

Instructions for Use

Accessories for HS Surgical Microscope Systems

Eyepiece Heads, Tocular,
Beamsplitters, Vertiscopes,
Double Iris Diaphragm,
Stereoscopic Co-Observer,
Camera Attachments, Front Lens

Look closer. See further.

HAAG-STREIT GROUP

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1 Manufacturer's Details and Contact Information

Manufacturer of the surgical microscope system is

Haag-Streit AG
Gartenstadtstrasse 10
3098 Koeniz
Switzerland

European Community Authorised Representative (EC-REP):

Haag-Streit Deutschland GmbH
Rosengarten 10
22880 Wedel
Germany

If you have any questions, please provide your local sales representative the reference and serial numbers for the relevant components. You can obtain these from the respective components' type label.

You will find the contact details for your local sales representative in the notes pages of these instructions. A current list of local sales representatives worldwide can be found on the Haag-Streit website
(https://haag-streit.com/en/contact/distributors).

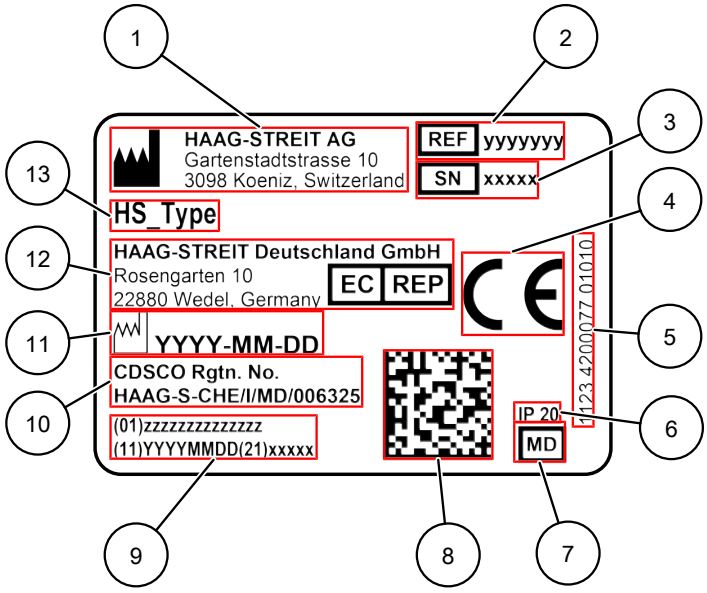


Illustration 1: Type Label

	Name
1	Manufacturer
2	Reference Number. (*REF*)
3	Serial Number (*SN*)
4	CE - Conformity Label (*CE*)
5	Label Identification
6	Degree of Protection by Enclosure (*IP-Code*)
7	*Medical Device*
8	QR-Code (*UDI* information)

	Name
9	Code (*UDI*): – (01): Global Trade Item Number (*GTIN*) – (11): Date of Manufacture – (21): Serial Number (*SN*)
10	Registered Number at Central Drugs Standard Control Organisation (*CDSCO*)
11	Date of Manufacture according to ISO 8601
12	European Community Authorized Representative (*EC-REP*)
13	Product Name

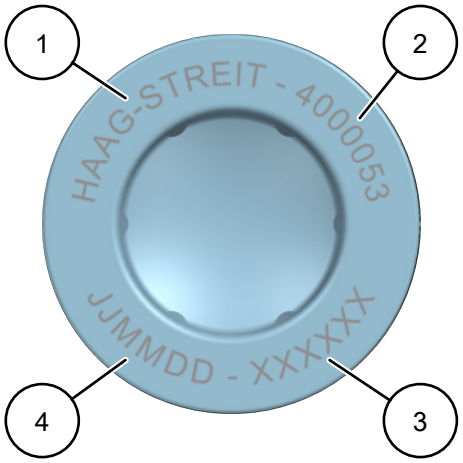


Illustration 2: Labeling of the Sterilizable Covers (Example)

	Name
1	Manufacturer
2	Reference Number (*REF*)
3	Serial Number (*SN*)
4	Date of Manufacture

2 Information for Safety

Residual Risks

The equipment from Haag-Streit has been designed and produced according to state of the art standards and best practices at the time of manufacture. However, some residual risks remain and are indicated on the equipment and in the form of safety messages (WARNING, CAUTION, NOTICE) in this document.

Explanation of Warnings



DANGER

Will lead to serious injury or death.

Follow the instructions to avoid a hazard.



WARNING

May lead to serious injury or death.

Follow the instructions to avoid a hazard.



CAUTION

May lead to light or moderately serious injuries.

Follow the instructions to avoid a hazard.



NOTICE

May lead to material damage and / or operating error.

Follow the instructions to avoid a hazard.

2.1 General warnings



CAUTION

Risk of limited treatment options!

If defects are not detected, the surgical microscope system may not offer all functions during surgery.

a) Before each use, make sure that all electrical and mechanical connections are firmly seated and free of defects.

b) Regularly check the functionality and quality of the magnified vision.

c) Do not use the system in case of any obvious defects, error states or functional restrictions. Call the Haag-Streit Service.



CAUTION

Risk of unexpected moving parts!

Parts that move unexpectedly can cause injuries.

a) Perform the weight balance of the microscope axis after the attachment of additional accessories or if orientation was changed.

b) Make sure that the carrier unit is still balanced.

2.2 Warnings and Symbols



Follow the instructions

Read the instructions for use before operating the surgical microscope system.

3 Legal Information

The part of the surgical microscope system described in these instructions for use supports the intended use of the surgical microscope system.

3.1 Important Notes

Obligatory Reporting of Serious Incidents

Any serious incident occurring in relation to the product must be reported to Haag-Streit and the competent authority of the member state in which the user and/or the patient is established.

First Installation and Commissioning

The first installation and commissioning of the medical device must be done in accordance with the instructions in the service manual for the medical device. The first installation and commissioning of the medical device must be performed by the authorized local representative or by Haag-Streit directly.

An installation report, stating the full and error free functionality of the medical device, must be signed by both parties after the medical device has been installed and is commissioned.

Liability for Function and Damage

If the device is modified, repaired or serviced improperly, the warranty of Haag-Streit is void. Only personnel authorized by Haag-Streit may modify, repair or service the device.

Liability for Precaution

The user shall always take precaution appropriate to the application to be able to end the surgical procedure without the surgical microscope system.

Accessories

External accessories from 3rd party manufacturers must only be connected to the system after authorization by Haag-Streit. The interfaces and the combination of systems have to be validated.

Maintenance

The device must only be serviced or repaired following the service manual of the surgical microscope system.

Modifications and maintenance must only be performed by persons explicitly authorized by Haag-Streit. For maintenance only original parts from Haag-Streit as well as approved parts from third-party suppliers have to be installed. After maintenance or technical modifications, the device must be readjusted following the service manual of the surgical microscope system.

In case of technical inquiries, the device name, the reference number (*REF*), and the serial number (*SN*) need to be indicated.

For installation, dismantling and replacement of components, the actual national laws and directions regarding medical products (e.g. traceability, approval of added components, electrical safety) have to be followed. In case of doubt, please contact Haag-Streit.

4 Accessories

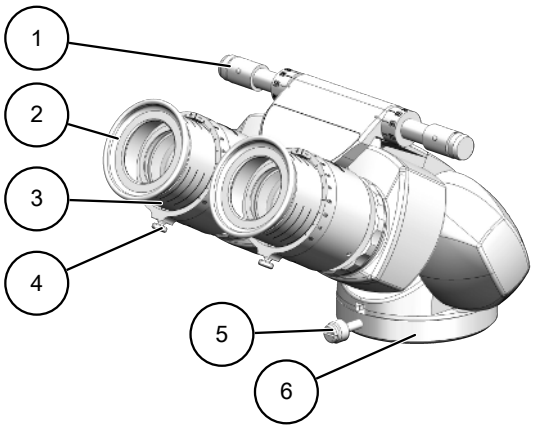
4.1 Eyepiece heads

4.1.1 Intended use

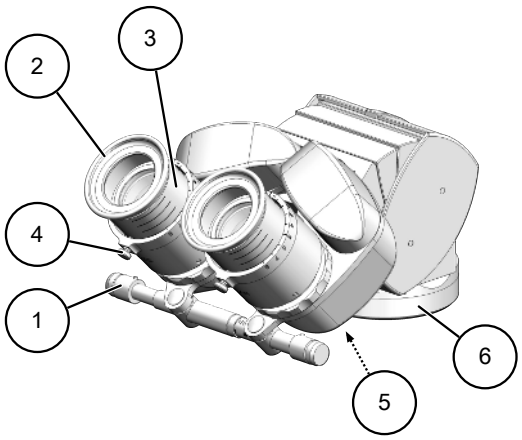
The eyepiece heads are part of a surgical microscope system. They enable stereoscopic vision in combination with a Haag-Streit surgical microscope. The eyepiece heads feature an option to set the individual pupillary distance and to correct possible visual impairment of the user. Due to the large pivoting range the 200° and 160° eyepiece head can be easily adapted to individual working conditions, thus making ergonomic work possible.

4.1.2 Overview Eyepiece head

Eyepiece 200°, 10 x



Eyepiece head 160°, 10 x



	Name	Note
1	PD Adjustment	Adjusts the ocular spacing to fit the pupillary distance.
2	Eye cups	Retract when using glasses (only with loosened knurled screw, see section Adjusting the Diopters [▸ 12]).
3	Ocular	Adjust diopter compension (only with loosened knurled screw, see section Adjusting the Diopters [▸ 12]).
4	Knurled screw	For fixing the ocular tube.
5	Knurled screw	For fixing the protective cap.
6	Protective cap	For protecting the lower connection area during transport or storage.

4.1.3 Combinations

Accessories	REF	Eyepiece head 200°, 10x	Eyepiece head 160°, 10x
		4000026	4000025
HS Hi-R NEO 900	4000037	x	x
HS Hi-R NEO 900A	4000038	x	x
TOCULAR	4000056	x	x
Double Iris Diaphragm	4000013	x	x
Beamsplitter 50:50	4000006	x	x
Beamsplitter T	4000007	x	x
VERTISCOPE U	4000061	x	x
VERTISCOPE T-R	4000060	x	x

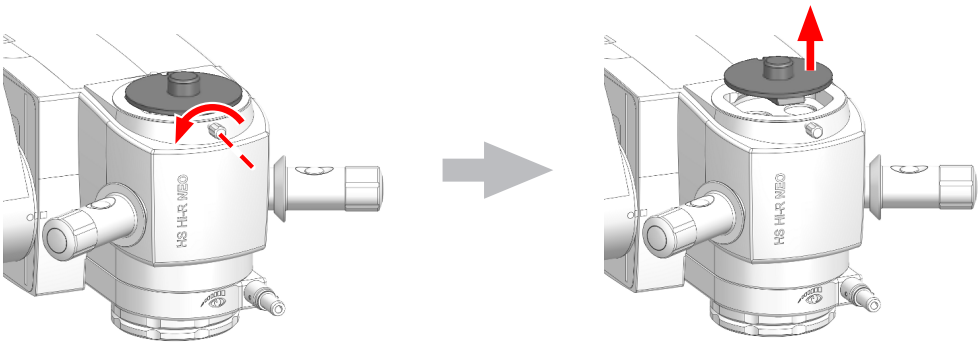
4.1.4 Installation

WARNING

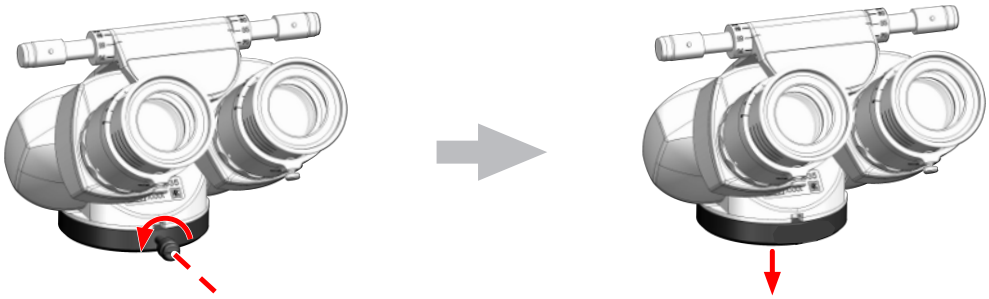
Danger to persons due to falling parts!

a) Ensure that all components are firmly fixed to each other.

