General instructions for reprocessing

Information about reprocessing of medical devices of Ruck Ophthalmologische Systeme GmbH

According to EN ISO 17664

CE 0123

General instructions for reprocessing – for reusable medical devices

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Abbreviations

CDD	Cleaning- and disinfection device
CJD	Creutzfeldt-Jakob-Disease
EC-Rep	Authorised Representative
KRINKO	Kommission für Krankenhaushygiene und Infektionsprävention
Ruck GmbH	Ruck Ophthalmologische Systeme GmbH
Bytec LM	Bytec Legal Manufacturer GmbH
vCJD	variant Creutzfeldt-Jakob-Disease

1. Introduction

The medical products from Bytec LM, which are distributed by Ruck and are intended for reuse, are placed on the market in non-sterile condition and must always be processed properly before each use. The reprocessing of reusable medical devices that are intended for sterile use generally includes the following individual steps, which we also consider essential to protect patients, users and third parties from possible health risks:

- Preparation
- Cleaning, disinfection and drying
- Maintenance and examination
- Labelling
- Packaging
- Sterilization

However, the responsibility for effective reprocessing lies with the respective reprocessor of the medical devices, considering the information provided by the manufacturer. As part of this responsibility, it should be noted that all reprocessing procedures must be validated. This means that:

- basically, only device- and product-specific validated procedures for cleaning, disinfection and sterilization are used,
- the used equipment is regularly maintained and checked and
- the validated reprocessing parameters are adhered to for each reprocessing cycle.

It should be noted that the person(s) responsible for the reprocessing of the medical devices is(are) knowledgeable in order to carry out a proper and quality-assured reprocessing. In case of any serious incident related to one of the mentioned products occurred, please immediately report to the legal manufacturer and the competent authority of your member state.
With the provision of this general reprocessing instruction according to EN ISO 17664-1, the reprocessor has validated procedures available which enable the reusable products of Ruck to be reprocessed properly. It ensures that safety and performance are guaranteed before the first and every further use.

2. Applicable standards

EN ISO 17664-1, ISO 17664-2.

3. Validity

Tab. 1 Products intended for reprocessing in the appendix describes all products for which this general reprocessing instruction applies.

4. Limitation of reprocessing

Tab. 1 Products intended for reprocessing in the appendix describes the maximum permissible reprocessing cycles for each product.

5. Cautions and warnings

The cautions and warnings are presented as follows:

> ⚠ **CAUTION**
>
> Cautions require special attention and serve to prevent damage to the device. Non-compliance with this warning can lead to damage of property or the environment.
>
> 1

> ⚠ **WARNING**
>
> Warnings have highest importance. They contain warnings about possible physical injuries. Observe without exception.
>
> 2

The following cautions and warnings apply to these reprocessing instructions:

> ⚠ **CAUTION**
>
> Improper handling can damage sensitive products, e.g. the I / A handles or the phaco needles.
>
> R01

> ⚠ **CAUTION**
>
> A sudden cooling phase or cool irrigation fluid can cause stress cracks due to the high temperature difference.
>
> R02

WARNING

The reprocessing of medical devices that are intended for single use is not permitted. A (repeated) reprocessing with subsequent use can lead to risks for patients, users and third parties.

R03

WARNING

Residues of cleaning agents that remain on the product due to improper rinsing can cause serious damage to the patient.

R04

WARNING

Effective sterilization is only possible on dry, cleaned and disinfected products.

R05

WARNING

Exceeding the maximum permissible reprocessing cycles can impair the performance and safety of the medical device and become a risk for patients, users and third parties.

R06

WARNING

Deviations from the reprocessing methods described can both impair the sterilization efficiency and lead to damage to the products.

