

OCULUS BIOM[®] 5



CONDITIONING INSTRUCTION BIOM[®] 5 AND ACCESSORIES

Preface

This Conditioning Instruction explains how to condition the BIOM® 5. It is valid for all re-usable components and accessories of the BIOM® 5 that must be sterile for use. To ensure safe operation, it is essential that you use the device correctly. For this reason, you should thoroughly familiarize yourself with the contents of this Conditioning Instruction before operating the device. In particular, pay attention to the safety instructions.

This Conditioning Instruction describes how to condition the following BIOM® 5 models:

- BIOM® 5c and 5cl (long version)
- BIOM® 5m and 5ml (long version)

Due to ongoing development, the diagrams shown in the Conditioning Instruction may depict minor changes to the devices delivered.

If you have any questions or would like additional information about your device, please do not hesitate to contact us by phone, mail or fax. Our service team will gladly assist.

OCULUS Optikgeräte GmbH

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1 Safety Instructions

- ➔ Carefully read through the Conditioning Instruction.
- ➔ Keep the Conditioning Instruction in a safe place. You must have access to these during the conditioning process.
- ➔ Observe the legal requirements for accident prevention.
- ➔ Heed the supplementary conditioning information supplied with certain products.

The current version of this manual can be downloaded at www.oculus.de, or you can request a copy from OCULUS Optikgeräte GmbH.

1.1 Used Graphic Symbols

1.1.1 In this Manual



Caution

Denotes a potentially hazardous situation which can easily result in minor physical injury or property damage.



Note

Denotes situations which could result in incorrect findings, denotes user instructions and useful or other important information.



Information

Denotes important information about the product and its use, which require special attention.

1.2 On the Device

Example: Symbols on the BIOM® 5 Sterilization Insert

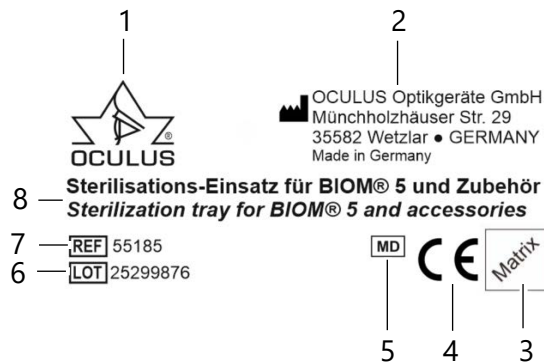


Fig. 1-1: Symbols on the BIOM® 5 Sterilization Insert

No.	Description	No.	Description
1	Manufacturer logo	5	Medical device
2	Name and address of the manufacturer	6	LOT number
3	Machine-readable matrix code	7	Article number
4	CE marking	8	Name of device

1.3 Safety Instructions for Use



Caution

Risk of injury or material damage if the conditioning procedure is done incorrectly
 → Observe the following safety instructions.



Caution

Risk of personal injury or property damage due to equipment modifications that could jeopardize safety
 → The BIOM® 5 Sterilization Insert must not be modified without the manufacturer's permission.

1.3.1 Information about the Conditioning Personnel

→ Ensure that the conditioning is done by duly trained personnel only, who due to their qualifications or knowledge and practical experience, can guarantee proper handling.

1.3.2 Conditioning Information



Caution

Risk of injury if the BIOM[®] 5 is not sterile

If the patient or his bodily fluids come into contact with the BIOM[®] 5, it can become contaminated, e.g. when putting it away.

→ Make sure that the BIOM[®] 5 is cleaned, disinfected and sterilized. Condition the BIOM[®] 5 before the first and every subsequent use.

- Comply with the legal provisions in force in your country, and with the hygiene and waste disposal regulations of the hospital or clinic.
- Condition the BIOM[®] 5 only after you have fully understood this instruction manual.
- The BIOM[®] 5 and all sterilisable components of the BIOM[®] 5 must be cleaned, disinfected and sterilized prior to initial use and prior to every subsequent use. To do so, take the BIOM[®] 5 out of the packaging.
- Make sure that only validated device and product-specific procedures are used for cleaning/disinfection and sterilization and that the validated parameters are observed for each cycle.
- Use a machine (disinfector) for cleaning/disinfection purposes. This is much more effective.

1.3.3 Notes on Returning



Caution

Personal injury caused by contaminated BIOM[®] and components

- Before returning the product to OCULUS: Prepare the BIOM[®] and sterilisable components according to this Conditioning Instruction.
 - Send only visibly prepared OCULUS products back to OCULUS.
-

2 Conditioning Procedure

- Cleaning/Disinfection
 - Dismount BIOM® 5
 - Pre-cleaning
 - Cleaning/disinfection by machine or
 - Manual cleaning/disinfection
- Sterilizing
 - Preparation for sterilization
 - Steam sterilization

