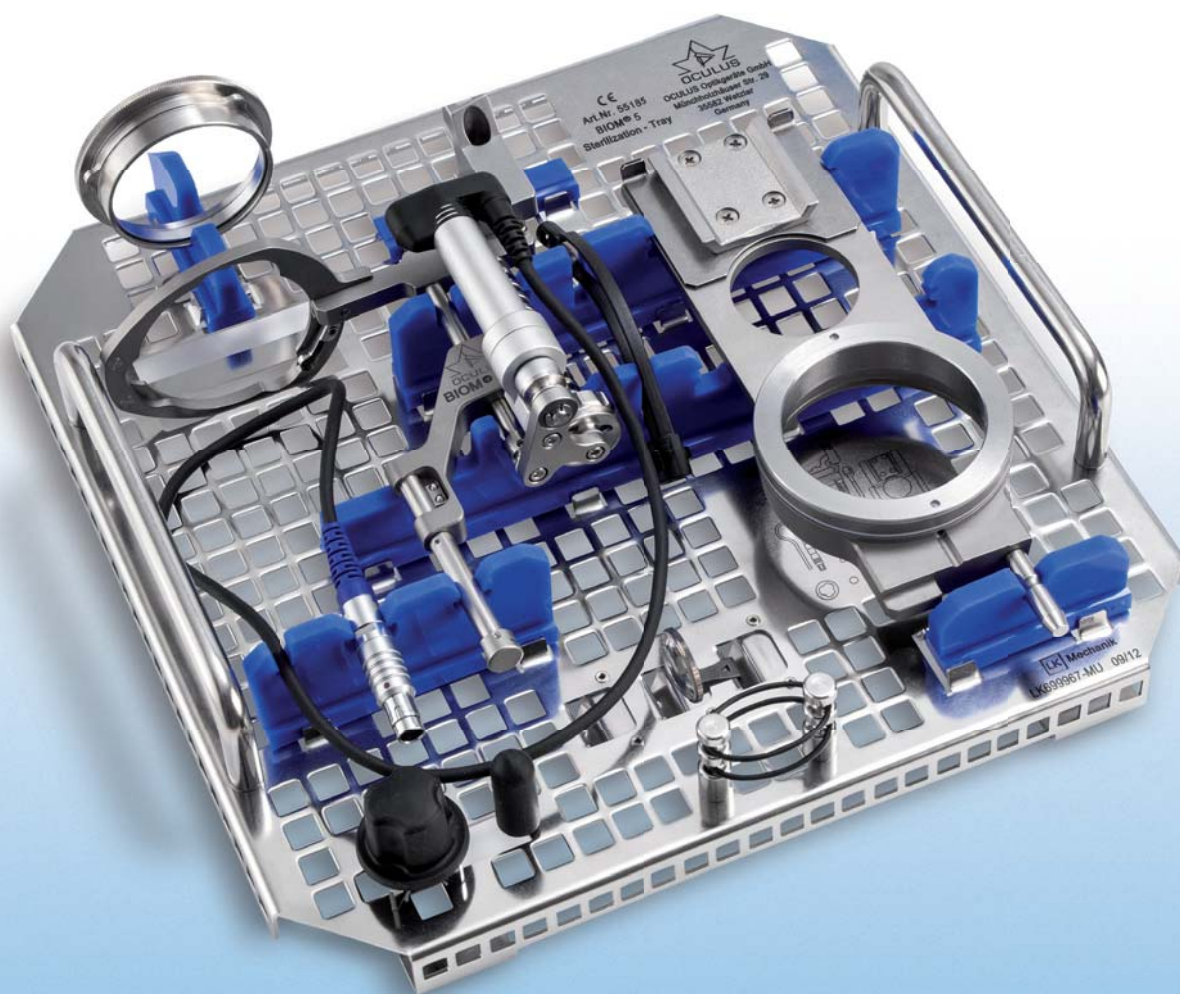


OCULUS | BIOM® 5



CONDITIONING INSTRUCTIONS BIOM® 5 and Accessories

Notes on this Instruction Manual

This instruction manual explains how to condition the BIOM® 5. It is valid for all reusable 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 instruction manual before operating the device. In particular, pay attention to the safety instructions.

