCHWIND medical device the **operator** must consider the applicable, normative regulations and directives.

The most important of these are:

1. **Council Directives concerning Medical Devices MDD 93/42/EEC**, as amended
   (Regulation valid for EEC countries; please consider the valid national regulations)
2. **Medical Device Operator Regulation – MPBetreibV**
   (Regulation valid only for Germany; please consider the valid national regulations)

9.3 Restrictions of Use and Safety Precautions

The purpose of safety precautions and preventive measures is to reduce the possibility of coming in contact with the laser radiation and to avoid other risks.

Please strictly follow the notes listed below:

IMPORTANT NOTE

Device use by trained personnel only!

The use and operation of the Naumann-Rings is allowed to persons only, who are authorized representatives of the operator trained by SCHWIND or by SCHWIND certified representatives, or those persons that received a training from the operator authorized and trained representative. Refer to chapter 4.1 Qualification and Training.

9.4 Patient Safety

WARNING

Risk of injury!

Take care not to injure the patient when positioning or operating the medical device. Make sure that the patient remains calm and relaxed during the treatment.

While handling any material which come into direct contact with the patient, precautionary measures must be met in order to prevent disease transmission.

Any complication or difficulty in using the device that could generate misunderstanding or ambiguities need to be taken into account to avoid risks to the user and the patient.

9.5 Safety Design

- Use the medical device only for its intended purpose (refer to chapter 2.1 Intended Purpose and Use)
- Provide proper and secure conditions for the product.
- Maintain all documentation in good condition and store them with the system / device.
- Make sure that none of the labels on the Naumann-Rings are removed or made illegible.

9.6 Device Labelling

9.6.1 Identification Label of the Naumann-Rings

The Naumann-Rings is labelled as shown below (Figure 8).

The number on the label under "DI" contains the “Device Identifier” number of both masks, which has been lasered directly on the mask.The serial number (SN) and the device identifier (DI) number are just a sample in the labels below. These are adapted in a production process to the masks that are packaged.

Figure 8: Naumann-Rings Identification label (example)

9.6.2 Explanation of Symbols of Identification Label

The following symbols are shown in the identification label:

REF	Article number
SN	Serial Number
DI	Device Identifier

	Refer to instruction manual
	Storage conditions / Lagerungsbedingungen
	Keep away from rain
	Keep away from sunlight
	Non Sterile
	CE sign. Confirms the conformity with the Directive for Medical Devices **MDD 93/42/EEC.**
	Datamatrixcode (International article number) Contents are the articel number and serial number

9.7 Conformity with Safety Standards

9.7.1 Essential Performance

The essential performance of the product is:

“Enabling sharp edges of corneal ablations by blocking the laser radiation within or outside the edge.”

The manufacturer identified performance characteristics which are required for the intended use. A loss or degeneration of the identified performance characteristics doesn’t lead to an unacceptable risk. Therefore the device has no essential performance characteristics.

9.8 Shipping and Delivery

The shipping of the Naumann-Rings shall be performed by SCHWIND or authorized local SCHWIND representative. After delivery of device units, check for outside damages of delivered boxes and its completeness according to delivery list.

10 DEVICE CONTROL AND OPERATION

10.1 General Operation Notes

IMPORTANT NOTE

The operation of the Naumann-Rings is only allowed by a trained medical personnel.

This serves your personal security and the protection of the Naumann-Rings from damage.

10.2 Treatment

10.2.1 Start the Laser

Start the SCHWIND AMARIS excimer laser according the AMARIS User Manual.

IMPORTANT NOTE

KPL treatments require a high number of laser pulses. For this reason we recommend to perform always once a "Gas-exchange" before starting your KPL treatment day

10.3 Planning a Penetrating Keratoplasty

10.3.1 AMARIS Main Menu

In AMARIS **Main Menu** by choosing one of the buttons**<New> or <Import>** (Screenshot 1) you will be able to plan a new treatment or to load a previously planned treatment file for the keratoplasty surgery.

Screenshot 1: AMARIS Main Menu with buttons for treatment planning (import)

Button <**Import**>

By pressing the **<Import>** button in the **Main Menu** you will be able to import treatment files which have been created before by using the SCHWIND CAM – PTK-CAM software module installed on a SCHWIND diagnostic workstation or laser.

To import a previously planned treatment file a valid Fluence test is necessary.

After import of the selected file the SCHWIND CAM software will be started automatically and the user sees the treatment plan with possibility to change the treatment parameter.

Button <New>

By pressing the <**New**> button in the Main Menu the SCHWIND CAM software will be started automatically. Running the <PTK-CAM> module by pressing the button PTK-CAM on the SCHWIND CAM Welcome Screen starts this module.

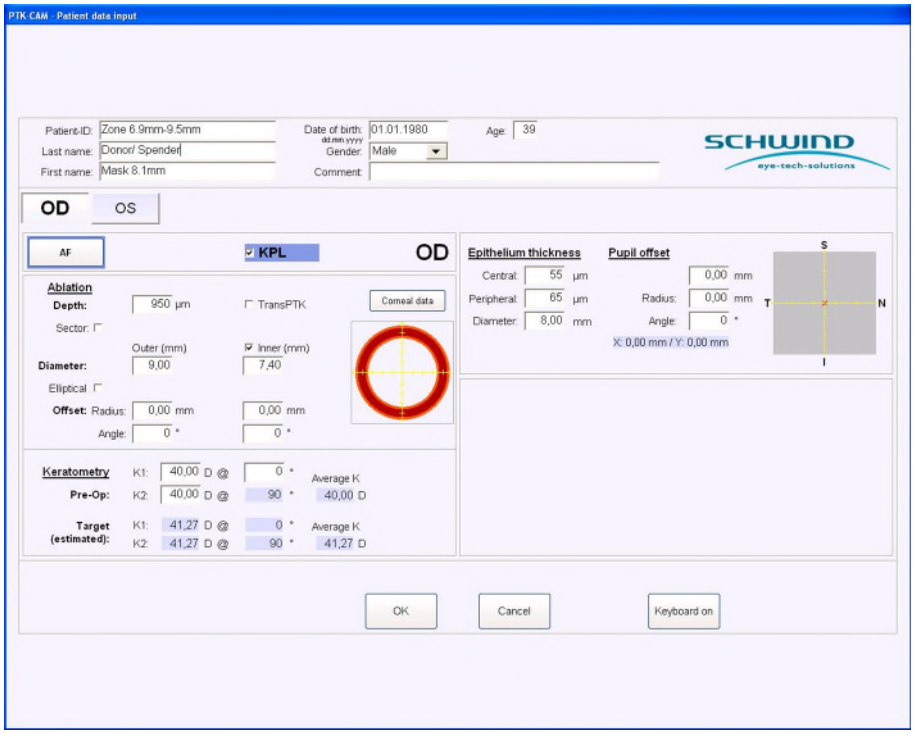
After PTK-CAM is started, you are able to input the relevant patient and treatment data.
Please refer to the latest version of "PTK-CAM_Treatment Guideline".

IMPORTANT NOTE

SCHWIND eye-tech-solutions provide prepared KPL treatment-files for different treatment diameter. We strongly recommend to use the SCHWIND prepared treatment files. The provided treatment files can be fully adjusted to the user needs. Please ask SCHWIND eye-tech-solutions or your local SCHWIND representative for relevant files and support

10.3.2 PTK-CAM Patient data and Parameter Entry

In case you won`t use or edit the SCHWIND prepared treatment files, please consider for treatment planning the following PTK parameter settings (Screenshot 2). Parameters in Patient Data Input Menu, which are following not mentioned to change must be kept as default.

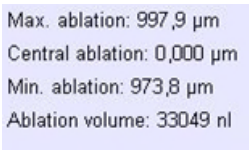


Screenshot 2: PTK-CAM Patient Data Input Menu (example)

- Activate click-box <KPL>, otherwise the max. allowed ablation depth is 150µm
- Enter K-readings or import <Corneal data>.

Enter Ablation <Depth>, but consider that the actual calculated laser ablation depth (max.) is influenced from entered K-reading and treatment outer diameter. As higher the K-reading and as larger the diameter, as higher the final calculated ablation depth (max.) will be. Final calculated ablation depth (max.) is first shown within the PTK-CAM Main Menu (Screenshot 3)

- Example:
  Entered ablation depth = 950µm
  K-Reading = 40D
  Outer diameter = 9.0mm



Screenshot 3: Ablation information

➢ **Note:** The software won't allow treatments with ablation higher than 999µm.