2.1 Components of the BIOM® 5 to be Conditioned

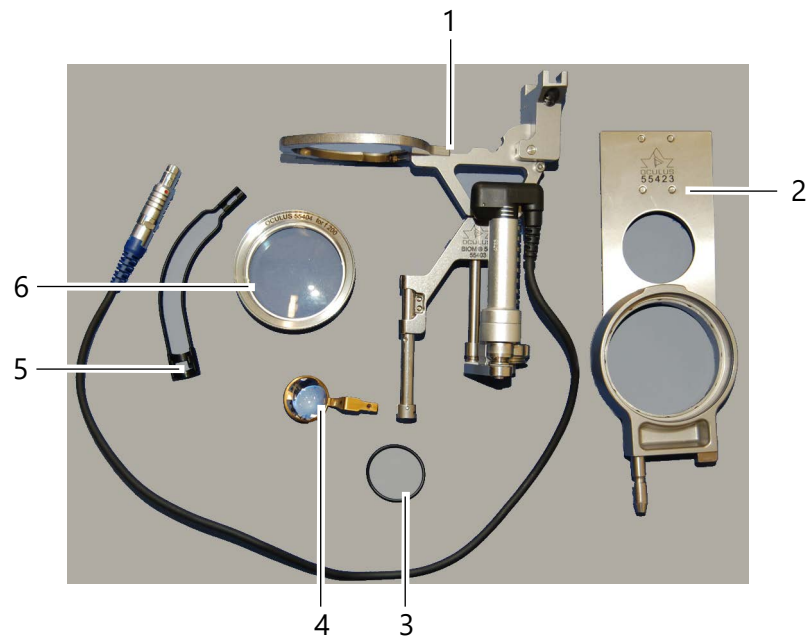


Fig. 2-1: Components of the BIOM® 5cl

No.	Description	No.	Description
1	BIOM® 5cl	4	Ophthalmoscopy magnifying loupe
2	Adapter plate	5	Cable duct
3	Drive belt	6	Reduction lens

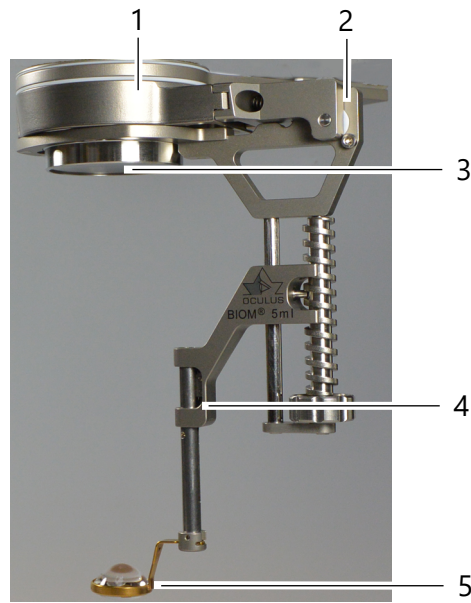


Fig. 2-2: Components of the BIOM® 5ml

No.	Description	No.	Description
1	Adapter plate	4	Safety rod
2	Housing with swivel mechanism	5	Front loupe
3	Reduction lens		

A list of other components that you can condition and other conditioning accessories can be found in → Chapter 6 (page 31).

2.2 Preparation for Cleaning and Disinfection



Recommendation:

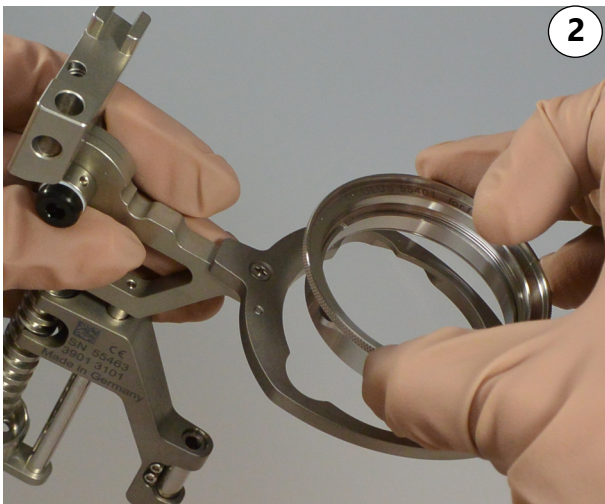
- ➔ Clean or disinfect the BIOM[®] 5 by machine, as this is much more effective.
- ➔ Start pre-conditioning immediately after receiving the equipment in the conditioning station.

2.2.1 Dismount BIOM[®] 5

You must dismount the BIOM[®] 5 before you condition it.

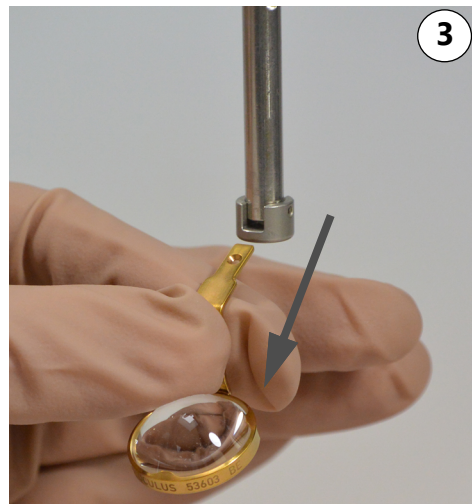


- ➔ Pull the BIOM[®] 5 off the adapter plate. To do so, swing out the BIOM[®] 5



- ➔ Take out the reduction lens and put it down onto the soft pad.

