Care and Maintenance for Reusable Microkeratome Accessories

In accordance with ISO 17664-1 and ISO 17664-2

CLEANING, DISINFECTION, STERILIZATION AND MAINTENANCE

This general reprocessing guide applies to MORIA Reusable Microkeratome Accessories used in ophthalmic surgeries for refractive or keratoplasty procedures. Specific, validated reprocessing instructions are enclosed; they include detailed warnings, applicable accessories, and any special limitations or additional instructions.

Deviations from this reprocessing guide are the sole responsibility of the user/facility. This Guide is written in accordance with ISO 17664-1 and ISO 17664-2.

The Reusable Accessories of the MORIA Microkeratome system is intended for performing lamellar resections on the patient's eye or on donor corneal tissue, and consists of:

- Reusable Suction Ring
- Reusable Keratome Metallic Head
- Handpiece (Electrical or Pneumatic), Hose for Pneumatic Handpiece
- Artificial Chamber (AC)
- Guide Ring for Artificial Chamber (AC)
- ALTK Applanating Lenses

MORIA MICROKERATOME	Suction Ring	Keratome Head	Electrical Handpiece	Pneumatic Handpiece & Flexible Hose	Artificial Chamber (AC)	Guide Ring for AC	ALTK Applanating Lenses
OUP SYSTEM	19391/xx[1] 19519/-1 19391/xx/OV[2]	-	19345	-	-	-	-
M2/M2SU SYSTEM	19325/xx[3] 19379/-1	19327/110 19327/130	19326	-	-	-	-
ONE USE ALTK SYSTEM	-	-	-	19155 and 19353	19161 and 19162	19168	-
OUP ALTK SYSTEM	-	-	19175	-		19173	-
CBm ALTK SYTEM	19309/xx[4]	19170/xx[5]	-	19303 and 19353		19171 or 19172	19310, 19311 and 19165, 19166

[1] xx = -1, 0, 1, 2, 3
[2] xx = 1, 2 ,3
[3] xx = -1, 0, 1, 2, 3
[4] xx = - 1, 0, 1, 2
[5] xx = 110, 130, 200, 250, 300, 350, 400

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1. GENERAL INFORMATION

The Reusable Microkeratome Accessories have been specifically designed to ensure optimal performance and safety, provided that the cleaning, disinfection, sterilization, and maintenance instructions are strictly followed in accordance with ISO 17664-1 and ISO 17664-2.

In the event of a malfunction, abnormal wear, or any doubt regarding the proper condition of the device, it is imperative to discontinue its use and have it inspected without delay by MORIA or an authorized representative.

MORIA strongly recommends performing annual maintenance and inspection of all reusable products to maintain their original performance and ensure continued compliance with the microkeratome's initial specifications.

2. CLEANING, DISINFECTION, STERILIZATION and MAINTENANCE

The following sections outline the reprocessing procedures applicable to MORIA Reusable Microkeratome Accessories.

Reprocessing shall be performed by trained personnel in a controlled reprocessing environment (e.g. Central Sterile Services Department), using equipment maintained and qualified according to applicable standards.

As not all accessories are compatible with conventional reprocessing methods (e.g., immersion cleaning or autoclave steam sterilization), MORIA has developed and validated dedicated reprocessing protocols for each accessory category, in compliance with the Spaulding classification:

- Critical devices (contact with sterile tissue):
  - Keratome Metallic Heads
    - Cleaning followed by terminal sterilization is mandatory
- Semi-critical devices (contact with intact mucous membranes):
  - Suction Rings, Artificial Chambers, Guide Rings for Artificial Chambers, Applanating Lenses, Flexible Hoses
    - Cleaning followed by sterilization or high-level disinfection is mandatory
- Non-critical devices (no direct patient contact):
  - Electrical and Pneumatic Handpieces,
    - Cleaning followed by intermediate-level or low-level disinfection, or sterilization is required

For details, refer to **Appendix 1 - Compatibility of Microkeratomes Accessories with Reprocessing Steps**

2.1 Important Information/Recommendations for Use

Reusable devices are not delivered sterile and must be cleaned and sterilized or disinfected before use.