This instruction manual 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 instruction manual 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



OCULUS is certified according to DIN EN ISO 13485, setting high standards of quality where development, manufacture, quality assurance and service regarding the entire range of products are concerned.

Table of Contents

1	Applicability.....	1
2	Safety Instructions.....	1
2.1	About this Manual	1
2.1.1	Used Graphic Symbols.....	2
2.2	Safety Instructions for Use	2
3	Conditioning Procedure.....	4
4	Components of the BIOM® 5 to be Conditioned	5
5	Cleaning and Disinfection	6
5.1	Preparation: Dismantle the BIOM® 5	6
5.2	Pre-Cleaning	8
5.3	Cleaning/Disinfection by Machine	9
5.3.1	Information About Cleaning/Disinfection by Machine	9
5.3.2	Cleaning and Disinfecting by Machine.....	10
5.4	Manual Cleaning/Disinfection	13
5.5	Cleaning in an Ultrasonic Bath (Optional)	14
6	Steam Sterilisation	15
6.1	Prior to Steam Sterilisation	15
6.1.1	Function Check Prior to Steam Sterilisation.....	15
6.1.2	Lubrication.....	18
6.1.3	Packaging.....	19
6.2	Steam Sterilisation.....	19
7	Storage.....	20
8	Disposal.....	20
9	Guarantee and Service.....	20
9.1	Manufacturer and Service Address	21
10	Overview: Permitted Sterilisation Method – List of Articles.....	22
11	Consumables and Sterilisable Accessories.....	25
12	Appendix.....	25

1 Applicability

These conditioning instructions explain how to condition the BIOM® 5. They apply for all models and accessories of the BIOM® 5. A list of exactly which these are is given in [sect. 10, page 22](#).

Example: Symbols on the BIOM® 5 sterilisation insert

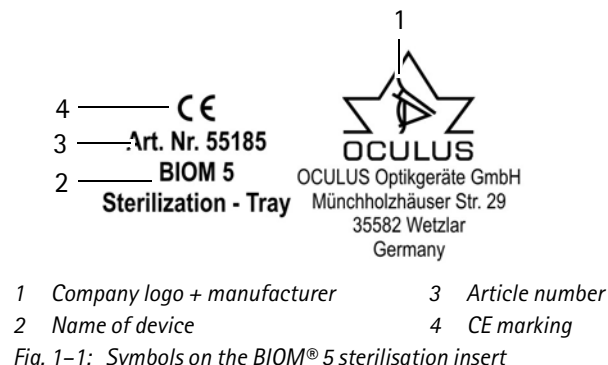


Fig. 1-1: Symbols on the BIOM® 5 sterilisation insert

2 Safety Instructions

2.1 About this Manual

- ➔ Carefully read through the conditioning instructions.
- ➔ Keep the conditioning instructions 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, Wetzlar.

2.1.1 Used Graphic Symbols



Attention

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.



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

2.2 Safety Instructions for Use



Attention

Risk of injury or material damage if the conditioning procedure is done incorrectly

→ Observe the following safety instructions.

Risk of personal injury or property damage due to equipment modifications that could jeopardize safety

→ The BIOM® 5 sterilisation insert must not be modified without the manufacturer's permission.

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.

Conditioning Information



Attention

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 sterilised. 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 sterilised 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 sterilisation and that the validated parameters are observed for each cycle.
- ➔ Use a machine (disinfector) for cleaning/disinfection purposes. This is much more effective.