Fig. 2-3: Dismounting the Components



- ➔ Pull off the front loupe and put it down onto the soft pad.

For BIOM® 5c and BIOM® 5cl only:



→ Detach the cable duct from the plug.



→ Take off the drive belt.



1
Before sterilizing, check that the drive module is secure. If it is loose, tighten the Allen screw, 2 mm, at the drive module, or call in your hospital technician.

Fig. 2-4: Remove additional components of the BIOM® 5c or BIOM® 5cl

2.2.2 Pre-Cleaning

Cleaning tools

- Cold water
- Water pistol

Procedure

- Place the BIOM® 5 in cold water for five minutes. The BIOM® 5 must be fully covered.
- Flush the gaps, joints and cavities (the marked locations) for 15 seconds with the water pistol.

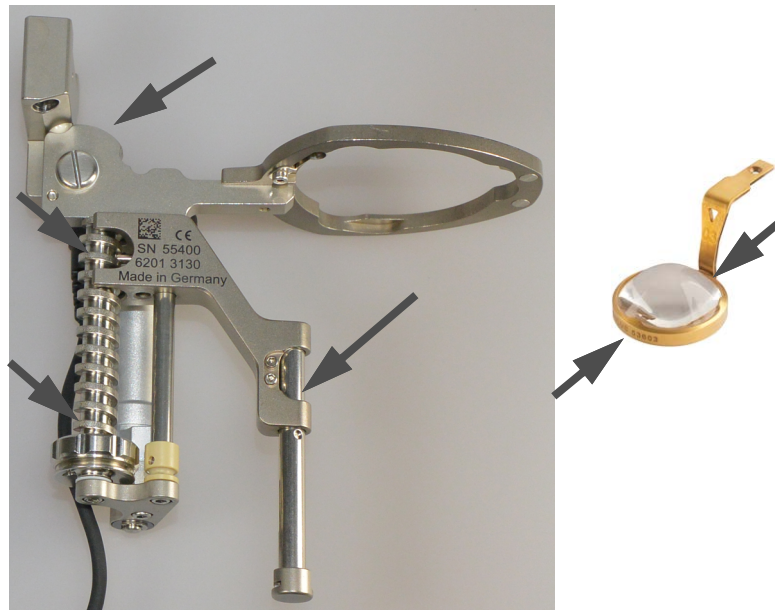


Fig. 2-5: Pre-cleaning

You can now clean the components either by machine → Chapter 2.3 (page 15) or manually → Chapter 2.4 (page 19).

2.3 Cleaning/Disinfection by Machine

2.3.1 Information About Cleaning/Disinfection by Machine

Cleaning/Disinfection Unit (CDU)

→ Make sure that the CDU meets the following criteria.

It must

- have been tested for efficiency (e.g. DGHM I or FDA approval, or CE marking, in conformity with DIN EN ISO 15883-1)
- Use a tested disinfection program (at least 5 minutes at 90°C) for thermal disinfection, as with chemical disinfection, there is a risk of disinfectant residues being left on the products.
The A_0 value = 3000 must be reached.
- Use water of a quality that meets the requirements of DIN EN 285 (including mineralized water with an electrical conductivity of approx. 15 μ S/cm).
- Use air that meets the compressed air requirements in a hospital, for drying purposes.

→ Make sure that the detergent and the disinfectant do not react with each other. Also see → Chapter 7 "Appendix" (page 32).

→ Regularly inspect and service the CDU in accordance with in-house specifications.

Detergents and Disinfectants

→ Make sure that the detergents and disinfectants meet the following criteria.

The detergent (e.g. neodisher MediClean concentration 0.5%, Dr. Weigert, Hamburg) must

- be suitable for cleaning the products.
- be compatible with the disinfectant that is used.
- be listed with the DGHM (German Society for Hygiene and Microbiology)



Note

Risk of malfunctions and surface damage if alkaline detergents are used.

If you use alkaline detergents:

- Properly neutralize after use in accordance with the manufacturer's specifications.
- Check whether the chemicals that are used are compatible with the products. Alkaline detergents can attack the surfaces of the products and lead to malfunctions.

If thermal disinfection (at least 5 minutes at 90°C) is not performed, the disinfectant must:

- Be of a proven efficiency (e.g. have DGHM or FDA approval, or CE marking).
 - Be compatible with the detergent that is used.
- Always adhere to the detergent and disinfectant concentrations specified by the manufacturer.

Cleaning method

The following cleaning method was used for validation of the steam-autoclavability of the BIOM® optics:

See → Chapter 7 (page 32)



Use the cleaning method that meets the requirements of your national standards.