Recommendations for Use:

- Detergent:

  Detergents should be used at the concentration and temperature specified by the detergent manufacturer to ensure optimal cleaning performance.
  Rinsing procedures must be strictly followed to ensure the complete removal of all detergent residues. Inadequate rinsing may result in chemical residues that could adversely affect subsequent processing steps or compromise device integrity.
  Certain alkaline detergents are specifically formulated to be compatible with medical devices. However, users must consult the detergent manufacturer's instructions, limitations, and warnings to verify material It is recommended to use cleaning solutions containing low-foaming detergent agents (enzymatic, non-enzymatic, or alkaline) with a pH range between 6.0 and 8.0.
  compatibility and to identify any components that may be adversely affected by the cleaning agents.
- Water:

  The use of hard water should be avoided. Softened tap water may be used for most rinsing steps; however, purified water should be used for the final rinse to prevent mineral deposits.
- Manual Cleaning Tools:

  Tools required for manual cleaning include surgical scrub brushes, soft low-lint cloths, cotton-tipped applicators, and brushes of various sizes and lengths.
  Do not use abrasive cleaning tools (e.g., scouring pads or metal brushes), as these may reduce precision, cause scratches, or damage metal surfaces.
  Cleaning tools must be cleaned and inspected after each use. The cloth should be clean, lint-free, and replaced frequently. Brushes must be kept clean; worn brushes and disposable cleaning tools should be discarded.

- Disassembling before treatment/cleaning
  All components of the device must be disassembled prior to cleaning. The suction ring, metallic head, artificial chamber, guide ring for the AC, handpiece, flexible hose, and ALTK applanation lenses must each be cleaned separately.
- Warnings:
  - Do not immerse handpieces (electrical or pneumatic) or the flexible hose in water.
  - Do not steam sterilize electrical handpieces or ALTK applanation lenses in an autoclave.
  - To prevent damage to the connectors and ensure proper electrical handpiece function, never pull on the cables or hold the motor by its cable.
  - Do not use abrasive materials or scrapers to clean any device components; use soft brushes instead.

2.2 Initial Treatment at the Point of Use

Cleaning begins at the point of use to prevent soil and contaminants from drying on the devices.

2.2.1 Initial Treatment for Immersible Devices

This procedure applies only to the suction ring, keratome head, artificial chamber, guide ring for the AC, and ALTK applanation lenses.

For detailed instructions, refer to **Appendix 2 - Manual Cleaning Instructions for Immersible Devices** or **Appendix 3 - Automated Cleaning Instructions for Immersible Devices**, depending on the chosen protocol.

2.2.2 Initial Treatment for Non-Immersible Devices

This procedure applies only to the handpiece (electrical or pneumatic) and the flexible hose.

For detailed instructions, refer to **Appendix 4 - Wiping Cleaning Instructions for Non-Immersible Devices**.

2.3 Containment and Transportation

Used devices must be transported to the reprocessing location (Center Sterile Reprocessing) in closed or covered containers to prevent contamination risks.

2.4 Cleaning

2.4.1 Manual Cleaning Instruction for Immersible Devices

This procedure applies only to the suction ring, keratome head, artificial chamber, guide ring for the AC, and ALTK applanation lenses.

For detailed instructions, refer to **Appendix 2 - Manual Cleaning Instructions for Immersible Devices**

2.4.2 Automated Cleaning Instruction for Immersible Devices

This procedure applies only to the suction ring, keratome head.

For detailed instructions, refer to **Appendix 3 - Automated Cleaning Instructions for Immersible Devices**

2.4.3 Wiping Cleaning for Non-Immersible Devices

This procedure applies only to the handpiece (electrical or pneumatic) and the flexible hose.

For detailed instructions, refer to **Appendix 4 - Wiping Cleaning Instructions for Non-Immersible Devices**.

2.5 Inspection and Maintenance

After cleaning and drying:

- Check the general condition of the devices (e.g., no broken parts, free and functional movement).
- Ensure that there is no oxidation or residue.
- Verify that the device remains identifiable (e.g., markings are visible).
- Make sure the device has not been subjected to impact and is free from marks or signs of wear, particularly on parts that come into contact with the patient or medical staff.

Prior to each steam sterilization cycle, it is recommended to lubricate the pneumatic handpiece. Proper lubrication ensures optimal performance and extends the service life of the device.

For detailed instructions, refer to **Appendix 5 - Lubrication Instructions prior to Sterilization**

2.6 Packaging and Storage Between Cleaning and Disinfection or Sterilization

Reusable devices that are stored between cleaning and sterilization or disinfection must be thoroughly dried to prevent microbial contamination that may result from moisture.
Containment devices may be stacked for storage. Store in a clean, dry, and dust-free environment.

