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Instruction for Use

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Original Instruction

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# Getting Started

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## C-eye Cross-Linking (CXL) Kit in conjunction with SCHWIND Excimer Laser



## "Getting Started" – Instructions for Use

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### C-eye Cross-Linking Kit at SCHWIND Excimer Laser

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## "Getting Started" – Instructions for Use

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### General Information

## 1 General Information

### 1.1 Notes to the User

This **Getting Started Instruction for Use** contains important instructions and information for the user regarding the application of the **C-eye Cross-Linking Kit** in conjunction with SCHWIND excimer laser. The **C-eye Cross-Linking Kit** consist of the C-eye (CXL) device itself and the C-eye Sliding Unit for AMARIS laser.



#### **IMPORTANT NOTE**

Before starting the handling and the operation of the C-eye Cross-Linking Kit at SCHWIND excimer laser, SCHWIND eye-tech-solutions recommends making oneself familiar with the instructions in this manual!



#### **IMPORTANT NOTE**

The **Getting Started Instruction for Use** does not contain the information which is necessary for safe and effective operation and application of the C-eye (CXL) device, the SCHWIND excimer laser and the Patient Bed according with the intended use.

The Instruction for use is valid in combination with the following documents only:

- C-eye (Instructions for Use) by C.S.O. srl
- SCHWIND AMARIS User Manual
- SCHWIND Patient Bed User Manual

Please do not use the C-eye Cross-Linking Kit in conjunction with SCHWIND excimer laser before reading the documents listed above. Follow all instructions and notes in the manuals listed above.



#### **IMPORTANT NOTE**

The English manual is the ORIGINAL INSTRUCTION, which is legally binding.

Translations of these must bear the words "Translation of the Original Instructions".

## "Getting Started" – Instructions for Use

### General Information

#### 1.2 Scope of Documentation

The scope of delivery of Accompanying Documentation is handled via delivery of the SCHWIND AMARIS, which includes the C-eye Cross-Linking Kit at SCHWIND excimer laser device.

The product documentation consists of:

- **Accompanying Documentation "SCHWIND MEDICAL PRODUCTS"** with:
  - Medical Apparatus Book "SCHWIND MEDICAL PRODUCTS" (EN) or (DE)
  - CD/DVD-ROM "Product Documentation SCHWIND AMARIS" as listed below:

Name	Article Number
Accompanying Documentation (with Medical Apparatus Book)	202160x-01 (EN), 202160x-02 (DE)
Product Documentation CD/DVD „SCHWIND AMARIS“ (includes the manuals for SCHWIND AMARIS, C-eye (CXL) device, Patient Bed, and the relevant manuals as listed in chapter 1.1, current version)	163430x

- Getting Started – **C-eye Cross-Linking (CXL) Kit in conjunction with SCHWIND Excimer Laser** (this manual), included on the SCHWIND AMARIS Product Documentation CD-ROM).



#### **IMPORTANT NOTE**

In case the **C-eye device is delivered separately**, the Instructions for Use by C.S.O. srl. are delivered as print version only with the medical device itself.

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## "Getting Started" – Instructions for Use

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### General Information

#### 1.3 Symbols for Warnings, Precautionary Measures and Notes

The following conventions are used in this manual:



**WARNING!**

This symbol advises the user of serious danger for the patient and the user.



**CAUTION!**

The symbol informs the reader that particular care is required for safe and efficient operation of the system.



**IMPORTANT NOTE**

This symbol provides the user with useful or additional information.

#### 1.4 Copyright

Copyright © 2023 SCHWIND eye-tech-solutions GmbH, Kleinostheim. All rights reserved. Pages or parts of this document may not be reproduced or passed to third parties in any form, i.e. either electronically, mechanically or by any other means without prior written authorization from SCHWIND eye-tech-solutions.

## "Getting Started" – Instructions for Use

### Safety

## 2 Safety



### IMPORTANT NOTES

This Getting Started Instruction for use does not contain all the comprehensive safety notes for safe operation and application of the C-eye (CXL) device, the SCHWIND excimer laser and the Patient Bed, themselves.