2.3.2 Procedure

- Check whether the components have been pre-cleaned → Chapter 2.2.2 (page 14).
- Place the components of the BIOM® 5 into the disinfectant basket or into a sterilization tray.
- Secure the loupes in the tray with the holders provided for that purpose. Loose loupes could get scratched.
- To ensure that the effectiveness of the cleaning/disinfection is not impaired, make sure that the components do not touch each other.
- Place the disinfectant basket or the sterilization tray with the components in the CDU.
For stackable disinfection baskets or sterilization trays, heed the manufacturer's instructions.
- To prevent water stains on the optics, keep the loupes and reduction lenses as vertical as possible during the cleaning process.

- Start the cleaning program → Chapter 7 (page 32), e.g.:
 - 3 Minute pre-wash cycle with cold water
 - Empty
 - Clean for 5 minutes at 55°C with cleaning detergent
 - Empty
 - 3 Minute rinse cycle with cold, demineralized water
 - Empty
 - 2 Minute rinse cycle with demineralized water
 - Empty
 - At the end of the program: Remove the disinfectant basket or the sterilization tray from the disinfectant.
 - Check whether the BIOM® 5 needs to be dried with compressed air.
-



- Conduct a function test before you sterilize the BIOM® 5 with steam → Chapter 2.6.1 (page 21).
-

For more information about these jobs, refer to → Chapter 7 (page 32).

OCULUS Sterilization Insert

You can use the specially designed Sterilization Insert (OCULUS Art.-No. 55185) for the BIOM® 5 and its accessories.

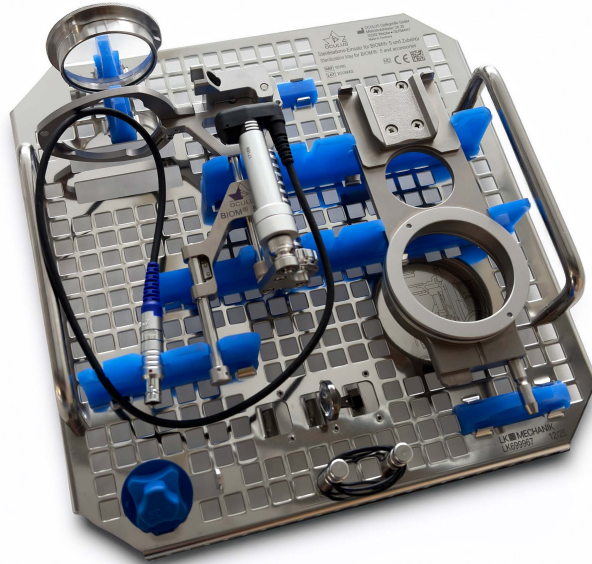


Fig. 2-6: Components of the BIOM® 5 on the Sterilization Insert

Dimensions of the OCULUS Sterilisation Insert	
Width	240mm
Depth	245mm
Height	53mm
Total height, loaded	80mm

One adapter plate, the BIOM® 5, one reduction lens, at least one front loupe, 2 rubber drive belts, sterile cap for the knurled screw, SDI® control knob belong together. These components can be put into the special insert and placed into a suitable sterilization container for sterilization in the steam autoclave.

2.4 Manual Cleaning/Disinfection

The method described below has been validated for manual cleaning/disinfection:



If you clean and disinfect your equipment manually, you must verify your procedure independently and validate it specific to the product and the method.

2.4.1 Cleaning Tools

- Cleaning solution with 0.8% detergent (Cidezyme/Enzol from Johnson & Johnson)
- Water

2.4.2 Procedure



→ Perform a manual disinfection in accordance with the requirements of the VAH or the applicable standards.

- Check that the components have no visible signs of soiling → Chapter 2.2.2 (page 14).
- Place the components in the cleaning solution for 5 minutes at 40 °C. The BIOM[®] 5 must be fully covered.
- Rinse the components for 5 seconds under running water (static pressure 4.2bar).

2.5 Cleaning in an Ultrasonic Bath (optional)



Note

If the fluid in the ultrasonic bath is too dirty, the cleaning effectiveness will be impaired and there is a risk of corrosion. The criterion is a visibly dirty fluid.

→ Change the cleaning solution based on the operating conditions. This must be changed regularly, at least once a day.

- When cleaning with ultrasound, adhere to the soaking times (at least 3 minutes) and concentrations specified by the manufacturer of the cleaning additive.
- Use the quantity of fluid specified by the manufacturer of the ultrasonic bath.
- Heed the following instructions:
 - Insert the BIOM[®] 5 in its unfolded state, with the swivel head of the BIOM[®] 5 at an angle.
 - The loupe holder of the BIOM[®] 5 must be fully pulled out to the stop.