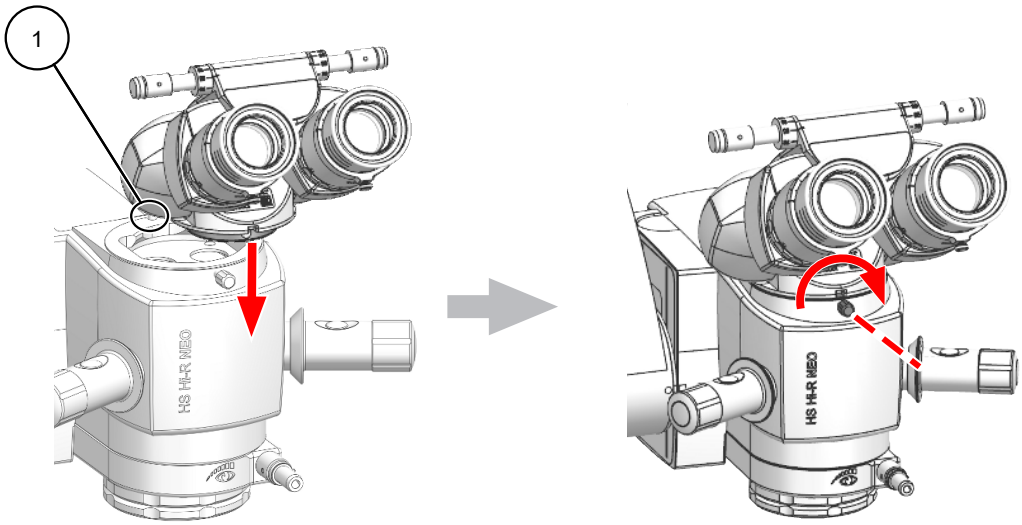
1. Loosen the grooved screw counterclockwise.
2. Take off the lid.



3. Loosen the screw.
4. Remove the protective cap.



5. Place the eyepiece head on the surgical microscope. Make sure that the pin (1) matches the backwards groove.
6. Fasten the knurled screw clockwise.



4.1.5 Operation

CAUTION

Risk of infection!

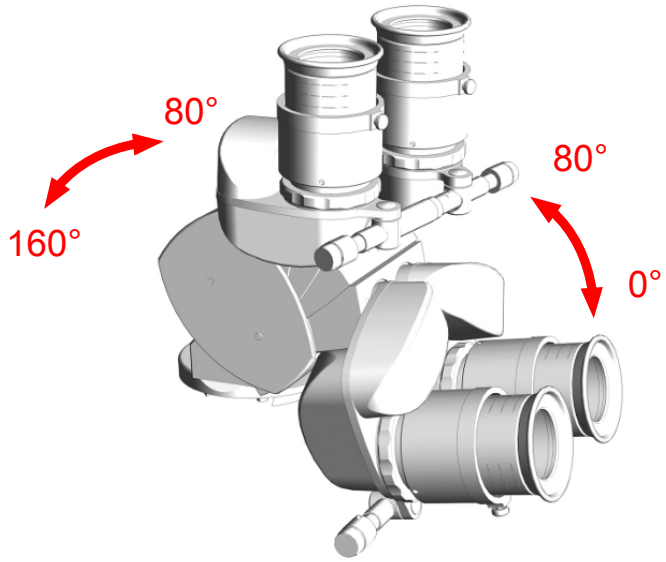
Non-sterile control elements of the surgical microscope system may be touched by the surgeon during surgery.

a) Control elements that need to be touched by the surgeon must be protected by sterile covers.

Adjusting vertical angle

Eyepiece head 160°, 10 x

To use the full range of 160°, it is required to rotate the eyepiece head when mounting it onto the microscope.

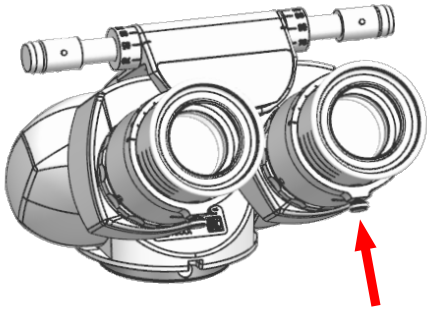


1. Move the eyepiece head to its desired angle.
2. If necessary, reinstall the eyepiece rotated by 180°. See Installation [▸ 10]

Adjusting the Diopters

With Camera

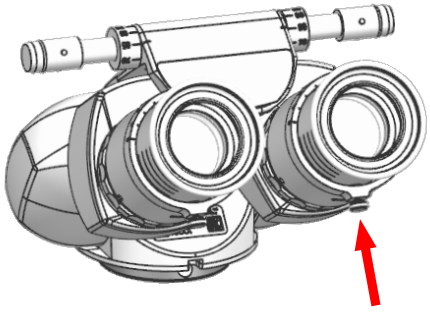
1. Set the surgical microscope to low magnification.
2. Focus the microscope so that the picture on the monitor is sharp.
3. Set the surgical microscope to high magnification.
4. Focus the microscope so that the picture on the monitor is sharp.
5. Adjust the pupillary distance of the eyepieces.
6. Loosen the knurled screws counterclockwise.



7. Adjust the eye cups by pulling out or pushing in, so eyelashes do not touch the lenses. Users of glasses may set the eye cups at the lowest position.
8. Turn the eyepiece's diopter setting to the highest value position (e.g. +5 D).



9. While looking through the surgical microscope with one eye only, turn the eyepiece’s diopter setting in the direction of the lowest value position (e.g. -5 D).
10. Stop when the image is clear for the first time.
11. Fasten the knurled screw.



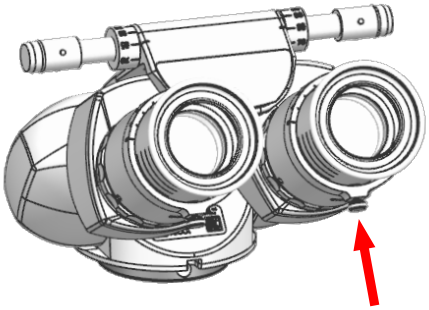
12. Repeat the eyepiece adjustment for the second eye.
13. Remember the settings for each eye and adjust the microscope to these values every single time you look through the microscope.

⇨ If the diopters of the oculars are properly adjusted, the image through the microscope as well as the camera image on the screen are clear and sharp.

Without Camera

Follow the steps if you are not prone to *instrumental myopia*.

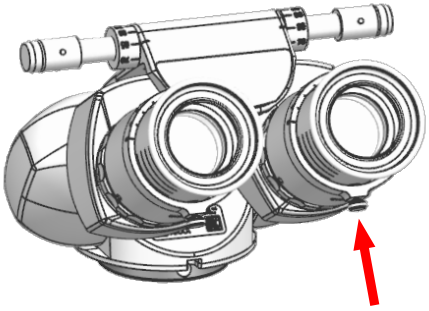
1. Loosen the knurled screw.



2. Adjust the eye cups by pulling out or pushing in, so eyelashes do not touch the lenses. Users of glasses may set the eye cups at the lowest position.
3. Set the diopter settings to "0*D*" or to the physican's spectacle value if he or she is operating without glasses and the visual acuity is known.



4. Fasten the knurled screw.



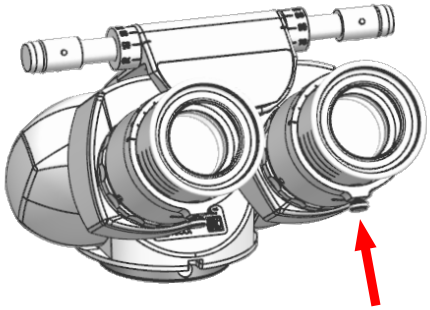
5. Set the surgical microscope to low magnification.
6. Focus the surgical microscope until the image in the eyepieces is sharp.

7. Set the surgical microscope to high magnification.
8. Focus the surgical microscope until the image in the eyepieces is sharp.

⇨ If the diopters of the oculars are properly adjusted, the image through the microscope is clear and sharp.

Follow the steps if you are prone to *instrumental myopia*.

9. Adjust the pupillary distance of the eyepieces.
10. Loosen the knurled screws counterclockwise.
11. Adjust the eye cups by pulling out or pushing in, so eyelashes do not touch the lenses. Users of glasses may set the eye cups at the lowest position.

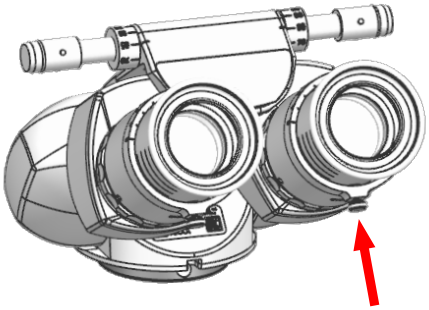


12. Turn the eyepiece's diopter setting to "0*D*".
13. Set the surgical microscope to low magnification.
14. Focus the surgical microscope until the image in the eyepieces is sharp.
15. Set the surgical microscope to high magnification.
16. Turn the eyepiece's diopter setting to the highest value position (e.g. +5 D).



17. While looking through the surgical microscope with one eye only, turn the eyepiece’s diopter setting in the direction of the lowest value position (e.g. -5 D).
18. Stop when the image is clear for the first time.

19. Fasten the knurled screw.

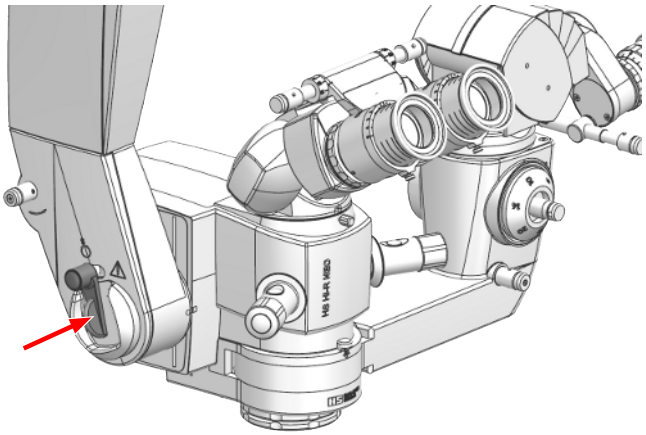


20. Repeat the eyepiece adjustment for the second eye.
21. Remember the settings for each eye and adjust the microscope to these values every single time you look through the microscope.