R07

6. Initial treatment at the place of use

6.1. Clean the used products in accordance to your requirements for occupational health and infection protection immediately after use. Pay particular attention to the following:

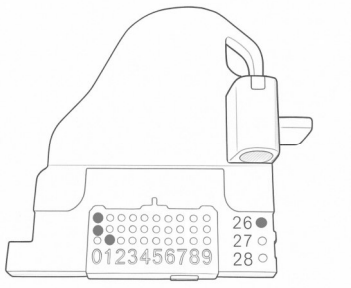
- For initial treatment, generally use water that has at least drinking water quality.
- Separate connected medical devices. Pay attention to the instructions for use, to the information in the relevant chapter of the accessories manual for Qube pro and to *Tab. 1 Products intended for reprocessing* in the appendix (e.g.: phaco handle and phaco needles.).
- If necessary, disassemble products according to the instructions in the relevant chapter in the accessories manual for Qube pro (e.g.: oil infusion unit).
- Remove coarse dirt under running water.
- You can use soft, lint-free cloths or soft brushes as an aid.
- Do not use detergents.
- Do not use metal brushes or steel wool.

6.2. Place the used products properly in suitable closed systems, such as instrument trays or sterile goods containers:

- Be careful not to damage sensitive products (see caution R01).
- Use dry disposal to prevent corrosion and maintain the value of the products.
- Ideally, the transport system is suitable for going through the subsequent process of machine reprocessing.

6.3. Apply the products to the reprocessing unit for medical devices within one hour after use.

6.4. The product 03QA20 has a marking area on the rear side that indicates the year of production and the identification number. This marking is used to identify the side elements during reprocessing.



The lower row of markings contains the numbers 0 to 9. The identification number is determined by drilling holes in the corresponding positions.

Example: Drilled dots at positions "0," "0," and "1" result in the identification number 001. The years are listed to the right of the marking area. The corresponding year of production is indicated by drilling the respective marking point. In the example shown, the marking is set at "26" – the product was manufactured in 2026.

7. Treatment before cleaning

7.1. Carry out an initial treatment of the products used as described under *Initial treatment at the place of use* if not already done.

7.2. Perform an ultrasonic cleaning with the following process parameters:

Detergent:	Dr. Weigert, neodisher MediClean forte
Concentration:	2 %
Duration:	5 Min.
Temperature:	Room temperature
Frequency:	35 kHz

7.3. When loading, make sure that all surfaces can come into contact with the cleaning solution without restrictions.

7.4. After ultrasonic cleaning, rinse the inner lumen of hollow instruments at least once with a 20 ml syringe filled with deionized water (see warning R04).

8. Cleaning and disinfection

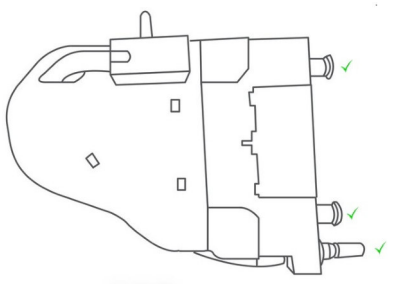
8.1. We recommend using a cleaning and disinfection device (CDD) that complies with the EN ISO 15883 series for machine cleaning.

8.2. When loading the CDD, note that all surfaces can come into contact with the cleaning solution without restrictions.

8.3. Connect all products with inner lumen to the flushing ports by their Luer-connectors and ensure that there are no disconnections during the process:

- There is a risk of carryover of cleaning agent residues if inner lumens are not effectively rinsed (see warning R04).

- Take special care for *03QA20 – Side Element for Cassette Body*. All three Luer-connectors shall be connected to the flushing ports. Ensure that the open end of the tubing system is not connected to establish proper flow.



- Accessories without a Luer-connector (e.g. silicone sleeves) must be secured against disconnection from the flushing port using adapters or other measures.