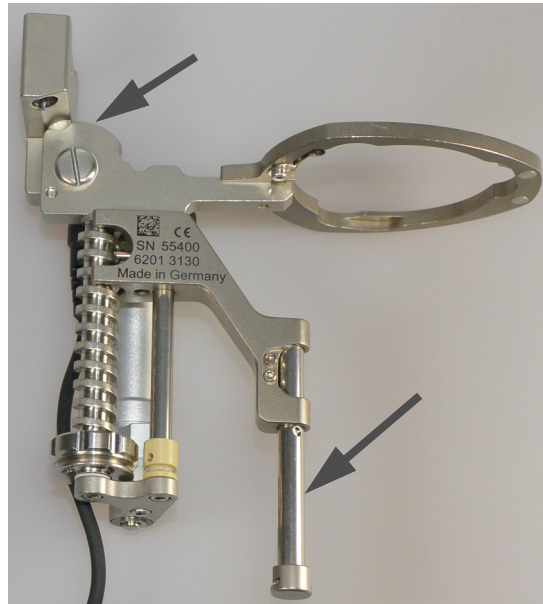


Fig. 2-7: Cleaning in an ultrasonic bath

- The products must always be completely submerged in the cleaning solution
- Place the products on trays only
- To ensure the effectiveness of the ultrasonic bath and to prevent damage to the optics, attach the loupes to specially designed holders.

2.6 Steam Sterilization



Caution

Improper cleaning/disinfection is a health risk.

- After cleaning/disinfecting the components, check whether they are macroscopically clean, i.e. free from visible soiling, corrosion or damage.
- If impurities are found: Clean/disinfect the components again.
- If corrosion or damage is found: Do not use corroded or damaged components again for a surgical procedure.

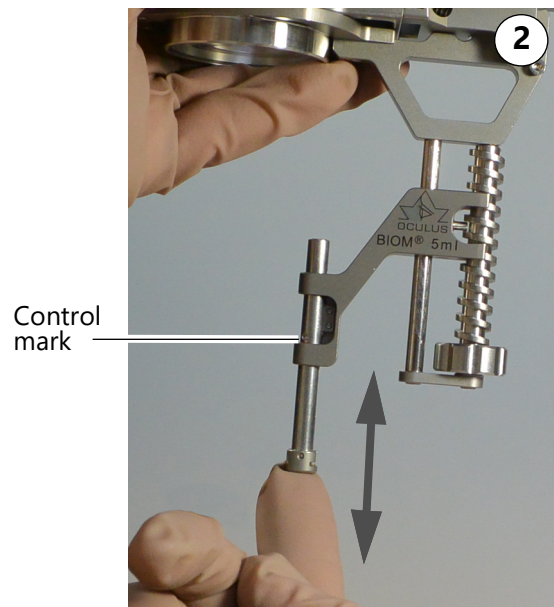
2.6.1 Function Check Prior to Steam Sterilization

You must check the moving parts of the BIOM[®] 5 prior to packaging and steam-sterilizing them to ensure their function.

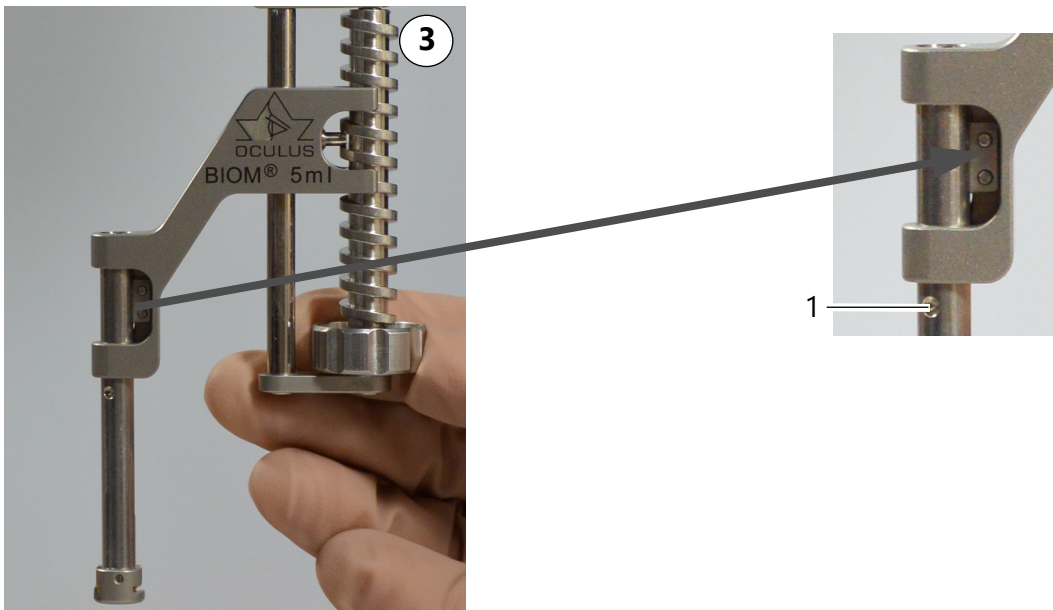
- Check all moving parts of the BIOM[®] 5
- Pay particular attention to the following:
 - Smooth movement of the articulated joint
 - Function of the safety rod of the front loupe
 - Function of the focusing knob



- Flip the BIOM[®] 5 towards the adapter plate. Make sure that the housing body can be shifted without resistance.