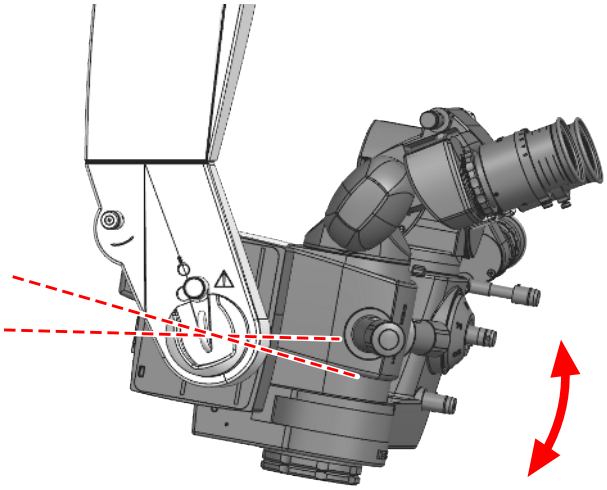
⇨ If the diopters of the oculars are properly adjusted, the image through the microscope is clear and sharp.

Adjusting the Focus

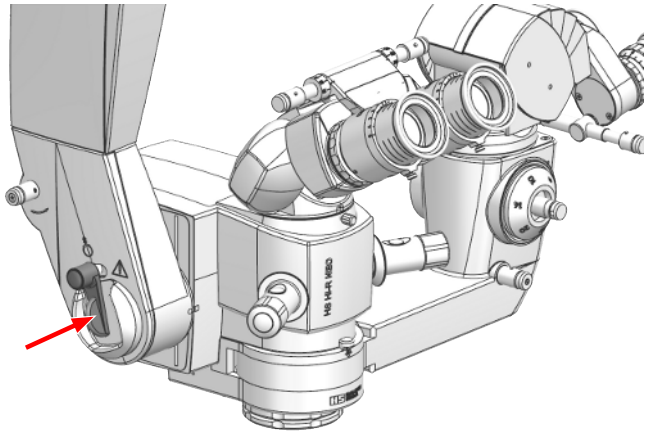
1. Use the foot switch to set the magnification.
2. Set the magnification to minimum.
3. For tilting the microscope use the "Pre-adjustment of the microscope tilt" lever.



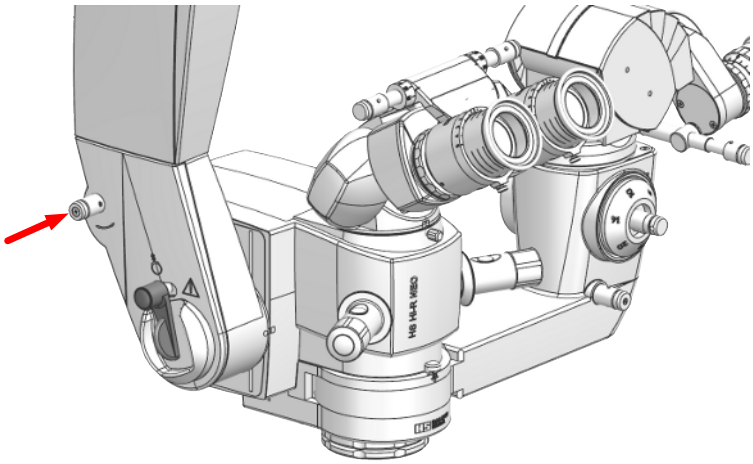
4. Tilt the microscope.



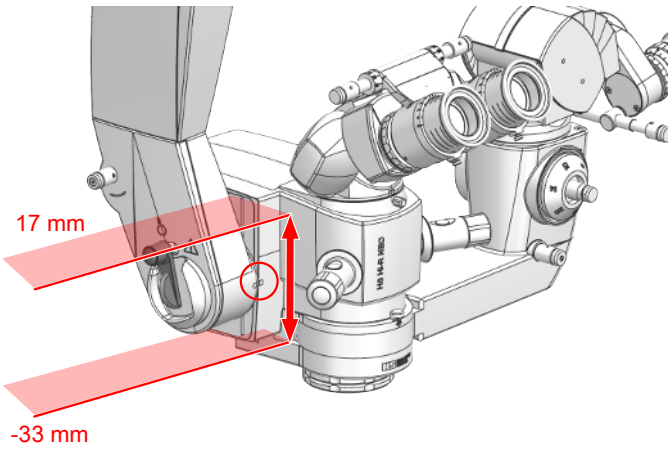
5. Release the "Pre-adjustment of the microscope tilt" lever.



6. Use the "Microscope presetting" rotary knob to fine-tune the microscope tilt within a range of ±10° from the pre-adjusted tilt.



7. Use the foot switch to focus the microscope in a range of -33 mm to 17 mm out of the homing position.



8. Set the magnification to maximum.
9. Readjust the focus of the surgical microscope.
10. Set the desired magnification.

4.2 TOCULAR

4.2.1 Intended use

The TOCULAR supplements the intended use of the surgical microscope system and is intended to add an angle scale to the optical path, especially for the alignment of toric lenses.

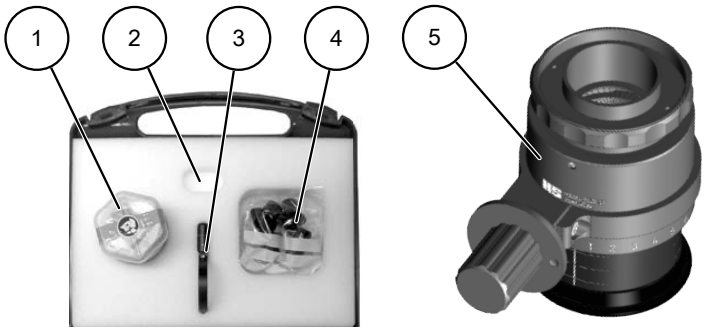
It can be mounted to eyepiece heads 200°, 10x (REF 4000026) and 160°, 10x (REF 4000025).

4.2.2 Operating Principle

Before surgery, the axis must be determined with a keratoscope or biometer. The vertical and/or horizontal coordinates are marked on the eye using a sterilizable pre-marker.

After implantation of the IOL, the microscope zoom is adjusted to show the dye mark in the field of view of the eyepieces. Using the knob on the TOCULAR, the crosshairs are rotated so that the large scaled markings are aligned with the dye markings on the eye. Now the IOL can be positioned using the medium and small crosshair markers.

4.2.3 Overview



	Name	Note
1	Ocular	with reticle plate
2	Allen wrench size 2	Tool
3	Eyepiece clamp	
4	Caps	sterilizable
5	TOCULAR	Fully assembled

4.2.4 Combinations

Accessories	REF	TOCULAR
		4000056
Eyepiece head 160°, 10x	4000025	x
Eyepiece head 200°, 10x	4000026	x

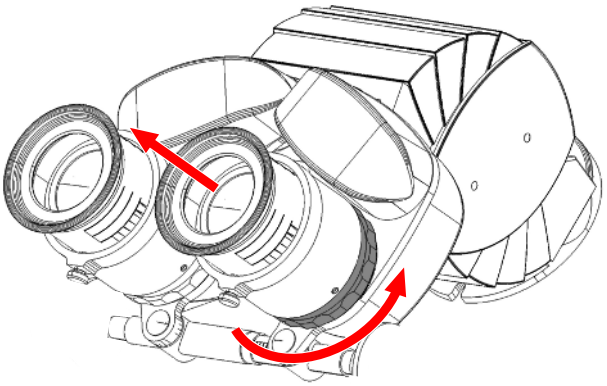
4.2.5 Installation

WARNING

Danger to persons due to falling parts!

a) Ensure that all components are firmly fixed to each other.

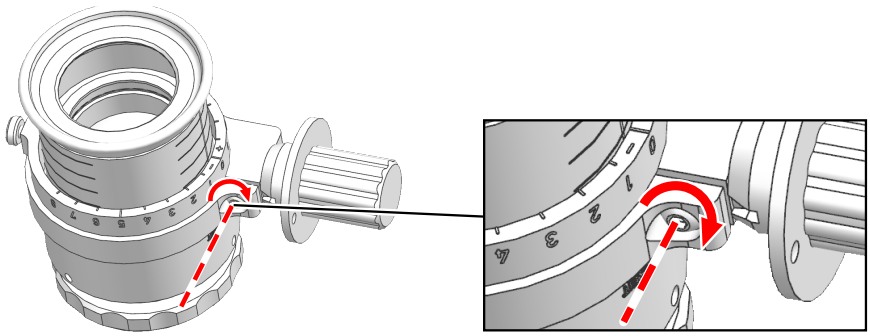
1. Loosen the illustrated ocular union nut counterclockwise.



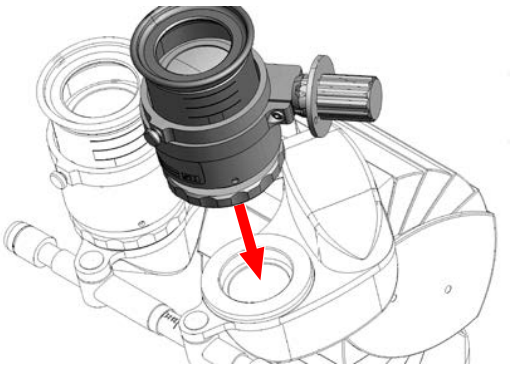
2. Unpack the ocular with reticle plate.
3. Mount the eyepiece clamp on the ocular with reticle plate. Loosen the screw with Allen wrench size 2 if the clamp is too tight to slide on.



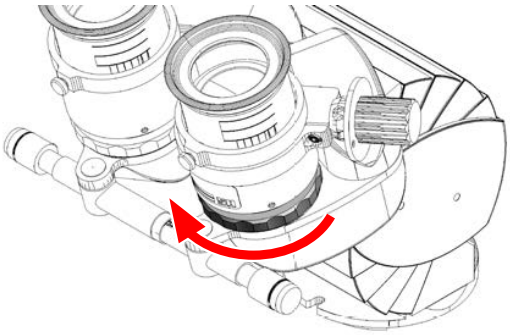
4. Fasten the screw with Allen wrench size 2.



5. Place the TOCULAR on the eyepiece.



6. Fasten the illustrated union nut clockwise.



4.2.6 Operation

CAUTION

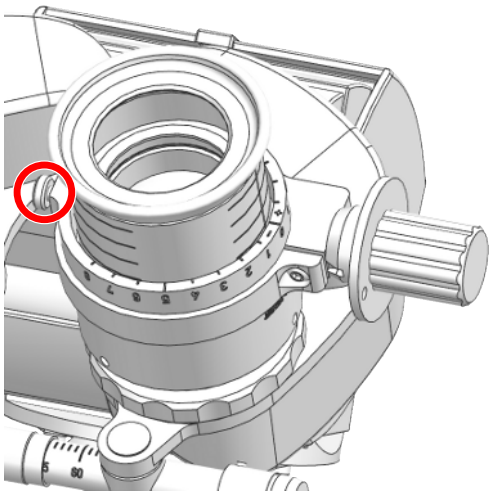
Risk of infection!

Non-sterile control elements of the surgical microscope system may be touched by the surgeon during surgery.

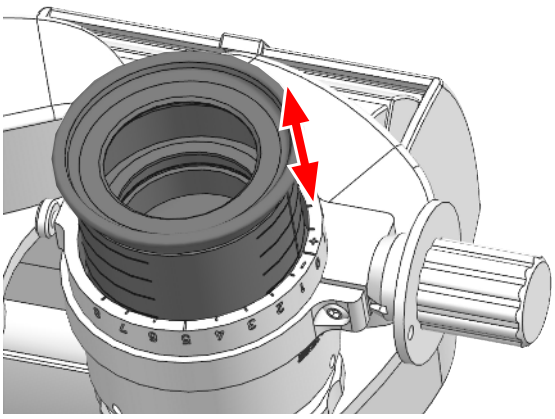
a) Control elements that need to be touched by the surgeon must be protected by sterile covers.