➢ Enter Outer and Inner diameter according the planned Naumann-Ring size to be used for surgery. We recommend to use the diameter settings for circular and elliptical masks as shown in the following tables.

IMPORTANT NOTE

Please consider that the laser ablation zone includes always an automatically added transition zone of 0.5mm for inner and outer diameter

Settings - Circular Masking Rings

The drawings below (Figure 9) are just for better illustration and do not show the correct sizes and ratios.

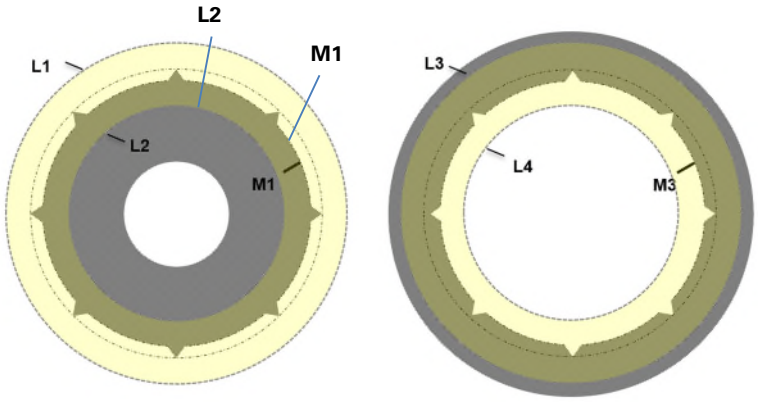


Figure 9: Inner Ring Mask (left) and Outer Ring Mask (right)

Table 1: Settings for donor graft (circular ring mask)

Graft				
Mask Size in mm	PTK diameter settings in mm		Laser ablation zones in mm	
M1 = Nominal Size	Outer	Inner	L1	L2
5,6	6,5	5,1	7,0	4,6
6.1	7,0	5,6	7,5	5,1
6,6	7,5	6,1	8.0	5.6
7.1	8,0	6,6	8.5	6,1
7.6	8,5	7,1	9.0	6,6

Graft				
8.1	9,0	7,6	9.5	7,1
8.6	9,5	8,1	10.0	7,6

Table 2: Settings for recipient cornea (circular ring mask)

Recipient				
Mask Size in mm	PTK diameter settings in mm		Laser ablation zones in mm	
M3 = Nominal Size	Outer	Inner	L3	L4
5,5	6,4	5,0	6,9	4,5
6.0	6,9	5,5	7,4	5,0
6,5	7,4	6,0	7,9	5.5
7.0	7,9	6,5	8.4	6,0
7.5	8,4	7,0	8,9	6,5
8.0	8,9	7,5	9.4	7,0
8.5	9,4	8,0	9,9	7,5

IMPORTANT NOTE

SCHWIND eye-tech-solutions delivers sets of Naumann-Rings 7.5 mm, 8.0 mm, and 8.5 mm (nominal mask sizes for the recipient) as standard size recommendation.

Settings - Elliptical Masking Rings

The drawings below (Figure 10) are just for better illustration and do not show the correct sizes and ratios.

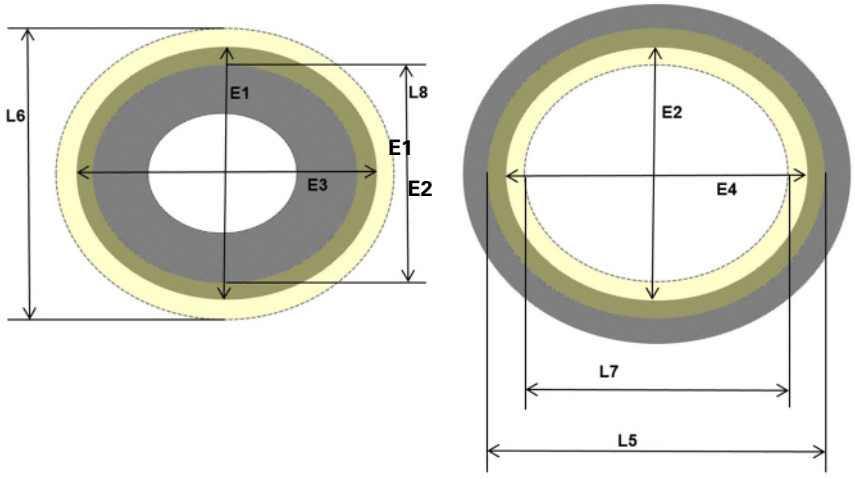


Figure 10: Inner elliptical mask (left) and outer elliptical mask (right)

Elliptical laser ablation zones are identical for graft and recipient

Long axis always in 180°

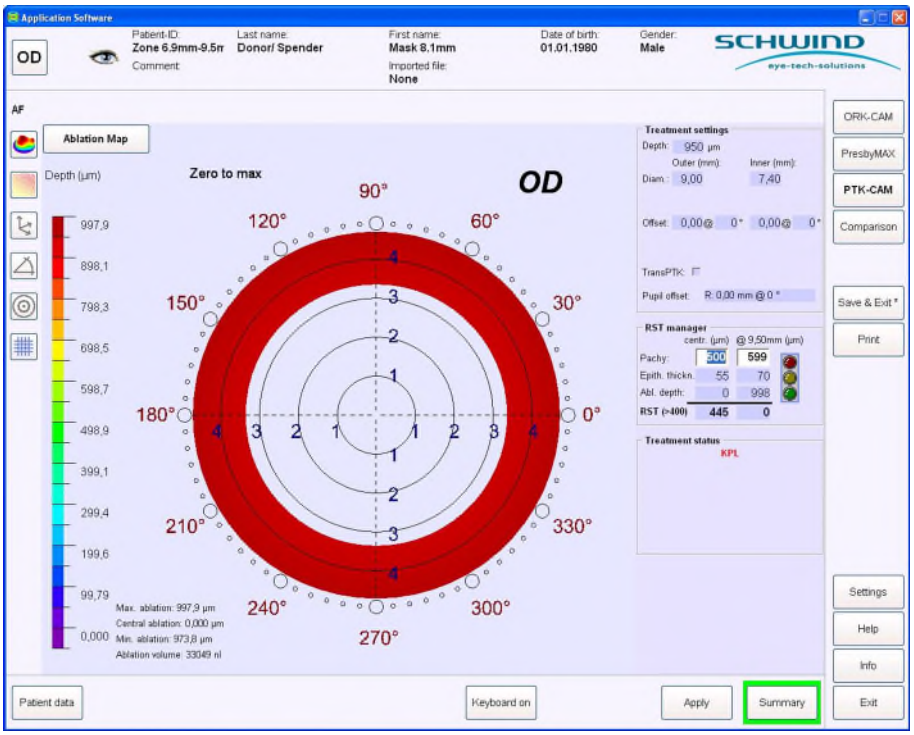
Short axis always in 90°

Table 3: Settings for donor graft and recipient cornea (elliptical ring mask)

Graft & Recipient											
Mask Size in mm				PTK diameter settings in mm				Laser ablation zones in mm			
E1	E2	E3	E4	Outer		Inner		L5	L6	L7	L8
Short		Long		Long	Short	Long	Short	Long	Short	Long	Short
7.1	7.0	8.1	8.0	8,8	7,8	7,2	6,2	9,3	8,3	6,7	5,7
7.6	7.5	8.6	8.5	9,3	8,3	7,7	6,7	9,8	8,8	7,2	6,2

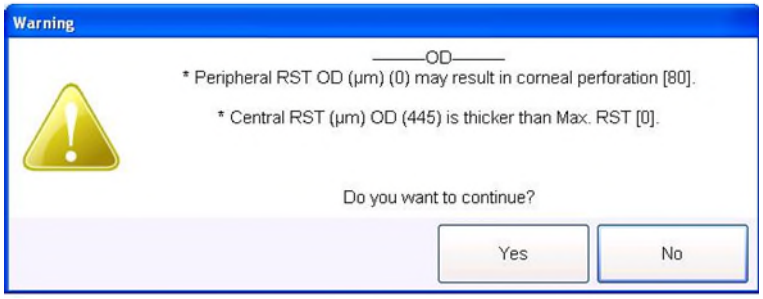
➢ After complete entry of treatment parameters confirm entered data with <**OK**> and you will be delegated to the PTK-CAM Main Menu (Screenshot 4).