For details on packaging for terminally sterilized medical devices and storage boxes, refer to **Appendix 6 - Packaging Instructions for Sterilization and Storage**.

2.7 Disinfection, Sterilization

2.7.1 Sterility Assurance of sterilization processes

When performed according to the validated parameters described in this guide, steam sterilization and VH_2O_2 sterilization achieve a Sterility Assurance Level (SAL) of 10^{-6}, in accordance with applicable international standards.

2.7.2 Steam Sterilization for Autoclavable Devices

This procedure applies only to the suction rings, keratome heads, artificial chambers, guide rings for the AC, pneumatic handpieces, and flexible hoses.

For detailed instructions, refer to **Appendix 7 - Steam Sterilization Instructions for Autoclavable Devices**.

2.7.3 Disinfection for Non-Autoclavable Devices

This procedure applies only to electrical handpieces. The wiping disinfection procedures described achieve intermediate-level disinfection. This kind of procedure is intended only for accessories classified as non-critical and do not replace sterilization.

For detailed instructions, refer to **Appendix 8 - Disinfection Instructions for Non-Autoclavable Devices**

2.7.4 VH_2HO_2 Sterilization for Non-Autoclavable Devices

This procedure applies only to electrical handpieces (except for 19326) and ALTK applanating lenses.

For detailed instructions, refer to **Appendix 9 - VH2O2 Sterilization Instructions for Non-Autoclavable Devices**.

2.8 Storage After Disinfection, Sterilization

Sterile-packaged devices should be stored in a designated, limited-access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

The shelf life depends on the type of sterile barrier employed, the storage method, and the environmental and handling conditions. Each health care facility should define a maximum shelf life for sterilized medical devices prior to use.

2.9 Limitations Reprocessing

MORIA does not specify a maximum number of uses for its reusable devices.

The service life of each device depends on several factors, including the method and duration of use, the procedures performed between uses, and the reprocessing treatments applied. The lifespan is also influenced by wear and potential damage during use, the type of sterile barrier employed, storage conditions, environmental factors, handling, and reprocessing parameters.

When MORIA's recommended reprocessing procedures are properly followed, repeated processing has minimal impact on the integrity and performance of the instruments.

A thorough inspection, followed by a functional test prior to use, is the most reliable method to determine whether a device should be withdrawn from service or sent for repair.

Devices shall be withdrawn from service immediately if any of the following are observed:

- Cracks, deformation, corrosion, or surface damage
- Reduced cutting performance or abnormal mechanical behavior
- Loss of markings or device identification
- Evidence of incomplete cleaning or persistent residue

Improper, ineffective, or insufficient maintenance may shorten the device's service life and will void the instrument warranty.

3. WARRANTY

The warranty covers any malfunction, material damage, or manufacturing defect in products used in accordance with the instructions provided in this leaflet.

This warranty does not affect the application of statutory guarantees under national legislation governing the sale of consumer goods.

Any equipment to be returned must first be cleaned and disinfected or sterilized, then shipped in its original packaging.

3.1 Exclusions

- Any damage resulting from failure to follow the instructions described in this guide.
- Any damage resulting from transport, improper use or negligence, incorrect handling, system modification, inadequate maintenance, or the use of parts or accessories not supplied or recommended by MORIA in this guide.
- Any defect or malfunction of the system occurring outside the warranty period (as defined in the "Warranty Period" section).
- Normal wear and tear.

3.2 Warranty Period

- The warranty takes effect on the date the equipment is shipped.
- The warranty is valid for a period of 12 months from the effective date.
- In addition to the standard one-year warranty, any repairs performed are guaranteed for three months from the date of invoicing.

4. Safety

4.1 Symbols used in this Guide

Symbol	Meaning	Note
	Warning	Improper operation may result in serious injury[1] or death to the user, patient
	Caution	Improper operation may result in bodily injury[2] or property damage

[1]Serious injury means an injury that results in vision loss, causes subsequent complications, or requires hospitalization or long-term outpatient treatment.
[2]Bodily injury means an injury, burn, or similar condition that does not require hospitalization or long-term outpatient treatment.