Notes on returning



Attention

Personal injury caused by contaminated BIOM® and components

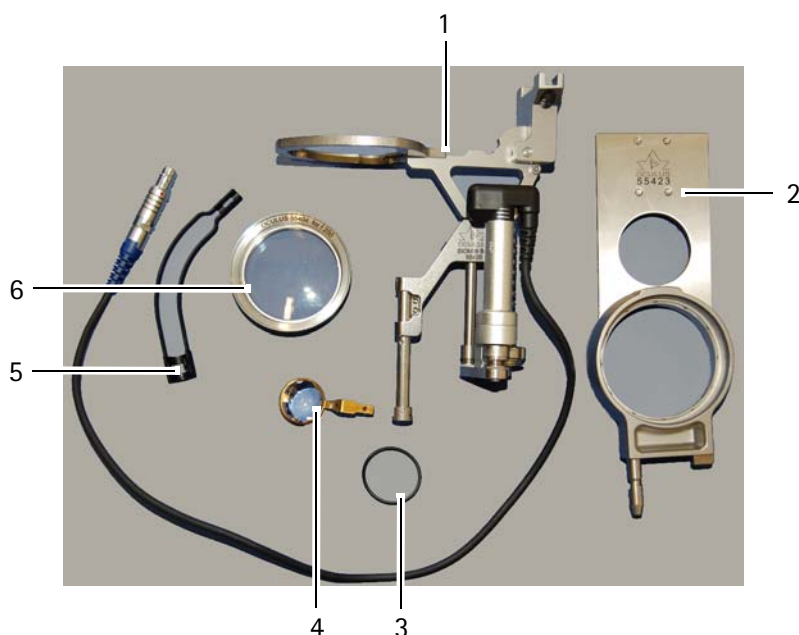
- ➔ Before returning the product to OCULUS: Prepare the BIOM® and sterilisable components according to this treatment instructions.
- ➔ Send only visibly prepared OCULUS products back to OCULUS

3 Conditioning Procedure

- Cleaning/Disinfection
 - Preparation
 - Cleaning/disinfection by machineor
 - Manual cleaning/disinfection
- Sterilising
 - Preparation for sterilisation
 - Steam sterilisation

4 Components of the BIOM® 5 to be Conditioned

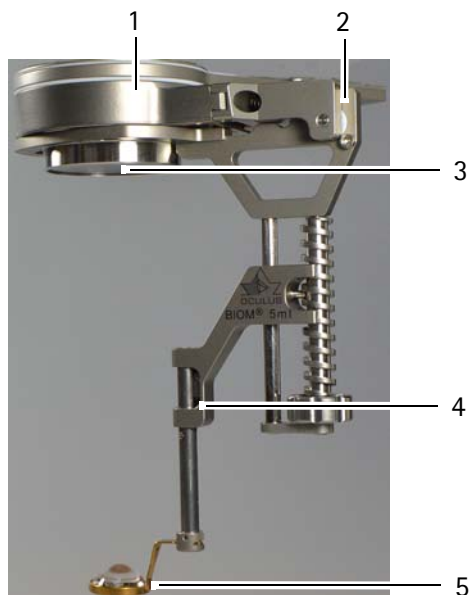
BIOM® 5c/cl



- | | | | |
|---|---------------------------------|---|----------------|
| 1 | BIOM® 5c | 5 | Cable duct |
| 2 | Adaptor plate | 6 | Reduction lens |
| 3 | Drive belt | | |
| 4 | Ophthalmoscopy magnifying loupe | | |

Fig. 4-1: Components of the BIOM® 5c

BIOM® 5m/ml



- | | | | |
|---|-------------------------------|---|-------------|
| 1 | Adaptor plate | 4 | Safety rod |
| 2 | Housing with swivel mechanism | 5 | Front loupe |
| 3 | Reduction lens | | |

Fig. 4-2: Components of the BIOM® 5m

A list of other conditionable components and other conditioning accessories is given in [sect. 11, page 25](#).

5 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.

5.1 Preparation: Dismantle the BIOM® 5

You must dismantle the BIOM® 5 before you condition it.



- Pull the BIOM® 5 off the adaptor plate. To do so, swing out the BIOM® 5



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



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

Fig. 5-1: Dismounting the components

For BIOM® 5c and BIOM® 5cl only:



→ Detach the cable duct from the plug.



→ Take off the drive belt.



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

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

5.2 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.