- Slide the safety rod of the loupe holder up and down several times to check that it runs smoothly. After the test, the rod must be pulled fully down to the stop.



→ Check that the knob turns easily and shorten the total length until the adjuster is at the uppermost position.

→ Check whether all fastening screws are present (e.g. screws at the feather key of the safety rod). The control mark must be below the guide.

Fig. 2-8: Test the Safety Functions



Caution

Risk of injury if components are damaged

- If a component does not pass the function test, do not use that component for a surgical procedure.
- Send the components to OCULUS Service or an authorized dealer.
Before sending: Clean, disinfect and sterilize the components. Comply with hospital regulations and all applicable national regulations and laws.

2.6.2 Lubrication

If necessary, you can lubricate the moving parts of the BIOM® 5 prior to steam sterilization to guarantee their function.

Materials needed:

- Lint-free cloth
- Silicone-free maintenance substance which is suitable for the steam sterilization



Notes

Risk of malfunctions and surface damage if oils containing silicone or other substances are used

Silicone components can solidify during the subsequent sterilization process (steam sterilization) and cause the instrument to seize up.

- Heed the instructions provided with the maintenance oil.
- Do not use any silicone-based maintenance oils.

If you use substances other than those specified in this manual, you must verify that those substances meet the requirements of DIN EN ISO 17664.

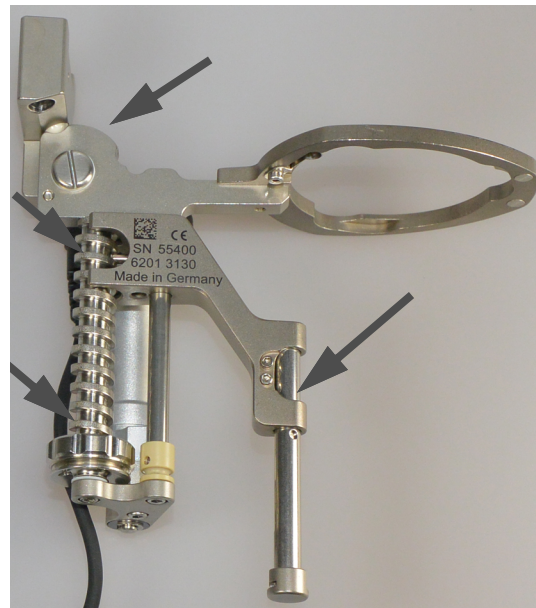


Fig. 2-9: Lubrication

- Lubricate only those locations marked with an arrow.
- Remove any excess maintenance oil with a lint-free cloth.

2.6.3 Packaging

The sterilization container (incl. filter material) must meet the following criteria:

- Compliance with the standards DIN EN 868 / ANSI AAMI ISO 11607
 - Suitable for steam sterilization (heat resistant up to 137°C, adequate steam permeability).
- Prior to sterilization, place the components in a sterilization tray and put this into the sterilization container.

If you use disposable sterilization packages, these must also meet the criteria specified above.

2.6.4 Steam Sterilization

- Make sure that only cleaned and disinfected components are sterilized. The optics can be either be double shrink-wrapped or secured in the sterilization insert from OCULUS Optikgeräte GmbH for autoclaving.
- Use one of the following sterilization processes:

Fractionated Pre-Vacuum Process

- Use a steam sterilizer validated according to DIN EN 13060 or DIN EN 285 and DIN EN 17665-1/GOST R ISO 11134 (valid commissioning and product-specific performance evaluation).

The parameters for this process are as follows:

- 3 Pre-vacuum phases
- Sterilization temperature: 132°C
- Minimum exposure time: 3 minutes
- Drying time: 1 minutes

Gravitation Process:

The minimum parameters for this process are as follows:

- Sterilization temperature: 132°C
 - Minimum exposure time: 15 minutes
 - Drying time: 1 minutes
- Adhere to the specified times and temperatures at minimum. Generally speaking, you may exceed the specified times and temperatures. However, longer sterilization times and higher temperatures increase the stress on the materials, which could cause them to age prematurely. The maximum sterilization temperature is 134°C (plus tolerance in acc. with GOST R ISO 11134).



If, for technical reasons, you use other sterilization processes, shorter sterilization times and lower temperatures, you must validate these.

3 Storage and Disposal

3.1 Storage

- Comply with hospital regulations and the applicable national regulations and laws for storage of the conditioned products.

3.2 Disposal

Prior to disposal:

- Clean, disinfect and sterilize the components. Comply with hospital regulations and all applicable national regulations and laws.

4 Guarantee and Service

Please note the following guarantee provisions:

- Prior to and while operating the device, it is important that you heed the safety instruction.
- BIOM[®] 5 carries a guarantee to which you are entitled in accordance with the legal provisions. This guarantee excludes parts subject to wear, such as the drive module of the BIOM[®] 5 and the drive belts.
The drive module is guaranteed for 100 sterilization cycles, or max. 6 months from the date of purchase.
- All guarantee claims will be rendered null and void, if:
 - The BIOM[®] 5 is tampered with by non-authorized persons. Improper modifications and repairs may result in considerable hazards to users and patients.
 - The recommended cleaning, disinfection and sterilization instructions are not followed.
 - Damage is caused by unauthorized modifications, misuse, or incorrect applications.
- Any transport damage must be reported immediately to the shipping company. Have the transport damage noted on the bill of lading so that complaint handling and compensation of damages can proceed in an orderly manner.
- In general, our Business and Shipping Terms applicable on the date of purchase shall apply.