4.2 Symbols Used on the Device

SYMBOL	MEANING
	Catalogue number
	Batch code
	Serial number
	Quantity
	Manufacturer
	Date of manufacture
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Consult instruction for use or consult electronic instructions for use
	Caution
	Discard in a separate collection bin
	Patient information web site
	Medical device
	CAUTION for USA only: US federal laws restrict this device to sale by, or on the order of, a physician.
	Unique device identifier
	Product compliant with MDD 93/42/CEE or MDR 2017/745

5. Contact

If you encounter any technical problems with our products, please contact MORIA headquarters or your local distributor.

The latest versions of the user manuals and additional information about our systems are available on the MORIA website:

http://www.moria-surgical.com

6. INCIDENTS / ACCIDENTS



IMPORTANT WARNINGS
If any serious incident occurs in relation to the device or its accessories, please contact:
MORIA: correspondant-materiovigilance@moria-int.com
or your Local Distributor
or the Competent Authority of the Member State in which you are located.

7. APPENDICES

7.1 Appendix 1 - Compatibility of Reusable Microkeratome Accessories with Reprocessing Steps

COMPATIBILITY OF MORIA REUSABLE MICROKERATOME ACCESSORIES WITH REPROCESSING STEPS

⚠ Certain MORIA Reusable Microkeratome Accessories may be incompatible with conventional reprocessing methods, such as immersion cleaning or steam sterilization in an autoclave.

MORIA has developed and validated appropriate reprocessing methods for each accessory category, in accordance with the Spaulding classification (Non-Critical, Semi-Critical, and Critical Devices).

7.1.1 General Compatibility

- The Suction Ring, Keratome Head, Artificial Chamber, and Guide Ring are suitable for immersion cleaning.
- The Suction Ring, Keratome Head, Artificial Chamber, Guide Ring, and Pneumatic Handpieces are suitable for steam sterilization in an autoclave.
- Electrical and Pneumatic Handpieces must not be immersed.
- Electrical Handpieces and ALTK Applanating Lenses must not be autoclaved.

7.1.2 Validated Reprocessing Steps by Device Category

Device Type	Validated Reprocessing Steps
Immersible Devices	Manual Cleaning in an Ultrasonic Bath or Automated Cleaning in a Washer-Disinfector
Non-Immersible Devices	Wiping Cleaning
Autoclavable Devices	Steam Sterilization
Non-Autoclavable Devices	Intermediate-Level Wiping Disinfection
Non-Autoclavable Devices	VH_2O_2 (Vaporized Hydrogen Peroxide) Sterilization

7.1.3 Table of Recommended Reprocessing Steps

MORIA Accessories	Manual Cleaning	Automated Cleaning	Wiping Cleaning	Wiping Disinfection	Steam Sterilization	VH202 Sterilization
Suction Ring	**YES**	**YES**	-	-	**YES**	-
Keratome Head	**YES**	**YES**	-	-	**YES**	-
Electrical Handpiece	**NO**	**NO**	**YES**	**YES**	**NO**	**YES**[6]
Pneumatic Turbine and Flexible Hose	**NO**	**NO**	**YES**	-	**YES**	-
Artificial Chamber (Ac)	**YES**	-	-	-	**YES**	-
Guide Ring for AC	**YES**	-	-	-	**YES**	-
ALTK Applanating Lenses	**YES**	-	-	-	**NO**	**YES**

[6] Only for the V-PRO system from STERIS and for handpieces 19345 and 19175

Legend:
YES = Recommended and validated
NO = Not compatible
- = Not applicable

Notes
- All reprocessing procedures must follow validated parameters defined by MORIA in accordance with ISO 17664-1 and ISO 17664-2.
- Only use cleaning and disinfecting agents recommended for ophthalmic surgical instruments.
- Ensure complete drying before assembly or sterilization.
- Regular inspection is required to verify absence of wear, corrosion, or damage.

7.2 Appendix 2 - Manual Cleaning Instructions for Immersible Devices

MANUAL CLEANING FOR IMMERSIBLE DEVICES

APPLICABLE ONLY TO SUCTION RINGS, KERATOME HEADS, ARTIFICIAL CHAMBERS, GUIDE RINGS FOR AC AND ALTK APPLANATING LENSES.