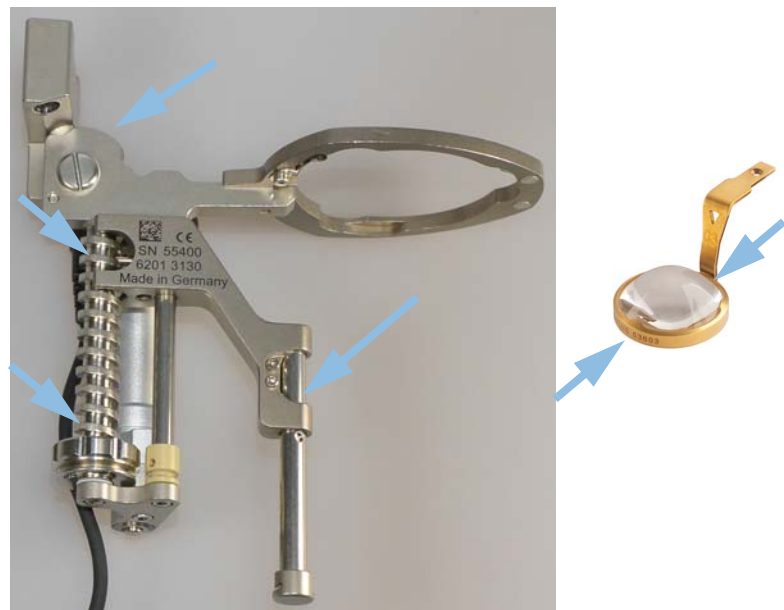


Fig. 5-3: Pre-cleaning

You can now clean the components either by machine ([sect. 5.3, page 9](#)) or manually ([sect. 5.4, page 13](#)).

5.3 Cleaning/Disinfection by Machine

5.3.1 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 programme (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 demineralised water with an electrical conductivity of approx. 15µS/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 *"Appendix" on page 25*

- 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 neutralise 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 [sect. 12, page 25](#)



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

5.3.2 Cleaning and Disinfecting by Machine

- ➔ Check whether the components have been pre-cleaned, [sect. 5.2, page 8](#).
- ➔ Place the components of the BIOM® 5 into the disinfectant basket or into a sterilisation 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 sterilisation tray with the components in the CDU.

For stackable disinfection baskets or sterilisation 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 programme, see [sect. 12, page 25](#), 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, demineralised water
 - Empty
 - 2 Minute rinse cycle with demineralised water
 - Empty
- ➔ At the end of the programme: Remove the disinfectant basket or the sterilisation tray from the disinfectant.
- ➔ Check whether the BIOM® 5 needs to be dried with compressed air.



- ➔ Conduct a function test before you sterilise the BIOM® 5 with steam, [sect. 6.1.1, page 15](#).
-

For more information about these jobs, refer to [sect. 12, page 25](#).

OCULUS Sterilisation Insert

You can use the specially designed sterilisation insert, OCULUS Art. No. 55185 for the BIOM® 5 and its accessories.

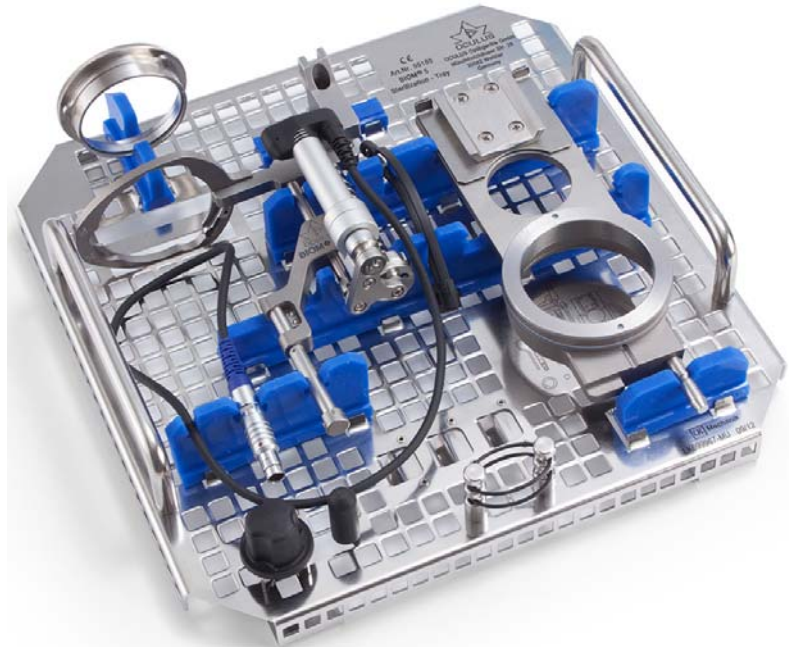


Fig. 5-4: Components of the BIOM® 5 on the sterilisation insert

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

One adaptor 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 sterilisation container for sterilisation in the steam autoclave.

