# RESIGHT 500 / RESIGHT 700

Instructions for Use

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All other trademarks in this document are the property of their respective owners.

The instructions in this document may show illustrations of optional accessories or components. These illustrations are for illustrative purposes and do not necessarily show the features of your unit. Information on the structure and connections of the respective component or accessory can be found in the relevant Instructions for Use, if applicable.

# Table of Contents

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# 1 Notes on the instructions for use

## 1.1 Device name

RESIGHT 500 / 700 is referred to as "device" in these Instructions for Use.

## 1.2 Scope of application

These Instructions for Use apply to devices with the following identification:

- Reference number: 302721-9020-000 (RESIGHT 500)
- Reference number: 302721-9030-000 (RESIGHT 700)

## 1.3 Purpose and storage of the documentation

These Instructions for Use explain the safety features, functions and performance parameters of the device. They contain instructions on the safe use of the device and identify measures for its care and maintenance.

Correct operation of the device is imperative for its safe and successful function.

*Action*

- ▶ Read these Instructions for Use before setting up and using the device the first time.
- ▶ Keep the Instructions for Use accessible for all users at all times.
- ▶ Pass the Instructions for Use to future owners of the device.

## 1.4 Questions and comments

*Action*

- ▶ If you have any questions or comments concerning these Instructions for Use or the device itself, please contact ZEISS Service.

You can find the ZEISS representative for your country online on the following website: www.zeiss.com/med

## 1.5 Conventions in this document

Certain types of information are specially marked in this document for better recognition.

### 1.5.1 Conventions in all text areas

- This is a list.
  - This is a second level list.

This is a cross-reference: Conventions in this document [▷ 7].

This is **bold type**.

This is `software code` or `program text`.

Names of software dialogs, fields or menus and software messages are marked by quotation marks:

- "View" menu.
- "Do you want to save the settings?"

The steps in menu and file paths are separated by slashes:

- "File / Save as"
- "My documents / Documents"

Keys, buttons, knobs, levers and other operating controls are marked by square brackets:

- [START] key
- [Next] button

### 1.5.2 Conventions in a course of action

**⚠ WARNING!**

**This is warning information about hazards that can cause death or severe injuries if not avoided.**

The warning message names the possible consequences.

▶ This is a measure with which hazards can be prevented.

**⚠ CAUTION!**

**This is warning information about hazards that can cause injuries if not avoided.**

The warning message names the possible consequences.

▶ This is a measure with which hazards can be prevented.

**NOTE**

**This is warning information about hazards that can cause property damages if not avoided.**

The warning message names the possible consequences.

▶ This is a measure with which hazards can be prevented.

*Prerequisite*

☑ This is a requirement that must be met before the start of a sequence of actions.

*Action*

1. This is a command.
2. **CAUTION! This is a warning message about hazards that can occur during a single action.** This is a command.

   ⇨ This is the result of a sequence of actions.

## 1.6 Other applicable documents

| Document type | Document title | Document number | Optional |
|---|---|---|---|
| IFU | Reprocessable Products (Asespsis) | G-30-1560 | no |

# 2 Safety notes

## 2.1 Target group

These Instructions for Use are intended for physicians, specialized medical and technical personnel, and nurses who are responsible for preparing, operating or maintaining the device following training.

It is the duty of the equipment owner/operator to train and instruct all operating personnel.

## 2.2 Area of use

### 2.2.1 Intended use

The fundus viewing system is an accessory for surgical microscopes that is used in surgery on the posterior segment of the eye. It enables stereoscopic imaging of the posterior segment and the retina.

### 2.2.2 Normal use

RESIGHT 500 and RESIGHT 700 are intended exclusively for ophthalmic surgical procedures in the posterior eye segment.

The fundus viewing system is mounted on the objective lens below the surgical microscope, and is swiveled into the beam path of the surgical microscope.

RESIGHT 700 is an electrically powered fundus viewing system.

RESIGHT 500 is a fundus viewing system which can be operated manually.

Both devices (the manual and electric versions) enable the stereoscopic viewing of the posterior eye segment (known as the fundus), which is required for special surgical methods.

The complete system comprises a focusing unit which is fitted to the surgical microscope using a dovetail mount. It consists of a sterilizable lens support with sterilizable aspheric lenses and sterilizable asepsis caps for the focus buttons on the focusing unit.

The device has been designed for use in hospitals, clinics and other medical institutions for humans.

**Before surgery:**

A sterile person opens the device's sterile packaging and fits the sterile parts such as the lens support, aspheric lenses and sterile asepsis caps for the focusing buttons onto the parts of the device that remain mounted on the microscope (focusing unit).

An assistant to the surgeon then positions the surgical microscope, with the device attached to it, over the patient's eyes for surgery.

**During surgery:**

The focus for the fundus viewing system can be controlled manually using the rotary knobs on each side.

With the electric version, the focusing function can also be controlled via the foot control panel.

The internal focus ensures that the surgical microscope no longer needs to be vertically moved. Accordingly, when working on the anterior segment of the eye, you can push the fundus viewing system out of the way without causing any blurring of the images viewed through the surgical microscope. In order to obtain different magnifications and fields of view, the surgeon or surgical assistant can switch between normal view and wide angle view by changing the resterilizable aspheric lenses in the lens support.

**After surgery:**

Once the procedure is finished, the surgeon swings the microscope, together with the device mounted on it, out of the operating area into the parking position. The sterile parts of the device, such as the lens support, aspheric lenses and sterile caps, are removed from the device by a sterile person and can be resterilized.

The part of the device that remains on the microscope (focusing unit) can be cleaned and disinfected.

The sterilizable aspheric lenses are fitted on the swiveling lens support mechanism of the sterilizable lens support, and can both be mounted opposite each other at an angle of 180°.

During surgery on the posterior segment of the eye, the surgical assistant can adjust the magnification of the surgical area by turning the lens turret 180° so as to switch to the other aspheric lens which has a different magnification or other characteristics for special patient requirements, for example if the eyes are small or deep-set.

After surgery the aspheric lens is removed from the lens turret and reprocessed separately.

### 2.2.3 Indication

The main applications for the RESIGHT 500 / 700 fundus viewing system comprise all eye surgery procedures performed on the posterior segment of the eye. The fundus viewing system is used for all surgical procedures requiring visualization of the posterior eye segment (e.g. the vitreous body) and/or the fundus, such as retinal detachment, macular membranes or holes, glasslike opacity, etc.

### 2.2.4 Contraindications

Provided that the RESIGHT 500 / 700 fundus viewing system is used within its intended purpose, there are no known contraindications.

### 2.2.5 Patient target group

| Anticipated indications of use | |
|---|---|
| Discipline | Ophthalmology |
| Patient target group: | No restriction |
| Age: | No restriction |
| Gender: | No restriction |

## 2.3 Responsibilities and duties of the responsible organization

**Operating personnel**

The device may be operated only by properly instructed and trained persons.

- ▶ Ensure that the operating personnel have been trained and instructed.
- ▶ Ensure that the operating personnel have read and understood the instructions for use.
- ▶ Keep the instructions for use available at all times for the operating personnel.
- ▶ To facilitate access for the entire operating personnel: If necessary, request further copies of the instructions for use from ZEISS.
- ▶ Specify the competencies for handling the device and state who is authorized for what tasks.
- ▶ Define rules for reporting errors and damage, and ensure these rules are known (see Notification to manufacturers and authorities [▷ 12]).
- ▶ Provide the necessary protective clothing.
- ▶ Regularly check compliance with the national laws and regulations concerning accident prevention and occupational health.

**Safety inspections**

- ■ Availability of the Instructions for Use
- ■ Visual inspection of system and accessories for damage and legibility of labels
- ▶ Contact the ZEISS Service team or authorized service personnel as soon as a change occurs in the device.

### Device modifications

**NOTE**

**Unauthorized interference with the device**

This device must not be modified without the manufacturer's approval. If the system is modified after consultation with the manufacturer, suitable inspections and testing by the ZEISS Service team or authorized specialist personnel must be completed to ensure subsequent safe use. The manufacturer is not liable for damage caused by unauthorized persons modifying the system. Furthermore, this forfeits any rights to claim during warranty period.

### Accessories and additional equipment

- If you want to connect accessories or additional equipment to the device: Contact your ZEISS representative [▷ 7].

Additional equipment connected to medical electrical devices must demonstrably comply with the corresponding IEC or ISO standards (e.g. IEC 60950 for data processing equipment).

Furthermore, any configurations must comply with the requirements stipulated in the standards for medical systems (see IEC 60601-1).

If you connect optional equipment to medical electrical systems, you are a system configurator and are thus responsible for ensuring that the system complies with the normative requirements for systems.

Local laws take precedence over the above normative requirements.

## 2.3.1 Messages to manufacturer and authorities

If a serious incident occurs in connection with this medical device affecting the operator or another person, the operator (or person responsible) must report this serious incident to the manufacturer and seller of the medical product. In the European Union, the operator must report this serious incident to the competent authority in his/her country.

## 2.4 Measures and duties of the operator

### Environmental conditions

Using the product in unsuitable ambient conditions may lead to damage, malfunction or injury.

- ▶ Make sure that the installation conditions and the operation of the product comply with the surgical requirements:
- Low vibration
- Clean environment
- Avoid extreme mechanical stress
- ▶ Do not use power-operated products included in the delivery package
- in explosive atmospheres,
- at a distance of less than 25 cm from flammable anesthetics or volatile solvents such as alcohol, benzine or similar substances.
- ▶ Do not store or use the product in damp rooms. Do not expose the product to water splashes, dripping water or sprayed water.
- ▶ Make sure that no liquid can penetrate the product.
- ▶ Operate the product only within the limits of the prescribed ambient requirements.
- ▶ Store and transport the product only within the limits of the ambient conditions stipulated.

Excessive temperature changes can lead to the condensation of moisture in the air and thus to the formation of dew on the lamp.

- ▶ Avoid moving the product between rooms with large temperature differences.

### Symbols and labels

- ▶ Observe the symbols and labels attached to the product and its packaging!

### Transport

- ▶ Transport the product over long distances (e.g. relocation, return for repair) only in its original packaging or special return packaging.
- ▶ Please contact your dealer or ZEISS Service for this purpose.

### Handling

Small, loose objects (e.g. screws) that get inside the device can damage the device.

- ▶ Do not place small, loose objects on the product.

**Patient information**

- ▶ Make sure that all residual risks related to the use of the medical device or accessory, including all foreseeable and undesired incidents or side effects, are communicated to the patient. Thereby, take into account all contraindications, safety notes, warning messages and restrictions.

## 2.5 Electromagnetic compatibility

The device is subject to special precautionary measures regarding electromagnetic compatibility (EMC). The following factors can cause EMC disturbances:

- Portable and mobile HF communication equipment in the vicinity of the device.
- Other devices set up in the vicinity or stacked together with the device.
- Accessories, cables and spare parts not specified in the Instructions for Use and not sold by ZEISS as spare parts.

You can prevent EMC disturbances by using the following precautionary measures:

- ▶ Comply with the Instructions for Use.
- ▶ The device must be installed and initially commissioned in accordance with the EMC notes in the Technical specifications section.
- ▶ Only use accessories, transformers, cables and spare parts specified in the Instructions for Use or approved by ZEISS for this device.
- ▶ If you are installing the device near or stacking it with other devices: Check the device is operating correctly in this configuration.

## 2.6 Requirements for operation

### 2.6.1 Before every use

#### 2.6.1.1 Hazards resulting from incorrect installation

The following safety measures must be observed to prevent injuries or damage:

- Make sure that the connecting components are properly set and that all screw connections are securely tightened.
- Make sure that all cables and plugs are in proper condition.
- Make sure that the device can be pushed in and out easily.
- Make sure that the lens support can be properly moved into and out of position.

- Ensure that there is sufficient free space for focus positioning when the device is attached to the surgical microscope.
- Make sure that you do not exceed the permissible total weight of the surgical microscope when mounting this accessory. Detailed information can be found in the Instructions for Use of the respective surgical microscope.

## 2.6.2 During operation

### 2.6.2.1 Hazards arising from the device swiveling in

If the device is mounted on the underside of the microscope and you steeply tilt the microscope, the fundus viewing system may unintentionally swivel in and injure the patient.

- ▶ Remove the device before tilting the surgical microscope at a steep angle.

## 2.6.3 After every use

### 2.6.3.1 Hazards arising from inadequate sanitation

Insufficient, incorrect or improper cleaning, disinfection or sterilization that does not comply with these Instructions for Use can expose the patient or medical staff to a considerable risk of infection.

- ▶ Follow the instructions in "Cleaning and disinfection [▷ 55]".
- ▶ Use only procedures validated by ZEISS to clean, disinfect and sterilize.
- ▶ Make sure that the validated parameters are complied with in each cycle.

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# 3 Description of the device

## 3.1 Labeling on the device

**⚠ CAUTION!**

**Risk of injury due to illegible labels!**

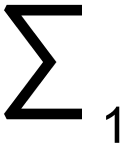
Over time, labels can become dirty or unidentifiable, making it difficult or impossible for hazards to be recognized or necessary operating instructions to be followed.

- ▶ For this reason, all safety, warning and operating instructions are to be kept in good condition at all times.
- ▶ Damaged labels are to be replaced immediately. For replacement labels, contact us or one of our authorized representatives.

| Symbol | Name | Explanation |
|---|---|---|
|  | System label for RESIGHT 500 | Provides information on:<br>■ Manufacturer<br>■ Device conformity |
|  | System label for RESIGHT 700 | Provides information on:<br>■ Manufacturer<br>■ Device conformity |
|  | UDI label RESIGHT 500 | Provides information on:<br>■ MD labelling<br>■ Date of manufacture<br>■ Machine readable label (barcode)<br>■ UDI Device Identifier (UDI-DI)<br>■ UDI Production Identifier (UDI-PI) |
|  | UDI label RESIGHT 700 | Provides information on:<br>■ MD labelling<br>■ Date of manufacture<br>■ Machine readable label (barcode)<br>■ UDI Device Identifier (UDI-DI)<br>■ UDI Production Identifier (UDI-PI) |
|  | Manufacturer | - |
|  | Date of manufacture | - |

| Symbol | Name | Explanation |
|---|---|---|
| SN | Serial number | - |
| REF | Reference number | - |
| CE | CE mark | - |
|  | WEEE label | Do not dispose of electrical and electronic devices along with normal domestic waste. The bar beneath the garbage bin icon declares that the device was "put into circulation" on August 13, 2005. |
| **LH175**<br>**LH200** | Lens support labeling | ■ LH175 - for main objective lens with focal length f = 175<br>■ LH200 - for main objective lens with focal length f = 200 |
| **V1.0**<br>**V2.0** | Focusing unit labeling | ■ V1.0 - for focusing unit with new locking knob [from SN 12xxx - 13999]<br>■ V2.0 - for focusing unit with new locking knob and OCT-capable optics [from SN 14xxx and higher] |
| **V1.0**<br>**V2.0** | Adapter plate labeling | ■ Adapter plates that are labeled with V1.0 or V2.0 can be combined with all focusing units<br>■ Adapter plates that are not labeled with the version number can only be combined with focusing units up to SN 11999 |
| **60D** | Aspheric lens labeling | Refractive power 60 diopters |
| **128D** | Aspheric lens labeling | Refractive power 128 diopters |