Adjust the Diopter Compensation

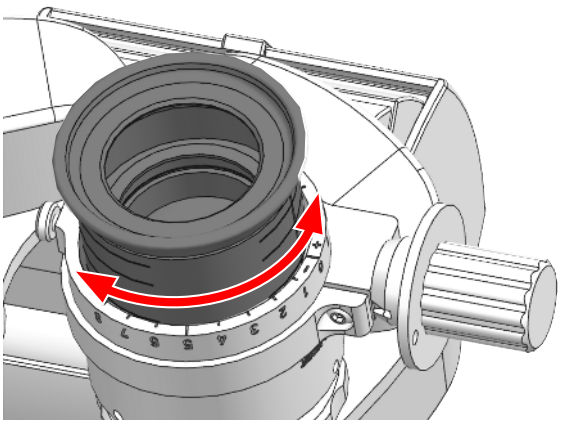
1. Loosen the knurled screw.



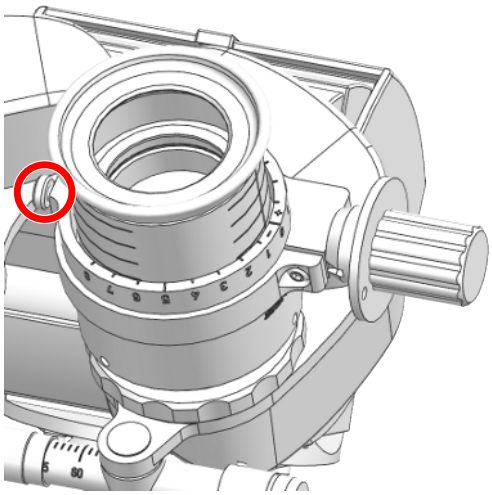
2. Retract for use with glasses.



3. Adjust the diopter compensation.

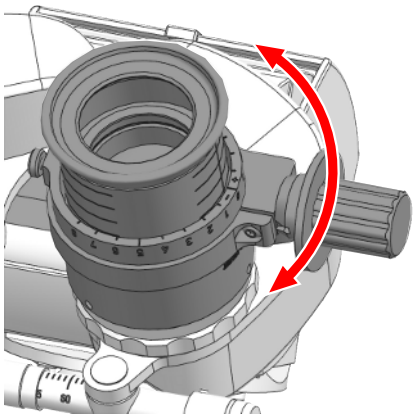


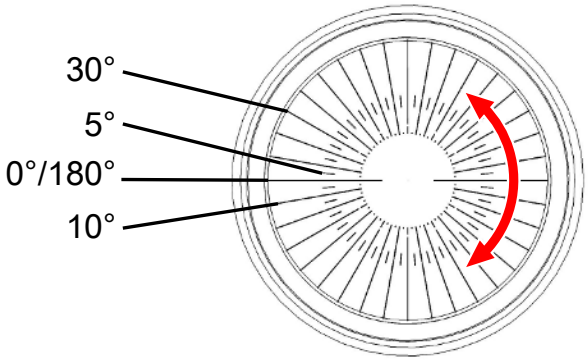
4. Fasten the knurled screw.



Adjust the Scale Rotation

1. Rotate the TOCULAR to adjust the scale.





4.3 Observation modules

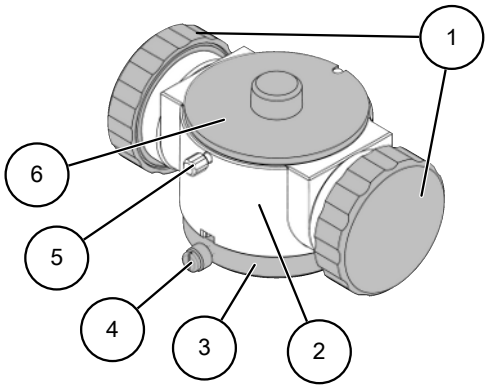
4.3.1 Intended use

Observation Modules

The observation modules are part of a surgical microscope system. They divide the observation light path, thus making observation possible. Using diverse connectors, a second eyepiece for a second person or a camera can be installed, for example.

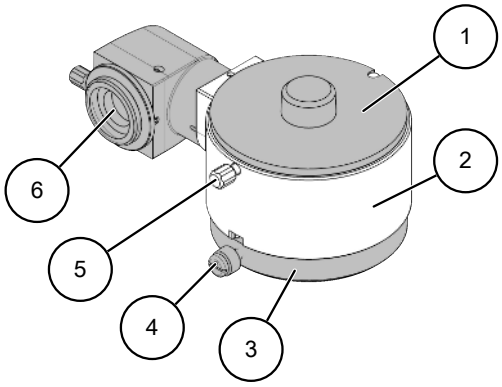
4.3.2 Overview

Beamsplitter 50:50



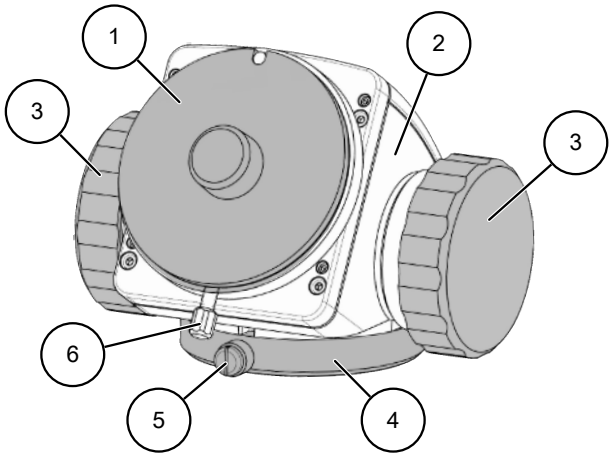
	Name	Note
1	Side covers (2 x)	Dust protection while storage.
2	Beamsplitter 50:50	For dividing the light beam.
3	Protective cap	Dust protection while storage.
4	Fixing screw	For protective cap (M4x14-PA)
5	Knurled screw	Fastener for lid and further accessories.
6	Lid	Dust protection while storage.

Beamsplitter T



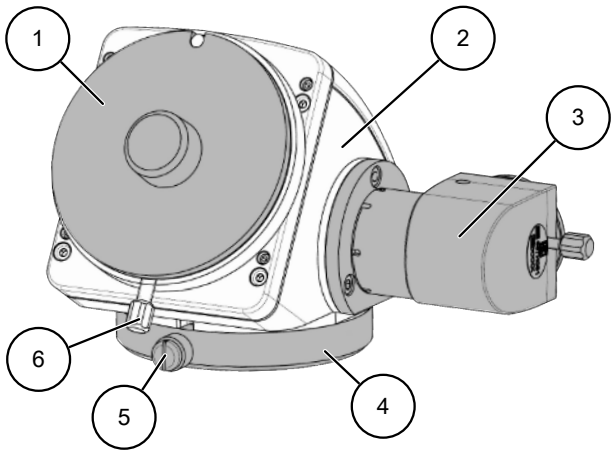
	Name	Note
1	Lid	Dust protection while storage.
2	Beamsplitter T	For dividing the light beam.
3	Protective cap	Dust protection while storage.
4	Fixing screw	For protective cap (M4x14-PA)
5	Knurled screw	Fastener for lid and further accessories.
6	C-mount 1/3" (micro)	(included)

VERTISCOPE U



	Name	Note
1	Lid	Dust protection while storage.
2	VERTISCOPE U	Vertiscope
3	Side cover (2x)	Dust protection while storage.
4	Protective cap	Dust protection while storage.
5	Fixing screw	For protective cap (M4x14-PA)
6	Knurled screw	Fastener for lid and further accessories.

VERTISCOPE T-R



	Name	Note
1	Lid	Dust protection while storage.
2	VERTISCOPE T-R	Vertiscope
3	C-mount 1/3" (micro)	(included)
4	Protective cap	Dust protection while storage.
5	Fixing screw	For protective cap (M4x14-PA)
6	Knurled screw	Fastener for lid and further accessories.

4.3.3 Combinations

Accessories	REF	Beamsplitter 50:50	Beamsplitter T
		4000006	4000007
HS Hi-R NEO 900A	4000038	x	x
HS Hi-R NEO 900	4000037	x	x
Eyepiece Head 160°, 10x	4000025	x	x
Eyepiece head 200°, 10 x	4000026	x	x
C-Mount 1/3" (micro)	4000059	x	incl.
C-Mount 1/3"	4000058	x	x
Stereoscopic co-observer 160°	4000054	x	x
Stereoscopic co-observer 0°	4000055	x	x
Double Iris Diaphragm	4000013	x	x

Accessories	REF	VERTISCOPE U	VERTISCOPE T-R
		4000061	4000060
HS Hi-R NEO 900A	4000038	x	x
HS Hi-R NEO 900	4000037	x	x
Eyepiece Head 160°, 10x	4000025	x	x
Eyepiece head 200°, 10 x	4000026	x	x
C-Mount 1/3" (micro)	4000059	x	incl.
C-Mount 1/3"	4000058	x	x
Stereoscopic co-observer 160°	4000054	x	x
Stereoscopic co-observer 0°	4000055	x	x
Double Iris Diaphragm	4000013	x	x

4.3.4 Installation

NOTICE

Risk of exceeding maximum weight load or excessive torque!

The additional weight of multiple observation modules may exceed the maximum weight load of the carrier or the maximum torque of the microscope.

a) Only use one observation module at the same time.

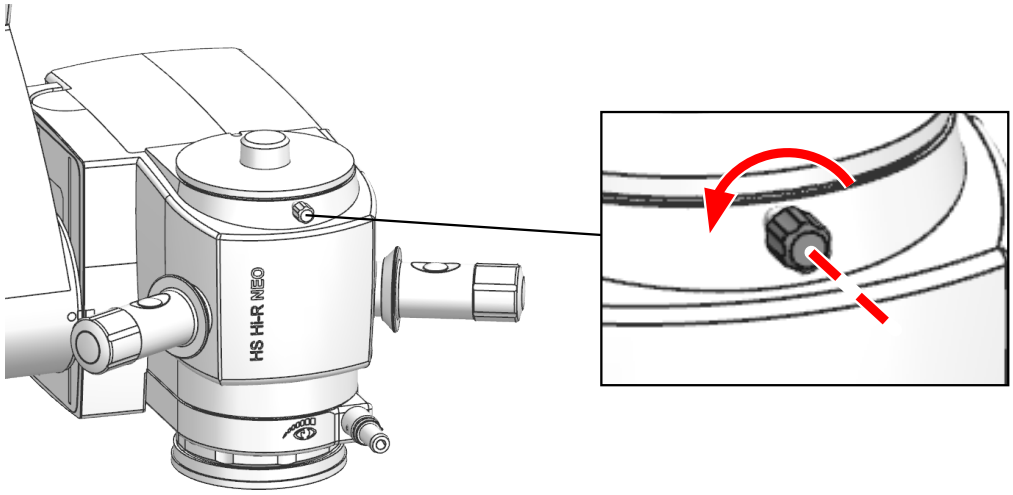
WARNING

Danger to persons due to falling parts!

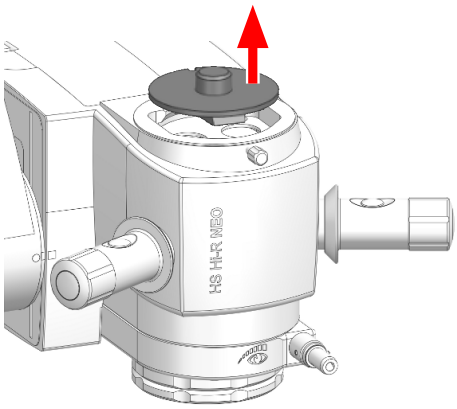
Ensure hat all components are firmly connected to each other.