5.4 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.

Cleaning tools

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

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, [sect. 5.2, page 8](#).
- ➔ 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 4.2 bar).

5.5 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

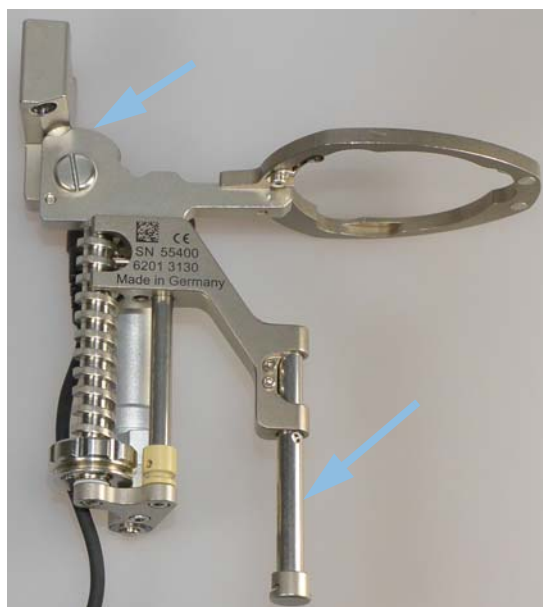


Fig. 5-5: Cleaning in an ultrasonic bath

- 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.

6 Steam Sterilisation

6.1 Prior to Steam Sterilisation



Attention

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.
-

6.1.1 Function Check Prior to Steam Sterilisation

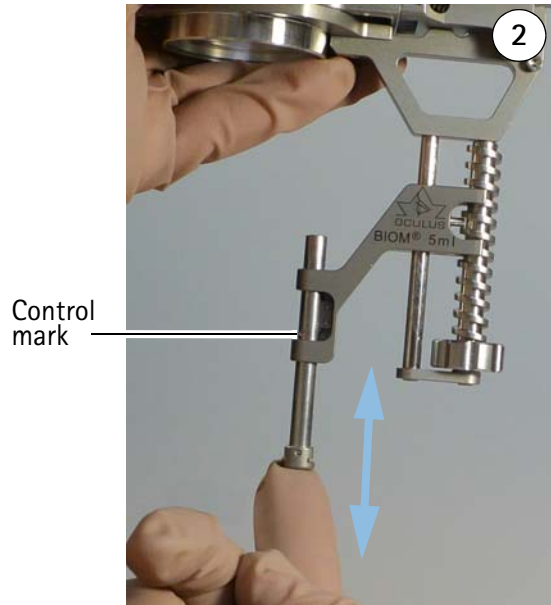
You must check the moving parts of the BIOM® 5 prior to packaging and steam-sterilising them to ensure their function.

- ➔ Check all moving parts of the BIOM® 5.

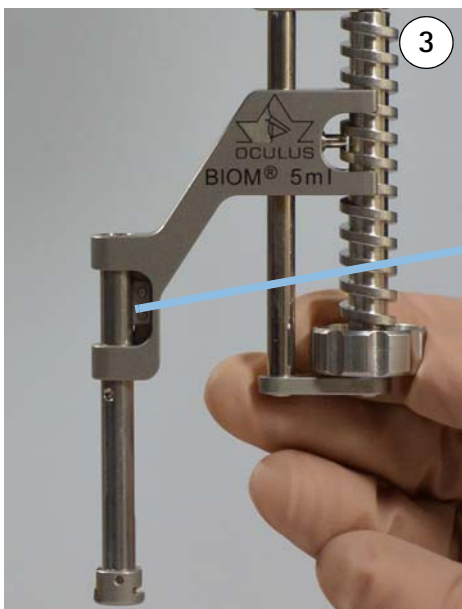
- ➔ Pay particular attention to the following:
 - Smooth movement of the articulated joint
 - Function of the safety rod of the front loupe
 - Function of the focussing knob



- ➔ Flip the BIOM® 5 towards the adaptor plate. Make sure that the housing body can be shifted without resistance.