## 3.2 Labeling on the packaging

| Symbol | Symbol | Explanation |
|---|---|---|
|  | "Top" direction indication | Indicates the correct upright position of the package. |
|  | Fragile | Handle with care |
|  | Protect from moisture | Protect packaging and packaged contents from moisture. |
|  | Do not stack | Stacking of the packages is not permitted. No load should be placed on the package. |
|  | Permissible temperature | The product may only be transported and stored within a temperature range of min. -40 °C to max. +70 °C. |
|  | Packing unit | Number of packaging units |
|  | Permissible relative air humidity | The product may only be transported and stored at a humidity of min. 10% and max. 90% RH. |
|  | Permissible atmospheric pressure | The product may only be transported and stored at an atmospheric pressure of min. 500 hPa and max. 1060 hPa. |

## 3.3 Design of the device

### 3.3.1 RESIGHT 500 system overview

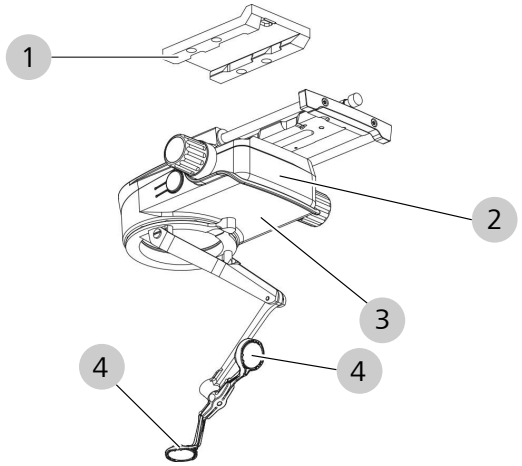



*Figure 1: System overview RESIGHT 500*

| | | | |
|---|---|---|---|
| 1 | Adapter plate | 2 | Manual focusing unit |
| 3 | Resterilizable lens support | 4 | Resterilizable aspheric lenses |

### 3.3.2 RESIGHT 700 system overview

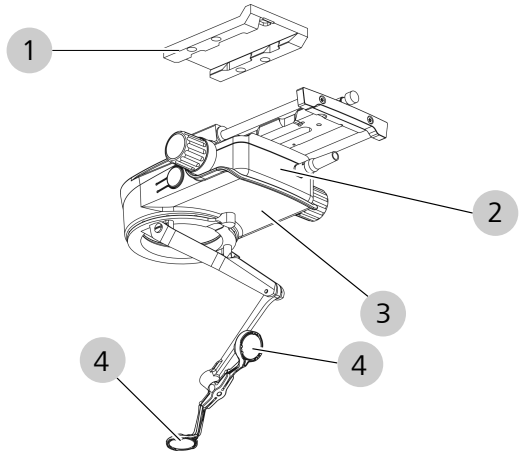



*Figure 2: System overview RESIGHT 700*

| | | | |
|---|---|---|---|
| 1 | Adapter plate | 2 | Electrical focusing unit |
| 3 | Resterilizable lens support | 4 | Resterilizable aspheric lenses |

### 3.3.3 Adapter plate

The adapter plate is used to attach the focusing unit to the surgical microscope.

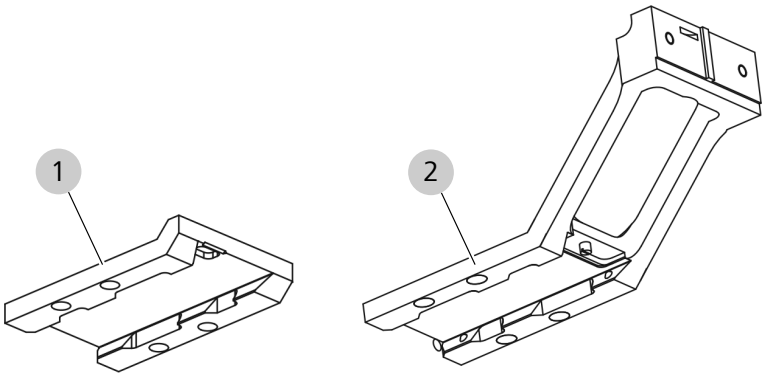



*Figure 3: Adapter plates*

| | | | |
|---|---|---|---|
| 1 | Adapter plate without mount for fiber slit illuminator | 2 | Adapter plate with mount for fiber slit illuminator (optional) |

### 3.3.4 Focusing unit

The focusing unit eliminates the need to refocus the surgical microscope. Thanks to the internal focus with Varioscope optics, the surgical microscope always remains on the same focal plane and thus enables individual focusing on the patient's retina.

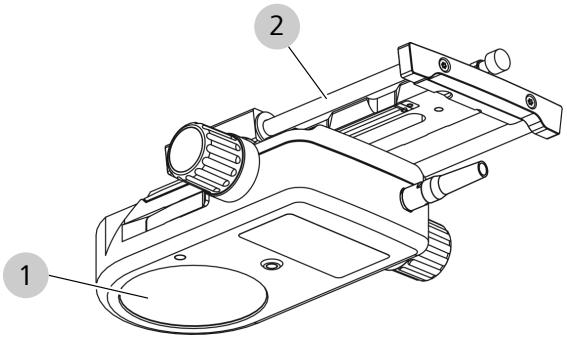



*Figure 4: Focusing unit*

| | | | |
|---|---|---|---|
| 1 | Internal focus with Varioscope optics | 2 | Sliding mechanism with locking knob |

### 3.3.5 Resterilizable lens support

The resterilizable lens support is used for sterile operation of the device and for aligning and changing the resterilizable aspheric lenses.

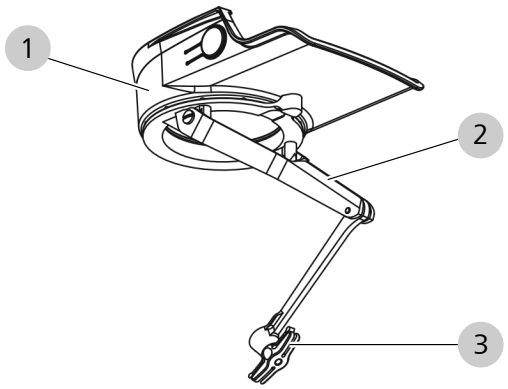



*Figure 5: Resterilizable lens support*

| | | | |
|---|---|---|---|
| 1 | Lens support | 2 | Lens support mechanism |
| 3 | Lens turret | | |

### 3.3.6 Resterilizable aspheric lenses

The resterilizable aspheric lenses produce a magnified intermediate image of the fundus area.

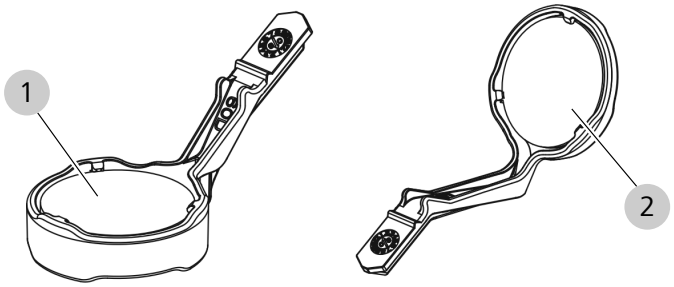



*Figure 6: Resterilizable aspheric lenses*

| | | | |
|---|---|---|---|
| 1 | Aspheric lens 60D (green) | 2 | Aspheric lens 128D (yellow) |

### 3.3.7 Mounting aid

The mounting aid is used to align the adapter plate for the focusing unit on the surgical microscope.

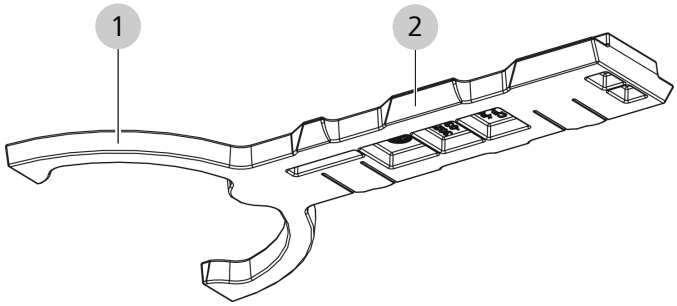



*Figure 7: Mounting aid*

| | | | |
|---|---|---|---|
| 1 | Adjustment head | 2 | Adjustment handle |

### 3.3.8 Connections on the RESIGHT 700

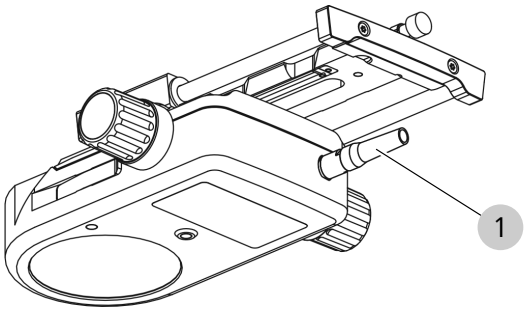



*Figure 8: Connections on the RESIGHT 700*

| | |
|---|---|
| 1 | Power supply connection for the electric focusing unit |

# 3.4 Control elements and displays

## 3.4.1 Lens support

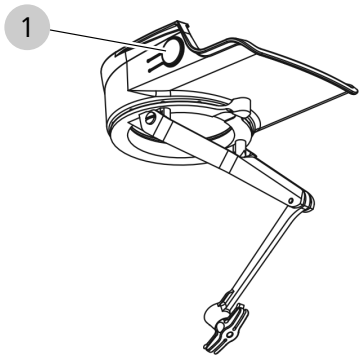



*Figure 9: Lens support controls*

| Item | Name | Explanation |
|---|---|---|
| 1 | Release buttons | Locked: the lens support is attached to the focusing unit<br>Unlocked: the lens support can be pulled forward. |

## 3.4.2 Focusing unit

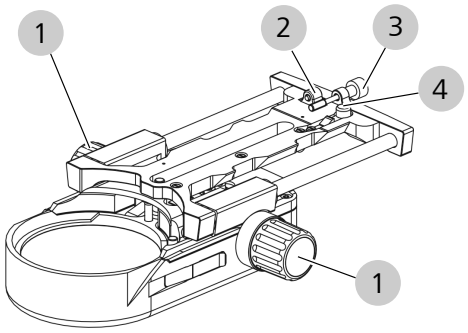



*Figure 10: Focusing unit controls*

| Item | Name | Explanation |
|---|---|---|
| 1 | Focusing knob | Adjusts the internal focus manually. |
| 2 | Adjustment screw | Aligns the objective lens of the fundus viewing system horizontally to the main objective lens of the surgical microscope. |

| Item | Name | Explanation |
|---|---|---|
| 3 | Focusing unit locking screw | Fixes the focusing unit on the adapter plate |
| 4 | Unlocking button | Releases the focusing unit from the adapter plate. |

## 3.5 Functional description

The fundus viewing system provides a detailed view of the retina. The fundus viewing system is mounted on the objective lens below the surgical microscope.

The sterile lens support (blue) is placed over the non-sterile focusing unit during preparation for surgery. For correct visualization of the fundus image, the lens support must correspond to the focal length of the main objective lens. If a main objective lens with a focal length of f=200 mm is used on the surgical microscope, the LH200 lens support must be used. The lens support can be turned in 30° increments to set the optimum working position. The lens support retracts automatically in the event of accidental patient contact. The lens turret on the lens support allows sterile access to a second aspheric lens with alternative magnification. You can choose between wide-angle and high magnification.

For work on the posterior segment of the eye, the fundus viewing system is swiveled into the optical path of the surgical microscope. The aspheric lens produces an intermediate image of the retina that can be viewed with the surgical microscope. Thanks to the internal focus of the fundus viewing system, the surgical microscope always remains on the same focal plane. Vertical movement of the surgical microscope is no longer necessary. When working on the anterior segment of the eye, the fundus viewing system can be pushed out of the way without causing any blurring of the images viewed through the surgical microscope.

The electrical communication between the RESIGHT 700 fundus viewing system and the surgical microscope occurs via the “accessory port upgrade kit” that is integrated in the stand. The upgrade kit is installed in the suspension system by Zeiss Service .

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# 4 Installation

## 4.1 Mounting RESIGHT

The adapter plates can be used to attach the devices to the following surgical microscopes:

- RESIGHT 500: S88 / OPMI Lumera T, OPMI Lumera i, OPMI Lumera 300 and OPMI Lumera 700
- RESIGHT 700: S88 / OPMI Lumera T, OPMI Lumera 700, ARTEVO 800 and ARTEVO 750/850

The different variants of the adapter plates and focusing units are combinable as follows:

| | **Focusing unit with label indicating version number V2.0 [from SN 14xxxx]** |
|---|---|
| | Focusing unit with new locking knob and OCT-capable optics |
| Adapter plate without label indicating version number | Not combinable |
| Adapter plate* with label indicating version number (V1.0) | Combinable |
| Adapter plate* with a label indicating the version number (V2.0) | Combinable |

* The adapter plate is available with or without an attaching device for the VISULUX fiber slit illuminator:

- Adapter plate 302721-9040-000 does not have an attaching device for the VISULUX fiber slit illuminator.
- Adapter plate 302721-9050-000 has an attaching device for the VISULUX fiber slit illuminator.

Each of these variants can be permanently mounted on the surgical microscope. The following pages contain individual mounting and configuration instructions.

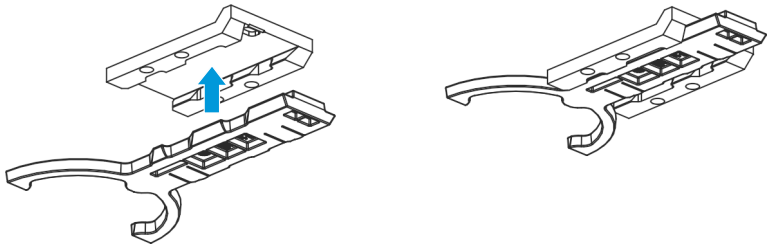
### 4.1.1 Mounting the adapter plate

*Prerequisite*

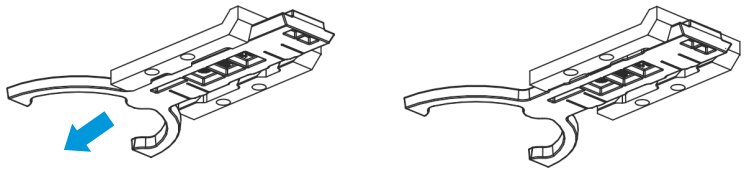
☑ The suspension arm of the stand is secured against unintentional lowering or jolting (see the Instructions for Use for the respective stand).

*Action*

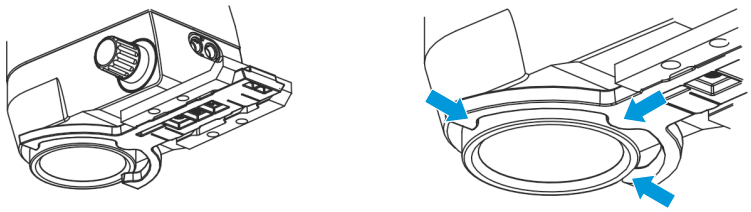
1. Press the mounting aid onto the adapter plate from below. The recesses on the mounting aid must line up with those on the adapter plate. If the device is used in conjunction with the VISULUX fiber slit illuminator, the adapter plate with the attaching device for the fiber slit illuminator must be mounted.



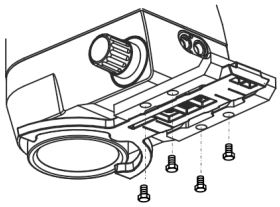
2. Slide the mounting aid on the adapter plate to the left as far as it will go.