10.3.3 PTK-CAM Main Menu



Screenshot 4: PTK-CAM Main Menu (example)

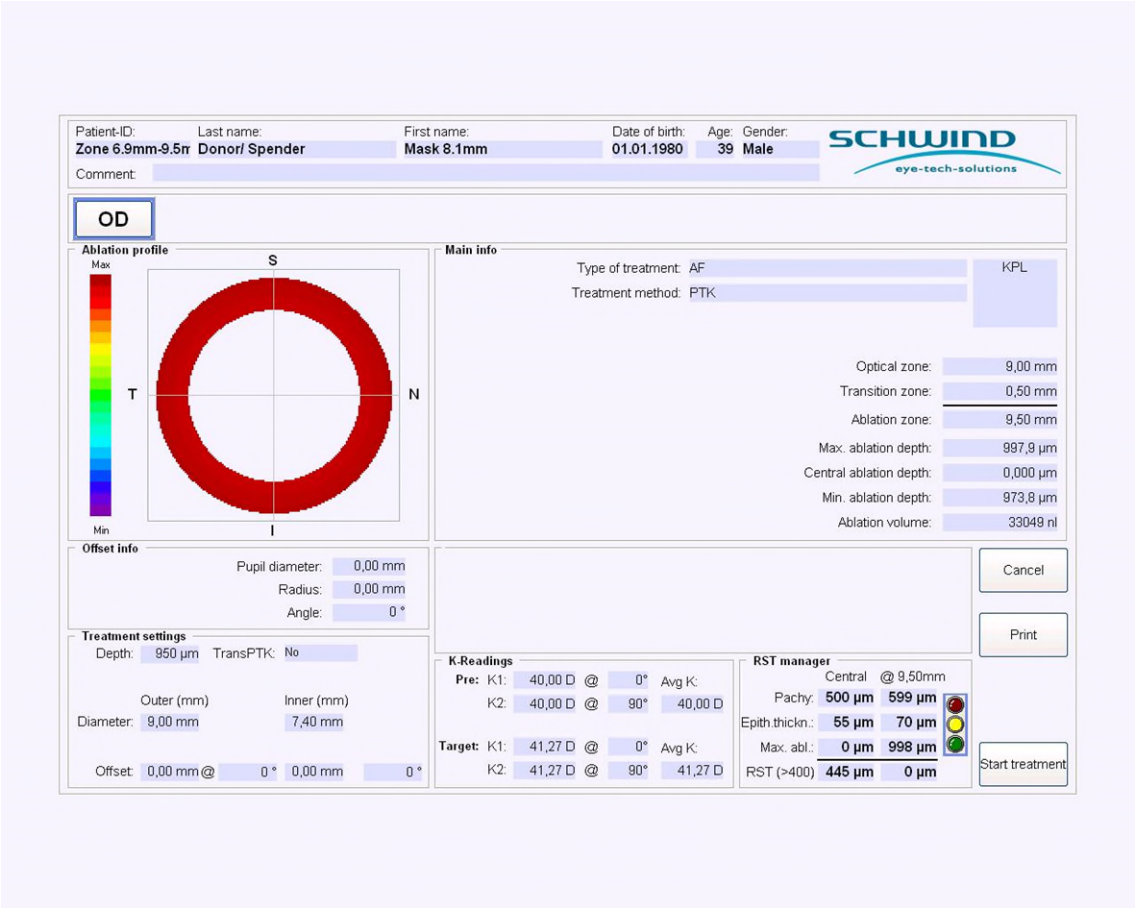
➢ Check the data and continue with <**Summary**>. After summary is pressed a "Warning" message will be displayed (Screenshot 5):



Screenshot 5: Warning „RST calculation result"

➢ Confirm the message, you will be then delegated to the “Summary Page”.

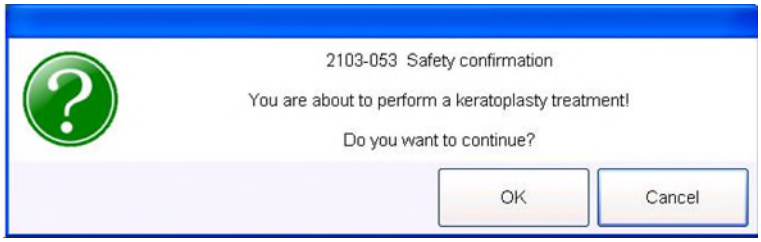
10.3.4 PTK-CAM Summary Page



Screenshot 6: PTK-CAM Summary Page (example)

➢ Check once more the treatment parameters and if data are OK continue with <**Start Treatment**> (Screenshot 6). After pressing <Start Treatment> you will be delegated to the AMARIS treatment menu.

➢ When screen is changing to treatment mode a further warning message appears (Screenshot 7). To continue treatment you must confirm the message with <**OK**>.



Screenshot 7: Warning „Keratoplasty treatment“

10.4 Laser Procedure

10.4.1 Creating the Corneal Graft

To prepare the corneal donor for laser treatment, the corneal donor must be fixed and pressurized in an artificial chamber.

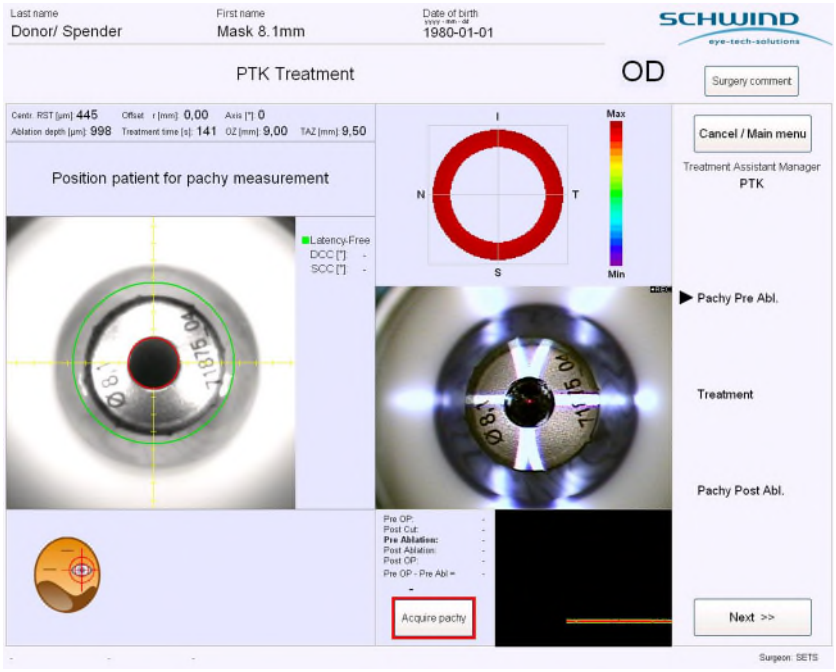
IMPORTANT NOTE

The corneal limbus must be levelled horizontally.

Consider to use additionally viscoelastic gel for creating pressure underneath the cornea which might improve the chance of less tissue-bonds after laser treatment is completed.

To protect the central donor cornea from dehydration, we recommend to put viscoelastic gel on the central part of the masking ring.

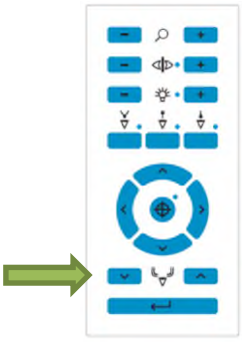
In treatment IR live-screen, center the displayed eye-tracker red ring to Naumann-Ring and adjust the focus lights (Screenshot 8).



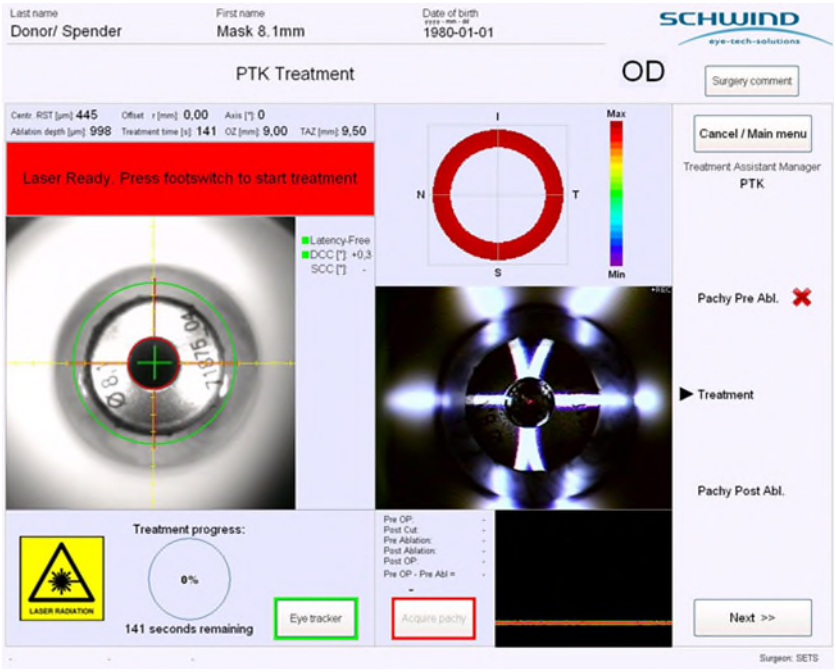
Screenshot 8: Alignment of Naumann-ring (donor) and adjustment of focus lights

TAM steps like „Pachy Pre Abl.“ which are not needed or not possible, must be skipped manuall by pressing the <**Next**> button.