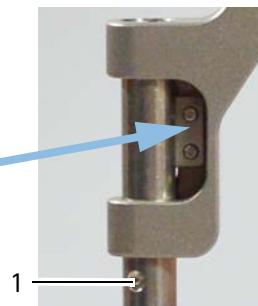


- ➔ Slide the safety rod of the loupe holder up and down several times to check that it runs smoothly. After the test, the rod must be pulled fully down to the stop.



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

Fig. 6-1: Test the safety functions



- ➔ Check whether all fastening screws are present (e.g. screws at the feather key of the safety rod). The control mark (1) must be below the guide.



Attention

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 sterilise the components.
Comply with hospital regulations and all applicable national regulations and laws.

6.1.2 Lubrication

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

Materials needed

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



Notes

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

Silicone components can solidify during the subsequent sterilisation process (steam sterilisation) 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.

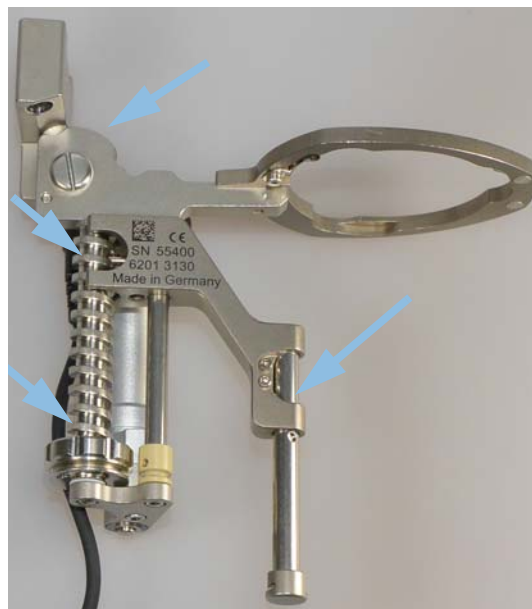


Fig. 6-2: Lubrication

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

6.1.3 Packaging

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

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

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

6.2 Steam Sterilisation

- ➔ Make sure that only cleaned and disinfected components are sterilised.

The optics can be either be double shrink-wrapped or secured in the sterilisation insert from OCULUS Optikgeräte GmbH for autoclaving.

- ➔ Use one of the following sterilisation processes:

Fractionated Pre-Vacuum Process

- ➔ Use a steam steriliser 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
- Sterilisation temperature: 132°C
- Minimum exposure time: 3 min
- Drying time: 1 min

Gravitation Process:

The minimum parameters for this process are as follows:

- Sterilisation temperature: 132°C
- Minimum exposure time: 15 min
- Drying time: 1 min
- ➔ Adhere to the specified times and temperatures at minimum.
Generally speaking, you may exceed the specified times and temperatures. However, longer sterilisation times and higher temperatures increase the stress on the materials, which could cause them to age prematurely.

The maximum sterilisation temperature is 134° (plus tolerance in acc. with GOST R ISO 11134).



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

7 Storage

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

8 Disposal

Prior to disposal:

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

9 Guarantee and Service

Please note the following guarantee provisions:

- Prior to and while operating the device, it is important that you heed the instruction manual and safety instructions.
- The 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 sterilisation 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 sterilisation 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.

9.1 Manufacturer and Service Address

Supplemental information is available from our Service Department or from our authorized representatives. Manufacturer and Service Address:

Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
D 35582 Wetzlar

Germany

Tel.: + 49 (0) 641 2005-0

Fax: +49 (0) 641 2005 - 295

E-mail: sales@oculus.de

www.oculus.de



USA:

OCULUS Surgical, Inc.
562 NW Mercantile Place, Ste. 104
Port St. Lucie, FL 34986, USA

Tel.: +1 772-236-2622 (outside of U.S.)

Tel.: +1 855-SDIBIOM (Toll free in U.S.)