Observe all safety instructions and requirements in the original **Instruction for Use 'C-eye'** of the manufacturer **C.S.O srl**.

Observe any other safety instructions and requirements provided by the SCHWIND user documentation of the SCHWIND AMARIS and Patient Bed.

This is meant for the safety of the patients, for your own safety and for the protection of the product from damage.

### 2.1 Training of Users and Operating Personnel

As with any technological highly developed medical product, the operation of the **C-eye Cross-Linking Kit at SCHWIND excimer laser** requires special training and abilities of the user's personnel.



### IMPORTANT NOTE

The **C-eye Cross-Linking Kit at SCHWIND excimer laser** **shall only be operated by authorized and suitably trained personnel!**

Likewise, the medical product shall only be used by persons specializing in ophthalmology with specific training in the preparation, calibration, and maintenance of the device and accessories, as well as special training in the use of the same in accordance with its intended use.



### **WARNING!**

**Insufficient training of the user can give rise to human errors when using the device with the consequent risk of injury to the patient.**

SCHWIND eye-tech-solutions or authorized representatives will instruct and train the user's personnel according to the respective user documentation as listed in chapter 1.2 Scope of Documentation.

The completion of training for the responsible **C-eye Cross-Linking Kit** (at SCHWIND excimer laser) operators and other persons involved must be documented in the **Medical Apparatus Book**. The **Medical Apparatus Book** is part of the equipment documentation provided by SCHWIND eye-tech-solutions with the SCHWIND AMARIS excimer laser.

## "Getting Started" – Instructions for Use

### Intention and Use of the C-eye Cross-Linking Kit

Demand or agree on regular refreshment training whenever you feel that you or your team needs further support.

### 3 Intention and Use of the C-eye Cross-Linking Kit

The **C-eye Sliding Unit** at SCHWIND Excimer laser systems makes it possible to easily use the **C-eye (CXL) device** by manufacturer C.S.O srl in conjunction with a SCHWIND excimer laser. With the **C-eye Cross-Linking Kit** which consist of the *C-eye (CXL) device* itself and the *C-eye Sliding Unit* for AMARIS laser, the treatment workflow can be optimised for the patient cohort where the user intends to combine a corneal laser treatment (SCHWIND) followed by corneal collagen cross-linking (CXL) with the C-eye (C.S.O. srl). The correct working distance of the C-eye device attached to the C-eye Sliding Unit for AMARIS laser is automatically given when the user appropriately adjusts the positioning slits of the SCHWIND excimer laser to patient's cornea.

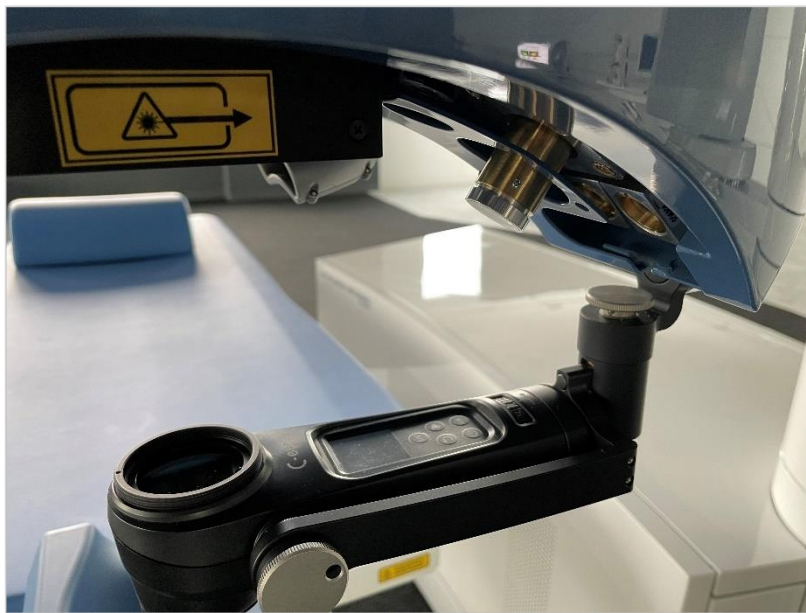


Figure 1: C-eye Cross-Linking (CXL) Kit in treatment position

The C-eye Cross-Linking Kit is mounted to and can be used in conjunction with:

- SCHWIND AMARIS 1050RS, AMARIS 750S / AMARIS 500E



#### **CAUTION**

**Do not install any devices other than those specified and approved by SCHWIND eye-tech-solutions.**

SCHWIND does not assume responsibility for any other combinations and the implications of misuse!