5 Overview: Permitted Sterilization Method – List of Articles

Article Name	Article No.	Cleaning Method	Approved Sterilization Processes						
			Steam clave	Auto-	STA- TIM 5000S/ G4	Plasma/ STER- RAD® 100S SHORT cycle	Plasma/ STER- RAD® 100NX® Standard cycle	V-Pro® Low Tem- perature Steril- ization System1	
			134 °C (273.2 °F)	132 °C (269.6 °F)	134 °C (273.2° F); 3,5 min				
Cover for sterilization container	10049877	manual, by machine	x	x					
Tray for sterilization container	10049876	manual, by machine	x	x					
Insert for sterilization container	55185	manual, by machine	x	x			x	x	x
Insert for sterilization container	55186				x		x	x	x
BIOM® 5m	55462	manual, by machine	x	x	x		x	x	x
BIOM® 5ml	55463	manual, by machine	x	x	x		x	x	x
BIOM® 5c	55400	manual, by machine	x	x	x		x	x	x
BIOM® 5cl	55403	manual, by machine	x	x	x		x	x	x
Drive module BIOM® 5c/cl	54176	manual, by machine	x	x	x		x	x	x
Cable conduct BIOM® 5	54178	manual, by machine	x	x	x		max. 10 times	max. 10 times	x
Adapter									
Adapter plate	55423	manual, by machine	x	x	x		x	x	x
Adapter plate	55424	manual, by machine	x	x	x		x	x	x

Adapter plate	55426	manual, by machine	x	x	x	x	x	x
Adapter plate	55431	manual, by machine	x	x	x	x	x	x
Adapter plate	55425	manual, by machine	x	x	x	x	x	x
Adapter plate	10007617	manual, by machine	x	x	x	x	x	x

Article Name	Article No.	Cleaning Method	Approved Sterilization Processes				Plasma/ STER-RAD® 100S SHORT cycle	Plasma/ STER-RAD® 100NX® Standard cycle	V-Pro® Low Temperature Sterilization System1
			Steam clave	Auto-	STATIM 5000S/G4				
			134 °C (273.2 °F)	132 °C (269.6 °F)	134 °C (273.2 °F); 3,5 min				
Adapter Accessories									
Sterile cap for knurled screw	54580	manual	x	x	x	x	x	x	
SDI®									
SDI® II e SDI® II m SDI® 3 c SDI® 4m SDI® 4e SDI® 4c	54800 54802 54805 54810 54812 54815 54820 54830 54300 54302 54305 54310 54312 54315 54320 54330 54331 54332	Sterilization not possible Wipe disinfection permitted, as for surgical microscope							
Rubber cap for SDI® II, SDI® 3 and SDI® 4 star knob	54335	manual, by machine	x	x	x	x			

Article Name	Article No.	Cleaning Method	Approved Sterilization Processes					Plasma/STER-RAD® 100NX® Standard cycle	V-Pro® Low Temperature Sterilization System1
			Steam clave	Auto-	STATIM 5000S/G4		Plasma/ STER- RAD® 100S SHORT cycle		
			134 °C (273.2 °F)	132 °C (269.6 °F)	134 °C (273.2 °F); 3,5 min				
Reduction Lenses									
Reduction lens for f = 175 mm on BIOM® 5m/c	55401	manual, by machine	x	x	x	x	x	x	x
Reduction lens for f=200 on BIOM® 5ml/cl	55404	manual, by machine	x	x	x	x	x	x	x
Reduction lens for f=200 on BIOM® 5m/c	55405	manual, by machine	x	x	x	x	x	x	x
Front Lenses for BIOM® 5									
Hi-res macula lens	53606	manual, by machine	x	x	x	x	x	x	x
WiFi-HD mini lens	53605	manual, by machine	x	x	x	x	x	x	x
90 D lens	53604	manual, by machine	x	x	x	x	x	x	x
WiFi-HD lens	53603	manual, by machine	x	x	x	x	x	x	x
Wide-field lens	53602	manual, by machine	x	x	x	x	x	x	x
Mini Wide-Field lens	53601	manual, by machine	x	x	x	x	x	x	x

¹ tested V-Pro® systems (sterilizing agent VAPROX® HC):