Fax: +1 772-336-1984

E-Mail: info@oculussurgical.com



10 Overview: Permitted Sterilisation Method – List of Articles

Article Name	Article No.	Cleaning Method	Approved Sterilisation Processes			Plasma/ STERRAD® 100S SHORT cycle	Plasma/ STERRAD® 100NX® Standard cycle	V-Pro® Low Temperature Sterilization System ¹
			Steam Autoclave		STATIM 5000S/G4			
			134° C (273.2° F)	132° C (269.6° F)	134° C (273.2° F); 3,5 min			
Sterilisation container	55180	manual, by machine	x	x				
Insert for sterilisation container	55185	manual, by machine	x	x		x	x	x
Insert for sterilisation 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
Antriebsriemen 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

Article Name	Article No.	Cleaning Method	Approved Sterilisation Processes				Plasma/ STERRAD® 100NX® Standard cycle	V-Pro® Low Temperature Sterilization System ¹
			Steam Autoclave		STATIM 5000S/G4	Plasma/ STERRAD® 100S SHORT cycle		
			134° C (273.2° F)	132° C (269.6° F)	134° C (273.2° F); 3,5 min			
Adaptor 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	Sterilisation not possible Wipe disinfection permitted, as for surgical microscope						
	54802							
	54805							
	54810							
	54812							
	54815							
	54820							
	54830							
	54300							
	54302							
	54305							
	54310							
	54312							
	54315							
	54320							
54330								
54331								
54332								
Rubber cap for SDI® II/3 star knob	05090090	manual, by machine	x	x	x	x		
Rubber cap for SDI® 4 star knob	54335	manual, by machine	x	x	x	x		

Article Name	Article No.	Cleaning Method	Approved Sterilisation Processes					Plasma/ STERRAD® 100NX® Standard cycle	V-Pro® Low Temperature Sterilization System ¹
			Steam Autoclave		STATIM 5000S/G4		Plasma/ STERRAD® 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

11 Consumables and Sterilisable Accessories

Article number	Designation
05090090	Sterilisable rubber cap for SDI® II and SDI® 3
54335	Sterilisable rubber cap for 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	Sterilisation container with insert for BIOM® 5 and accessories
55185	Insert for the sterilisation container for BIOM® 5
54187	Loupe washing holder
55190	Paper filters for sterilisation 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



Attention

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

12 Appendix

Product	All models and accessories of the BIOM® 5. You will find an itemized list in the Conditioning Instructions BIOM® 5	
Notes	<ul style="list-style-type: none"> ■ This guide is only intended to help you with the cleaning, disinfection and sterilisation process. For more detailed information, please refer to the Conditioning Instructions for the BIOM® 5 	<ul style="list-style-type: none"> ■ Other sterilisation 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 sterilise 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 programme, 5 minutes at 90°C, for A ₀ value=3000), detergent CDU, cold water, demineralised 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 MediClean (concentration 0.5%, Dr. Weigert, Hamburg) ■ Empty ■ 3 Minute rinse cycle with cold, demineralised water ■ Empty ■ 2 Minute rinse cycle with demineralised 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 4.2 bar). ■ 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 focussing knob■ whether all fastening screws are present	
Transport	Pack the products or the sterilisation tray with the components in accordance with standards DIN EN 868 / ANSI AAMI ISO 11607	
Sterilising	Fractionated Pre-Vacuum Process Material: Validated steam steriliser, 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■ Sterilisation temperature: 132°C■ Minimum exposure time: 3 min■ Drying time: 1 min	Gravitation Process: Minimum Parameters: <ul style="list-style-type: none">■ Sterilisation temperature: 132°C■ Minimum exposure time: 15 min■ Drying time: 1 min The maximum sterilisation temperature is 134° (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

Manufacturer and Service Address

Deutschland:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
D 35582 Wetzlar
Tel.: +49 (0) 641/2005-0
Fax: +49 (0) 641/2005-299
E-Mail: support@oculussurgical.de
www.oculus.de

USA:

OCULUS Surgical, Inc.
562 NW Mercantile Place, Ste. 104
Port St. Lucie, FL 34986, USA
Tel.: +1 772-236-2622 (outside of U.S.)
Tel.: +1 855-SDIBIOM (Toll free in U.S.)
Fax: +1 772-336-1984
E-Mail: info@oculussurgical.com