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## "Getting Started" – Instructions for Use

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### Intention and Use of the C-eye Cross-Linking Kit



#### **IMPORTANT NOTE**

The C-eye (CXL) device by manufacturer C.S.O srl has a physical connection to the SCHWIND excimer laser via the C-eye Sliding Unit but no electrical connection to it.

Beside other applications (refer to Instructions for Use 'C-eye' by C.S.O srl), the **C-eye Cross-Linking Kit** at SCHWIND excimer laser is used - together with a certain Procedure Kit 'Ribo-Ker' - for the combination of refractive or therapeutic laser treatments with cross-linking treatments, e.g. in patients with keratoconus.

The **C-eye device** itself includes many Treatment Protocols for Cross-Linking epi-on and epi-off, with continuous and pulsed UV irradiation. The UV-A (wavelength: 365 nm) irradiation profile is differentiated to compensate for the peripheral increase in corneal thickness.

For further product description refer to the C.S.O srl Instructions for Use '**C-eye**'.



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## "Getting Started" – Instructions for Use

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### Installation and Mounting

## 4 Installation and Mounting

### 4.1 General Notes

A service engineer of SCHWIND eye-tech-solutions or an authorized distributor will install the **C-eye Cross-Linking Kit / C-eye Sliding Unit** at the SCHWIND excimer laser if not already included in the initial delivery of the laser device.

The **C-eye (CXL) medical device** – as new order via SCHWIND eye-tech-solutions or already bought by the user / clinic beforehand – can be (de-)mounted easily with just turning a dial.

Please refer to the C.S.O srl Instructions for Use '**C-eye**' for more information and details.



#### **IMPORTANT NOTE**

Please contact your authorized local SCHWIND representative or the customer service department of SCHWIND eye-tech-solutions to organize the installation of the C-eye Cross-Linking Kit / C-eye Sliding Unit at SCHWIND excimer laser.



#### **CAUTION**

##### **Service by trained and authorized personnel only!**

Only suitably trained and from SCHWIND eye-tech-solutions authorized personnel may perform initial installation, modifications, and service of the C-eye Cross-Linking Kit / C-eye Sliding Unit at SCHWIND excimer laser.

##### **Damage of device!**

Do not make changes to any component of the respective device without the supplier's authorization!

We do not release for use with your specific system any parts and/or optional components that are not supplied with your order.

### 4.2 Mounting/Demounting the C-eye (CXL) Device

The need of mounting or demounting of the **C-eye (CXL) device at the SCHWIND AMARIS excimer laser** can be due to application purposes or other reasons, e.g. the CXL application at a slit lamp, the need to charge the device batteries, to "calibrate" the C-eye device on its "C-base" (i.e. verification of the UV emission value) before day-to-day use, etc.

## "Getting Started" – Instructions for Use

### Installation and Mounting



#### **CAUTION**

##### **Danger of falling C-eye (CXL) device!**

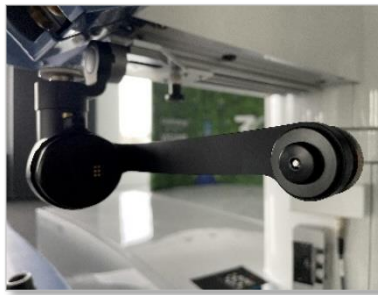
The device shall be correctly installed on the C-eye Sliding Unit at SCHWIND excimer laser.

For further product description refer to the C.S.O srl Instructions for Use 'C-eye' and make use of chapter [5.1 Installation: C-eye \(CXL\) device & SCHWIND Excimer Laser](#) (this document).