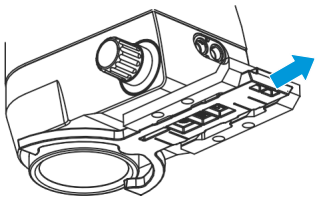
3. Adjust the adapter plate with the help of the mounting aid on the surgical microscope. The three alignment points in the mounting aid must make contact with the camera lens of the surgical microscope.



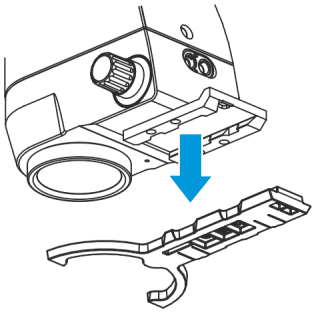
4. Screw the adapter plate in place under the surgical microscope by firmly tightening the four accompanying screws clockwise. Ensure that the three alignment points in the mounting aid are touching the camera lens of the surgical microscope.



5. Push the mounting aid away from the main camera lens of the surgical microscope so that the cutouts on the mounting aid line up with those on the adapter plate.



6. Take the mounting aid out of the adapter plate guide.



### 4.1.2 Mounting the focusing unit

**⚠ CAUTION!**

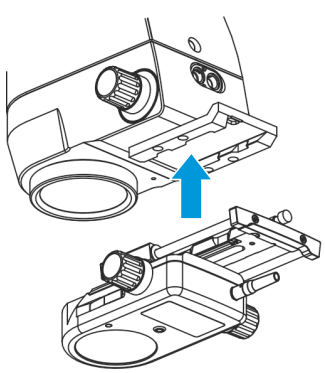
**Risk of injury caused by parts falling down!**

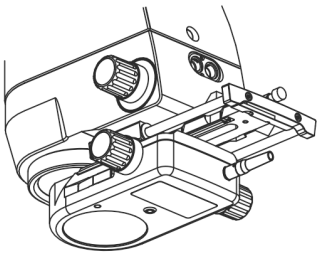
The focusing unit can separate from the adapter plate if it is not snapped in place and secured by the locking screw.

- ▶ Make sure that the alignment screw is not tightened so far that it blocks the locking mechanism, so that the focusing unit can audibly snap into place.
- ▶ Always comply with the following points when attaching the focusing unit.

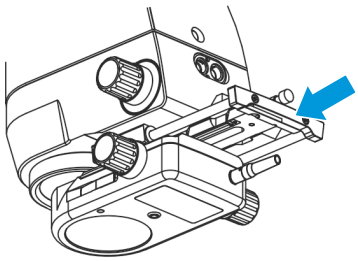
*Action*

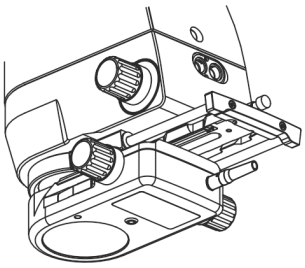
1. Press the focusing unit from below onto the adapter plate so that the recesses on the focusing unit line up with those on the adapter plate.





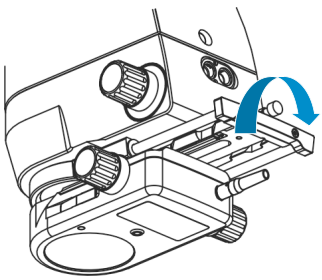
2. Push the focusing unit on the adapter plate in the direction of the objective lens of the surgical microscope up to the end stop until the focusing unit audibly snaps into place.



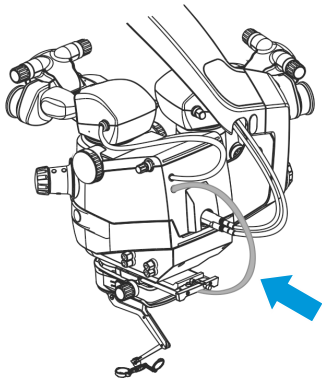


⇨ The focusing unit audibly snaps into place.

3. Screw the locking screw clockwise by hand as far as it will go.



4. For RESIGHT 700: Connect the power cable of the focusing unit to the connector socket at the back of the surgical microscope.

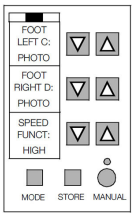


## 4.2 Configuring the foot control panel for S88 / OPMI Lumera T

In order to control the electrical internal focus of the RESIGHT 700 fundus viewing system via the foot control panel, you need to configure the stand accordingly. The configuration settings of the stand depend on the electronics integrated into the stand.

*Action*

1. In "Configuration Mode 1", assign the "PHOTO" function to key C or D of the foot control panel.




*Result*

✓ Once you have configured the C or D button, you can control the electrical internal focus of the RESIGHT 700 via the foot control panel. Note: The button assignments of the foot control panel depend on your system configuration (RESIGHT, Invertertube E and VISULUX [▶ 32]).

### 4.2.1 Button assignments when no accessories are connected

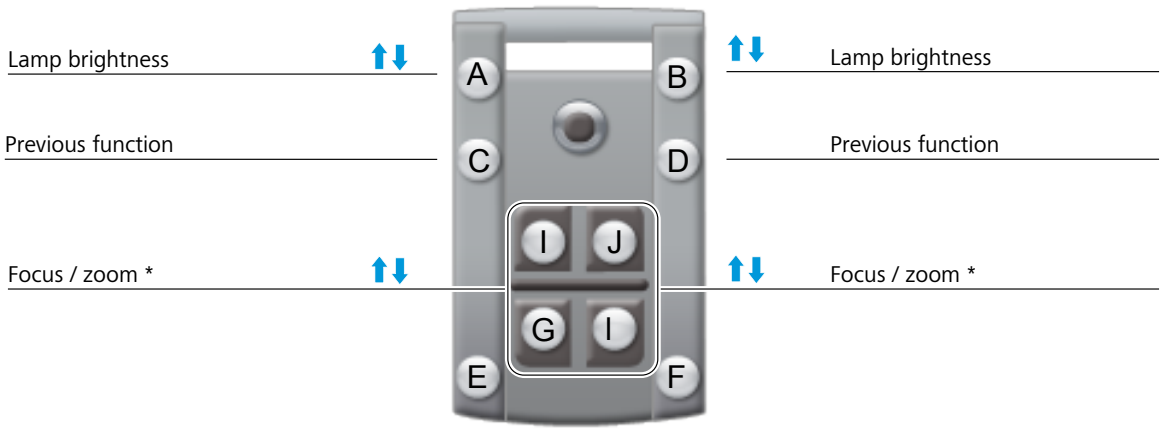



*Figure 11: Button assignments if Invertertube E, RESIGHT and VISULUX are not connected*

* The button assignments depend on the system configuration and may vary between vertical and horizontal assignments.

### 4.2.2 Button assignments with VISULUX connected

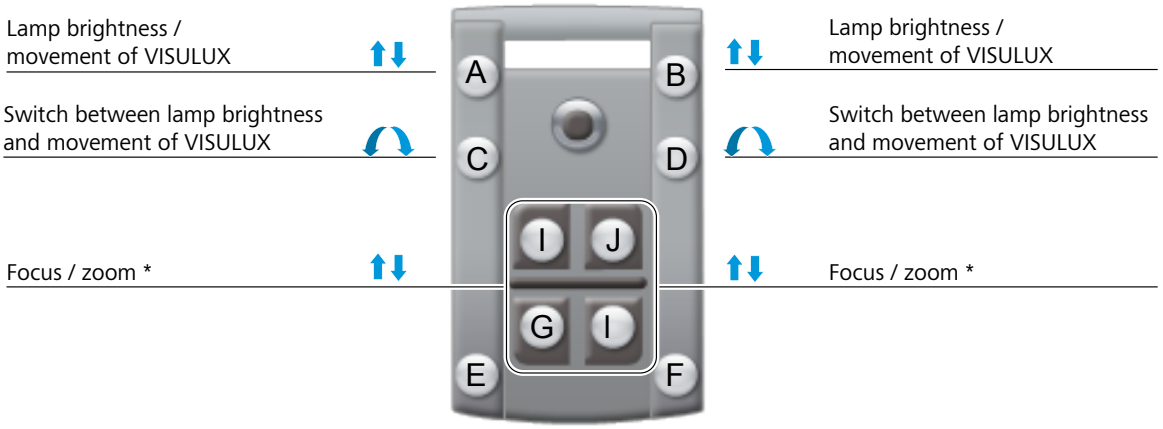



*Figure 12: Button assignments with VISULUX connected*

* The button assignments depend on the system configuration and may vary between vertical and horizontal assignments.

### 4.2.3 Button assignments with Invertertube E connected

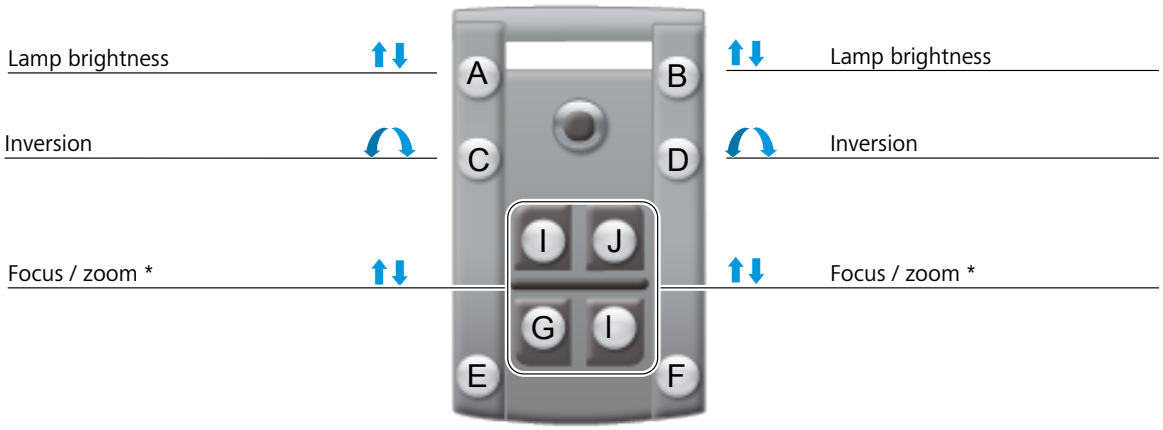



*Figure 13: Button assignments with Invertertube E connected*

* The button assignments depend on the system configuration and may vary between vertical and horizontal assignments.

### 4.2.4 Button assignments with Invertertube E and VISULUX connected

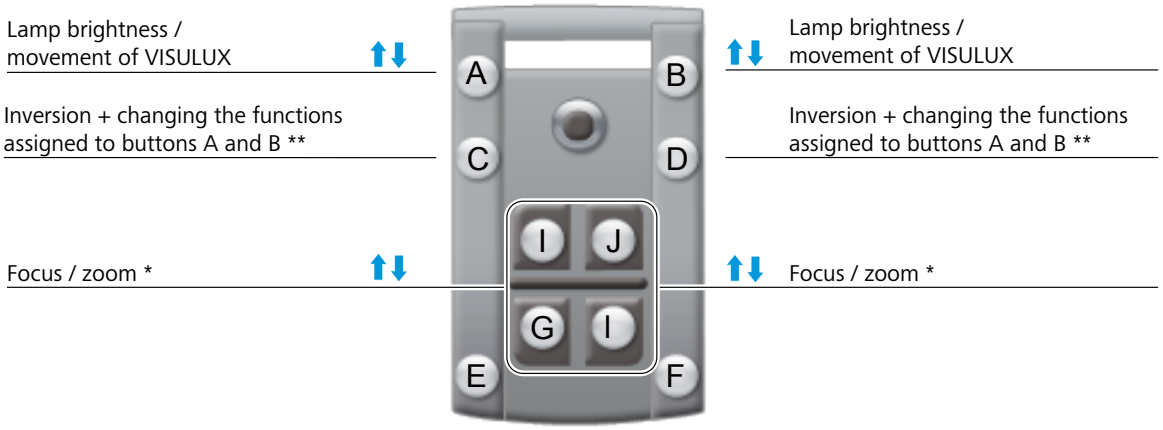



*Figure 14: Button assignments with Invertertube E and VISULUX connected*

* The button assignments depend on the system configuration and may vary between vertical and horizontal assignments.

** **Function 1:** Proceed as follows if you want to change the functions assigned to buttons A and B and rotate the Invertertube E at the same time: Press the C or D button once.

** **Function 2:** Proceed as follows if you want to retain the functions assigned to buttons A and B and only want to rotate the Invertertube E: Press button C or D once; while the Invertertube E is switching over, press button C or D again:

** **Function 3:** Proceed as follows if you want to change the functions assigned to buttons A and B without changing the state of the Invertertube E. Follow the instructions for Function 2, and press button C or D a third time when inversion has completed.

### 4.2.5 Button assignments with RESIGHT 700 connected

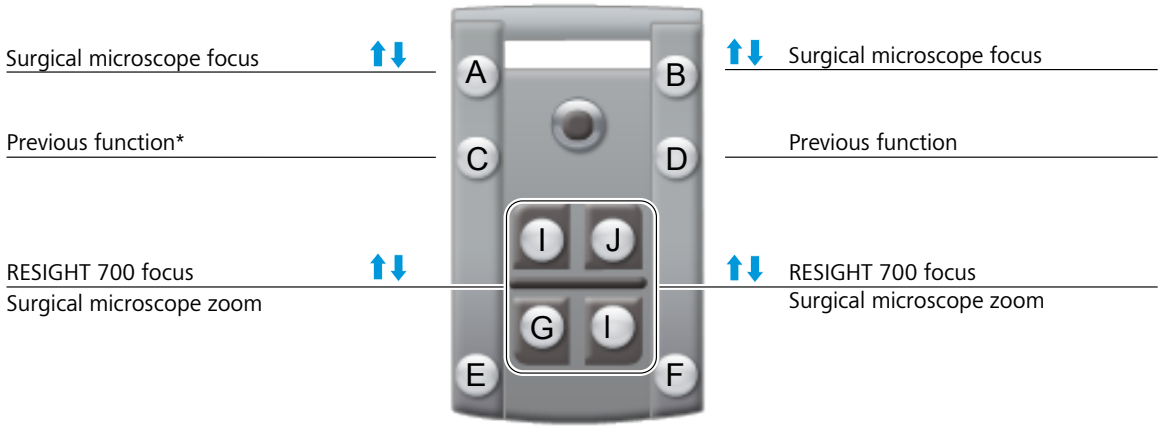



*Figure 15: Button assignment with RESIGHT 700 in the beam path*

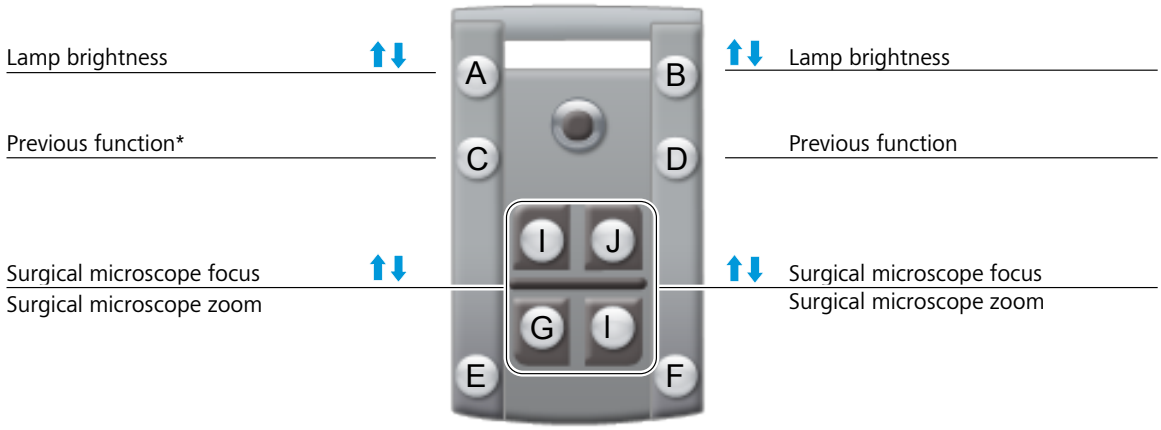



*Figure 16: Button assignments with RESIGHT 700 out of the beam path*

* The button assignments depend on the system configuration and may vary between vertical and horizontal assignments.