V-Pro® 1 Low Temperature Sterilization System

V-Pro® 1 Plus Low Temperature Sterilization System

V-Pro® 1 maX Low Temperature Sterilization System

V-Pro® 60 Low Temperature Sterilization System

6 Consumables and Sterilisable Accessories

Article number	Designation
54335	Sterilisable rubber cap for SDI® II, SDI® 3 and SDI® 4 (pack of 5)
54580	Sterilisable cap for knurled screw (pack of 5)
54176	Sterilisable drive belt (pack of 10)
54178	Cable duct for BIOM® 5c (pack of 5)
55180	Sterilization container with insert for BIOM® 5 and accessories
10049877	Cover for sterilization container for BIOM® 5 and accessories
10049876	Tray for sterilization container for BIOM® 5 and accessories
55185	Insert for the sterilization container for BIOM® 5
54187	Loupe washing holder
55190	Paper filters for sterilization container (100 pcs/box)
01 54538 01 002	Knurled screw M3 for dovetail mount 54511, 54537, 54538, 54552, 54622, 54623, 54121, 54142, 54144, 54622 01 000, 54623 01 000, 54552 01 000
546391	Set of knurled screws (pack of 2) for intermediate plate for Möller microscope



Caution

Personal injury caused by contaminated BIOM® and components

- Before returning the product to OCULUS: Prepare the BIOM® and sterilisable components according to this treatment instructions.
- Send only visibly prepared OCULUS products back to OCULUS.

7 Appendix

Product	All models and accessories of the BIOM® 5. You will find an itemized list in the Conditioning Instruction BIOM® 5	
Notes	<ul style="list-style-type: none"> ■ This guide is only intended to help you with the cleaning, disinfection and sterilization process. For more detailed information, please refer to the Conditioning Instruction for the BIOM® 5. 	<ul style="list-style-type: none"> ■ Other sterilization methods must be validated by the user. ■ Clean or disinfect the BIOM® 5 by machine, as this is much more effective.
Process Instructions	Due to the design of the product and the materials used, a definite limit of the maximum number of conditioning cycles that can be performed cannot be given. The serviceable life of the products depends on their function and the care with which they are handled.	Faulty Products <ul style="list-style-type: none"> ■ Before sending: Clean, disinfect and sterilize the components. Comply with hospital regulations and all applicable national regulations and laws. ■ Send the components to OCULUS Service or an authorized dealer.
Decontamination Preparations	No special measures necessary	
Preparations at the Site of Use	Detach the BIOM® 5 from the microscope	
Preparations at in the conditioning station	Dismantle the BIOM® 5	
Transport and Storage	Safe storage in a closed container and transport of the products to the conditioning location	
Pre-Cleaning	Material: Cold water, water pistol Procedure: <ul style="list-style-type: none"> ■ Place the BIOM® 5 in cold water for five minutes. The BIOM® 5 must be fully covered. ■ Flush out gaps, joints and cavities (the marked locations) for fifteen seconds with the water pistol. 	
Cleaning/Disinfection	Cleaning/disinfection by machine Material: CDU (with therm. disinfection program, 5 minutes at 90°C, for A ₀ value=3000), detergent CDU, cold water, demineralized water Procedure: <ul style="list-style-type: none"> ■ 3 Minute pre-wash cycle with cold water ■ Empty ■ 5 Minute cleaning cycle at 55°C with neodisher Medi-Clean (concentration 0.5%, Dr. Weigert, Hamburg) ■ Empty ■ 3 Minute rinse cycle with cold, demineralized water ■ Empty ■ 2 Minute rinse cycle with demineralized water ■ Empty ■ Check whether the BIOM® 5 needs to be dried off with compressed air 	Manual cleaning/disinfection Material: Cleaning solution with 0.8% detergent (Cidezyme/Enzol from Johnson & Johnson), water Procedure: <ul style="list-style-type: none"> ■ Check that the components have no visible signs of soiling. ■ Place the components in the cleaning solution for 5 minutes at 40°C. The BIOM® 5 must be fully covered. ■ Rinse the components for 5 seconds under running water (static pressure 4.2bar). ■ Optional: Clean in an ultrasonic bath.

Functional test	Check <ul style="list-style-type: none"> ■ Smooth movement of the articulated joint ■ Function of the safety rod of the front loupe. After conducting this check, the control mark must be at position (1) ■ Function of the focusing knob ■ whether all fastening screws are present 	
Transport	Pack the products or the sterilization tray with the components in accordance with standards DIN EN 868 / ANSI AAMI ISO 11607	
Sterilizing	Fractionated Pre-Vacuum Process Material: Validated steam sterilizer, in acc. with DIN EN 13060 or DIN EN 285 and DIN EN 17665-1/GOST R ISO 11134 Parameters: <ul style="list-style-type: none"> ■ 3 Pre-vacuum phases ■ Sterilization temperature: 132°C ■ Minimum exposure time: 3 min ■ Drying time: 1 min 	Gravitation Process: Minimum Parameters: <ul style="list-style-type: none"> ■ Sterilization temperature: 132°C ■ Minimum exposure time: 15 min ■ Drying time: 1 min The maximum sterilization temperature is 134°C (plus tolerance in acc. with GOST R ISO 11134.
Devices and substances validated in studies	Laboratory Washer: Miele G 7735 CD	Detergent: neodisher MediClean (concentration 0.5%, Dr Weigert, Hamburg)

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