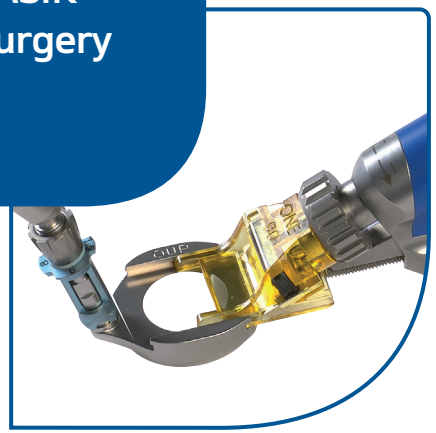
#65096

One Use-*Plus* & Epi-K™

Operator's Cleaning-Disinfection-Sterilization-Storage Instructions

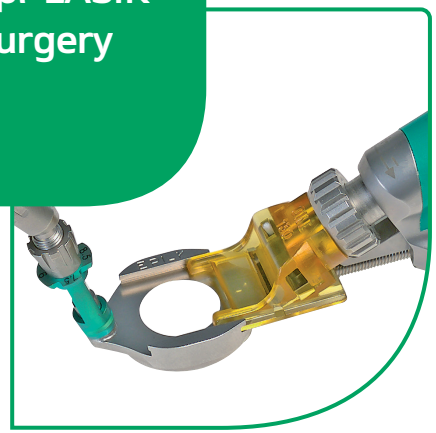
Extract from Epi-K™ user manual (#65043), One Use-*Plus* user manual (#65040) and One Use-*Plus* handpiece for Artificial Chamber addendum (#65106).

LASIK Surgery



One Use-*Plus* handpiece (#19345)

Epi-LASIK Surgery



Epi-K™ handpiece (#19342)

Keratoplasty

One Use-*Plus* handpiece for Artificial Chamber (#19175)

The following are only recommendations. They must be adapted according to the laws in the country of utilization.
All the products and solutions for cleaning and disinfection must be used according to the manufacturer's instructions.
The recommendations for cleaning, disinfection and sterilization are updated and available on MORIA's website: http://www.moria-surgical.com

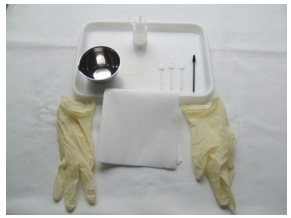
MORIA recommends to:

- avoid touching potentially contaminated areas,
- use gloves when performing cleaning and decontamination tasks,
- have at least two handpieces,
- switch handpiece between every patient/procedure.

I) CHECK-LIST

Cleaning Products:
- Moria disposable brush (#19149)
- Soft brush
- Cup
- Lint-free surgical wipes
- Gloves

Solutions:
- Cleaning solution
- Aldehyde-free detergent/disinfectant solution (e.g.: Alkazyme®, Alkapharm Laboratories)
- Filtered distilled or osmosis-treated water
- Clean, filtered compressed air (medical compressed air)
- Soda solution (1 N)



II) CLEANING-DISINFECTION-STORAGE OF THE HANDPIECE AND ELECTRICAL CABLE

Step 1: Disassembly

① Carefully disassemble keratome parts. Use Moria wrench if head is too tightly screwed on the handpiece.

② Discard the disposable head and aspiration tubing after each procedure in an appropriate container.

⚠ ***Warning:***
The reuse of single-use products, or the use of consumables other than those supplied by MORIA, may entail serious surgical consequences for the patient and damage the microkeratome.

Step 2: Cleaning

③ To clean the screw core of the motor and metallic parts, use Moria disposable brush moistened with cleaning solutions.

④ Dip the blade oscillation shaft of the handpiece in a sterile distilled water bath and run the handpiece back and forth 10 times.

⑤ Remove the handpiece from the cup, unplug it from the console, and wipe the oscillation shaft of the handpiece with a lint-free surgical wipe.

⑥ Cable can be cleaned with a lint-free surgical wipe moistened with cleaning solutions.

⑦ Air-dry the shaft of the handpiece with clean, filtered compressed air.

⚠ ***Warning:***
- ***The One Use-Plus, One Use-Plus for Artificial Chamber and Epi-K™ handpieces must be carefully cleaned after each surgical procedure.***
- *Do not use abrasives or scrapers to clean any elements of the system ; doing so may result in reduced precision, burrs and/or irregular tissue resection.*
- *Do not immerse the handpiece in the sterile distilled water bath.*
- *To prevent damaging the connectors and to ensure proper functioning of the handpiece, never pull on the cables and never hold the handpiece by its cable.*

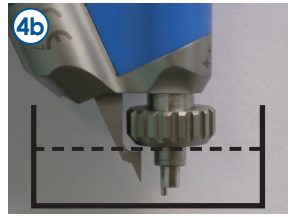
Step 3: Disinfection & Drying

⑧ Wipe each part of the handpiece with a lint-free surgical wipe moistened with disinfecting solutions.

⑨ Dry carefully with disposable instrument cleaner (lint-free) then with clean, filtered, compressed air.

⚠ ***Warning:***
- *It is imperative to verify that the devices are perfectly clean and free of any organic or other residues.*

- ***Do not sterilize the motors with ethylene oxide (EtO).***
- ***Do not autoclave the motors.***
- *No current sterilization process is compatible with One Use-Plus and Epi-K™ motors for refractive procedures. However, the One Use-Plus handpiece for Artificial Chamber (#19175) for corneal graft preparation is compatible with low temperature sterilization using hydrogen peroxide («plasma sterilization»). Refer to the instructions for use provided by manufacturers of plasma sterilization.*



Step 4: Storage

- Failure to completely dry the inside of the handpiece can result in oxidation.
- Do not store products that are not completely dry; doing so may create rust and result in irregular corneal resection.
- Do not store with formaldehyde tablets.