Always secure the observation module with the threaded pin. Do not use knurled screws

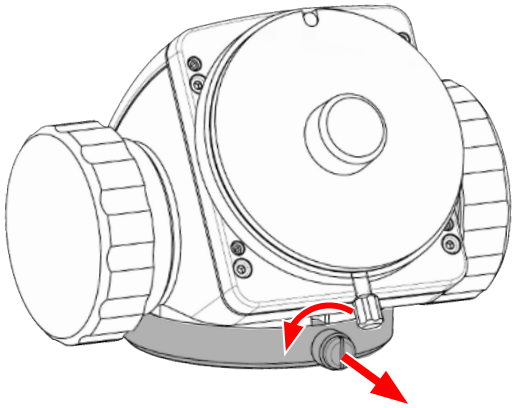
1. Loosen the grooved screw counterclockwise.



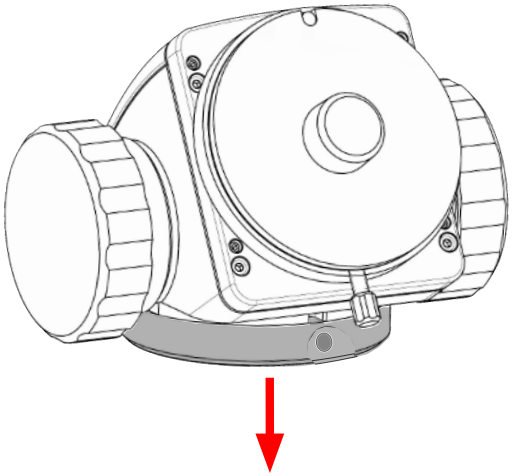
2. Take off the lid.



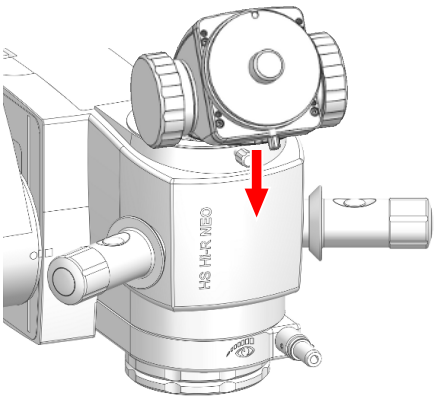
3. Loosen the grooved screw counterclockwise.



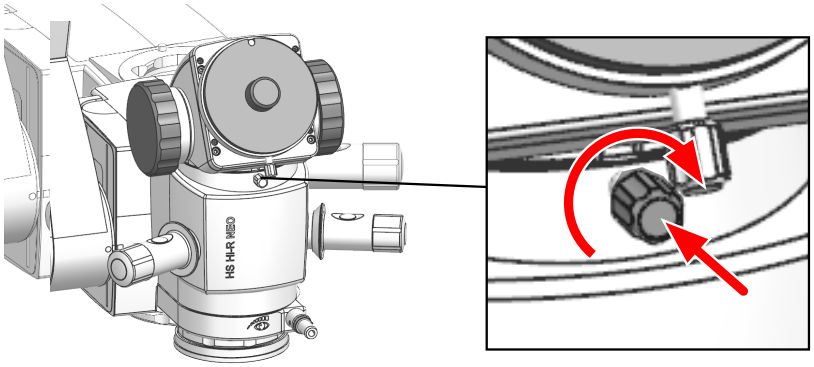
4. Remove the protective cap.



5. Place the accessory on the top of the microscope. Make sure that the pin matches the backwards groove.

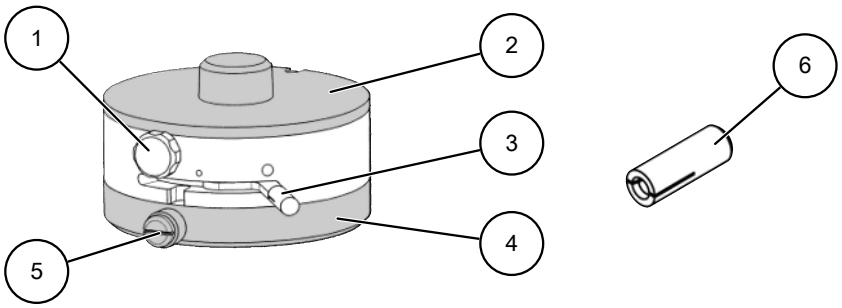


6. Fasten the knurled screw on the accessory clockwise.



4.4 Double Iris Diaphragm

4.4.1 Overview



	Name	Note
1	Knurled screw	For fixing accessory to the Double Iris Diaphragm.
2	Top cover	For protecting the upper connection area.
3	Lever	For opening or closing the Double Iris Diaphragm.
4	Cap	For protecting the lower connection area.
5	Fixing screw for the cap.	For fixing the cap.
6	Sterilizable Cap	Sterilizable protection caps for the lever.

4.4.2 Combinations

Accessories	REF	Double Iris Diaphragm
		4000013
Eyepiece Head 160°, 10x	4000025	x
Eyepiece Head 200°, 10 x	4000026	x
HS Hi-R NEO 900A	4000038	x
HS Hi-R NEO 900	4000037	x
Beamsplitter 50:50	4000006	x

Accessories	REF	Double Iris Diaphragm
		4000013
Beamsplitter T	4000007	x
VERTISCOPE U	4000061	x
VERTISCOPE T-R	4000060	x

4.4.3 Installation

NOTICE

Risk of exceeding maximum weight load or excessive torque!

The additional weight of multiple observation modules may exceed the maximum weight load of the carrier or the maximum torque of the microscope.

a) Only use one observation module at the same time.

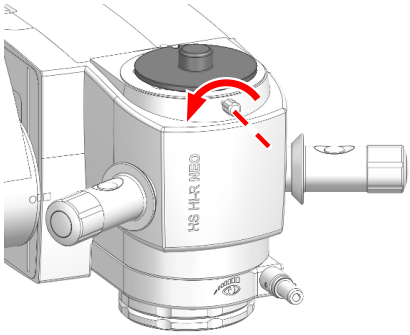
WARNING

Danger to persons due to falling parts!

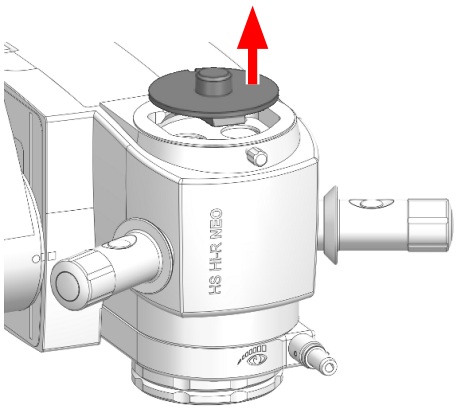
Ensure hat all components are firmly connected to each other.

Always secure the observation module with the threaded pin. Do not use knurled screws

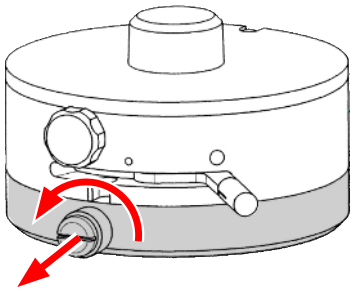
1. Loosen the grooved screw counterclockwise.



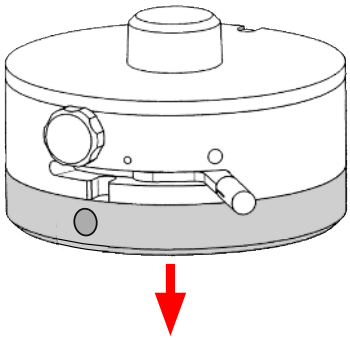
2. Take off the lid.



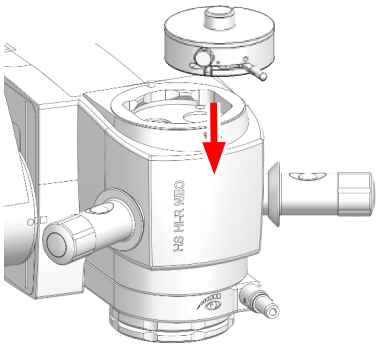
3. Loosen the grooved screw counterclockwise.



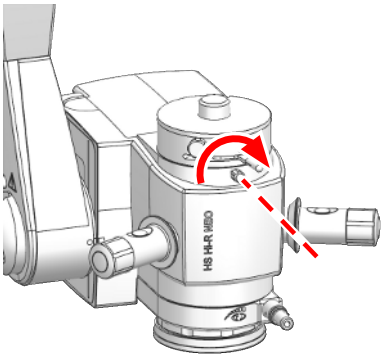
4. Remove the protective cap.



5. Place the Double Iris Diaphragm on the top of the microscope. Make sure that the pin matches the backwards groove.



6. Fasten the knurled screw on the microscope clockwise.



4.4.4 Operation

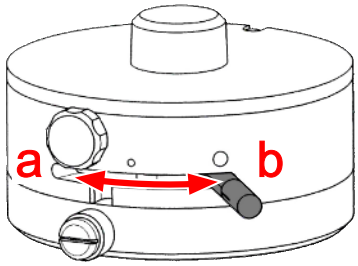


Illustration 3: Function of the Double Iris Diaphragm

1. Open the Double Iris Diaphragm (b) to reduce the depth of field and increase the brightness.
2. Close the Double Iris Diaphragm (a) to increase the depth of field and reduce the brightness. This may cause increased vignetting.

A closed iris diaphragm can reduce or negatively influence the red reflex. If the red reflex is not sufficient, the iris diaphragm should be opened

4.5 Stereoscopic Co-Oberserver

4.5.1 Intended use

The secondary stereoscopic observer is part of a microsurgical operating system. It can be installed on the auxiliary connector of the observation module to display a stereoscopic image. Due to the large pivoting range it can be easily adapted to individual working conditions, thus making ergonomic work possible.

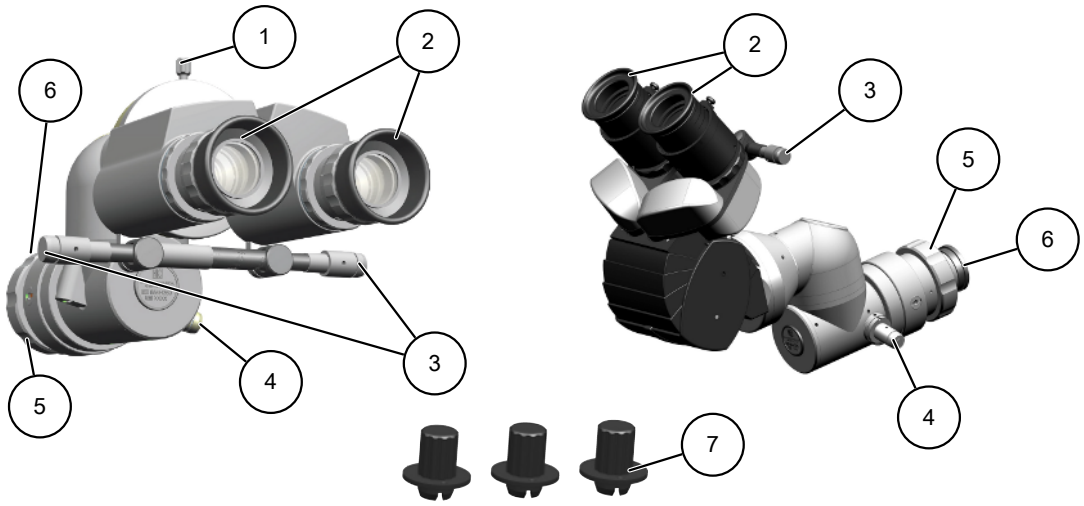
4.5.2 Overview

Stereoscopic Co-Observer 0°

REF 4000055

Stereoscopic Co-Observer 160°

REF 4000054



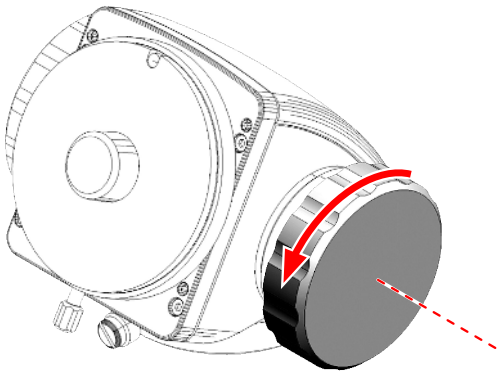
Item	Name	Note
1	Knurled screw	To fix the eyepiece.
2	Oculars	To adjust the diopter settings see section "Adjust the diopters" [12].
3	PD Adjustment	Adjusts the ocular spacing to fit the pupillary distance.
4	Image alignment	Rotate the image for horizontal alignment.
5	Connector ring	To join the observer with accessories of the surgical microscope.
6	Dust protection Cap	For protecting the microscope connector during storage and transport.
7	Sterilizable Cap (3x)	Sterilizable protection caps for controls of the "pd adjustment" and "image alignment".