When TAM step “Treatment” is reached (Screenshot 10) , the AMARIS request you to center the pupil and bring debris removal in surgery position by pressing the relevant button at the touch panel (Screenshot 9).

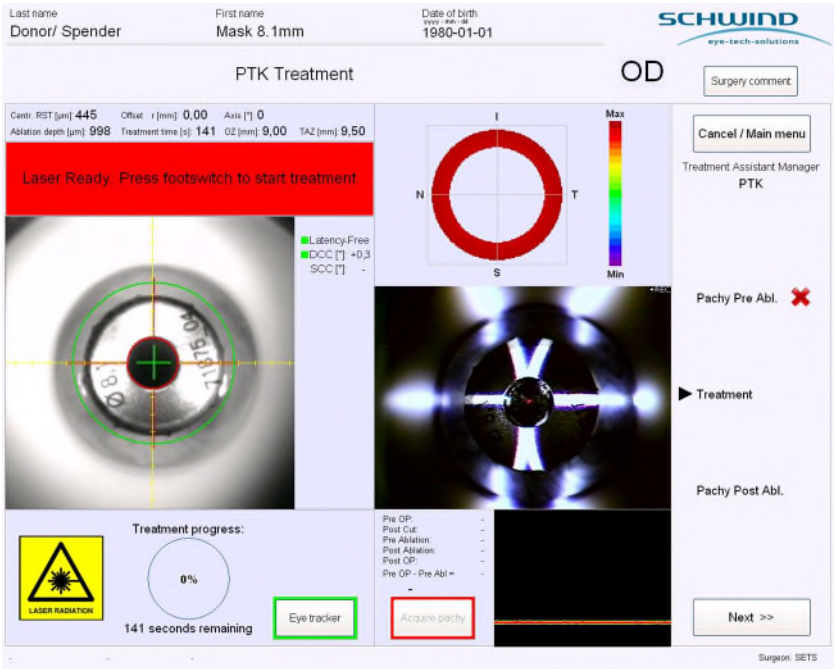


Screenshot 9: Touch panel „debris removal down“



Screenshot 10: After ring mask (donor) is properly aligned bring debris removal in surgery position „down“

When debris removal is in surgery position the AMARIS laser is ready for ablation (Screenshot 11).

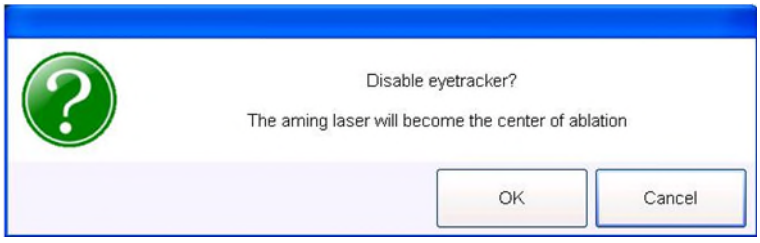


Screenshot 11: Eye tracker ist active and laser ready to start PTK treatment (donor)

IMPORTANT NOTE

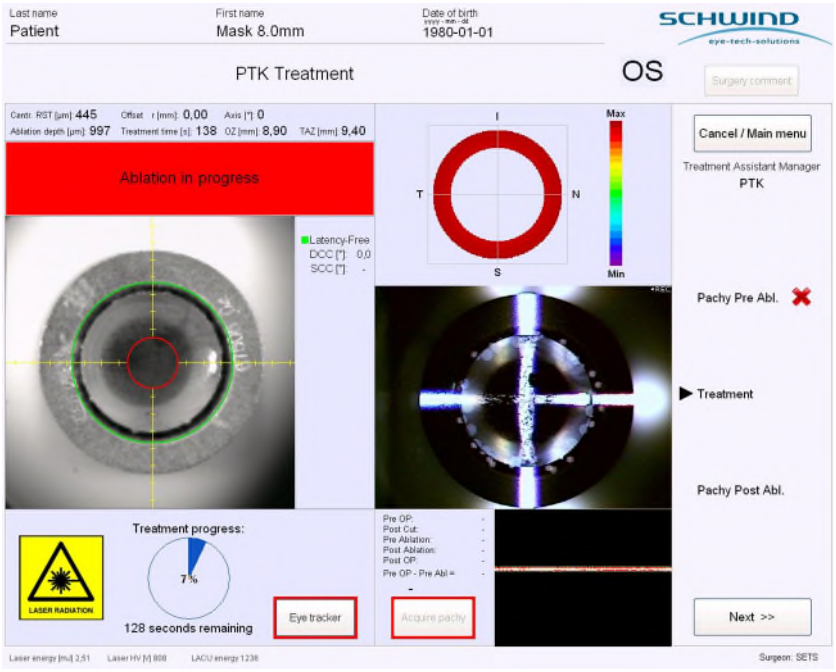
We recommend to switch-off the eye-tracking as no real pupil is available. The viscoelastic gel filled central hole of the ring is not suitable for the eye-tracker..

To switch-off the eye-tracker, please press once for short time the foot switch. Release the food pedal and switch-off the eye-tracker by pressing the <**Eye tracker**> button and confirm the displayed message (Screenshot 12).



Screenshot 12: Warning „Disable eyetracker"

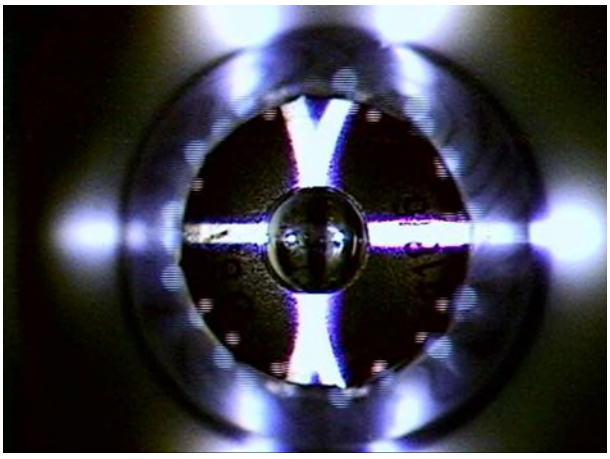
When eye-tracker is off which is indicated by the red frame surrounding the <**Eye-tracker**> button, check once again the centering and focus and if alignment is okay, start the treatment (Screenshot 13) by pressing the foot switch.



Screenshot 13: PTK treatment ablation (donor) in progress

During treatment check continously the masking ring is not moving and is well centered to the laser ablation.

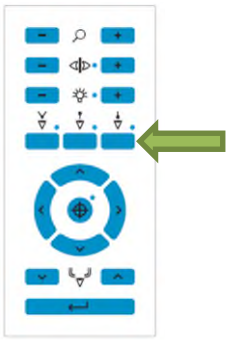
- Check position of the laser pulses, they must touch the outer margins of the mask as well as the outer corneal tissue close to the masking ring (Screenshot 14).