### 4.2.6 Button assignments with RESIGHT 700 and VISULUX connected

With this combination, the VISULUX fiber slit illuminator can no longer be moved by motor! The fiber slit illuminator can only be moved manually within a limited range.

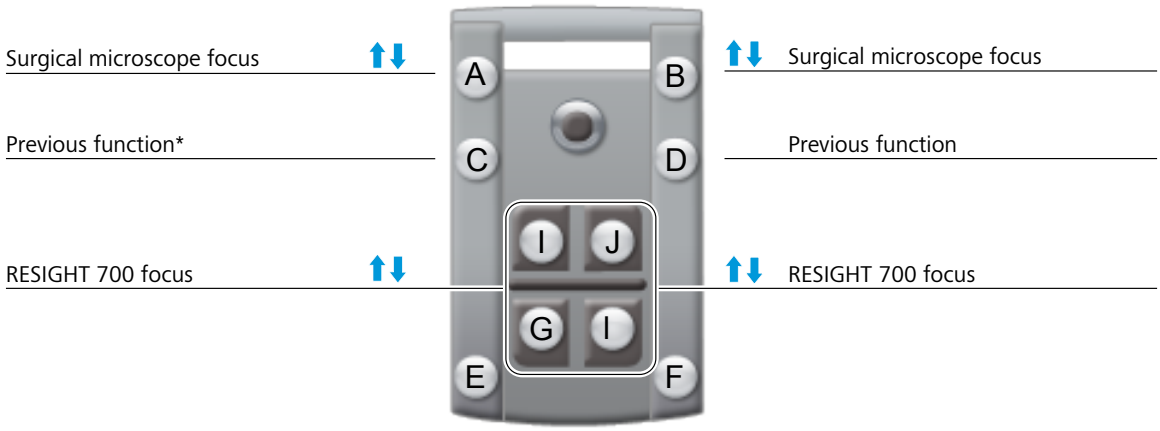



*Figure 17: Button assignment with RESIGHT 700 in the beam path*

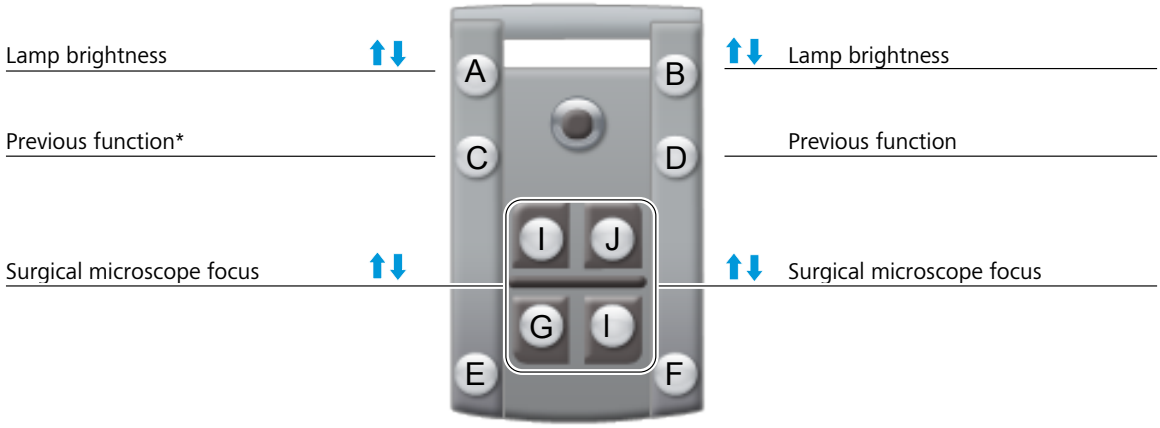



*Figure 18: Button assignments with RESIGHT 700 out of the beam path*

* The button assignments depend on the system configuration and may vary between vertical and horizontal assignments.

### 4.2.7 Button assignments with RESIGHT 700 and Invertertube E connected

Invertertube E automatically inverts the image when the RESIGHT 700 fundus system is moved into the beam path.

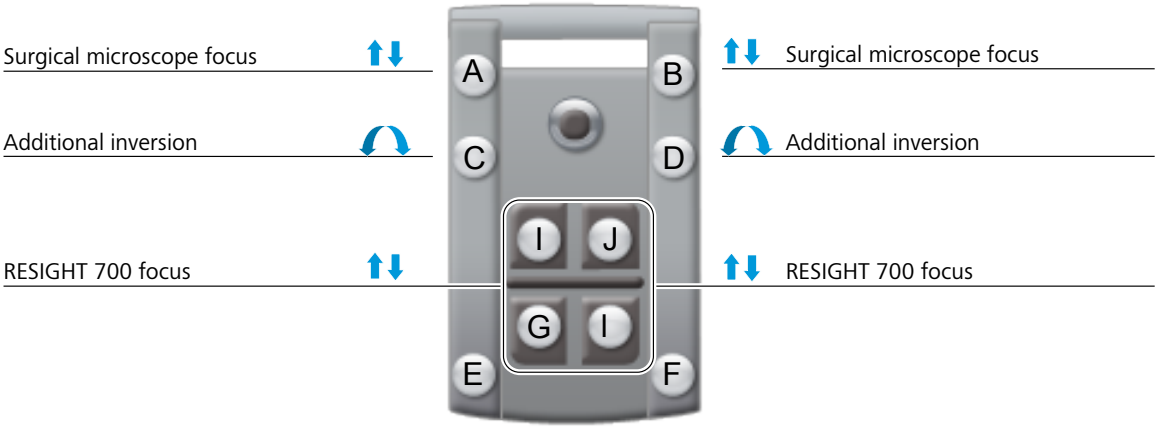



*Figure 19: Button assignments with RESIGHT 700 in the beam path*

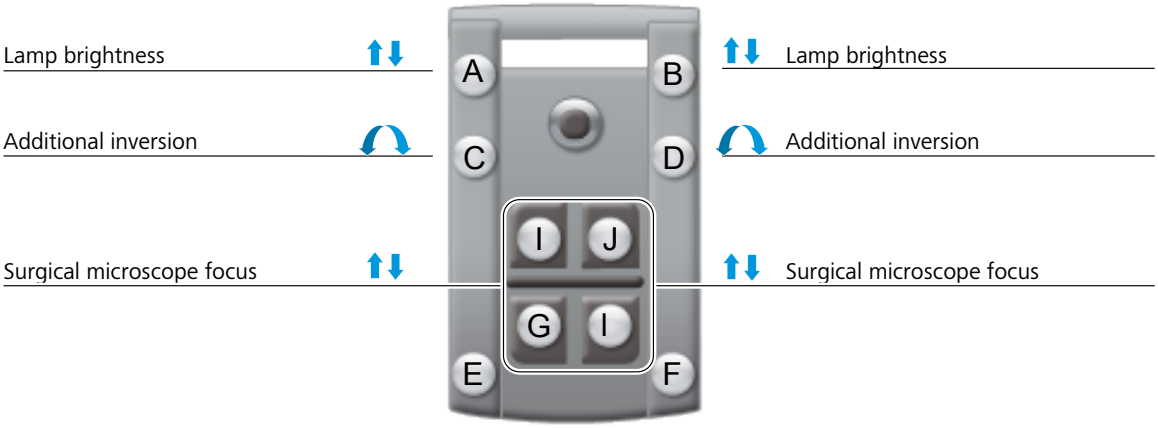



*Figure 20: Button assignments with RESIGHT 700 out of the beam path*

### 4.2.8 Button assignments with RESIGHT 700, Invertertube E and VISULUX connected

Invertertube E automatically inverts the image when the RESIGHT 700 fundus system is moved into the beam path.

With this combination, the VISULUX fiber slit illuminator can no longer be moved by motor! The fiber slit illuminator can only be moved manually within a limited range.

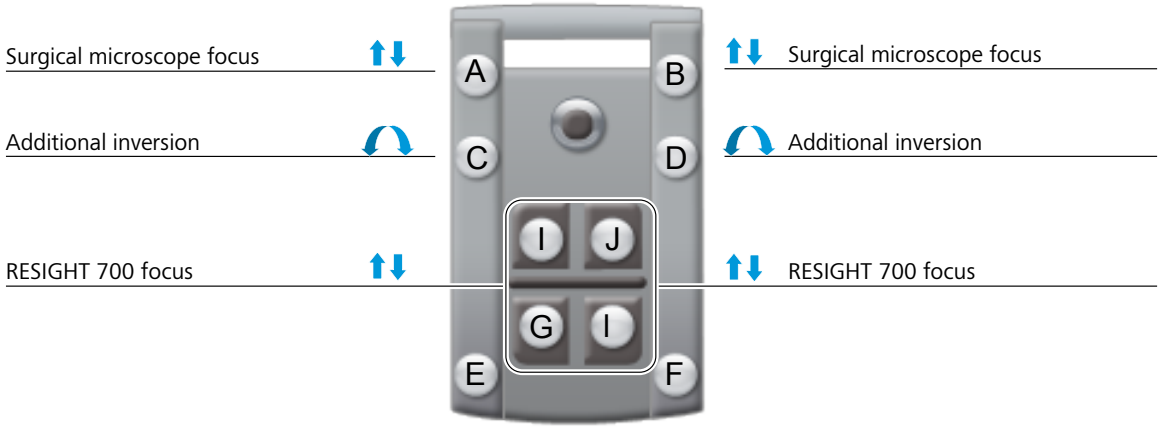



*Figure 21: Button assignments with RESIGHT 700 in the beam path*

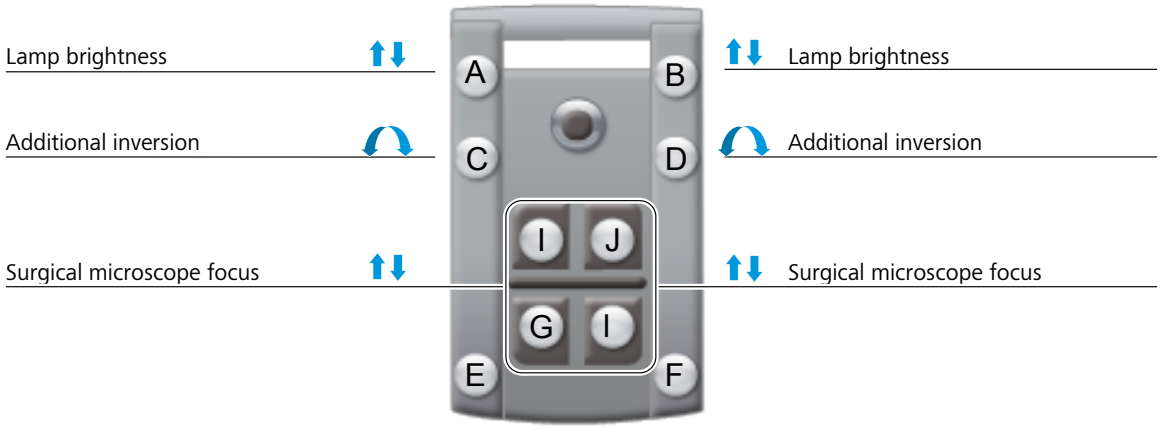



*Figure 22: Button assignments with RESIGHT 700 out of the beam path*

# 4.3 Configuring the foot control panel for OPMI Lumera 700 and ARTEVO 800

### Button functions when RESIGHT 700 is swiveled in

The foot control panel can be specially configured for each surgical profile. When the surgery profile is changed, the foot control panel button configuration specified for the respective profile is enabled.


If the RESIGHT function has been assigned to a surgery profile (surgery profile is identified with an "R"), you can assign the focus control of the surgical microscope (focus + / focus -) and of the RESIGHT fundus viewing system (RESIGHT focus + / RESIGHT focus - ) to any button of the foot control panel.

When you swivel in the RESIGHT 700, the surgery profile identified by an "R" will be activated and its foot control panel configuration will be loaded automatically.

If you do not wish to use the current configuration, you can change the buttons assignments of the foot control panel by going to "Advanced configuration > Foot control panel" in the menu.

In addition to the individually adjustable functions, a RESIGHT 700 focus reset is performed when the XY reset button is pressed or when the surgical microscope reaches the parking position. This places the focus of the connected RESIGHT 700 in the center position.

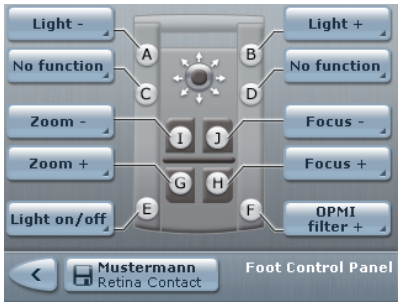
### Button functions when RESIGHT 700 is swiveled out

After the RESIGHT 700 has been swiveled out, the user-specific stored functions of the subsequent "surgical profile" will be applied.

### Changing the button assignments on the foot control panel

*Action*

1. Open the main menu.
2. Tap the [Additional Settings] menu button.
3. Tap the [Foot control panel] submenu button.
   ⇨ The "Foot Control Panel" menu will appear.




4. Tap the buttons whose assignments you would like to change.
   ⇨ The list of available functions will appear.
   ⇨ The "RESIGHT focus +" or "RESIGHT focus -" buttons will appear only if the RESIGHT "R" function has been assigned to a surgery profile.
5. Select the function you would like to assign to the selected button on the 14-function foot control panel.
   ⇨ The function will be displayed on the button.
6. To save the changes to the surgery profile: tap the  button.

Tip: Test the button assignments and functions on the 14-function foot control panel before each use when the patient is not present.

## 4.4 Configuring the foot control panel for ARTEVO 750/850

### Button functions when RESIGHT 700 is swiveled in

A special assignment of the foot control panel can be configured in CALLISTO eye for each surgical profile. When the surgery profile is changed, the foot control panel button configuration specified for the respective profile is enabled.

If the RESIGHT function has been assigned to a surgical profile (surgical profile is marked with "R"), the defined standard posterior surgical profile is automatically activated as soon as the RESIGHT 700 fundus viewing system is swiveled in.

### Button functions when RESIGHT 700 is swiveled out

When the RESIGHT module is swiveled out again, the first anterior surgical profile in the alphanumerically sorted list of surgical profiles is automatically activated.

### Changing the button assignments on the foot control panel

The buttons can be assigned user-specific functions in the "Operation" menu in CALLISTO eye and can be specified in OR profiles. You can find further information on specifying button assignments in the Instructions for Use "CALLISTO eye SW 5.0 - G-30-2116".

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# 5 Before every use

## 5.1 Attaching resterilizable components

**⚠ CAUTION!**

**Risk of infection!**

The patient or user can become contaminated if sterile accessories are not used.

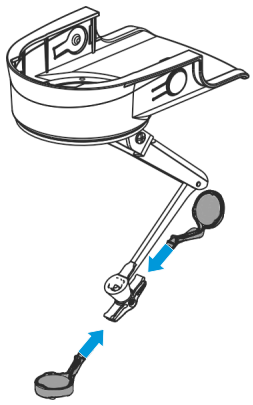
- ▶ The products contained in the asepsis sets must be cleaned, disinfected and sterilized before each use. This also applies to the first use after delivery.
- ▶ Only use the device with suitable, sterile accessories.