Accessories	MORIA References
Suction Ring	19391/xx, 19519/-1,19391/xx/OV, 19325/xx, 19379/-1, 19309/xx
Keratome Head	19327/xx, 19170/xx
Artificial Chamber	19161, 19162
Guide Ring for AC	19168, 19173, 19171, 19172
ALTK Applanating Lenses	19310, 19311, 19165, 19166

7.2.1 Initial Treatment for Immersible Devices

Keep the devices moistened after use and before cleaning.

1. Disassemble the devices
2. Immerse the devices in the cleaning solution[1] for at least 20 min within 30 min after surgery.

7.2.2 Cleaning for Immersible Devices

Pre-cleaning

1. Rinse with cold tap water (<30°C) for at least 30 seconds[2].
2. Immerse the device in the cleaning solution[1] (30-40°C) for at least 15 min to moisten and loosen soil.
3. Scrub all device surfaces with the cleaning solution using a soft cleaning brush, taking care not to damage the device, until all visible soil has been removed.
4. For devices with lumen: flush the cleaning solution through the lumen[3] five times, then flush with cold tap water (<30°C) [3] five additional times.
5. Rinse with cold tap water[2] (<30°C) for at least 30 seconds.

Manual Cleaning

1. Immerse the device in the cleaning solution[1] (30-40°C) and sonicate for at least 10 min in an ultrasonic bath.
2. Rinse with cold tap water[2] (<30°C) for at least 30 seconds.
3. For devices with lumen: flush demineralized water (30-40°C) through the lumen[3] five times.
4. Immerse in demineralized water (30-40°C) for at least 5min.
5. For devices with lumen: flush 70° alcohol through the lumen[3] five times.
6. Wipe and dry with filtered air.

[1]Refer to manufacturer's detergent recommendation of use regarding concentration, T°.
[2]Expose all surfaces and cavities to flowing water.
[3]Use a 5mL syringe to flush through the lumen.

Manual Cleaning Validation Study Information:

- Detergent Neodisher Mediclean Forte at 0.5% solutions (Dr Weigert, Hamburg, Germany) were used during the cleaning process validation.
- Trial Report reference: CLE_002

7.3 Appendix 3 - Automated Cleaning Instructions for Immersible Devices

AUTOMATED CLEANING FOR IMMERSIBLE DEVICES

APPLICABLE ONLY TO SUCTION RINGS AND KERATOME HEADS.

Accessories	MORIA References
Suction Ring	19391/xx, 19519/-1,19391/xx/OV, 19325/xx, 19379/-1, 19309/xx
Keratome Head	19327/xx, 19170/xx

7.3.1 Initial Treatment

Keep the devices moistened after use and before cleaning.

1. Disassemble the devices
2. Immerse the devices in the cleaning solution[1] for at least 20 min within 30 min after surgery.

7.3.2 Cleaning

Pre-cleaning

1. Rinse with cold tap water (<30°C) for at least 30 seconds[2].
2. Immerse the device in the cleaning solution[1] (30-40°C) for at least 15 min to moisten and loosen soil.
3. Scrub all device surfaces with the cleaning solution using a soft cleaning brush, taking care not to damage the device, until all visible soil has been removed.
4. For devices with lumen: flush the cleaning solution through the lumen[3] five times, then flush with cold tap water (<30°C) [3] five additional times.
5. Rinse with cold tap water[2] (<30°C) for at least 30 seconds.

Automated Cleaning (Washer-disinfector)[4]

1. Pre-cleaning with cold water (<30°C) for at least 2 minutes.
2. Cleaning with cleaning solution[1] (40-60°C) for at least 5 minutes.
3. First rinse with hot water (40-60°C) for at least 2 minutes.
4. Second rinse with cold water (<30°C) for at least 1 minute.
5. Final rinse with demineralized/osmosis water (90°C) for at least 3 minutes.
6. Thermal disinfection cycle (90°C) for at least 5 minutes.
7. Drying (110-120°C) for at least 20 minutes.