Screenshot 14: Laser pulses („reflections“) hitting the margin between cornea and circular mask (donor) for separation process

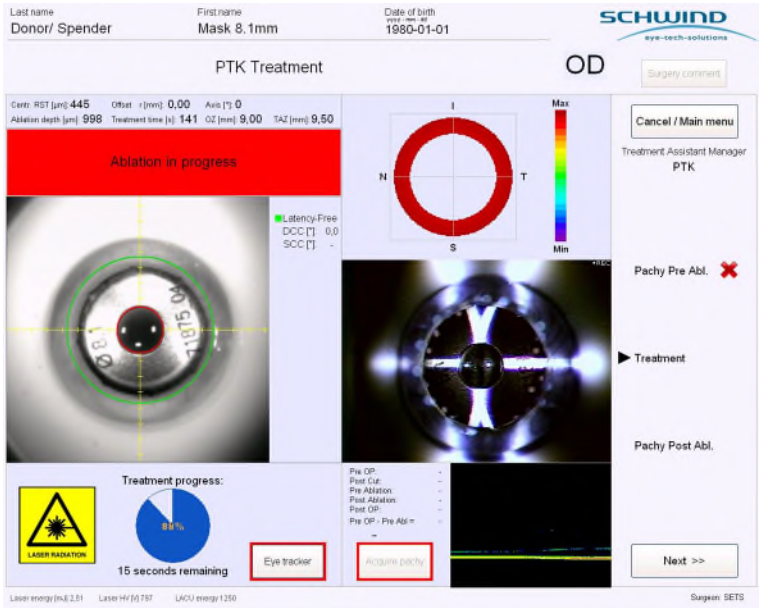
IMPORTANT NOTE

Activation of the red aiming laser (Screenshot 15) during laser ablation will make it easier to follow the laser spots, as they are additionally indicated by a red spot.



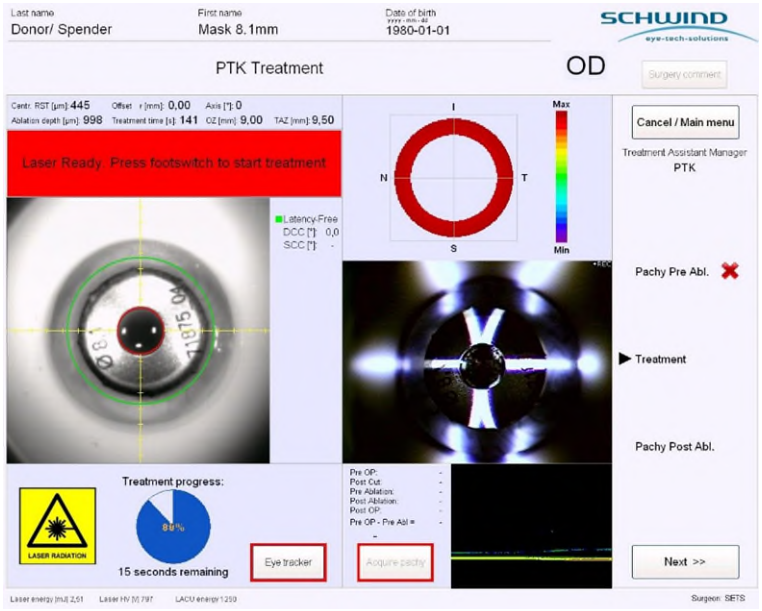
Screenshot 15: Touch panel „aiming laser (red)“

Most likely the donor cornea gets perforated before the “Treatment progress” is finished (100%) (Screenshot 16). The perforation becomes obvious by intruding chamber water that covers the ablated area. In that case it might be useful to continue the laser treatment for a few seconds more to ablate areas where still no chamber water is covering the corneal tissue.



Screenshot 16: PTK treatment ablation (donor) still in progress while the barrier to anterior chamber (water) breaks

PTK treatment (donor) is stopped by releasing the foot switch (Screenshot 17) when most of the ablated areas are filled with chamber water, because the water will protect the underlying tissue, i.e. no tissue is ablated anymore.



Screenshot 17: PTK treatment (donor) is not at 100% but aborted as no tissue is ablated anymore

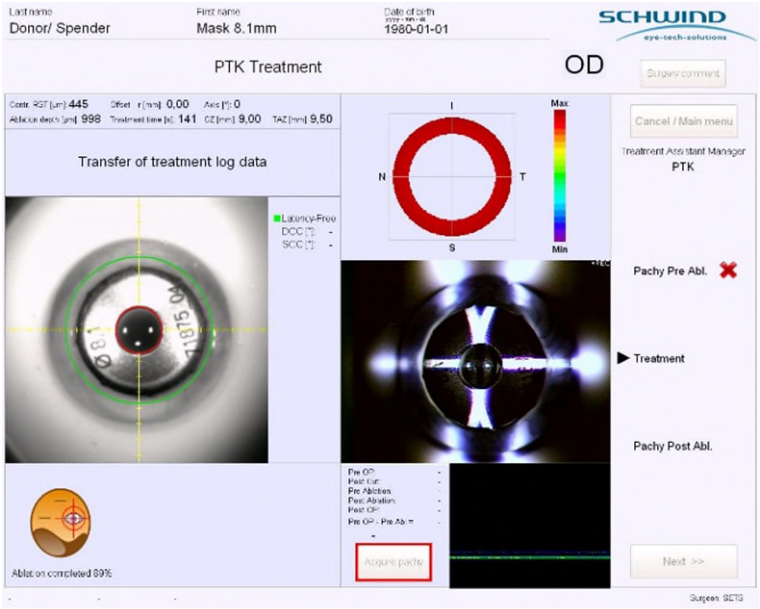
IMPORTANT NOTE

As the donor cornea typically will not completely perforate in all areas it might be necessary to cut the residual tissue bonds manually by using a corneal scissor

To abort treatment please press the <**Cancel/ Main Menu**> button.
A message (Screenshot 18) will appear, which must be confirmed <**OK**>.

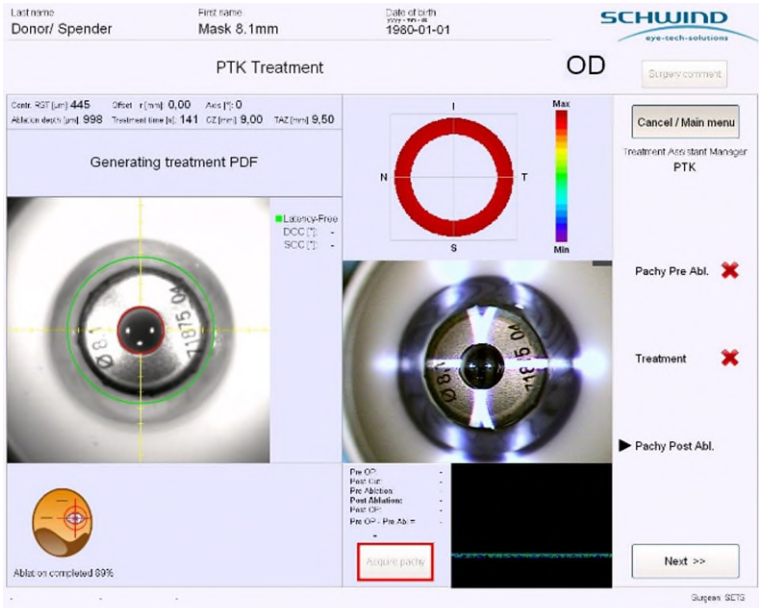
Screenshot 18: PTK treatment (donor) abort via <OK>

The treatment is aborted and the laser will save treatment log data (Screenshot 19)



Screenshot 19: Transfer of treatment log data after PTK treatment (abort) – donor

To come back to AMARIS Main Page, please press <**Cancel/ Main Menu**> again.The laser will create the PTK treatment report (*.pdf) (Screenshot 20) and will then delegate to the AMARIS Main Page.

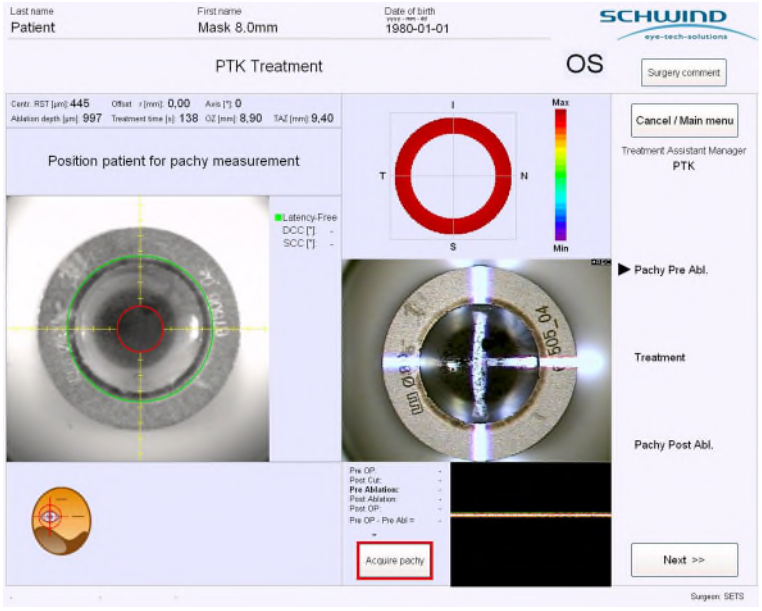


Screenshot 20: Generation of PTK treatment pdf (donor)

End of PTK laser treatment

10.4.2 Prepare Patient Cornea for Transplant.

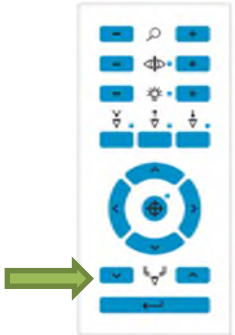
- Prepare the patient as usual for perforating keratoplasty.
- Mark the patients eye with ideally 8 symmetric marks.
- Place the recipient-masking-ring on the patients cornea and adjust the 8 notches according the 8 corneal marks.
- In treatment IR live-screen, center masking ring according displayed eye-tracker green ring and adjust the focus lights (Screenshot 21).