(a)



(b)



(c)

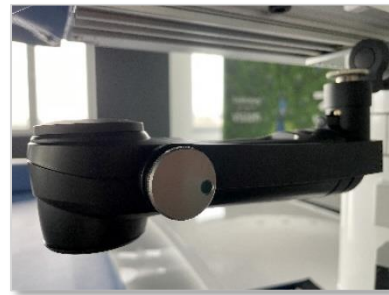


Figure 2: (De-) Mounting of the **C-eye device** by turning the dial (a) at the **C-eye support** (b) to (un-)fasten the **C-eye device** (c).



#### **CAUTION**

You must not use any screwdriver when (de-) mounting the **C-eye device** from **C-eye Sliding Unit** at SCHWIND excimer laser.

Make sure that connection between **C-eye support** and **C-eye device** is securely established before unhanding the **C-eye device**.



#### **IMPORTANT NOTE**

The **C-eye (CXL) device** in conjunction with the **C-eye Sliding Unit** is properly adjusted at SCHWIND excimer laser during the installation by suitably trained service personnel of SCHWIND eye-tech-solutions or authorized local SCHWIND representative, i.e. working plane of C-eye is in agreement with working plane of laser ablation area (C-eye working distance:  $36 \pm 5 \text{ mm}^{(*)}$ ).

(\*) The value indicated refers to the optimal distance between the anterior lens of the **C-eye** and the patient's eye (C-eye CAP excluded).

## "Getting Started" – Instructions for Use

### Device Operation

## 5 Device Operation



### IMPORTANT NOTE

The operation of the **C-eye Cross-Linking Kit** at SCHWIND excimer laser is allowed by trained personnel only!

Refer to Chapter "**DEVICE USE**" within Instructions for Use 'C-eye' by manufacturer C.S.O srl for explanation and details of the medical device storage, charging, check-UV (verification of the UV emission value) and use itself!

For information and details of **C-eye Procedure Kit** (includes **Ribo-Ker** riboflavin solution) to be used in conjunction with **C-eye**, refer to [www.emagine-eye.com/ribo-ker/](http://www.emagine-eye.com/ribo-ker/).

The following sub-chapters describe the use of the **C-eye Cross-Linking Kit** in conjunction with SCHWIND excimer laser as an extra.

### 5.1 Installation: C-eye (CXL) device & SCHWIND Excimer Laser

How to install the **C-eye (CXL) device** on the **C-eye Sliding Unit** at SCHWIND excimer laser:



### CAUTION

**Danger of falling C-eye (CXL) device. The device shall be correctly installed on the C-eye Sliding Unit at SCHWIND excimer laser.**

**Do not install any devices other than those specified and approved by SCHWIND eye-tech-solutions.**

SCHWIND does not assume responsibility for any other combinations and the implications of misuse!

- 1) Remove the side protection on the device.
- 2) Place the device base on the magnetic adapter of the **C-eye Sliding Unit**.  
*Remark: The button pad of C-eye shall face upwards.*
- 3) Tighten the dial of the **C-eye Sliding Unit** to the side hole in the device.
- 4) Unscrew the protective cap of the observation lens.
- 5) Remove the protective cap of the UV emitter.
- 6) Check that there is no damage to the device lens.
- 7) Install the disposable **C-eye CAP protection** on the UV emitter. The protection is made of biocompatible material in compliance with **ISO 10993** and is disposable.

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## "Getting Started" – Instructions for Use

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### Device Operation



#### **IMPORTANT NOTE**

The **C-eye CAP protection** is found in the **C-eye Procedure Kit** package.

Refer to Instructions for Use '**C-eye**' by manufacturer C.S.O srl for more information and details if necessary.

### 5.2 Patient Positioning: Cross-Linking Kit & SCHWIND Excimer Laser

How to position the patient for the treatment in conjunction with the **C-eye Cross-Linking Kit** at SCHWIND excimer laser:



#### **IMPORTANT NOTE**

For information on how to store, charge, check-UV (i.e. verification of the UV emission value) and use the **C-eye (CXL) device** itself, refer to the instructions for use of the manufacturer C.S.O srl.



#### **CAUTION**

The inhibition time of **Ribo-Ker** (riboflavin solution) for C-eye (CXL) device use is between 10 and 20 minutes, depending on the clinical CXL protocol used, i.e. before the cornea is illuminated with UV-A light.