4.5.3 Combinations

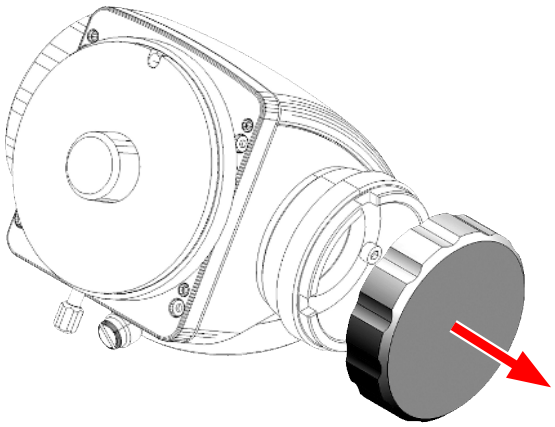
Accessories	REF	Surgical microscope system	
		Stereoscopic co-observer 0°	Stereoscopic co-observer 160°
		4000055	4000054
Beamsplitter 50:50	4000006	x	x
VERTISCOPE U	4000061	x	x

4.5.4 Installation

1. Turn the protective cap counterclockwise.



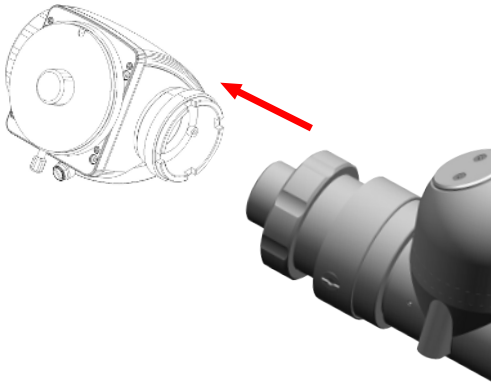
2. Remove the protective cap.

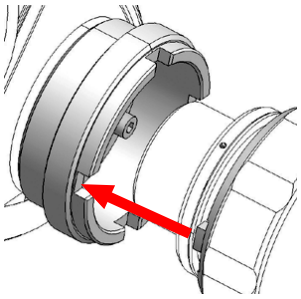


3. Remove the protective cap.

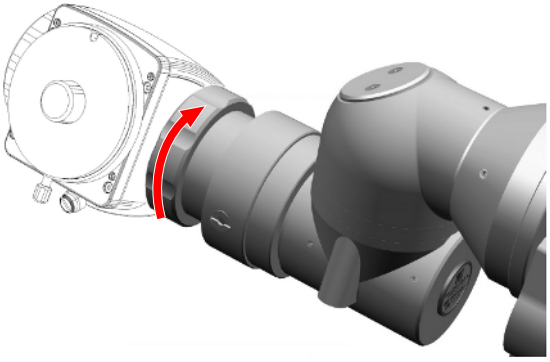


4. Place the accessory at the side of the observation module.





5. Hand-tighten the locking ring clockwise.



6. Check if the connection is firm.

4.5.5 Operation

CAUTION

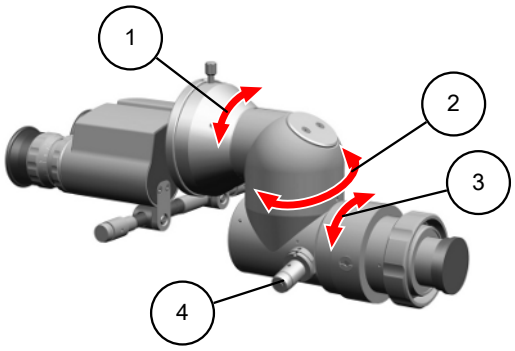
Risk of infection!

Non-sterile control elements of the surgical microscope system may be touched by the surgeon during surgery.

a) Control elements that need to be touched by the surgeon must be protected by sterile covers.

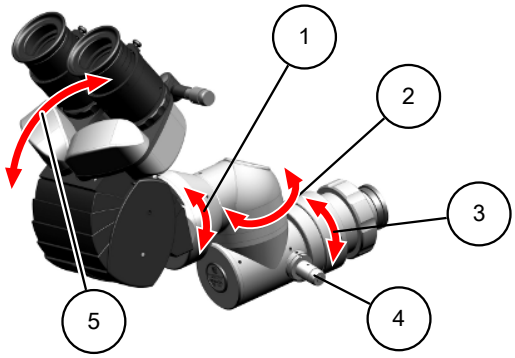
Stereoscopic co-observer 0°

REF 4000055



Stereoscopic co-observer 160°

REF 4000054



Item	Note
1	Adjust Eyepiece Rotation only To adjust the diopter settings see section Adjust the diopters [▶ 12].
2	Adjust z-axis
3	Adjust x-axis
4	Rotate the image for horizontal alignment
5	Tilt the eyepiece head (only Stereoscopic Co-Observer 160°)

4.6 Camera attachments

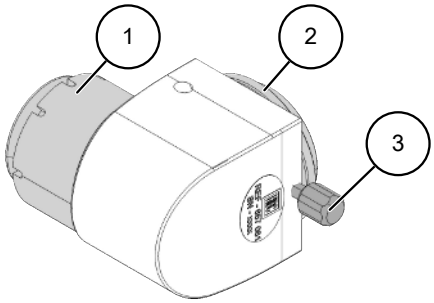
4.6.1 Intended use

Camera attachments supplement the intended use of the surgical microscope system. They are used to connect the surgical microscope system to a camera for documenting the surgery.

4.6.2 Overview

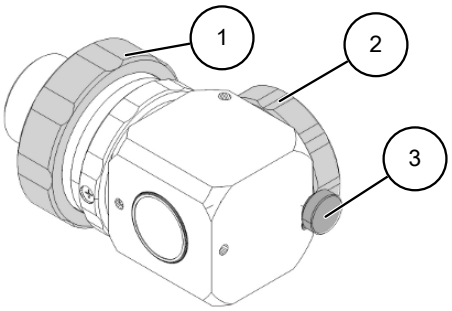
C-Mount 1/3" (micro)

REF 4000059



C-Mount 1/3"

REF 4000058



Item	Name
1	Connection to Beamsplitter or Vertiscope
2	Camera connection
3	Screw to fix the rotation of the camera.

4.6.3 Combinations

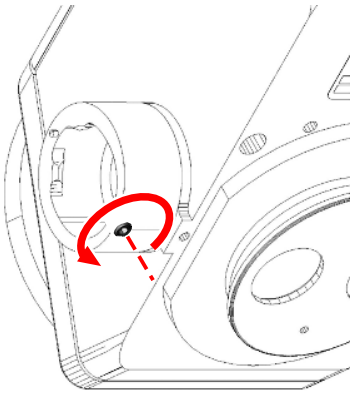
Accessories	REF	C-Mount 1/3" (micro)	C-Mount 1/3"
		4000059	4000065
Beamsplitter 50:50	4000006	-	x
Beamsplitter T	4000007	incl.	-
VERTISCOPE U	4000061	-	x
VERTISCOPE T-R	4000060	incl.	-

4.6.4 Installation

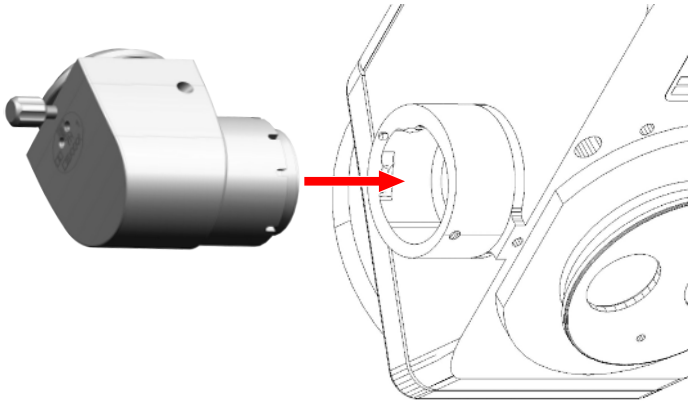
C-Mount 1/3" (micro)

REF 4000059

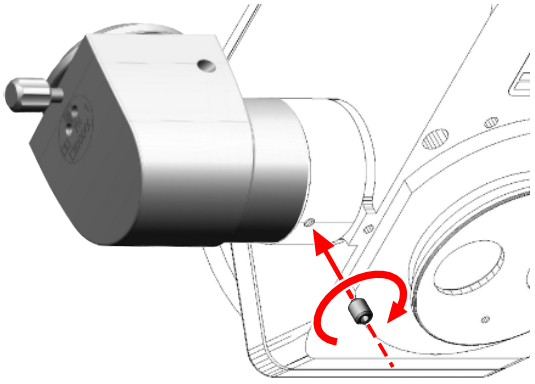
1. Loosen the grub screw with Allen wrench size 2 counterclockwise.



2. Insert the module into the holder. Make sure that the pin matches the groove of the desired position (angle).



3. Fasten the grub screw with allen key size 2 clockwise.



WARNING

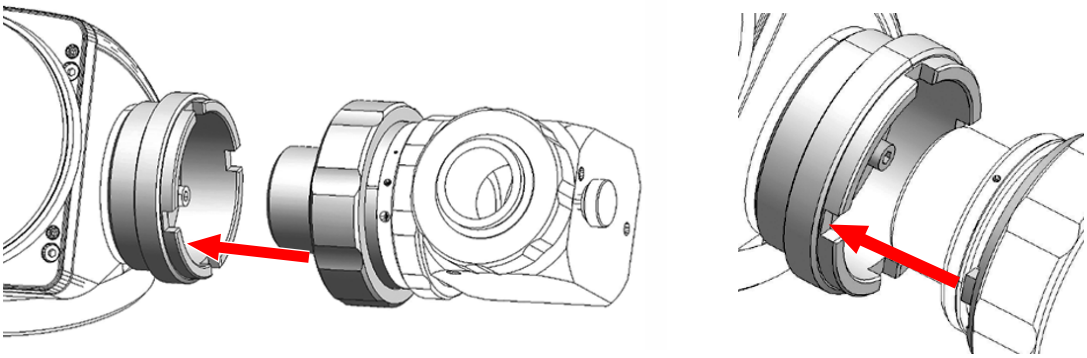
Danger to persons due to falling parts!

a) Ensure that all components are firmly fixed to each other.