8.4. Secure small parts that cannot be secured in any other way in special small parts baskets.

8.5. The following procedure has been validated for the proof of machine cleaning and disinfection for reusable products:

CDD		Miele PG 8535
Process step		**Parameter**
Pre-rinse	Duration	1 Min.
	Detergent	Tap water
	Temperature	Cold water inlet
Cleaning	Duration	10 Min.
	Detergent	Dr. Weigert, Neodisher MediClean forte
	Concentration	0,5 %, in tap water
	Temperature	55 °C - 1,5 °C
Neutralization	Duration	1 Min.
	Detergent	Dr. Weigert, Neodisher Z
	Concentration	0,1%, in deionized water
	Temperature	Cold water inlet
Intermediate rinse	Duration	1 Min.
	Detergent	Deionized water
	Temperature	Cold water inlet
Final rinse and thermal disinfection	Duration	5 Min.
	Detergent	Deionized water
	Temperature	90 °C + 1,5 °C

8.6. The steps *Neutralization* and *Intermediate rinse* are very important to prevent alkaline carryover of cleaning agent residues (see warning R04).

8.7. The specified parameters for thermal disinfection correspond to an equivalent A_0 value of 3000 according to EN ISO 15883–1. Higher A_0 values are therefore covered by this validation.

9. Drying

9.1. It is necessary that the products are dried after automatic cleaning and disinfection.

9.2. The following CDD–program has proven itself in practice:

Process step		Parameter
Drying	Duration:	15 Min.
	Temperature:	109 °C ± 1,5 °C

9.3. After machine drying, note the additional information of *Tab. 1 Products intended for reprocessing* in the appendix and carry them out.

9.4. Validation of the drying process is within the responsibility of the operator. Make sure that only dry products are handed over to the following process steps (see warning R05).

10. Maintenance and examination

10.1. Carry out a visual check for the cleanliness and functionality of the products. Pay special attention to clogged inner lumens.
10.2. Use a magnifying glass or a microscope as an aid.
10.3. The criteria for sorting out products are as follows:

- Corroded surfaces.
- Damaged surfaces, cables, silicon tubes or connectors.
- Deformed phaco tips or I/A handles.
- Material degradation

10.4. If a visual inspection reveals that a product is not clean, carry out steps *cleaning, disinfection* and *drying* again.
10.5. Now, if necessary, assemble disassembled products according to the instructions in the relevant chapter in the accessories manual for Qube pro.

11. Packaging

11.1. Before sterilization, the products must be packed in a sterile barrier system suitable for the following sterilization process, storage and transport, which is adapted to the properties of the product. If necessary, with a protective packaging.
11.2. In accordance with EN ISO 11607–1, packaging that meets the following requirements is suitable:

- Enable sterilization.
- Ensurance of sterility when stored correctly.

11.3. The described reprocessing procedure was validated in sterile bags, which consist of a combination of paper and film with a seal in accordance to EN ISO 11607–1.

12. Sterilization

12.1. Please note that only dry, cleaned and disinfected products may be sterilized (see warning R05).

12.2. We expressly recommend the use of a sterilization process according to the standard *EN ISO 17665 – Sterilization of health care products – Moist heat*.

12.3. The following procedure has been validated to demonstrate successful sterilization for reusable products from Ruck:

Steam autoclave	Lautenschläger ZentraCert
Procedure:	Steam sterilization (fractional pre-vacuum process)
Pre-vacuum cycles:	At least 3
Temperature:	134 °C + 1,5 °C
Duration:	3 Min.
Drying time:	-

12.4. The drying time depends on the device used and the load. The operator is responsible for validating the drying time.

12.5. Allow the products to cool down completely at room temperature (see caution R02).

12.6. Exceeded sterilization duration > 3 Min are covered by this validation and do also lead to products that are free from living microorganisms.

13. Storage

13.1. Always store processed products packaged, dry, dust-protected, clean and free of pests.

13.2. The final storage period must be validated by the operator, depending on the packaging used.

14. Transport

14.1. Use suitable means for inner-clinical transport in order not to endanger the integrity of the sterile barrier and the mechanical integrity of the product.