*Prerequisite*

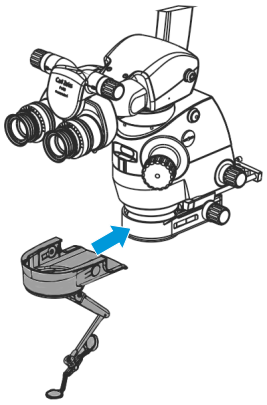
☑ Sterilized components may only be touched under sterile conditions!

*Action*

1. Attach the sterile aspheric lenses to the sterile lens turret.



2. Unfold the sterile lens support and slide it onto the focusing unit from the front until it audibly clicks into place.



*Result*

✓ The lens support audibly snaps into place.

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# 6 Operation

## 6.1 Safety during operation

**⚠ CAUTION!**

**Hazard due to incompatible lens support mechanism!**

In order for the fundus to be depicted correctly, the lens support must correspond to the focal length of the main objective lens. Using the wrong lens support can result in the fundus being viewed incorrectly and may cause damage to the device.

- ▶ Only use the lens support that is intended for the main objective lens.

**⚠ CAUTION!**

**Risk of injury due to jammed lens support mechanism!**

A jammed lens support mechanism may injure the eye of the patient if the surgical microscope makes a downward vertical movement.

- ▶ Before every operation, ensure that the lens support mechanism can be easily folded and unfolded.

**⚠ CAUTION!**

**Live current in device housing!**

If either the user or the patient come into contact with the device housing while it is under a live current, this may result in paralysis of the muscles in the heart or extremities.

- ▶ Additional devices may only be connected if they meet the relevant IEC or ISO standards.

## 6.2 Adjusting the downward travel limit on the carrier system

*Prerequisite*

- ☑ The fundus viewing system has been mounted on the surgical microscope and the locking knob has been firmly tightened.
- ☑ The foot control panel has been connected to the suspension system and configured.

*Action*

1. For more information on the exact working method, please see the following pages.

### OPMI Lumera 300

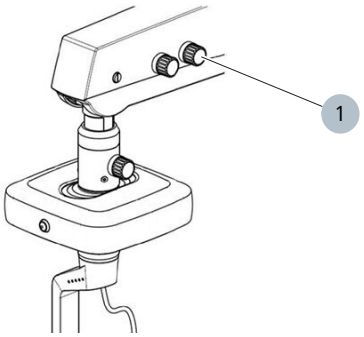



*Figure 23: Adjusting the downward travel limit on the OPMI Lumera 300*

| | |
|---|---|
| 1 | Adjustment screw |

*Action*

1. Loosen the screw for the upward/downward movement.
2. Lower the surgical microscope until it can be focused on the surgical field (depending on the focal length of the objective lens). While doing so, make sure that it is at a sufficiently safe distance from the surgical field.
3. Firmly retighten the screw for the upward/downward movement.
4. Lower the surgical microscope again to the lowest limit stop and check the safety distance.

The limit of downward travel is only effective in the lower part of the suspension arm's vertical movement range (starting from the arm's horizontal position). If you wish to use the suspension arm's full range of vertical movement, lower the suspension arm as far as it will go and then firmly retighten the screw.

### OPMI Lumera i

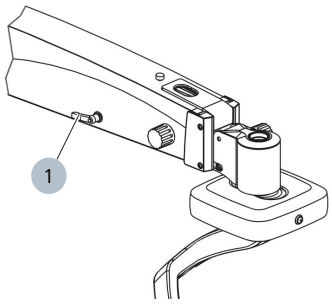



*Figure 24: Adjusting the downward travel limit on the OPMI Lumera i*

| | |
|---|---|
| 1 | Locking lever |

*Action*

1. Loosen the locking lever for the upward/downward movement.
2. Lower the surgical microscope until it can be focused on the surgical field (depending on the focal length of the objective lens). At the same time, ensure that it is at a sufficiently safe distance from the surgical field.

3. Firmly retighten the locking lever for the upward/downward movement.
4. Check this setting before moving the aspheric lens into the beam path and before each surgical procedure.

### S88 / OPMI Lumera T, OPMI Lumera 700, ARTEVO 800 and ARTEVO 750/850

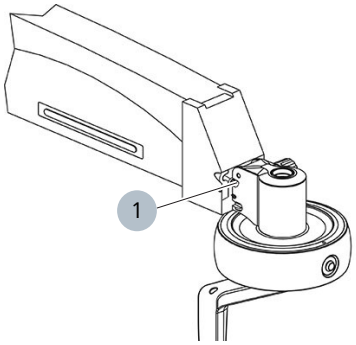



*Figure 25: Adjusting the downward travel limit, example with S88 / OPMI Lumera T*

| | |
|---|---|
| 1 | Orange adjustment screw |

*Action*

1. Loosen the orange adjustment screw by a few turns.
2. Press one of the magnetic brake release buttons on the surgical microscope and lower it until it can be focused on the surgical field (depending on the focal length of the objective lens). At the same time, ensure that it is at a sufficiently safe distance from the surgical field.
3. Turn the orange adjustment screw clockwise as far as it will go.
4. Check this setting before moving the aspheric lens into the beam path and before each surgical procedure.

# 6.3 Setting up and operating RESIGHT

**⚠ CAUTION!**

**Injury to the patient's eye!**

Incorrect operation, or a jammed lens support mechanism on the RESIGHT fundus viewing system, may cause injury to the patient's eye and impair image quality. To avoid this hazard, always configure the following system settings next to, and not above, the patient first:

- ▶ Adjust the illumination of the patient's eye through the surgical microscope to a level which ensures that the fundus is exposed to as little light as possible.
- ▶ With the RESIGHT fundus viewing system moved out of the beam path, always position the microscope body in such a way that index dot (A) (if present on the microscope) of the microscope's focal point is in the middle of the upper triangle (B) of the marking. 

- ▶ Select a medium magnification (e.g. 1.0).
- ▶ With the RESIGHT fundus viewing system moved out of the beam path, lower the surgical microscope to a point where the RESIGHT fundus viewing system never touches the patient.
- ▶ Set the downward travel limit of the respective stand so that the suspension arm cannot be lowered beyond the required level.

**⚠ CAUTION!**

**Injury to the patient’s eye**

A surgical opening in the patient's eye which is maintained for a long period during a vitrectomy procedure reduces lacrimation and causes increased dryness in the cornea.

- ▶ During the procedure, the lack of lacrimation must be compensated by the use of BSS or a viscoelastic agent.

To use the RESIGHT fundus viewing system, perform the following steps:

*Action*

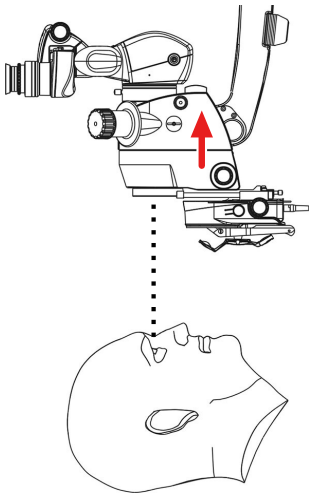
1. Step 1: Focus the surgical microscope [▷ 47]
2. Step 2: Fold down the lens support mechanism [▷ 47]
   - Option 1
   - Option 2
   - Option 3
3. Step 3: Slide RESIGHT into the beam path [▷ 51]
4. Step 4: Change the aspheric lenses (optional) [▷ 52]
5. Step 5: Slide RESIGHT out of the beam path [▷ 53]

### 6.3.1 Step 1: focus the surgical microscope

We recommend that you deactivate the depth of field (DoF) management system for focusing.

*Action*

1. Focus the surgical microscope on the patient's cornea using the foot control panel.
2. To compensate for the depth of field range of the surgical microscope which totals several millimeters at a low magnification, move the surgical microscope upward to a level just before the image goes out of focus.

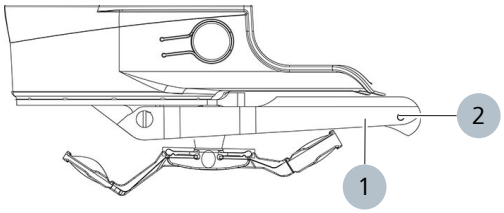


### 6.3.2 Step 2: fold down the lens support mechanism

If little space is available above the patient's face (due to respiratory tubing, etc.), you can first move the RESIGHT fundus viewing system into position with the lens support mechanism folded up (Step 3: slide RESIGHT into the beam path [▷ 51]) and then fold down the lens support mechanism as described below.

The lens support mechanism is magnetically held in position on the lens support. You first have to overcome the magnetic force when folding down the lens support mechanism. There are three methods of folding down the lens support mechanism:

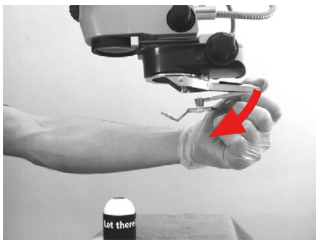
**Method 1:**

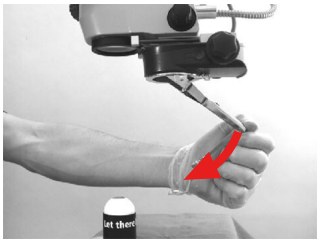



*Action*

1. Hold the lens support mechanism (1) at the hinge (2) with your thumb and forefinger. Place your forefinger under the lens support mechanism to ensure that the lens support mechanism cannot fall on the patient's eye.

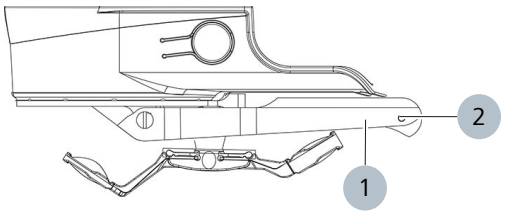
2. Slowly pull down the lens support mechanism at the hinge until it has folded out completely. Make sure not to touch the non-sterile RESIGHT fundus viewing system in this process.





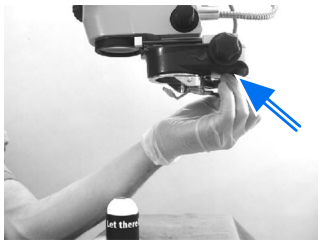
**Method 2:**

The lens support mechanism can be rotated clockwise or counter-clockwise 360°. You can turn the lens support mechanism towards you and then fold it down:

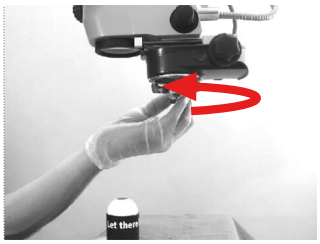



*Action*

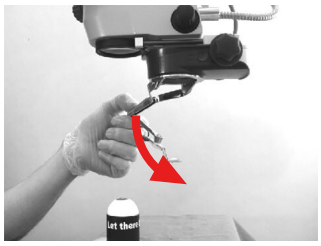
1. Hold the lens support mechanism (1) at the hinge (2) with your thumb and forefinger. Place your forefinger under the lens support mechanism to ensure that the lens support mechanism cannot fall on the patient's eye.



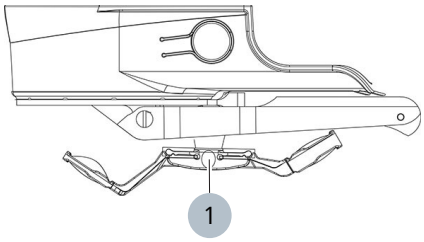
2. Turn the lens support mechanism towards you.



3. Slowly pull down the lens support mechanism at the hinge until it has folded out completely.

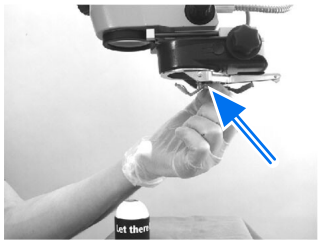


**Method 3:**

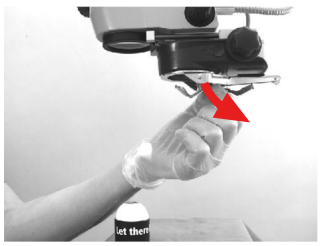



*Action*

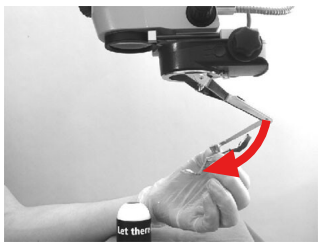
1. Hold the joint (1) with your thumb and forefinger.

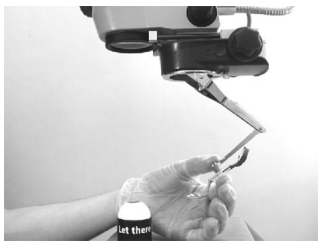


2. Apply counterpressure to the joint with the back of your thumb to detach the lens support mechanism from the magnetic lock.



3. Slowly pull down the lens support mechanism until it has folded out completely.





### 6.3.3 Step 3: slide RESIGHT into the beam path

If little space is available above the patient's face (due to respiratory tubing, etc.), you can first move the RESIGHT fundus viewing system into position with the lens support mechanism folded up and then fold down the lens support mechanism (Step 2: fold down the lens support mechanism [▷ 47]).

When you use the Invertertube E, it inverts the image automatically when you move the RESIGHT fundus viewing system into the beam path.

**⚠ CAUTION!**

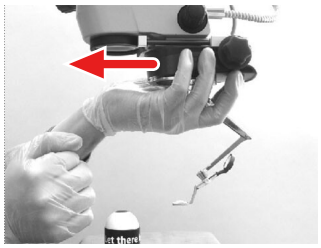
**Risk of injury!**

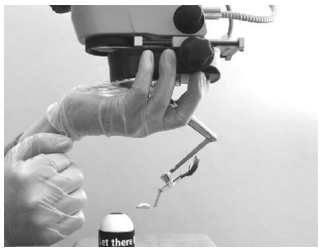
When you use the external focusing module for focusing, the distance of the RESIGHT fundus viewing system from the patient's eye is changed. If the distance is too short, the lens support mechanism may touch the patient's eye.

- ▶ When using the external focusing module, make sure that the lens support mechanism does not come into contact with the patient's eye.

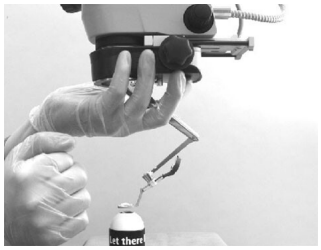
*Action*

1. Move the RESIGHT fundus viewing system over the patient's eye. Lift the lens support mechanism in this process to prevent the aspheric lens from accidentally hitting the patient's eye.





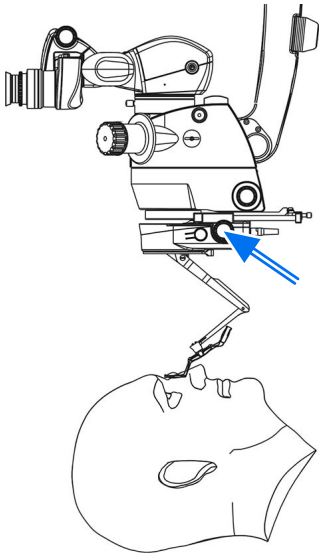
2. Slide in the RESIGHT fundus viewing system as far as it will go; it must audibly snap into place.



   ⇨ If you see a shadow in the image, the RESIGHT fundus viewing system is not properly in position.