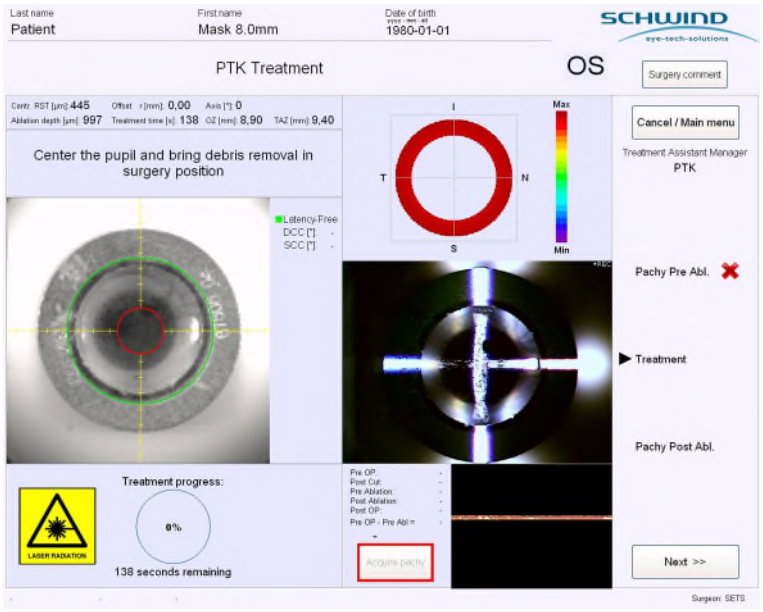
Screenshot 21: Alignment of Naumann-Ring (recipient) and adjustment of focus lights

- TAM steps like „Pachy Pre Abl.“ which are not needed or not possible, must be skipped manuall by pressing the <**Next**> button.

- When TAM step “Treatment” is reached (Screenshot 23) the AMARIS request you to center the pupil and bring debris removal in surgery position by pressing the relevant button at the touch panel (Screenshot 22).

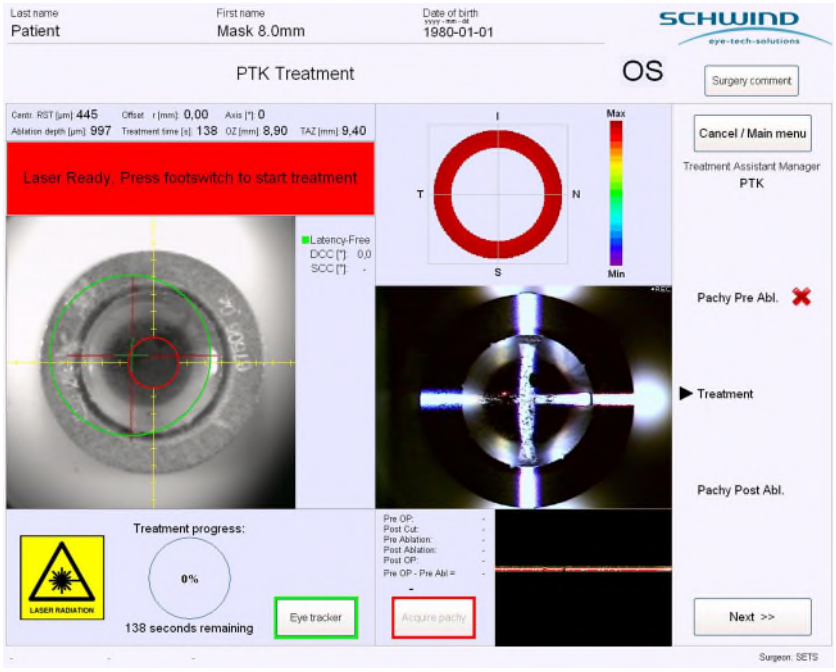


Screenshot 22: Touch panel „debris removal -down“



Screenshot 23: After ring mask (recipient) is properly aligned bring debris removal in surgery position „down“

- When debris removal is in surgery position the AMARIS laser is ready for ablation (Screenshot 24):



Screenshot 24: Eye tracker is active and laser ready to start PTK treatment (recipient)

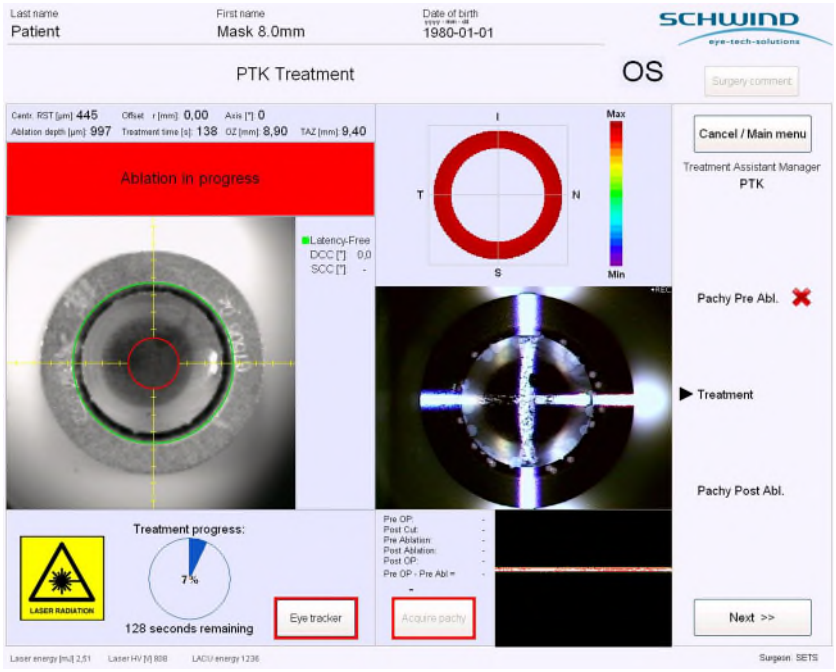
IMPORTANT NOTE

As obvious in screenshot 24 the eye-tracker is most likely not able to detect properly the center of the masking ring. For this reason we recommend to switch-off the eye-tracking in general.

➢ To switch-off the eye-tracker, please press once for short time the foot switch. Release the food pedal and switch-off the eye-tracker by pressing the <**Eye tracker**> button and confirm the displayed message (Screenshot 25):

Screenshot 25: Warning „Disable eyetracker“

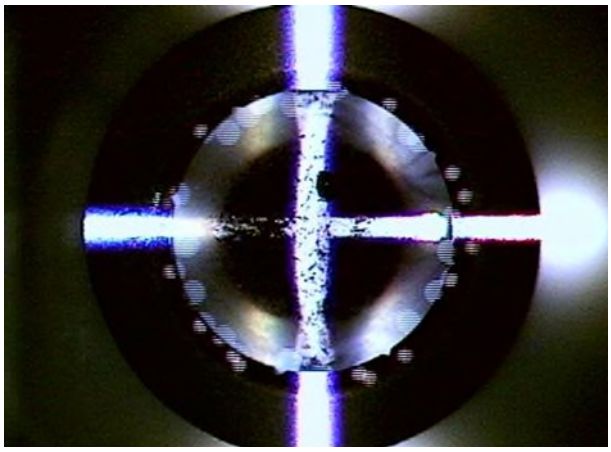
➢ When eye-tracker is off which is indicated by the red frame surrounding the <**Eye tracker**> button, check once again the centering and focus and if alignment is okay, start the treatment (Screenshot 26) by pressing the foot switch.