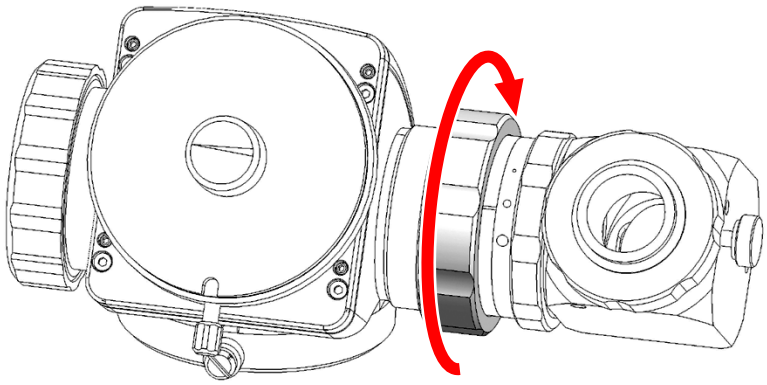
C-Mount 1/3"

REF 4000058

1. Insert the module into the holder. Make sure that the pin matches the groove of the desired position (angle).

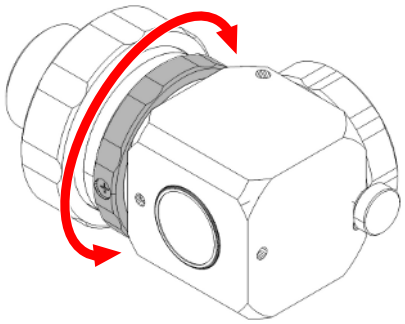


2. Fasten the locking ring clockwise.



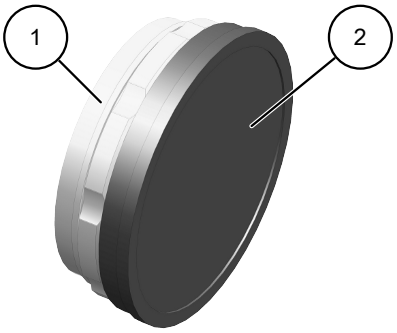
4.6.5 Operation

1. Use the knurled ring of the C-Mount 1/3" (micro) to adjust the depth of field



4.7 Front lens

4.7.1 Overview



Item	Name	Note
1	Front lens	For microscopes.
2	Protective Cap	To protect front lens from dust and shocks.

4.7.2 Intended use

The front lenses are part of a microsurgical operating system. Due to their diverse focal lengths, they can be used to adjust the microscope's working distance to individual working conditions, which makes ergonomic work possible.

4.7.3 Combinations

Accessories	REF	Front Lens focal length 175 mm	Front Lens focal length 200 mm
		4000031	4000033
HS Hi-R NEO 900A	4000038	x	x
HS Hi-R NEO 900	4000037	x	x

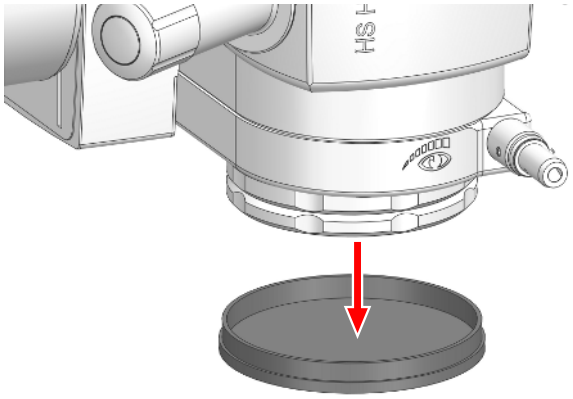
4.7.4 Installation

WARNING

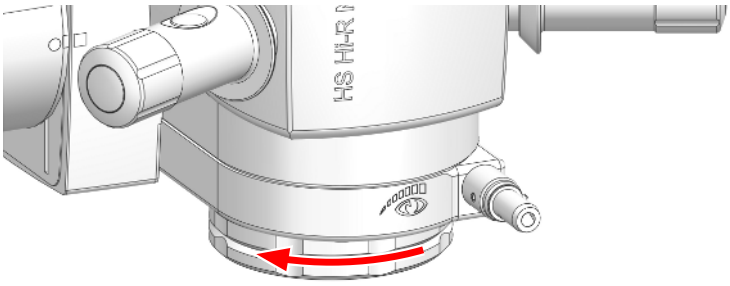
Danger to persons due to falling parts!

a) Ensure that all components are firmly fixed to each other.

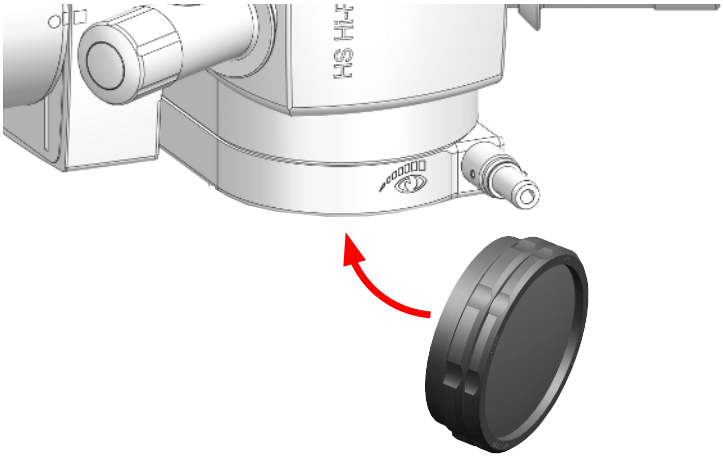
1. Remove the protective cap.



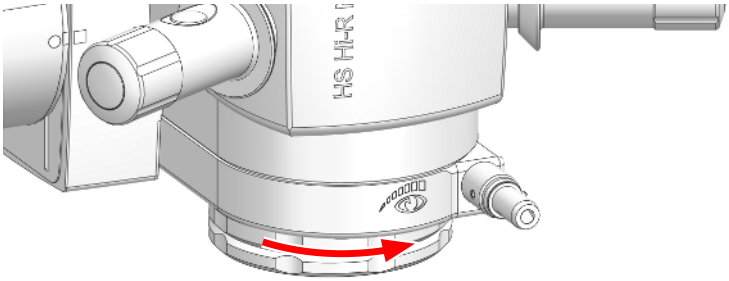
2. Remove the existing lens counterclockwise.



3. Carefully place the front lens on the bottom of the microscope.



4. Slightly tighten the front lens clockwise.



5 Before each Operation

5.1 Visual Guide for Cleaning and Disinfection

Color	Note
Green	Parts that are intended for cleaning and disinfection.
Black	Parts that are intended to be touched by the user. They must be cleaned and disinfected before and after each surgical intervention.
Gray	Parts that are not intended for cleaning and disinfection.

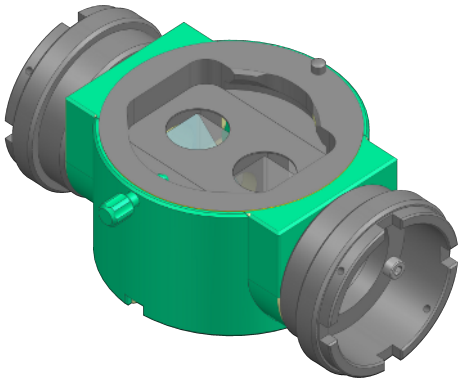
TOCULAR

REF 4000056



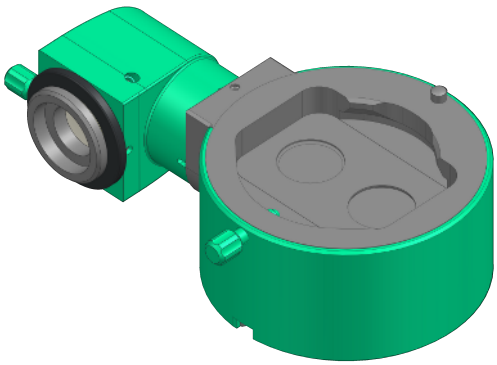
Beamsplitter 50:50

REF 4000006



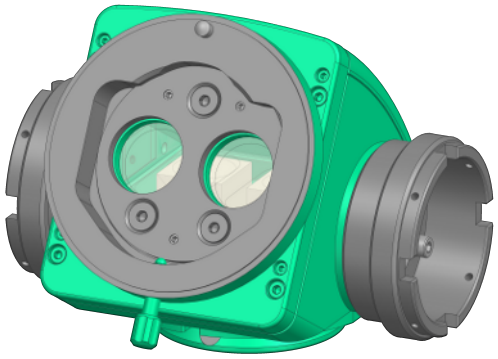
Beamsplitter T

REF 4000007



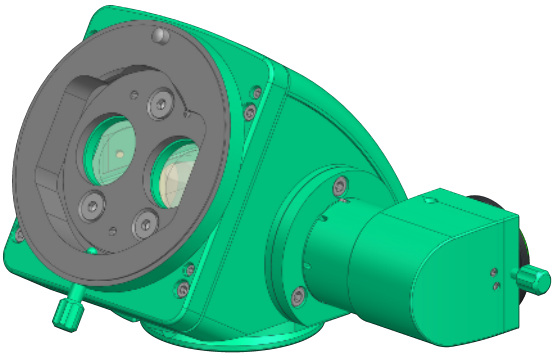
VERTISCOPE U

REF 4000061



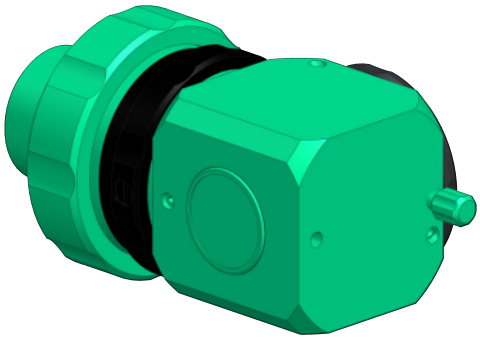
VERTISCOPE T-R

REF 4000060



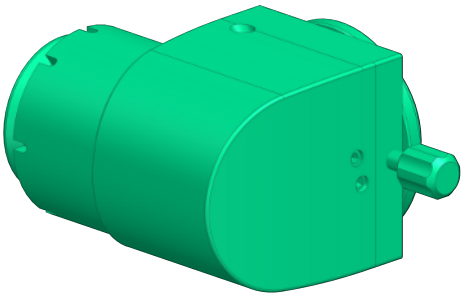
TV attachment 1/3" C-mount

REF 4000058



TV attachment 1/3" C-mount (micro)

REF 4000059



5.2 Cleaning

Perform the cleaning, disinfection, and/or sterilization before each use.

The operator must ensure that the preparation is performed within a suitable validated procedure in accordance with the respective national regulations.

The treatment process must at least meet the following requirements:

- Cleaning agent and disinfectant must be approved for the treatment of medical products.
- Cleaning and disinfecting devices and agents must accord to internationally recognized standard.
- Steam sterilization must be in accordance with internationally recognized standards if applicable.

Refer to the instructions provided by the manufacturer of the disinfectant regarding recommended concentration and contact time.

1. Make sure that no cleaning agent can ingress into the housing of the surgical microscope system.
2. Make sure that no cleaning agent can get onto the glass surfaces or lenses, unless cleaning agents are specifically intended for this purpose.
3. Use slightly soaked wipes with sufficient amount of cleaning agent.
4. Perform disinfection afterwards with disinfectant.