3. Turn off the illumination on the surgical microscope and turn on the endo illumination.
4. Focus the RESIGHT fundus viewing system on the retina. Use the focusing knobs on the RESIGHT fundus viewing system for manual focusing, or the buttons on the foot control panel for motorized focusing. You can configure these buttons in such a

way that they are used for the focusing function of the RESIGHT fundus viewing system when it has been moved into the beam path.

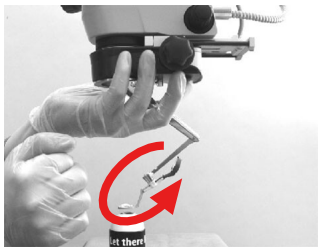


5. The surgical microscope no longer needs to be vertically moved for focusing. When working on the anterior segment, you can therefore move the RESIGHT fundus viewing system out of the beam path without causing blurring of the image.
6. To obtain a larger or smaller image section, use the buttons on the foot control panel for focusing the external focusing module. Note that the button assignments of the foot control panel are automatically reconfigured if the RESIGHT 700 fundus viewing system is used.

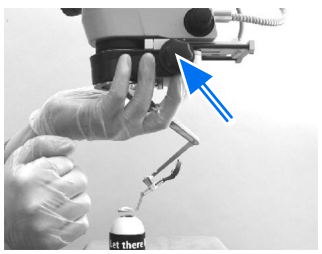
### 6.3.4 Step 4: change the aspheric lenses (optional)

*Action*

1. To change the aspheric lens, turn the lens turret in 90° increments until the desired position has been reached.



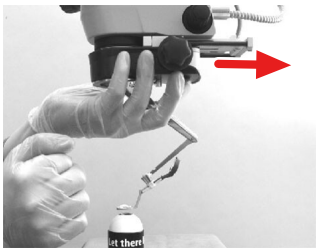
2. Refocus the RESIGHT fundus viewing system using the focusing knobs or the buttons on the foot control panel.

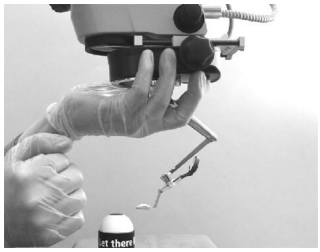


### 6.3.5 Step 5: slide RESIGHT out of the beam path

*Action*

1. After using the RESIGHT fundus viewing system, slide it out as far as it will go, until you hear it snap into the parking position. Lift the lens support mechanism in this process to prevent the aspheric lens from accidentally hitting the patient's eye.





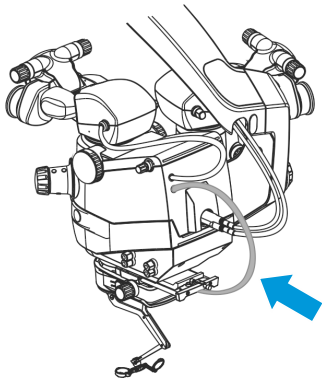
⇨ If you see a shadow in the image, the RESIGHT fundus viewing system has not been moved out as far as it will go.

⇨ When you use the Invertertube E, it automatically cancels the inversion when you move the RESIGHT fundus viewing system out of the beam path.

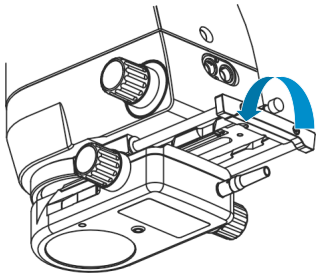
## 6.4 Removing the focusing unit

*Action*

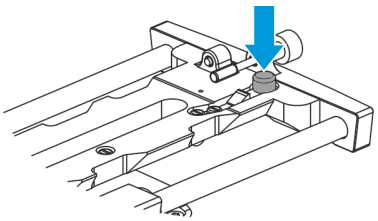
1. If required: Disconnect the electrical connection of the focusing unit to the surgical microscope.

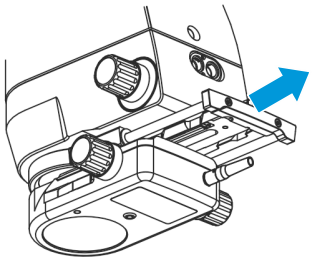


2. Hold the focusing unit with one hand and loosen the locking screw. Turn it counterclockwise.



3. Press and hold down the unlocking button and pull the focusing unit backwards from the adapter plate.

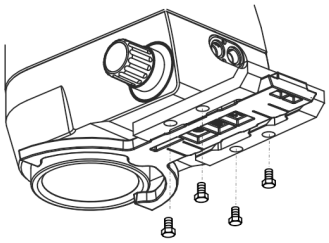


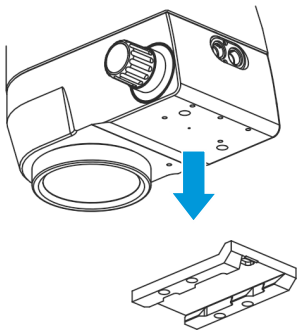


## 6.5 Removing the adapter plate

*Action*

1. Remove the adapter plate by turning the four screws on the underside of the adapter plate counterclockwise.





# 7 Cleaning and disinfection

## 7.1 Preparation of non-sterilizable components

### 7.1.1 Cleaning and disinfecting agent

#### 7.1.1.1 Cleaning agents

| | Unit | Order number |
|---|---|---|
| Optics cleaning kit | 1 piece | 000000-2096-685 |
| Microfiber cleaning cloth | 1 piece | 000000-1439-266 |
| Optical lens wipes | Available from specialized dealers | |

### 7.1.2 Cleaning

Clean the device before the first use and after every use.

#### 7.1.2.1 Cleaning optical surfaces

The multi-layer T* coating of the optical components (e.g. eyepieces, objective lenses) ensures optimal image quality. Even slight contamination of the optics or a fingerprint impairs the image quality. Clean the exterior surfaces of the optical components (eyepieces, objective lenses) only when necessary:

*Action*

- ▶ Do not use any chemical agents.
- ▶ Use a clean and grease-free brush to remove dust.

TIP: For the regular cleaning of surgical microscope's objective lenses and eyepieces, we recommend the optics cleaning set and Cleaning agents [▷ 55] available from ZEISS.

#### 7.1.2.2 Prevention of fogging

We recommend using an anti-fogging agent to prevent fogging of optical surfaces. Anti-fogging agents like the ones offered by opticians for applications with eyeglasses are also suitable for optical surfaces from ZEISS.

*Action*

- ▶ Please observe the Instructions for Use supplied with each anti-fogging agent.

Anti-fogging agents not only ensure fog-free eyepiece optics, they also clean the eyepiece optics and protect them from dirt, grease, dust, lint and fingerprints.

#### 7.1.2.3 Cleaning mechanical surfaces

All mechanical surfaces of the system can be cleaned by wiping them with a damp cloth.

*Action*

- ▶ Do not use any aggressive or abrasive cleaning agents.
- ▶ Clean off any residue using a mixture of 50% ethyl alcohol and 50% distilled water to which a dash of household dish-washing liquid has been added.

### 7.1.3 Disinfection

#### 7.1.3.1 Disinfecting the mechanical surfaces

The maximum concentrations for application are:

- For alcohol (tested with isopropyl alcohol): 60%
- For aldehyde (tested with glutaraldehyde): 2%
- For quaternary compounds (tested with DDAC): 0.2 %

To achieve maximum disinfection, disinfectants with an alcohol concentration higher than 70% can be used. There is a chance that long-term use of such disinfectants may cause the device's surfaces to become dull or matte, or may loosen the adhesive labels on the device without causing them to fall off. However, the use of such disinfectants will never impair device performance or endanger patients.

**NOTE**

**Surface damage caused by use of the wrong disinfectants!**

Performing disinfection with the wrong disinfectants may result in damage to the surfaces of the device.

- ▶ Use an aldehyde and/or alcohol-based disinfectant. The addition of quaternary compounds is acceptable.
- ▶ In order to prevent surface tensions, you may use only the disinfecting components specified above.

*Action*

- ▶ Disinfect all of the required surfaces.

## 7.2 Preparation of resterilizable components

### 7.2.1 General principles

The following resterilizable components must be cleaned, disinfected and sterilized after each use:

- Lens support (302721-9060-000, 302721-9070-000)
- Aspheric lenses (302721-9100-000, 302721-9080-000)
- Asepsis caps (305810-9001-000)

The lens support, aspheric lenses and asepsis caps must be cleaned, disinfected and sterilized before each use. This applies in particular to the first use following delivery, as all components are delivered non-sterile (clean and disinfect after removing the protective transport packaging; sterilize after packing).

Proper cleaning and disinfection are vital prerequisites for effective sterilization. If possible, a cleaning/disinfecting device should be used for cleaning and disinfecting. Due to the reduced effectiveness and reproducibility, a manual method should only be used if a cleaning/disinfecting device is not available. We recommend using the method validated by ZEISS and described in these Instructions for Use for cleaning, disinfecting and sterilizing.

*Action*

- Please note that the following sterilization methods are not permitted:
  - ⇨ Flash sterilization
  - ⇨ Hot air
  - ⇨ Radiation
  - ⇨ Formaldehyde or ethylene oxide
  - ⇨ Plasma sterilization.
- As part of your responsibility for the sterility of the lens support, aspheric lenses and asepsis caps, pleasure ensure during use that:
  - ⇨ A validated procedure is implemented
  - ⇨ The validated parameters are complied within each cycle.
  - ⇨ The devices used (cleaning/disinfecting device, sterilizer) are regularly checked and serviced
- Also observe the legal provisions applicable in your country and the hygiene regulations of the doctor's office and hospital. This applies in particular to the different requirements with regard to effective prion inactivation.

EU: Classification as semi-critical B according to the RKI guideline (Robert Koch Institute) is recommended. The final classification must be made by the user, taking into account the actual field of use.

### 7.2.2 Pre-cleaning

Remove any gross contaminants from the lens support, aspheric lenses and asepsis caps immediately after use (within 2 hours).

**NOTE**

**Improper handling during reprocessing!**

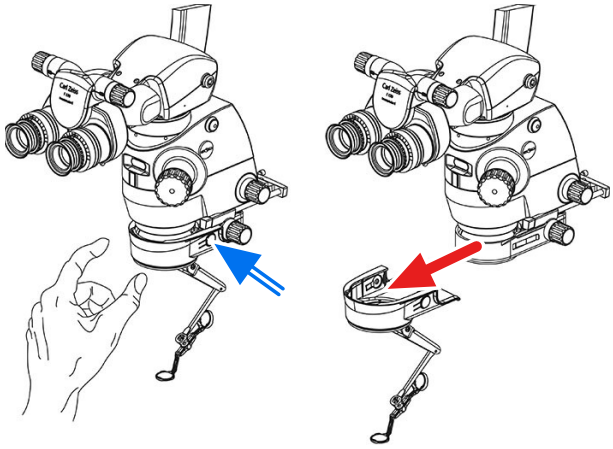
The RESIGHT metal tray, lens support, aspheric lenses and asepsis caps can be damaged.

- ▶ Take care not to scratch the components throughout reprocessing.
- ▶ Never clean the components with a hard brush or abrasive agents; only use a lint-free cloth.

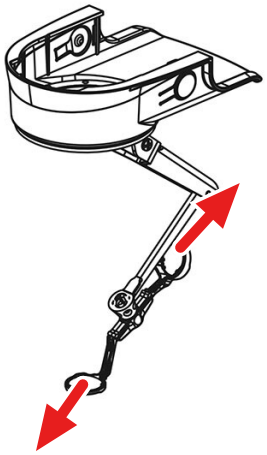
| | |
|---|---|
| **Material** | ■ Soft brush or clean soft cloth<br>■ Water (drinking water quality or better)<br>■ Cleaning solution which<br>– does not contain any aldehyde (this would fix blood contaminants),<br>– has a tested effectiveness (e.g., DGHM or FDA approval or CE mark),<br>– is suitable for cleaning the lens support, the aspheric lenses and the asepsis caps and is compatible with the components (see "Material resistance") |

*Action*

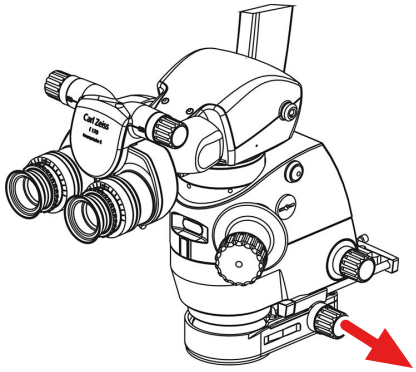
- ▶ Remove the lens support from the fundus viewing system. To do this, press the release button of the lens support and pull the lens support forwards.



- ▶ Pull the aspheric lenses out of the lens turret.



- ▶ Pull the asepsis caps off the two focusing buttons of the fundus viewing system.



- ▶ Place the components into a pH-neutral enzymatic cleaning agent with surfactants (consisting of no more than 5% surfactants)
- ▶ Place the components in said cleaning agent as specified for the effectiveness of the cleaning agent, at least for 20 minutes.
- ▶ Turn the lens turret and move all joints back and forth 10 times to moisten all swivel surfaces and joints.
- ▶ Rinse the components under hot water (drinking water quality or better) for one minute.

Please note that the disinfectant used during pretreatment serves only for decontamination purposes to protect persons against blood-borne pathogens. It is no substitute for the subsequent disinfection.

### 7.2.3 Machine cleaning and disinfecting

It is absolutely necessary that the concentrations specified by the manufacturer of the cleaning agent and, if applicable, disinfectant are adhered to. EU customers: If possible, a tested program for thermal disinfection (A0 value > 3000 or, if older devices are used, at least 10 min. at 93 °C) should be used (chemical disinfection risks leaving residual disinfectant on the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps).

**⚠ CAUTION!**

**Risk of infection!**

- ▶ Cleaning of the lens support, aspheric lenses and asepsis caps must be performed only in the RESIGHT metal tray.

| | |
|---|---|
| **Cleaning agent:** When selecting the cleaning agent, ensure | ■ that it is suitable for cleaning the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps made of metal and plastic,<br>■ that it has a neutral or alkaline pH, that – unless thermal disinfection is used – a suitable disinfectant with tested effectiveness (e.g., DGHM or FDA approval or CE mark) is additionally used, and that this disinfectant is compatible with the used cleaning agent,<br>■ that the chemicals used are compatible with the lens support, aspheric lenses and asepsis caps (see "Material durability"). |

| | |
|---|---|
| **Cleaning/disinfecting device:** When selecting the cleaning/disinfecting device, ensure | ■ that the disinfecting device has a tested effectiveness,<br>■ that an approved program for thermal disinfection is used, if possible. Cleaning with a cleaning or disinfecting device must comply with the validated parameters described in the following chapter. EU customers: A cleaning/disinfecting machine of the type Miele G 7882 was used for validation.<br>■ that the program used is suitable for the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps and includes sufficient rinsing cycles,<br>■ that post-rinsing is only done with fresh solutions of suitable quality for the process and that filtered air is used for drying,<br>■ that the cleaning/disinfecting device is serviced and checked at regular intervals. |

*Action*

- ▶ Place the components in the RESIGHT metal tray.
- ▶ Rinse the components with water (drinking water quality or better).
- ▶ Clean the components with a neutral or alkaline cleaning agent.
- ▶ When using an alkaline cleaning agent, neutralize the components with water that is of drinking quality or better, and a neutralizer.
- ▶ Rinse the components with water (drinking water quality or better). Using demineralized and deionized water for the last rinse cycle prior to thermal disinfection may prolong the service life of the components because it removes tap water residues which might react with the components under the influence of heat.
- ▶ Perform thermal disinfection when the A0 value > 3000 using demineralized and deionized water or water with a higher quality (e.g., drinking water purified by reverse osmosis).
- ▶ Let the components air-dry completely at room temperature (at least 10 minutes) or dry the components with purified compressed air. Do not use cleaned, hot compressed air!
- ▶ Verify that the components are completely dry after completion of the cleaning and disinfection cycle.
- ▶ Verify that any residual cleaning agents and disinfectants have been removed from the components after completion of the cleaning and disinfection cycle (if necessary, use an appropriate residue indicator test or a suitable indicator paper which is recommended by the manufacturer of the cleaning and disinfecting agent).