[1]Refer to manufacturer's detergent recommendation of use regarding concentration, T°.
[2]Expose all surfaces and cavities to flowing water.
[3]Use a 5mL syringe to flush through the lumen.
[4]For instrument with lumen, connect to washer-disinfector if possible – if not possible, after washer cycle: flush demineralized water through lumen (30 to 40°C, 5 times), then wipe and dry with micro- filtered compressed air

Automated Cleaning Validation Study Information:

- Detergent Neodisher Mediclean Forte at 0.5% solutions (Dr Weigert, Hamburg, Germany) were used during the cleaning process validation.
- Automatic cleaning process validation had been performed with DS 500 SLC Washer Disinfector from Steelco (Miele group member)
- Trial Report reference: CLE_001

7.4 Appendix 4 - Wiping Cleaning Instructions for Non-Immersible Devices

WIPING CLEANING FOR NON-IMMERSIBLE DEVICES

APPLICABLE ONLY TO ELECTRICAL HANDPIECES, PNEUMATIC HANDPIECES AND FLEXIBLE HOSES.

Accessories	MORIA References
Electrical handpiece	19175, 19345, 19326
Pneumatic handpiece	19155, 19303
Flexible hose	19353

7.4.1 Initial Treatment for Not Immersible Devices

1. Wipe the entire device[4] with a lint-free surgical wipe moistened with the cleaning solution[1,2].
2. Wipe the entire device[4] with a lint-free surgical wipe moistened with distilled water[2].

7.4.2 Cleaning for Not Immersible Devices

1. Spray the cleaning solution[1] on the entire device[4] until all parts are thoroughly wet.
2. Wipe the entire device[4] with a lint-free surgical wipe moistened with the cleaning solution[1,2] until soil and organic matter have been visibly removed.
3. For electrical handpieces: rinse the screw core of the motor with a brush[5] moistened with distilled water (see Figure 1).
4. Wipe the entire device[4] with a lint-free surgical wipe moistened with distilled water[2]
5. Dry carefully with a lint-free surgical wipe[3] then with clean, filtered, compressed air.

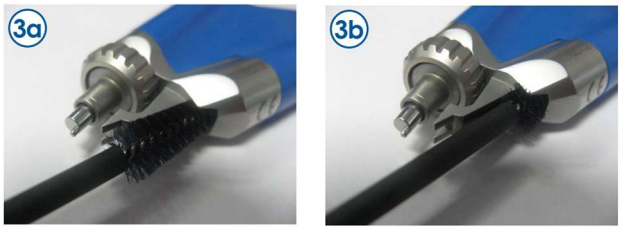


Figure 1: Rinsing of the screw core with a brush[5]

[1]Refer to manufacturer's detergent recommendation of use.
[2]Replace the wipe when it becomes dry.
[3]Replace the wipe when it becomes too wet.
[4]For handpieces: including metallic parts and cable.
[5]Use MORIA disposable brush 19149X25.

Wiping Cleaning Validation Study Information:

- CaviCide spray and CaviWipes wipes (cleaning and disinfection products from Metrex) were used during the wiping cleaning validation.
- Trial Report reference: CLE_003

7.5 Appendix 5 - Lubrication Instructions prior to Sterilization

LUBRICATION PRIOR TO STERILIZATION

APPLICABLE ONLY TO PNEUMATIC HANDPIECES.

Accessories	MORIA References
Pneumatic Handpiece	19155, 19303

Pneumatic handpieces must be lubricated before each steam sterilization cycle using an appropriate lubrication spray and nozzle[1,2].

1. Insert the tip nozzle into the smaller of the two large tubes (see Figure 2), which is the air intake hole, and always hold the spray can in an upright position.
2. Cover the larger of the two air tubes (the air exhaust hole) and the turbine head with a clean tissue (see Figure 3), then spray for 1 second[3].
3. Keep the pneumatic handpiece in an upside-down position for 2 min (see Figure 4) prior to steam sterilization to allow excess lubricant to drain onto a lint-free cloth.



Figure 2

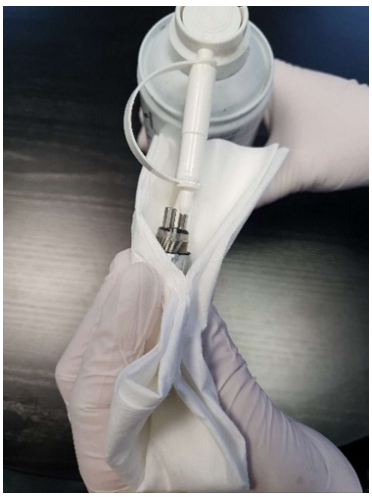


Figure 3



Figure 4

[1]The use of KaVo lubrication spray is recommended.
[2]Refer to the manufacturer's instructions for proper spray application..
[3]A single burst of KaVo spray is sufficient to lubricate the turbine while preventing excess lubricant inside the mechanism.