Screenshot 26: PTK treatment ablation (recipient) in progress

During treatment check continously the masking ring is not moving and is well centered to the laser ablation.

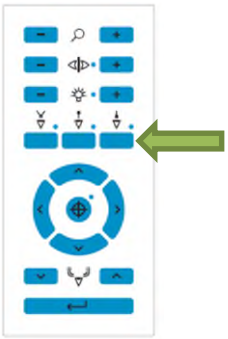
➢ Check position of the laser pulses, they must touch the inner margins of the mask as well as the inner corneal tissue close to the masking ring (Screenshot 27).



Screenshot 27: Laser pulses („reflections“) hitting the margin between cornea and circular mask (recipient) for separation process

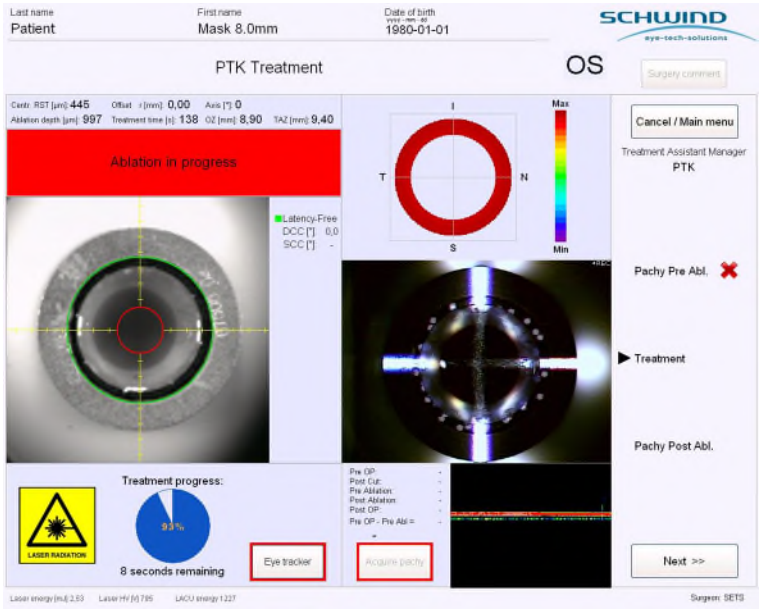
IMPORTANT NOTE

Activation of the red aiming laser (Screenshot 28) during laser ablation will make it easier to follow the laser spots, as they are additionally indicated by a red spot.



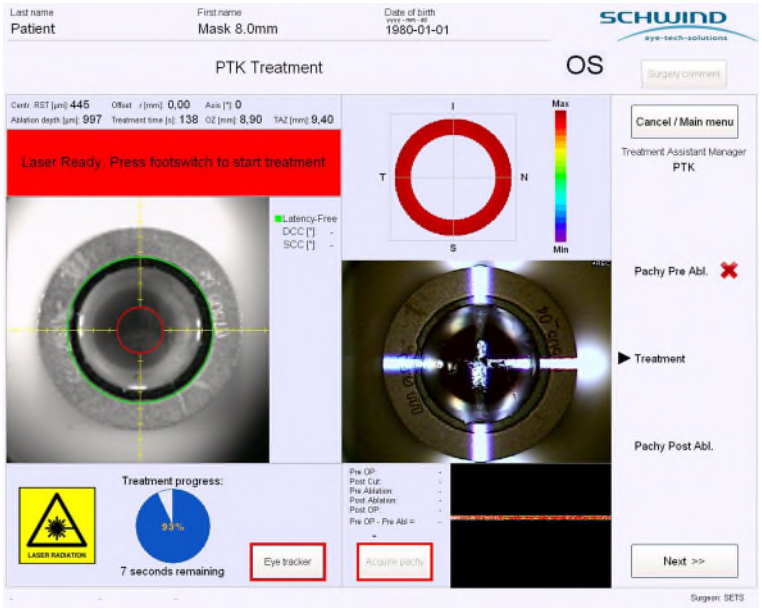
Screenshot 28: Touch panel „aiming laser (red)“

- Most likely the recipient cornea gets perforated before the “Treatment progress” is finished (100%) (Screenshot 29). The perforation becomes obvious by intruding chamber water that covers the ablated area. In that case it might be useful to continue the laser treatment for a few seconds more to ablate areas where still no chamber water is covering the corneal tissue.



Screenshot 29: PTK treatment ablation (recipient) still in progress while the barrier to anterior chamber (water) breaks

- PTK treatment (recipient) is stopped by releasing the foot switch (Screenshot 30) when most of the ablated areas are filled with chamber water, because the water will protect the underlying tissue, i.e. no tissue is ablated anymore.



Screenshot 30: PTK treatment (recipient) is not at 100% but aborted as no tissue is ablated anymore

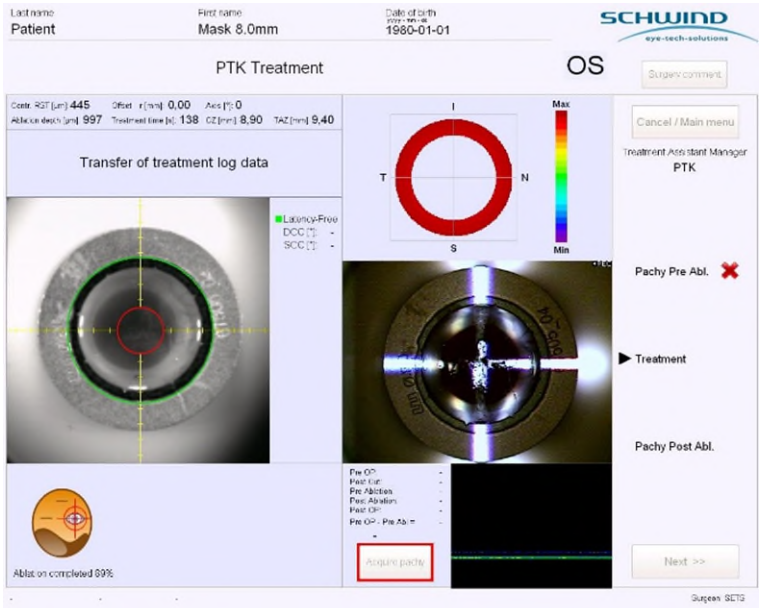
IMPORTANT NOTE

As the recipient cornea typically will not completely perforate in all areas it might be necessary to cut the residual tissue bonds manually by using a corneal scissor.

- To abort treatment please press the <**Cancel/ Main Menu>** button.
  A message will appear, which must be confirmed <**OK**> (Screenshot 31).

Screenshot 31: PTK treatment (recipient) abortion via <OK>

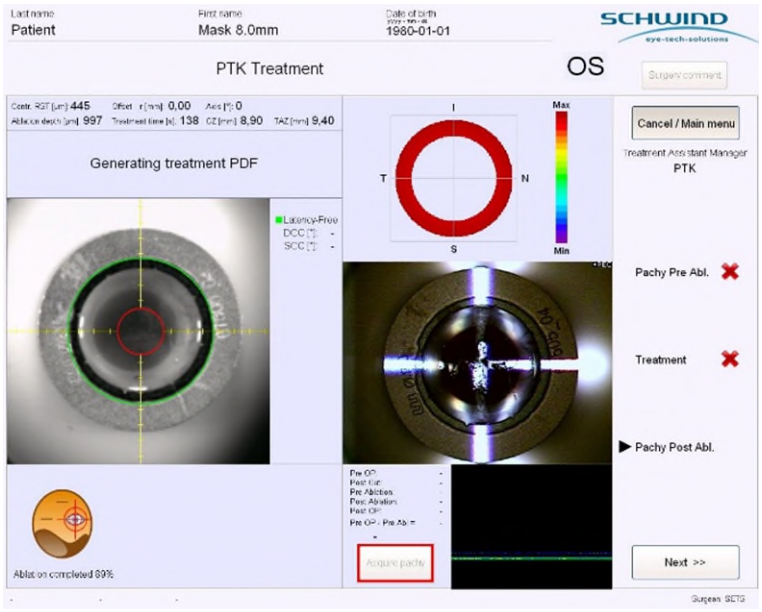
- The treatment is aborted and the laser will save treatment log data (Screenshot 32).



Screenshot 32: Transfer of treatment log data after PTK treatment (abort) - recipient

- To come back to AMARIS Main Page, please press <**Cancel/ Main Menu**> again.