EU customers: The agents used for validation are the cleaning agent Sekumatic Multiclean (0.7% V/V) and the neutralizer Sekumatic FNP (0.1% V/V).

### 7.2.4 Manual cleaning and disinfection

If possible, a cleaning/disinfecting device should be used for cleaning and disinfection. Due to the reduced effectiveness and reproducibility, a manual method should only be used if a cleaning/disinfecting device is not available.

| | |
|---|---|
| **Cleaning agents and disinfectants:** When selecting the cleaning agent and disinfectant, ensure | ■ that they are suitable for cleaning and/or disinfecting the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps,<br>■ that you use a disinfectant with tested effectiveness (e.g. DGHM or FDA approval or CE mark) and that this disinfectant is compatible with the used cleaning agent,<br>■ that the chemicals used are compatible with the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps (see "Material durability").<br>If possible, combined cleaning and disinfecting agents should not be used. Combined cleaning and disinfecting agents can only be used in cases of very low contamination (no visible contaminants). It is absolutely necessary that the concentrations and exposure times specified by the manufacturer of the cleaning agent and, if necessary, disinfectant are kept. Only use a fresh solution whose quality is suitable for the process and filtered air for drying. |

*Action*

- ▶ Place the components into a solution consisting of no more than 5% surfactants and enzymes for 20 minutes at room temperature. EU customers: The agents used for validation are the cleaning agent Sekumatic Multiclean (0.7% V/V) and the neutralizer Sekumatic FNP (0.1% V/V).
- ▶ **NOTE! Do not clean the components with metal brushes, steel wool etc. so as not to damage the surfaces.** Brush the entire surface with a medium-hard toothbrush under warm, running water (drinking water quality or better) for at least one minute until no more residue is visible.
- ▶ Brush and rinse the components under cold distilled and deionized water or water with a higher quality (e.g., drinking water purified by reverse osmosis) for at least one minute.

  ⇨ The components are cleaned.
- ▶ Place the components into a solution consisting of no more than 5% surfactants and enzymes for 30 minutes at room temperature. EU customers: A 2.5% Sekusept Plus solution (V/V) was used for validation.
- ▶ Then completely immerse the components in cold, demineralized and deionized water or in water of a higher quality (e.g. drinking water purified by reverse osmosis) for one minute.
- ▶ Subsequently, wipe the surface of the components with a non-fluffy cloth.
- ▶ Verify that any residual cleaning and disinfecting agents have been removed from the components after completion of the cleaning / disinfection cycle. If necessary, use an appropriate

residue indicator strip or a suitable indicator paper which is recommended according to the operating instructions issued by the manufacturer of the cleaning and disinfecting agent.

- ▶ **NOTE! Never dry the components in an oven, a microwave, a drying oven, etc. in order to prevent damage to the materials.** Let the components air dry, or dry the components with purified compressed air.
- ▶ Verify that the components are completely dry after completion of the cleaning/disinfection cycle.
  - ⇨ The components are disinfected.

### 7.2.5 Control

The cleaning, disinfection and sterilization procedures for the lens support, aspheric lenses, asepsis caps and RESIGHT metal tray were validated as follows:

- Lens support: 200 times
- Aspheric lenses: 200 times
- Asepis caps: 250 times
- RESIGHT metal tray: 500 times

**⚠ CAUTION!**

**Risk of infection!**

- ▶ As part of your responsibility for the sterility of the lens support, aspheric lenses and asepsis caps, please ensure that you comply with the maximum number of sterilization cycles. You can monitor the sterilization cycles via the serial number of the RESIGHT metal tray.

*Action*

- ▶ Check all components after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipping and contamination (particularly in the interior).
- ▶ The lens supports may fade due to repeated reprocessing. However, this has no negative consequences for the further use of the lens supports.
- ▶ Eliminate damaged components and dispose of such components according to the applicable local and national legal regulations.
  - ⇨ Components which are still contaminated must be cleaned and disinfected once more.

### 7.2.6 Sterilization

#### 7.2.6.1 Packing for sterilization

For sterilization, the components must be packed in a container suitable for steam sterilization or in a suitable packaging material with a sterile barrier (permeable for air to escape and steam to

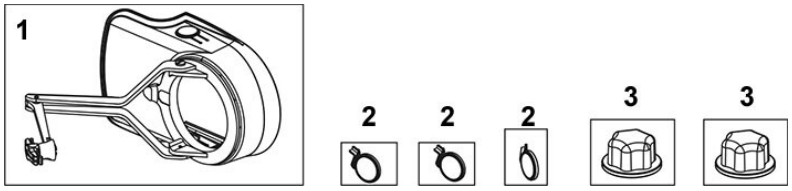
penetrate). This protects the lens support, aspheric lenses and the asepsis caps during sterilization and makes it possible for the steam to penetrate and the air to escape. Pockets of air can negate the sterilization.

There are two possibilities of packing the cleaned and disinfected lens support, aspheric lenses and asepsis caps for sterilization.

**Variant 1 - Packing components individually**

*Action*

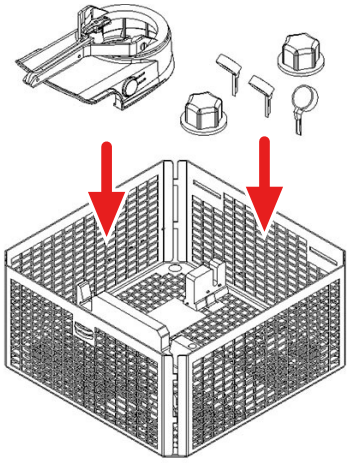
1. Pack the lens support (1), aspheric lenses (2) and asepsis caps (3) individually in packaging suitable for steam sterilization and seal them accordingly.



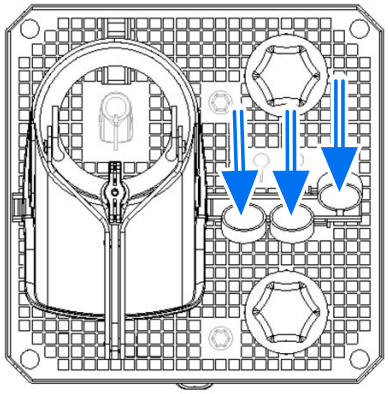

**Variant 2 - Packing the RESIGHT metal tray in a container with a sterile barrier**

*Action*

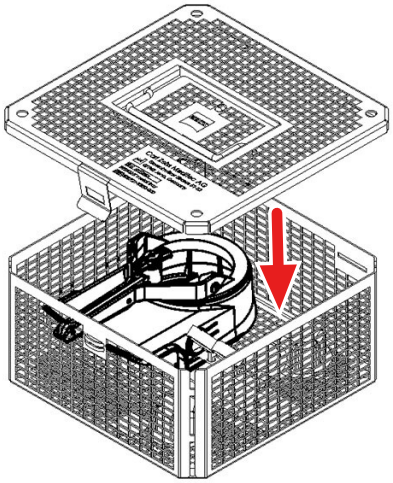
1. Place the lens support, asepsis caps and aspheric lenses into the marked inlets of the RESIGHT metal tray.



2. Turn the aspheric lenses to push them into the marked silicone receptacles.



3. Close the cover of the RESIGHT metal tray.



4. Before sterilizing, pack the RESIGHT metal tray with the components into a suitable container with a sterile barrier (e.g. a sealed bag). The sterilization container and the filter must comply with ISO 11607-1:2006.

#### 7.2.6.2 Sterilization

For sterilization, we recommend using the method validated by ZEISS described below.

**⚠ CAUTION!**

**Risk of infection!**

Please ensure, within your area of responsibility for the sterility of the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps during use,

- ▶ that the devices used (disinfector, sterilizer) are regularly checked and serviced,
- ▶ The validated parameters are complied within each cycle.

| | |
|---|---|
| **Steam sterilization of single components** | ■ Fractionated vacuum method or gravitation method (with sufficient drying)<br>■ Steam sterilizer in accordance with EN 13060:2014 or EN 285:2009<br>■ The steam sterilizer should be validated in compliance with ISO 17665-1:2006<br>■ Sterilization temperature 132 °C – 138 °C (270 °F – 280 °F; plus tolerance as specified in ISO 17665-1:2006) |

| | |
|---|---|
| | ■ Fractionated vacuum process: Sterilization time at least 4 minutes at 132 °C (270 °F) or sterilization time at least 3 minutes at 134 °C (273 °F)<br>■ Gravitation process: Sterilization time at least 10 minutes at a minimum of 132 °C (270 °F) to a maximum of 138 °C (280 °F) |
| **Steam sterilization with RESIGHT metal tray** | ■ Loading in accordance with the validated loading pattern<br>■ Fractionated vacuum method or gravitation method (with sufficient drying)<br>■ Steam sterilizer in accordance with EN 13060:2014 or EN 285:2009<br>■ The steam sterilizer should be validated in compliance with ISO 17665-1:2006<br>■ Sterilization temperature 132 °C – 138 °C (270 °F – 280 °F; plus tolerance as specified in ISO 17665-1:2006)<br>■ Fractionated vacuum process: Sterilization time at least 4 minutes at 132 °C (270 °F) or sterilization time at least 3 minutes at 134 °C (273 °F)<br>■ Gravitation process: Sterilization time at least 10 minutes at a minimum of 132 °C (270 °F) to a maximum of 138 °C (280 °F) |

A longer sterilization time is possible, but may have a negative effect on the service life of the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps.

*Action*

▶ Sterilize the RESIGHT metal tray, lens support, aspheric lens and asepsis caps according to one of the steam sterilization methods listed above (ISO 17665-1:2006).

▶ Do not subject the RESIGHT metal tray to temperatures higher than 141 °C (286 °F)!

▶ Allow the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps to cool down to ambient temperature following sterilization and before re-use or disposal.

The asepsis caps for the focusing knobs supplied by ZEISS can also be sterilized using the procedure described in Instructions for Use G-30-1560, “Preparing Resterilizable Products”. The corresponding Instructions for Use are included with the asepsis caps.

### 7.2.7 Storage

**⚠ CAUTION!**

**Patient contamination!**

If the lens support, aspheric lenses, asepsis caps and RESIGHT metal tray are stored too long, the packaging can no longer maintain its function as a sterile barrier, and germs can reach sterile parts.

- ▶ After completion of the cleaning or cleaning/disinfection cycle, check the lens support, aspheric lenses, asepsis caps and RESIGHT metal tray for corrosion, damaged surfaces, splinters and contaminants (especially inside).
- ▶ We therefore recommend that you write the respective sterilization date onto the container(s) or external sterile barrier and define the maximum storage time.
- ▶ Follow the local regulations if they are different from the proposal made. The customer is responsible for labeling.

**⚠ CAUTION!**

**Patient contamination!**

If the lens support, aspheric lenses, asepsis caps and RESIGHT metal tray enter into the area of sterile goods without having been sterilized or if the user fails to recognize that the RESIGHT metal tray has not been sterilized, there is a risk of contamination to the patient.

- ▶ We therefore recommend that you write the respective sterilization date onto the container(s) or external sterile barrier and define the maximum storage time. Follow the local regulations if they are different from the proposal made.
- ▶ Store the lens support, aspheric lenses, asepsis caps and RESIGHT metal tray in a dry and clean place after sterilization.
- ▶ Protect the lens support, aspheric lenses, asepsis caps and RESIGHT metal tray against direct solar radiation.

### 7.2.8 Use in the sterile area

**⚠ CAUTION!**

**Contamination of the lens support, aspheric lenses and asepsis caps!**

- ▶ Touch the RESIGHT metal tray and its contents only when you are sterile and only in the sterile OR area.
- ▶ Have a non-sterile person open and give you the sealable bag.
- ▶ Ensure that you are sterile when you remove the RESIGHT metal tray or remove the cover of the RESIGHT metal tray.
- ▶ Remove the sterilized components and mount them on the system. Make sure that the sterile components are securely positioned.
- ▶ Put the RESIGHT metal tray aside.
- ▶ Repeat the process (cleaning, disinfection and sterilization) after using the sterile components. Please read the corresponding chapter in these Instructions for Use regarding this.

### 7.2.9 Disposal

**NOTE**

**Environmental damage!**

- ▶ Clean, disinfect and sterilize the RESIGHT metal tray, lens support, aspheric lenses and asepsis caps completely prior to disposal.
- ▶ For disposal, also observe the legal provisions applicable in your country (IEC 60601-1) and the hygiene regulations of the doctor's office or hospital.

### 7.2.10 Reusability

The lens support, aspheric lenses, asepsis caps and RESIGHT metal tray can be reused provided they are treated with the appropriate care and they are undamaged and clean.

**⚠ CAUTION!**

**Risk of infection!**

- ▶ The user bears full responsibility for the use of damaged and/or contaminated components. Failure to comply with this requirement excludes any liability.

### 7.2.11 Material resistance

*Action*

- ▶ When selecting the cleaning agent and disinfectant, ensure that they do not contain the following:
  - – Organic, mineral and oxidizing acids (minimum permissible pH value: 5.5)

- Strong lyes (maximum permissible pH value: 11 at application temperature)
- Organic solvents (e.g., alcohol, ether, ketone, benzine)
- Oxidants (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

▶ Do not use metal brushes or steel wool to clean the lens support, aspheric lenses, asepsis caps or the RESIGHT metal tray.

▶ The use of ultrasound is not permitted either.

▶ Do not expose the lens support, aspheric lenses, asepsis caps or RESIGHT metal tray to dry heat or temperatures above 141 °C (286 °F). The lens supports may fade due to repeated reprocessing. However, this has no negative consequences for the further use of the lens supports.

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# 8 Maintenance

## 8.1 Lubricating the lens support

| | |
|---|---|
| **Material** | Aesculap STERILITi® oil spray |

*Action*

1. Dry the completely cleaned and disinfected lens support.
2. Spray some STERILITi® oil spray onto the hinges of the lens support.



3. Move the oiled hinges several times.
4. Remove any excess oil using a lint-free cloth.

## 8.2 Retrofitting the accessory port

The electrical communication between the RESIGHT 700 fundus viewing system and the surgical microscope occurs via the “accessory port upgrade kit” that is integrated in the stand.

**⚠ CAUTION!**

**Damage caused by improper retrofitting!**

If a retrofit is performed, the "accessory port upgrade kit" is installed by a service technician; new systems come with a factory-installed port.

- ▶ Do not retrofit the accessory port for the RESIGHT 700 fundus viewing system by yourself; contact ZEISS Service.

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# 9 Troubleshooting

## Hazards arising from the device not being fully functional

If an error occurs which cannot be fixed by using the "Troubleshooting" section, or if you notice anomalies such as restrictions or noise development in the course of movement:

- ▶ Mark the device as non-functional.
- ▶ Notify ZEISS Service or an authorized service representative.