7.6 Appendix 6 - Packaging Instructions for Sterilization and Storage Box

PACKAGING FOR STERILIZATION AND STORAGE

Accessories	Sterilization Tray MORIA References	Storage Box MORIA References
Suction Ring	22519513[1], 25519330[1], 2519343[1]	-
Keratome Head	25519330[1], 2519343[1]	-
Artificial Chamber	22519167[1]	-
Guide Ring for AC	22519167[1]	-
Pneumatic Handpiece and Hose	22519139[1]	-
Electrical Handpiece	STERIS tray[3] only for 19345, 19175	22519514[2], 22519331[2], 22519174[2]
ALTK Applanating Lenses	STERIS tray[3]	22519169[2]

7.6.1 General Information

The packaging for terminally sterilized medical devices should meet the following requirements:

- be suitable for steam sterilization and comply with EN ISO 11607-1
- provide adequate protection for both the devices and the sterilization packaging against mechanical damage.

Packaging of devices in tray:

- The set of devices shall be placed in dedicated MORIA sterilization trays or cases to ensure adequate protection of the instruments. Trays or cases with lids shall be wrapped in a standard medical-grade steam sterilization wrap, using the AAMI double-wrap method or an equivalent validated process.
- A rigid container system may also be used for sterilization, provided it is validated for the intended sterilization method.

Packaging of devices individually:

- Medical-grade steam sterilization pouches of appropriate sizes shall be used to double-package individual devices. The inner pouch shall be sufficiently large to contain the instrument without stressing the seals or tearing the material, yet small enough to fit within a secondary pouch without compromising the integrity of the overall package.

7.6.2 List of Dedicated Packaging per System

Accessories	OUP system	M2/M2SU system	ONE USE ALTK SYSTEM	OUP ALTK SYSTEM	CBm ALTK SYTEM
Suction Ring	22519513[1]	25519330[1]	-	-	22519343[1]
Keratome Head	-		-	-	
Electrical Handpiece	22519514[2] STERIS tray[3]	22519931[2]	-	22519174[2] STERIS tray[3]	-
Pneumatic Handpiece and Flexible Hose	-	-	22519139[1]	-	22519139[1]
Artificial Chamber (AC)	-	-	22519167[1]		
Guide Ring for AC	-	-			
ALTK Applanating Lenses	-	-	-	-	22519169[2] STERIS tray[3]

[1]Steam sterilization tray
[2]Storage box for non-autoclavable devices - do not use for sterilization.
[3]VH_2O_2 sterilization tray: VP004 or P0033 from STERIS - do not use an aluminum tray.

7.7 Appendix 7 - Steam Sterilization Instructions for Autoclavable Devices

STEAM STERILIZATION FOR AUTOCLAVABLE DEVICES

APPLICABLE ONLY TO SUCTION RINGS, KERATOME HEADS, PNEUMATIC HANDPIECES, FLEXIBLE HOSES, ARTIFICIAL CHAMBERS AND GUIDE RINGS FOR AC.

Accessories	MORIA References
Suction Ring	19391/xx, 19519/-1,19391/xx/OV, 19325/xx, 19379/-1, 19309/xx
Keratome Head	19327/xx, 19170/xx
Pneumatic Handpiece	19155, 19303
Flexible Hose	19353
Artificial Chamber	19161, 19162
Guide Ring for AC	19168, 19173, 19171, 19172

- Steam autoclave sterilization using a pre-vacuum (forced air removal) cycle is recommended by MORIA for reusable devices. The minimum sterilization parameters are provided in the table below.
- The sterilizer manufacturer's recommendations shall always be followed. When sterilizing multiple devices set in a single cycle, ensure that the maximum load specified by the manufacturer is not exceeded.
- Device sets shall be properly prepared and packaged in trays and/or cases that allow adequate steam penetration and direct contact with all device surfaces.
- The devices and/or device trays shall undergo a complete sterilization drying cycle, as residual moisture from autoclaves may lead to staining, discoloration, or corrosion.