- 1) Place the patient on the SCHWIND Patient Bed in horizontal position.
- 2) Position the patient under the SCHWIND excimer laser and align the patient's eye to be treated with the joystick of the SCHWIND Patient Bed (with support of the microscope).  
*Please refer also to the chapter **Joystick Operation** in Instruction for Use of the SCHWIND PATIENT BED.*
- 3) Adjust the correct height of the patient's eye in the same way like patient positioning for cornea treatment at SCHWIND excimer laser.  
*Please refer also to the chapter **Positioning Slits** in Instruction for Use of the SCHWIND AMARIS.*

## "Getting Started" – Instructions for Use

### Device Operation

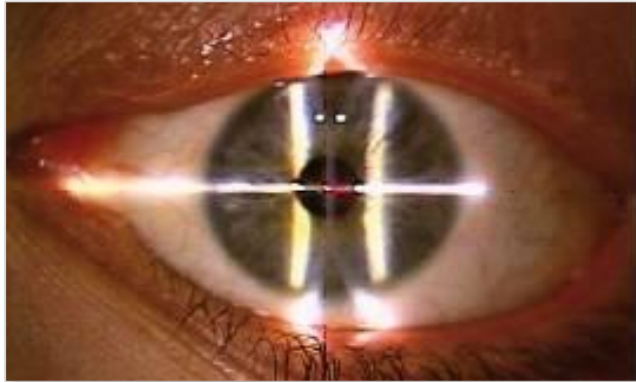


Figure 3: Correct height adjustment of the patient's eye with the help of the SCHWIND AMARIS positioning slits

- 4) The correct treatment distance ( $36 \pm 5$  mm) for the application of the C-eye (CXL) device is now adjusted.



#### **CAUTION**

Do not move and change the SCHWIND Bed in HEIGHT position (i.e. up or down direction) anymore after Positioning Slits are properly aligned to patient's eye for treatment (refer to steps 1 to 4 above)!

The surgeon selects the desired treatment protocol on the **C-eye (CXL) device**. To start the application of UV light and the Cross-Linking procedure itself the C-eye (CXL) device must be placed into treatment position. This is achieved by using the lateral positioning and swivel bolt of the **C-eye Sliding Unit** and the possibility to swivel the **C-eye** in horizontal position.

- 5) Turn the C-eye device (attached to C-eye Sliding Unit) towards the User by approx.  $110^\circ$  when in parking position next to the SCHWIND excimer laser tower, i.e. a swivelling from y-axis (approx.  $90^\circ$ ) to x-axis (approx.  $200^\circ$ ).

## "Getting Started" – Instructions for Use

### Device Operation



Figure 4: C-eye (CXL) device attached to C-eye Sliding Unit in parking position (90°) (next to SCHWIND excimer laser tower)



Figure 5: C-eye (CXL) device attached to C-eye Sliding Unit and turned towards the User by approx. 110°

- 6) C-eye (CXL) device is moved from parking position to treatment area: move the C-eye from right to left on the C-eye Sliding Unit by pulling down the lateral positioning bolt first until the end position is reached.



#### **IMPORTANT NOTE**

Take care that the swivel bolt clicks into place, i.e. end position of the C-eye Sliding Unit is reached.



Figure 6: C-eye (CXL) device attached to C-eye Sliding Unit moved from parking position to treatment area

- 7) Turn the C-eye device (attached to C-eye Sliding Unit) slightly back by approx. 20° to be perpendicular aligned to patient's head. The device is now swivelled over the patient's eye.



## "Getting Started" – Instructions for Use

### Device Operation



Figure 7: C-eye Cross-Linking (CXL) Kit in treatment position, i.e. device is swivelled over the patient's eye



#### **CAUTION**

When switching between eyes OD / OS of the same patient for treatment, first make sure to turn the C-eye device (attached to C-eye Sliding Unit) by approx. 20° away from patient's eye that was treated, in direction of the User. Otherwise, you may hit the nose of the patient with the C-eye device when SCHWIND patient bed is moved without slightly swivelling.