## 9.1 Faults in the fundus viewing system

| Fault | Cause | Solution |
|---|---|---|
| RESIGHT 700: Motorized focusing system is inoperative. | Stand power plug not connected. | ▶ Connect the power plug. |
| | Stand power switch is not switched on. | ▶ Press the power switch. |
| | Power supply cable of the RESIGHT 700 is not connected. | ▶ Connect the power cable of the RESIGHT 700. |
| | Connection to the foot control panel is not established. | ▶ Establish the connections. |
| | Power failure | ▶ Contact the in-house electrician. |
| | Motorized focusing has failed or is faulty. | ▶ Disconnect the fundus viewing system from the power supply. To do this, disconnect the power cable from the surgical microscope.<br>▶ Turn the focusing knob on the fundus viewing system until you can see a sharp image through the eyepieces of the surgical microscope. |
| RESIGHT 700: Temporary functional failure of wireless foot control panel (FCP WL) | Weak radio signal | ▶ If a connection cable is available, establish the cable connection. |
| | Disrupted radio signal | ▶ If a connection cable is available, establish the cable connection. |
| | Batteries are dead | ▶ Replace the batteries. |
| | No pairing with stand | ▶ Pair the foot control panel with the stand. |

| Fault | Cause | Solution |
|---|---|---|
| Manual focusing | Despite using the available focusing range, the operating field cannot be fully focused. | ▶ In the event of a fault in the focusing function, if the focusing area is insufficient or if the image quality is inadequate, we advise switching to a contact lens. |
| Poor image | The objective lenses of the focusing unit's internal focus are contaminated. | ▶ Clean the objective lenses. |
| | Interpupillary distance of the tube is not set correctly. | ▶ Adjust the interpupillary distance of the tube. |

# 10 Technical specifications

## 10.1 Regulatory information

**Classification of the device according to IEC 60601-1**

The device is classified as follows:

- Degree of protection against electric shock: Class I
- Degree of protection against water ingress: IP 20
- Operating mode: continuous operation
- Electromagnetic compatibility (EMC): The RESIGHT 700 fulfills IEC 60601-1-2, Class A (as per CISPR 11)

## 10.2 Electrical data

| | Unit | Value |
|---|---|---|
| Maximum power consumption | W | 15 |
| Rated voltage | V | + 15 (±10%) |
| Current consumption | A | 1 |
| Electrical output | V | 24 |
| | A | 0.5 |

## 10.3 Mechanical data

| | Unit | Value |
|---|---|---|
| Focusing range with lens support LH175 | mm | 31 (position of intermediate image) |
| Focusing range with lens support LH200 | mm | 38 (position of intermediate image) |

## 10.4 Weight

| | Unit | Value |
|---|---|---|
| Lens support + focusing unit RESIGHT 500 | kg | 0.45 |
| Lens support + focusing unit RESIGHT 700 | kg | 0.50 |
| Adapter plate with VISULUX adapter | kg | 0.081 |
| Adapter plate without VISULUX adapter | kg | 0.033 |

## 10.5 Dimensions and swiveling ranges

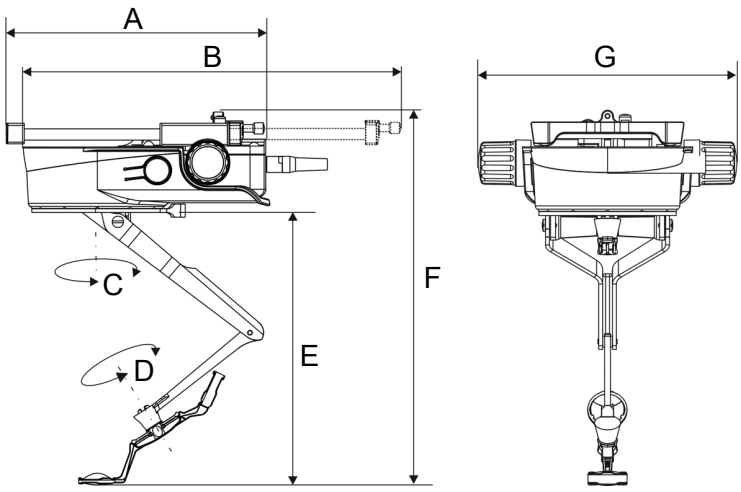


*Figure 26: Dimensions and swiveling ranges*

| | Item | Value |
|---|---|---|
| Length, swiveled out | A | 138 mm |
| Length, swiveled in | B | 200 mm |
| Rotation angle of lens support (30° increments) | C | 360° |
| Rotation angle of lens turret (90° increments) | D | 360° |
| Height, lens support folded out | E | 147 mm |
| Height, lens support folded out (with focusing unit) | F | 198 mm |
| Width | G | 128 mm |

## 10.6 Ambient requirements for operation

| | Value |
|---|---|
| Temperature | +10 °C ... +40 °C |
| Rel. humidity | 30% ... 75% |
| Air pressure | 700 hPa ... 1060 hPa |

## 10.7 Ambient requirements for transport and storage

| | Value |
|---|---|
| Temperature | -40 °C ... + 70°C |
| Rel. humidity (without condensation) | 10% ... 90% |
| Air pressure | 500 hPa ... 1060 hPa |

## 10.8 Guidelines and manufacturer's declaration for electromagnetic compatibility

RESIGHT 700 is subject to specific precautions with regard to electromagnetic compatibility (EMC). In order to avoid the occurrence of EMC interference, RESIGHT 700 may only be installed, operated and maintained in the manner indicated in these Instructions for Use and only with components supplied by ZEISS.

**⚠ CAUTION!**

**Danger from electromagnetic radiation!**

Electrical devices can affect each other as a result of their electromagnetic radiation. The use of non-approved components (accessories, transformers of all types, cables) can cause increased emissions or reduce the device's immunity.

- With the exception of the combination of the devices described in these Instructions for Use, do not operate the device in direct proximity to other devices.
- Only use accessories, transformers, cables, and spare parts which are specified in these instructions for use or which are approved by ZEISS for this device.
- Do not use any portable or mobile RF communication equipment near the device as it is not possible to exclude the possibility that device functionality will be impaired.
- Please follow the EMC guidelines in the following pages.

### 10.8.1 Electromagnetic interference

| RESIGHT 700 is intended for operation in an electromagnetic environment as specified below. The customer or user of the RESIGHT 700 is responsible for ensuring that the device is operated in such an environment. | | |
|---|---|---|
| **Interference measurements** | **Compliance** | **Electromagnetic environment - guideline** |
| HF emissions CISPR 11 | Group 1 | RESIGHT 700 must emit electro-magnetic energy in order to properly function. This can affect nearby electronic devices. |
| HF emissions CISPR 11 | Class A | RESIGHT 700 is intended for use in all facilities, including locations in residential environments and those directly connected to the public power supply network which also supplies residential buildings. |
| Harmonic emissions as per IEC 61000-3-2 | N/A | |
| Emission of voltage fluctuation / flicker as per IEC 61000- 3-3 | N/A | |

### 10.8.2 Electromagnetic immunity

| RESIGHT 700 is intended for operation in an electromagnetic environment as specified below. The customer or user of RESIGHT 700 is responsible for ensuring that the device is operated in such an environment. | | | |
|---|---|---|---|
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic dis- charge (ESD) as per IEC 61000-4-2 | ±6 kV<br>contact discharge<br>±8 kV<br>air discharge | ±6 kV<br>contact discharge<br>±8 kV<br>air discharge | Floors should be made of wood or concrete or be covered with ceramic tiles. If the flooring contains synthetic materials, the relative humidity must be at least 30%. |
| Fast transient/ burst immunity as per IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | For the key performance features:<br>±2 kV for power supply lines<br>±1 kV for input/output lines<br>Reduced compliance level for video signals. This means that fast transients/bursts on the power supply line or on signal and video lines may cause disturbances in the video image. | The quality of the supply voltage should be that of a typical business or hospital environment. |

| | | | |
|---|---|---|---|
| Surge voltages (surges) as per IEC 61000-4-5 | ±1 kV line-to-line voltage<br>±2 kV line-to-ground voltage | ±1 kV line-to-line voltage<br>±2 kV line-to-ground voltage | The quality of the supply voltage should be that of a typical business or hospital environment. |
| Voltage dips, short interruptions and voltage variations as per IEC 61000-4-11 | < 5% $U_T$<br>(> 95% dip in $U_T$)<br>for 1/2 cycle<br>40% UT<br>(60% dip in $U_T$)<br>for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$)<br>for 25 cycles<br>< 5% $U_T$<br>(95% dip in $U_T$)<br>for 5 s | The test level achieved in the test corresponds to active medical devices not equipped with an integrated power source (battery, UPS …).<br>Line voltage dips may therefore lead to flickering of the light source.<br>Major or prolonged voltage dips may cause flickering and deactivation of the light source or system. | The quality of the supply voltage should be that of a typical business or hospital environment. If the user of RESIGHT 700 requires continued function even in the event of interruptions in the power supply, we recommend powering the RESIGHT 700 from an uninterruptible power supply. |
| Power frequency (50/60 Hz) magnetic field as per IEC 61000-4-8 | 3 A/m | 3 A/m | Magnetic fields in the power frequency should correspond to the typical values that are found in business and hospital environments. |
| Note: $U_T$ is the AC voltage supply before application of the test level. | | | |

### 10.8.3 Electromagnetic immunity for non-life-supporting ME equipment and ME systems

| RESIGHT 700 is intended for operation in the electromagnetic environment specified below. The customer or the user of RESIGHT 700 is responsible for ensuring that the device is operated in such an environment. | | | |
|---|---|---|---|
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| | | | Portable and mobile radio communication equipment should not be used closer to the RESIGHT 700, including its cables, than the recommended safety distance that is calculated using the equation applicable to the transmission frequency involved.<br>**Recommended separation distance** |

| | | | |
|---|---|---|---|
| Conducted RF disturbances as described in IEC 61000-4-6 | 3 $V_{effective\ value}$ 150 kHz to 80 MHz | 3 V | *d = 1.2 SQRT(P)* |
| Emission of RF disturbances according to IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | *d = 1.2 SQRT(P)* for 80 MHz to 800 MHz<br>*d = 2.3 SQRT(P)* for 800 MHz to 2.5 GHz<br>where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d is the recommended safety distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Theoretically, field strengths of stationary transmitters such as base stations for mobile telephones and mobile land radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast transmitters cannot be predicted accurately. To assess the electromagnetic environment with respect to stationary RF transmitters, a site study of the electromagnetic phenomena should be considered. If the measured field strength in the location in which the RESIGHT 700 is used exceeds the above applicable RF compliance level, the RESIGHT 700 should be monitored to ensure normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RESIGHT 700.

[b] Field strengths should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz

### 10.8.4 Recommended separation distances

RESIGHT 700 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RESIGHT 700 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RESIGHT 700 as recommended below – depending on the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter** W | **Separation distance according to transmitter frequency** m | | |
|---|---|---|---|
| | **150 kHz to 80 MHz** | **80 MHz to 800 MHz** | **800 MHz to 2.5 GHz** |
| | d = 1.2 SQRT(P) | d = 1.2 SQRT(P) | d = 2.3 SQRT(P) |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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# 11 Accessories and components

These Instructions for Use also describe accessories and components that are not necessarily included in the individual delivery scope. A current accessories and components list can be obtained from your ZEISS contact person.

You can find the ZEISS representative for your country online on the following website: www.zeiss.com/med

Only use accessories and components authorized by ZEISS for this device. Device safety during operation cannot be guaranteed if accessories and components that are not authorized by ZEISS are used.

## 11.1 Accessories

These Instructions for Use describe accessories that are not essential components of the individual deliveries. A current list of accessories can be obtained from your ZEISS contact partner.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

Use only accessories and spare parts which are approved by ZEISS for this device. When using accessories and spare parts that are not approved by ZEISS, safe operation of the device cannot be guaranteed.

## 11.2 Spare parts

### 11.2.1 Aspheric lenses and accessories (sterilizable)

| Label | Specifications | Cat. no. |
|---|---|---|
| Aspheric lens | 60D | 302721-9100-000 |
| Aspheric lens | 128D | 302721-9080-000 |
| RESIGHT metal tray | Container for lens support and aspheric lenses | 302721-9250-000 |

### 11.2.2 Lens support (sterilizable)

| Label | Specifications | Cat. no. |
|---|---|---|
| Lens support | LH200 | 302721-9060-000 |
| Lens support | LH175 | 302721-9070-000 |

### 11.2.3 Adapter plate sets

| Label | Specifications | Cat. no. |
|---|---|---|
| Adapter plate set without mount for fiber slit illuminator | ■ Adapter plate<br>■ Mounting aid<br>■ 4x screws (M3 x 8) | 302721-9040-000 |
| Adapter plate set with mount for fiber slit illuminator | ■ Adapter plate + attachment option<br>■ Mounting aid<br>■ 4x screws (M3 x 8) | 302721-9050-000 |

### 11.2.4 Focusing units (including upgrade kit)

| Label | Specifications | Cat. no. |
|---|---|---|
| Focusing unit, Resight 700, electrical RESIGHT 700<br>■ Accessory port upgrade kit | - | 302721-9030-000<br>302721-8500-500 |
| Focusing unit, Resight 500, manual RESIGHT 500 | - | 302721-9020-000 |

### 11.2.5 Consumables

| Label | Specifications | Cat. no. |
|---|---|---|
| Optics cleaning kit | | 000000-2096-685 |
| 6-pack of asepsis caps | 22 mm | 305810-9001-000 |

# 12 Disposal

## 12.1 Disposal of the device

- ▶ Keep packing material in the event of a relocation or repair.
- ▶ If you would like to dispose of the original packing material, send it in for recycling via a recognized collection system.

The device contains electronic components with integrated batteries.

- ▶ Dispose of the device and integrated batteries correctly, in accordance with national legislation.

In accordance with applicable EU guidelines and national regulations at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

- ▶ For more information on disposing of the device, contact the ZEISS contact partner in your country.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

- ▶ If you resell the device or its components: Inform the buyer that the device is to be disposed of in accordance with the currently applicable regulations.

## 12.2 User information for the disposal of resterilizable components

- All resterilizable components must be completely cleaned, disinfected and sterilized before disposal.
- For disposal, also observe the legal provisions applicable in your country and the hygiene regulations of the doctor's office or hospital.

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# Glossary

**BSS**

Balanced Salt Solution

**CE labeling**

The CE marking indicates that the product to which it is affixed meets the requirements of all EC directives applicable to this product.

**D**

Diopter (unit of measurement of the refractive power of optical systems)

**DGHM**

Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. (German Society for Hygiene and Microbiology)

**Electromagnetic compatibility (EMC)**

EMC (electromagnetic compatibility) designates the normal, desired state in which technical devices do not impede each other as the result of undesired electric or electromagnetic effects (non-interference).

**EN**

European Standard (Europäische Norm)

**EU**

European Union

**FDA**

Food and Drug Administration (US authority)

**HF**

High frequency

**IEC**

International Electrotechnical Commission

**ISO**

International Organization for Standardization

**LH**

Lens support

**OPMI**

Surgical microscope

**RKI**

Robert Koch Institute

**UDI Production Identifier (UDI-PI)**

Unique Device Identification - Production Identifier

**UDI-DI**

Unique Device Identification - Device Identifier

**WEEE**

WEEE (Waste of Electrical and Electronic Equipment)

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# Index

**T**



**U**



**V**



**W**

**Carl Zeiss Meditec AG**

Goeschwitzer Strasse 51-52

07745 Jena, Germany

Germany

Internet: www.zeiss.com/med

Email: info.meditec@zeiss.com

Instructions for Use: www.zeiss.com/ifu

CE

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