15. Additional information

- All described procedures and recommendations are based on validation by independent, accredited test laboratories.
- Deviations from the described procedure or the cleaning agents used are fundamentally possible but are in the responsibility of the operator and must be validated separately.
- Specified permissible reprocessing cycles are only valid for the described procedure. Deviations may significantly shorten the lifetime of the medical devices
- Since operations in ophthalmology pose a risk with regard to the transmission of the CJD or vCJD, the KRINKO guideline *Hygiene Requirements for the Reprocessing of Medical Devices* recommends a sterilization holding period of **at least 5 minutes at 134 °C** in combination with an alkaline cleaning (see Appendix 7 of the guideline). For all products that are covered by these reprocessing instructions, it has been demonstrated that a sterilization holding time of 5 minutes does not result in any material changes that limit the performance or the safety of the medical device.

16. Contact to legal manufacturers

Sales and Technical Service

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Appendix

Tab. 1 Products intended for reprocessing

Legal manu-facturer	REF	Description	Permissible reproces-sing cycles	Disassembly	Additional information for drying
Med Contact	02BI46	Cable for bipolar diathermy for plastic for-ceps and endothermic pencils	50	See accessories manual	Dry plug with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	02IA21-1	I/A Handle 21 G, Tip angled 45° (with Sleeve)	50	Disassemble sleeve!	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	02IA33-1	I/A Handle 19 G, Tip angled 45° (with Sleeve)	50	Disassemble sleeve!	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	02IA34-1	I/A Handle 19 G, Tip angled 30° (with Sleeve)	50	Disassemble sleeve!	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	02IA36	Bimanual Aspiration Handle 21 G (with sandblasted tip, Ø 0,35 mm)	50	-	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	02IA37	Bimanual Aspiration Handle 21 G (with sandblasted tip, Ø 0,25 mm)	50	-	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	02IA38	Bimanual Irrigation Handle 21 G (with sandblasted tip, two ports Ø 0,5 mm)	50	-	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	02PH58	Phako Wrench 5R (Stainless Steel)	50	-	-
Bytec LM	02OEL10	Oil Injection Unit	50	See accessories manual	-
Bytec LM	02OEL32	Connection Tube for Silicone Oil Injection	50	-	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	03PH55	Phako Tip `Turbo`, 30°, Ø 1,2 mm / Ø 0,7 mm (low bubble)	50	Remove sleeve, unscrew the needle from the handle. At first delivery: Separate phaco tip and phaco wrench.	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar

Legal manu-facturer	REF	Description	Permissible reproces-sing cycles	Disassembly	Additional information for drying
Bytec LM	03PH60	Phako Tip Fragmentation, 30°, 20 G, Ø 0,85 mm / Ø 0,65 mm	50	Remove sleeve, unscrew the needle from the handle. At first delivery: Separate phaco tip and phaco wrench.	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	03PH62	Phako Tip `Turbo`, 30°, 0,89 mm (low bubble)	50	Remove sleeve, unscrew the needle from the handle. At first delivery: Separate phaco tip and phaco wrench.	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	03PH63	Phaco Tip `Mini Turbo`, 30°, (for incision size 1,8 mm)	50	Remove sleeve, unscrew the needle from the handle. At first delivery: Separate phaco tip and phaco wrench.	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	03PH66	Phaco Tip Fragmentation 30°, 23 G, Ø 0,60 mm / Ø 0,50 mm	50	Remove sleeve, unscrew the needle from the handle. At first delivery: Separate phaco tip and phaco wrench.	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar
Bytec LM	03PH90	Test chamber	25	Disassembly from the handle	-
Bytec LM	03PH95	Silicone sleeve light blue, 19 G	25	Disassembly from the handle	-
Bytec LM	03PH96	Silicone sleeve white, 20G	25	Disassembly from the handle	-
Bytec LM	03PH97	Silicone sleeve transparent, 21 G	25	Disassembly from the handle	-
Bytec LM	03PH98	Silicone sleeve orange, 23 G	25	Disassembly from the handle	-
Bytec LM	03QA20	Side Element for Cassette Body	50	Disassemble from Day Cassette System.	Dry inner lumina with filtered compressed air. Do not exceed 2.5 bar