Afterwards, repeat steps 2, 3, 4, and 7 from above for patient eye alignment of the contralateral eye.

- 8) Look through the microscope of the SCHWIND excimer laser and ensure that view on patient's eye is given. This makes observation possible before and during the Cross-Linking procedure.



#### **IMPORTANT NOTE**

For information on how to carry out a treatment with the **C-eye (CXL) device**, refer to the instructions for use of the manufacturer C.S.O srl., Italy.

Furthermore, **C-eye** requires **Ribo-Ker**, a CE marked 0.1% hypo-osmolaric riboflavin solution for corneal cross-linking, for all application purposes. Ribo-Ker is produced by the IROMED GROUP S.r.l., Italy, and the **C-eye Procedure Kit** - including Ribo-Ker riboflavin solution - is finally assembled by IROMED, too. Distribution of the C-eye Procedure Kit is carried out by EMAGine AG, Switzerland. [www.emagine-eye.com/ribo-ker/](http://www.emagine-eye.com/ribo-ker/)



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## **"Getting Started" – Instructions for Use**

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### **Device Operation**

- 9) Check the area of illumination of the C-eye device on the patient's cornea after the Cross-Linking procedure is started (pressing 'UV' at C-eye device) and adjust towards the diameter of the treatment zone, if necessary. The area of illumination can be observed in profile by the user. Make a further fine positioning of the illumination area in reference to the treatment area intended by slightly swivelling the C-eye device, if needed.
- 10) C-eye (CXL) device is moved back into parking position at the end of the individual Cross-Linking application: Turn the C-eye device (attached to C-eye Sliding Unit) by approx. 20° away from patient's eye in direction of the User, then move the C-eye from left to right on the C-eye Sliding Unit by pulling down the lateral positioning bolt first. After the end position of the sliding unit is reached, turn the C-eye device itself from approx. 200° (x-axis) to approx. 90° (y-axis) to be perpendicular aligned to the SCHWIND excimer laser tower. The device is back in parking position (refer to Figure 4).
- 11) Patient Bed is moved to exit position for the patient to leave the operation theatre.

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## Getting Started – Instruction for Use

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### Contact Addresses

## 6 Contact Addresses

### 6.1 Manufacturer/ Importer of C-eye (CXL) Device

**C.S.O. srl**  
**Costruzione Strumenti Oftalmici**  
Via Degli Stagnacci 12/E  
50018 Scandicci (FI), Italy  
[cso@csoitalia.it](mailto:cso@csoitalia.it)

### 6.2 Manufacturer/ Importer of C-eye Procedure Kit (Ribo-Ker)

#### Final Assembler of the C-eye Procedure Kit

**IROMED GROUP S.R.L.**  
Via Tempio del Cielo 3/5  
00144 Rome, Italy  
[info@iromedgroup.com](mailto:info@iromedgroup.com)

#### Importer of the C-eye Procedure Kit

**EMAGine AG**  
Gubelstrasse 12,  
CH-6300 Zug, Switzerland  
[sales@emagine-eye.com](mailto:sales@emagine-eye.com) / [support@emagine-eye.com](mailto:support@emagine-eye.com)

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## Getting Started – Instruction for Use

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### Contact Addresses

#### 6.3 Technical & Applicative Assistance

##### As distribution partner of C-eye (CXL) device:

SCHWIND eye-tech-solutions offers a comprehensive warranty and service support program. Included in this program is our service package.

Highly qualified representatives from our **Customer Service** department are available to support you and to solve any operational questions.

Should you have any questions, please do not hesitate to contact our Customer Service Support. 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**

Tel.: +49-(0)6027-508-0  
Email: [info@eye-tech.net](mailto:info@eye-tech.net)  
<http://www.eye-tech-solutions.com/>

**Customer Service**

**Technical Support:**  
Tel.: +49-(0)6027-508-333  
Fax: +49-(0)6027-508-245  
Email: [service@eye-tech.net](mailto:service@eye-tech.net)

**Application Support:**  
Tel: +49-(0)6027-508-350  
Email: [apm@eye-tech.net](mailto:apm@eye-tech.net)

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