After all appropriate items are cleaned, disinfected or sterilized, they should be inspected:

5. Check all items before and after each treatment for mechanical damage.
6. Replace damaged items.

7. Ensure that no visible impurities or contaminations remain on the items.
8. Ensure that glass surfaces are clean and free of streaks.

Manual cleaning	
Eyepiece head	**Materials required** – Disposable gloves – Damp cloths – Dry cotton or microfiber cloth – Cleaning agent (glutaraldehyde-based or alcohol-based) – Cleaning agent (pH 6 − 10) **Process** – Use disposable gloves. – Remove slight soiling such as fingerprints with the dry microfiber cloth. – If the glass surfaces are soiled with e.g dried blood or saline solution residue, clean it with a damp cloth. – Dry the surface with the dry cotton or microfiber cloth. – Perform disinfection afterwards with disinfectant. – Let disinfectant dry out in air.

Manual cleaning	
External surfaces	**Materials required** – Disposable gloves – Cloth (Damp cloth/single-use tissues or wipes, cotton or microfiber cloth) – Cleaning agent (glutaraldehyde-based or alcohol-based) – Cleaning agent (pH 6 − 10) **Process** – Use disposable gloves. – Soak cloth or wipes with a sufficient amount of cleaning agent. – Wipe off the contamination with a cloth soaked in cleaning agent. – Perform disinfection afterwards with disinfectant. – Let disinfectant dry out in air.

5.3 Disinfection

Parts, such as handles, push bars, knobs, oculars and framing of displays, that are intended to be used or touched by the user are colored in black. These parts should always be cleaned and disinfected before and after each surgical intervention although they might be covered by a sterile drape. See Visual Guide for Cleaning and Disinfection [▶ 42].

Additionally disinfect all other surfaces that are contaminated with tissue or blood after each surgical intervention as described in the table.

1. Make sure that no disinfectant can ingress into the housing of the surgical microscope system.
2. Avoid spraying the disinfectant directly onto surfaces.
3. Use slightly soaked wipes with sufficient amount of disinfectant.
4. Let disinfected surfaces dry out in air.
5. Be aware of the exposure time with the disinfectant.
6. Be aware of the applied concentration of utilized disinfectant.

In case of microsurgical interventions on MRSA-, VRE-infected patients or in general patients infected by nosocomial infections:

1. Use sterile sleeves.
2. Use **always** sterile caps (soft and hard)
3. Use a drape (recommended).

Even though the surgical microscope is covered by sterile caps and/or drape:

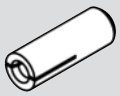
4. Perform disinfection although on parts that are covered by sterile caps and/or drape.
5. To eliminate any possible contaminations perform the disinfection of the following parts with special diligence:

– the outside housing of all *ocular tubes*.
– the hard-to-reach areas of the surgical microscope.
– all handles and bars.

Disinfection	
– Eyepiece head – Stereoscopic co-observer – Base of the *ocular tubes* of the observer. – Front lens	**Materials required** – Disposable gloves – Cloth (Damp cloth/single-use tissues or wipes, cotton or microfiber cloth) – Disinfectant (glutaraldehyde-based or alcohol-based) – Cleaning agent (pH 6 − 10) **Process** – Use disposable gloves. – Soak the cloth with sufficient amount of the disinfectant. – Wipe gently with the cloth into one direction. – Let disinfectant dry out in air.

5.4 Sterilization

It is not possible to sterilize the entire surgical microscope system. Only detachable parts like sterilizable caps for control elements can be sterilized.

Sterilizable Parts		
Stereoscopic Co-Observer 0° Stereoscopic Co-Observer 160° Tocular	4400637	
Double Iris Diaphragm	4400638	

The reuse of the sterilizable parts is limited to a maximum of 100 sterilization cycles. Use the information on the labeling of the sterilizable parts to track the remaining sterilization cycles. See Manufacturer's Details and Contact Information.

Sterilization	
Detachable and sterilizable caps for control elements	**Process** – Package the items according to hospital standards for sterile medical devices. – Sterilize the items via steam sterilization with fractionated pre-vacuum at 134 °C for at least 3 minutes (For US: 132 °C for at least 4 minutes). Steam sterilization is possible at up to 139 °C for up to 18 minutes. – Store the items according to hospital standards for storing sterile medical devices.

6 Troubleshooting



CAUTION

Risk of limited treatment options!

If defects are not detected, the surgical microscope system may not offer all functions during surgery.

a) Before each use, make sure that all electrical and mechanical connections are firmly seated and free of defects.

b) Regularly check the functionality and quality of the magnified vision.

c) Do not use the system in case of any obvious defects, error states or functional restrictions. Call the Haag-Streit Service.



NOTICE

Resettable error reoccurs twice or more

The error may be due to a systematic fault in the medical device and must be attended by Haag-Streit.

Please contact your local representative or Haag-Streit, stating the product name, type and serial number together with a description of the error and the circumstances under which the error occurs.

Troubleshooting Table

Malfunction	Cause	Remedy
The image of an Eyepiece, monitor or camera is missing, displaced, twisted or vignetted.	Incorrectly connected accessories.	Check connection of the accessories. – The connections must be firmly connected.

7 Maintenance

Perform maintenance in accordance with the instructions for use of the surgical microscope system.

We recommend to have the surgical microscope system regularly serviced by your Haag-Streit national representative.

8 Technical Data

Conformity	
Classification	CE Regulation (EU) 2017/745 Class I
Safety	EN 60 601-1 Appliance class I equipment
EMC	IEC 60 601-1-2
UMDNS	12-539
GMDN	64676 Ophthalmic surgical microscope
Degree of protection by enclosure (IP-Code)	IP20

Environment Data	
Operating temperature [°C]	+10 – +40
Operating, relative air humidity [%]	10 – 90
Operating, air pressure [hPa]	700 – 1060
Storage and transport, temperature [°C]	-20 – +70
Storage and transport, relative air humidity [%]	10 – 90
Storage and transport, air pressure [hPa]	600 – 1060

Technical Data	Eyepiece head 200°, 10 x	Eyepiece Head 160°, 10x
Identification		
REF	4000026	4000025
Mechanical data		
Height [mm]	119	167
Width [mm]	166	140
Depth [mm]	181	177
Weight [kg]	1.25	1
Vertical Angle Range	200°	160°
Optical data		
Refraction adjustment [dpt]	+ 5 ... - 8	
Pupil Distance [mm]	55 ... 75	
Eyepiece magnification	10 x	
Total magnification	7.6 x	8.4 x
Focal length [mm]	190	210
Opening [mm]	16	
Aperture [mm]	21	

Technical Data	TOCULAR
Identification	

Technical Data	TOCULAR
REF	4000056
Mechanical data	
Height [mm]	70
Width [mm]	74
Depth [mm]	80
Weight [kg]	0.15
Screen data	
Refraction adjustment [dpt]	+ 5 ... - 8
Eyepiece magnification	10 x
Focal length [mm]	25
Aperture [mm]	21

Technical Data	Beamsplitter 50:50		Beamsplitter T	
Identification				
REF	4000006		4000007	
Mechanical data				
Height [mm]	55		48	
Width [mm]	122		134	
Depth [mm]	75		84	
Weight [kg]	0.5		0.4	
Optical data				
Light distribution	left	right	left	right
Input [%]	50	50	50	50
C-Mount 1/3" / 1/3" (micro) [%]	-	-	-	10
Accessories [%]	25	25	-	-
Main eyepiece [%]	25	25	50	40

Technical Data	VERTISCOPE U		VERTISCOPE T-R	
Identification				
REF	4000061		4000060	
Mechanical data				
Height [mm]	89.5 (no caps)		89.5 (no caps)	
Width [mm]	113 (no caps)		133 (no caps)	
Depth [mm]	109		109	
Weight [kg]	0.8		0.7	
Optical data				
Light distribution	left	right	left	right
Input [%]	50	50	50	50
Accessoires [%]	25	25	-	10
Main eyepiece [%]	25	25	50	40

Technical Data	Double Iris Diaphragm
Identification	
REF	4000013
Mechanical data	
Height [mm]	19
Width [mm]	70
Weight [kg]	ca. 0.15

Technical Data	Secondary Stereoscopic co-observer 0°	Secondary Stereoscopic co-observer 160°
Identification		
REF	4000055	4000054
Mechanical data		
Height [mm]	145	203
Width [mm]	133	120
Depth [mm]	248	319
Weight [kg]	1.5	1.8
Optical data		
Refraction adjustment [dpt]	± 7	± 7
Eyepiece magnification	12.5 x	10 x

Technical Data	1/3" Camera Attachment (micro)	1/3" Camera Attachment
Identification		
REF	4000059	4000065
Mechanical data		
Height [mm]	30	28
Width [mm]	44	55
Depth [mm]	60	107
Weight [kg]	0.1	0.33

Technical Data	Front Lens focal length 175 mm	Front Lens focal length 200 mm
Identification		
REF	4000031	4000033
Mechanical data		
Height [mm]	20	
Diameter [mm]	65	
Weight [kg]	0.2	
Optical data		
Focal length [mm]	175	200
Working distance [mm]	165	190

9 Disposal



Dispose of the surgical microscope system and its components according to national and regional legislation.

Within the European Union, the surgical microscope system and its components are subject to EU-Directive on Waste of Electrical and Electronic Equipment and may not be disposed together with waste from private households.

The manufacturer shall take the surgical microscope system and its components back for proper recycling or disposal. Please contact your local Haag-Streit sales representative.

Glossary

CDSCO

CDSCO is the abbreviation for "Central Drugs Standard Control Organisation", India's national regulatory authority for drugs and medical devices.

CE

Originally CE stood for Communauté Européenne (European Community) later for Conformité Européenne. With the CE mark a manufacturer expresses conformity with the European legislation, specifically with European directives and European regulations.

diopters

Positive values represent magnifying opticals. Negative values represent reducing opticals.

EC-REP

EC-REP is the abbreviation for "European Community Authorized Representative". Medical device manufacturers located outside the EU must designate an authorized representative located in the EU to fulfill the CE requirements for placing medical devices on the EU market.

GMDN

GMDN is the abbreviation for "Global Medical Device Nomenclature", which is the European system defining the nomenclature for medical devices.

GTIN

GTIN is the abbreviation for "Global Trade Item Number", a unique and internationally recognized identification for a product with 14 digits.

instrumental myopia

Typically instrumental myopia develops when a person is looking through an optical system. This occurs due to the fact, that the image of the microscope is focused to infinity, thus the observer needs to focus to infinity, too. But the human mind still knows that the object is located at close proximity and makes the eyes to start accommodating. This has the result that the person looking through the optical system gets myopic and sets the focus wrongly. Since the camera is also adjusted to infinity, the person having instrumental myopia and setting the focus wrongly will have a clear image through the oculars but a blurred camera image on the screen.

IP-Code

IP xx, indicates how well a cabinet protects the circuits and switches against ingress of fluids.

MD

MD is the abbreviation for "Medical Device", which states that the given device is intended for medical use.

ocular tube

tube behind ocular

REF

REF is the abbreviation of the term "Reference Number". Each product and all spare parts have a unique reference number, by which they can be ordered.

SN

SN is the abbreviation of the term "Serial Number". Every product is given a unique serial number, by which the specific technical data can be retrieved.

UDI

UDI is the abbreviation for "Unique Device Identification". The UDI code enables medical device traceability and prevents product diversion and counterfeiting.

UMDNS

UMDNS is the abbreviation for "Universal Medical Device Nomenclature System", which is an international system defining the nomenclature for medical devices.

HS-Art. No. 1500 4000088 02020 web



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