- The laser will create the treatment report (*.pdf) (and will then delegate to the AMARIS Main Page (Screenshot 33)



Screenshot 33: Generation of PTK treatment pdf (recipient)

End of laser treatment

10.4.3 Transplant of Graft in Recipient Cornea

Finally the surgeon must implant and suture the graft at the recipient eye.

IMPORTANT NOTE

Consider published suture techniques after laser-assisted keratoplasty. Perforating or penetrating keratoplasty shall only be performed by specially trained medical doctor, physicians or surgeons who possess the necessary skills for therapeutic corneal transplant surgeries.

11 DISPOSABLES

11.1 General

The packaging of the manufacturer are a disposable package. The Naumann-Rings itself can be disposed after lifecycle in order to the clinic disposable procedure.

11.2 Sterile Packaging

The Naumann-Rings are delivered NON-STERILE. The packaging of the manufacturer are not intendedto use as a sterile packaging.

11.3 Storage and Handling Conditions

Storage Conditions

Environmental range	temperature	-5°C – 55°C or 23°F – 131°F
Relative humidity		No restriction

The Naumann-Ring is designed and intended to be re-used 10 times, inclusive cleaning and sterilisation cylces.

Do not use Naumann-Rings with other laser systems as recommended by the manufacturer. The use in conjunction with other laser systems can result in malfunctions. The use with laser systems which are not original SCHWIND may result in major or severe surgical consequences.

IMPORTANT NOTE

SCHWIND cannot be held liable for damages resulting from use in conjunction with other laser systems.

12 MAINTENANCE

12.1 General Notes

DANGER

Health hazards for surgical staff and patients!

Omission of effective pre-processing influences treatment results and endangers the health of OP personnel and the patient. Contact with patient secretions and / or processing solutions can endanger your health. Therefore, always wear prescribed protective equipment during preprocessing. Make sure that the cleaned parts do not come in contact with the patient.

PART B. PRODUCT DESCRIPTION

13 ANNEX

13.1 Declaration of Manufacturer

The Naumann-Rings have been developed according to the applicable requirements of the European Medical Device Directive 93/42/EEC and hence also according to its German equivalent Medical Device Law MPG [**1**]. The manufacturer SCHWIND has been authorized by the notified body "mdc" to develop, produce and inspect medical devices for ophthalmologic purposes and to market and service them.

Conformity of the device with the Directive and MPG is ensured only under the following preconditions:

- Delivery is accomplished by SCHWIND or an authorized local SCHWIND representative.
- All service and maintenance work is performed only by personnel who are authorized by SCHWIND.
- Accessories, consumables and disposables are only authorized and approved by SCHWIND or an authorized independent testing authority confirm a completely safe operation and interaction.

IMPORTANT NOTE

The **Declaration of Conformity** for the Naumann-Rings can be found in the documentation folder: "Accompanying Product Documentation "TREAT" Naumann-Rings.

13.2 Liability of the Manufacturer

SCHWIND does not assume any liability for:

- Injuries to persons, unless caused by gross negligence of the manufacturer
- Damages of properties
- Damages / destruction of equipment or software
- Data loss
- Financial, legal, commercial and productivity-related disadvantages for the company and the personal user

Or for the following courses of action:

- Lack of reading this Instruction for Use completely and carefully before starting operations with the Naumann-Rings .
- Lack of understanding the instructions provided in the user documentation and the explanations provided by the application specialists of SCHWIND or of the authorized local SCHWIND representative.
- Lack of observation of any other instructions and safety requirements provided by the user information of compatible devices and accessories for ensuring compatibility and safe operation of the combination between devices.

[1] MPG – Medizin-Produkte-Gesetz is the German Medical Device Regulation

- Use of any compatible device or accessory without having received adequate inspections and calibrations for proper use and measurements.
- Insufficient training of the user which can give rise to human errors when using the device with the consequent risk of injury to the patient.
- Use of the equipment by not suitably trained personnel.
- Use of this device for purposes different from its intended use or for its use outside the environment of an ophthalmic surgery.
- Any attempt to alter, modify or manipulate the product in a way not stipulated in the Instruction for Use of SCHWIND.
- Manipulation, alterations or damages to the device by technicians not authorized by SCHWIND or other third parties.
- Non-observance of the operating notes, warning symbols and safety instructions in this Instruction for Use.
- Operational error of user
- Computer virus
- Excessive force
- Power failure, voltage fluctuations, electromagnetic interference
- Inappropriate storage of the data medium (e.g. humidity or temperature influences)
- Erroneous deletion of data by user
- Negligence by user

13.3 Warranty

IMPORTANT NOTE

The duration of the warranty period for the Naumann-Rings is 12 months.

1. The warranty period begins with the delivery of the device to the user.
2. Warranty includes all defects of the device caused by defective parts or manufacturing faults. Malfunctions that are not caused by improper use are repaired under warranty. Damage caused by abuse or improper use is not repaired under warranty.
3. The legal warranty applies only to parts that are replaced or repaired by SCHWIND.
4. Damages or malfunctions have to be reported to SCHWIND or to the representative immediately.
5. The damaged parts have to be sent back to SCHWIND. When returning defective parts, please use the original packing or coordinate alternate packing with SCHWIND.
6. Deficiencies that arise from:
   - Non-standard or extraordinary use
   - Repairs without original parts
   - Incorrect treatment of the device
   - Inspections, services, device modifications or any form of manipulation of the system performed by unauthorized personnel will void the guarantee and will relieve SCHWIND from any responsibility.
7. SCHWIND grants no other warranty, either express or implied, concerning the abovementioned parts and their documentation. Any implied warranties of merchantability and fitness for the particular purpose are disclaimed.

8. SCHWIND shall not be liable for incidental, consequential, indirect or special damages of any kind, loss of information or data or other financial loss arising from or in connection with the sale or use of the product, whether based in contract, tort (including negligence) or any other theory.
9. The above-mentioned exclusion of liability is void if the cause of damage is based on intent or gross negligence. Furthermore it does not apply to damage due to lack of warranted quality and claims under product liability.
10. Product improvement initiatives based on technological development are not grounds for free-of-charge system upgrades.
11. The general conditions for sale, delivery and payment of SCHWIND are generally to be considered.

Consider also general warranty regulations of SCHWIND eye-tech-solutions GmbH.

13.4 Licence Agreement

The license agreements realized between the licensee and SCHWIND eye-tech-solutions GmbH are binding.

13.5 Copyright

13.6 Notes on the Instruction for Use

The purpose of this Instruction for Use is to familiarize the operator(s) of the Naumann-Rings with the design and operating principle.

The Naumann-Rings Instruction for Use contains the relevant information for the Naumann-Rings itself only!

IMPORTANT NOTE

Read this manual carefully and consider all instructions, as well as safety and warning notes before starting operation of the NAUMANN-RINGS.

Please keep the Instruction for Use and all related documents close to the medical device. Allow any user access to the Instruction for Use at all times, store it readily available.

IMPORTANT NOTE

If you have any questions regarding any matters, contact SCHWIND directly. Refer to chapter 15 Manufacturer / Technical Assistance / Application Support.

IMPORTANT NOTE

The present English version contains the ORIGINAL INSTRUCTIONS, which are legally binding. Translations of these must bear the words “Translation of the Original Instructions”.

13.7 Relevant Documentation

The Naumann-Rings Instruction for Use does contain all information necessary for the safe and effective operation of the Naumann-Rings.

Therefore consider the accompanying documents:

- **User Manual SCHWIND AMARIS**
- **User Manual SCHWIND CAM and PTK-CAM module**
- **Reprocessing Instruction for re-sterilisable SCHWIND Products**

14 ABBREVIATIONS

KPL	Keratoplasty
PK or PKP	Penetrating/Perforating Keratoplasty
PTK	Photo-Therapeutic Keratectomy
CAM	Custom Ablation Manager
TAM	Treatment Assistant Manager (of SCHWIND AMARIS)
Pachy	Pachymetry

15 MANUFACTURER / TECHNICAL ASSISTANCE / APPLICATION SUPPORT

SCHWIND eye-tech-solutions offers a comprehensive warranty and service support.

Highly qualified representatives from our SERVICE and CUSTOMER SUPPORT departments are available to support you and to solve any operational questions.

Should you have any questions, please do not hesitate to contact our Service or Customer Support Hotline. The Service Hotline is free of additional charges (only regular telephone charges are incurred).

Our customers outside of Germany should use the service hotline provided by our local distributor or authorized Service Representative first.

SCHWIND eye-tech-solutions GmbH

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