Steam Sterilization Cycle	Preparation	Exposure Time	Temperature[5]	Minimum Drying Time, in Room Chamber [6]
Pre-vaccum[1] [2]	Double-wrapped	18 min	134°C / 273°F	30 min
Pre-vacuum (UK)[3]	Double-wrapped	3 min	134°C / 273°F	30 min
Pre-vacuum (USA)[4]	Double-wrapped	4 min	132°C / 270°F	30 min

- Gravity displacement sterilization cycles are not recommended, as the required cycle times are excessively long and not suitable for devices with lumens.
- Flash (immediate-use) steam sterilization in unwrapped packaging and without the recommended drying time, with exposure at 132-134 °C (270-273 °F) for the times listed in the table, should be used only in emergency situations. Devices must be thoroughly cleaned and disassembled prior to sterilization.

[1]Recommended by the World Health Organization (WHO) and the French Ministry of Health (Guide DGS/RI3/2011/449 - December 2011) regarding the risk of TSE/CJD contamination.
[2]Germany: The Robert Koch Institute (RKI) recommends 134 °C (273 °F) for 5 minutes, extended to 18 minutes if an alkaline detergent was not used during cleaning, due to TSE/CJD contamination risks.
[3]Local or national specifications shall be followed where steam sterilization requirements are stricter or more conservative than those listed in the table.
[4]United States only: per ANSI/AAMI ST79.
[5]The sterilization temperature shall not exceed 140 °C (284 °F).
[6]Use the autoclave drying cycle to prevent oxidation or corrosion of devices.

Sterilization Validation Study Information:

- Devices packaged in dedicated MORIA trays, and wrapped using the double-wrapping method according to AAMI standards
- Trial Report reference: STE_002

WIPING DISINFECTION FOR NON-AUTOCLAVABLE DEVICES

APPLICABLE ONLY TO ELECTRICAL HANDPIECES.

Accessories	MORIA References
Electrical Handpiece	19175, 19345, 19326

1. Spray the disinfection solution[1] on the entire device (including metallic parts and cable) until all parts are thoroughly wet. Allow the solution to act for 3 minutes (see Figure 5 for handpieces).
2. Wipe the entire device (including metallic parts and cable) with a lint-free surgical wipe moistened with the disinfection solution[1,2] for at least 1 minute. Repeat the process 2 more times using new moistened wipes (see Figure 6 for handpieces).
3. Wrap the device with a new wipe moistened with disinfection solution[1] and allow it to act for 3 minutes. Repeat the process 3 more times using new moistened wipes to ensure a total wet contact time of 12 minutes
4. Wipe the entire device (including metallic parts and cable) with a lint-free surgical wipe moistened with distilled water[2]. Repeat the process 2 more times using new moistened wipes.
5. Dry carefully with a lint-free surgical wipe[3], then with clean, filtered, compressed air.



Figure 5: Application of cleaning and disinfection spray



Figure 6: Wiping with the cleaning and disinfection product, with emphasis on the metallic parts

[1]Refer to manufacturer's disinfectant recommendation of use.
[2]Replace the wipe when it becomes dry.
[3]Replace the wipe when it becomes wet.

Wiping Disinfection Validation Study Information:

- CaviCide spray and CaviWipes wipes (cleaning and disinfection products from Metrex) were used during the wiping disinfection validation.
- Trial Report reference: DIS_001

7.9 Appendix 9 - VH_2O_2 Sterilization Instructions for Non-Autoclavable Devices

VH_2O_2 STERILIZATION FOR NON-AUTOCLAVABLE DEVICES

APPLICABLE ONLY TO ELECTRICAL HANDPIECES AND ALTK APPLANATOR LENSES.

Accessories	MORIA References
Electrical Handpiece[1]	19175, 19345
ALTK Applanating Lenses	19310, 19311, 19165, 19166

The listed Electrical Handpieces[1] and ALTK Applanator Lenses are compatible with the low-temperature hydrogen peroxide (VH_2O_2) sterilization[2] using the V-PRO System from STERIS[3]

[1]Excluding 19326
[2]Do not use trays made of aluminum or the dedicated handpiece storage box. Aluminum is not compatible with VH_2O_2 sterilization. The dedicated storage boxes are not perforated.
[3]Sterilizers V-PRO max, V-PRO max2, V-PRO 60, V-PRO s2 - compatible with the Lumen, Non-Lumen and Flexible cycles

Hydrogen Peroxide Sterilization Validation Study Information:

- Devices packaged in STERIS trays VP004 and VP0033, and wrapped using the double-wrapping method according to AAMI standards
- Trial Report reference: STE_003

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