- When not in use :
  - The One Use-*Plus* handpiece should be kept in its storage box (#22519514) in a dry atmosphere.
  - The Epi-K™ handpiece should be kept in its storage box (#22519512) in a dry atmosphere.
  - The One Use-*Plus* handpiece for Artificial Chamber should be kept in its storage box (#22519174) in a dry atmosphere.

III) CLEANING-DISINFECTION-STERILIZATION-STORAGE OF THE REUSABLE SUCTION RINGS AND REUSABLE GUIDE RING

This protocol has been approved by the French XV/XX National Ophthalmological Hospital (CHNO) (Paris, France), Hygiene/ Sterilisation Department (Dr. Patrice RAT).

Step 5: Double cleaning

⑩ On leaving the operating theatre, immediately immerse the devices in an aldehyde-free detergent/ disinfectant solution for at least 15 minutes according to manufacturer recommendations.
⑪ Manual cleaning (or use a machine, provided that it does not recycle the cleaning products, after disassembling the device where appropriate).
⑫ Rinse the circuit with water.
⑬ Immerse the devices in an aldehyde-free detergent/ disinfectant solution (a different bath from the one above).
⑭ Manual cleaning (or use a machine, provided that it does not recycle the cleaning products).
⑮ Rinse using filtered distilled or osmosis-treated water.
⑯ Wipe the devices using a non-woven, lint-free, disposable surgical wipe.
⑰ Air-dry the devices with clean, filtered compressed air.

⚠ ***Warning:***

- *Manual cleaning: mechanical cleaning of the medical device using soft brushes; metal brushes and scouring pads are prohibited.*
- *Change the baths after each use.*
- *Incompatibility:*
  - *Do not use bleach.*
  - *Do not apply this protocol to products made of aluminium alloy.*
  - *Do not apply this protocol to heat-sensitive device (motor and turbine).*

Step 6: Deactivation of NTAs (Unconventional Transmissible Agents)

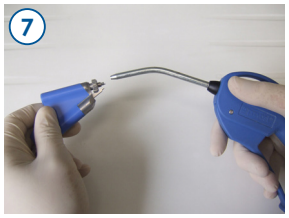
- On leaving the operating theatre, immediately immerse the devices in an aldehyde-free detergent/ disinfectant solution for at least 15 minutes according to manufacturer recommendations, and then rinse the devices.
- Cleaning, disinfectant and rinsing fluids must be stored in sealed containers and disposed of by appropriate procedures for contaminated biological liquid waste.
- Immerse the device in a soda solution (1 N) for one hour.
- Rinse the device manually three times (using water from the network), and check the pH when performing the last rinse to prevent any risk of burns (neutral pH). The last rinse must be carried out using microbiologically tested water.
- Wipe the device using a non-woven, lint-free, disposable surgical wipe, and reinstall the device in the normal disinfection/sterilization circuit.

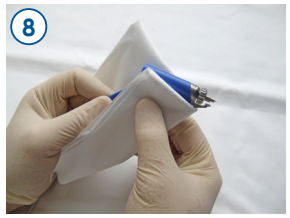
⚠ ***Warning:***

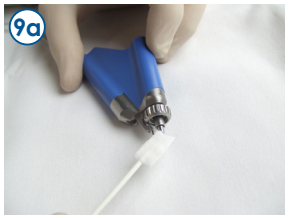
- *Inactivation of UTA (unconventional transmissible agents) (only for patients at risk of Creutzfeldt-Jakob disease – CJD questionnaire / please refer to French Ministry instruction DGS/R13/2011/449-December 2011)*
- *If the pH is not neutral, perform further rinses until an acceptable pH is reached (close to pH7).*

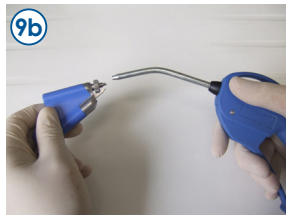
Step 7: Sterilization

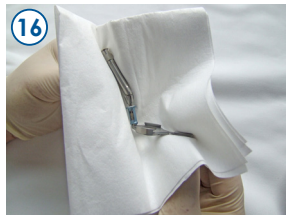
Sterilize the sterilization tray using an autoclave (moist heat sterilizer) at a temperature of at least 134°C for 18 minutes.

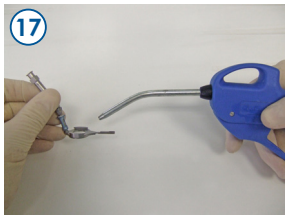


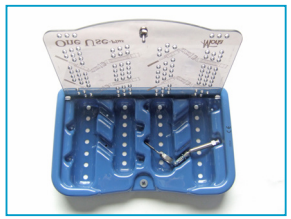












Moria

The One Use-*Plus*, One Use-*Plus* for Artificial Chamber and Epi-K™ systems have been designed for optimal operation, provided that the recommendations listed in their respective user manual are followed carefully. In order to maintain the original performance of your microkeratome, MORIA strongly recommends annual maintenance and servicing of all its reusable products.

As only MORIA and its agents are fully expert in MORIA products, servicing and maintenance must be carried out by MORIA or its approved agents.

MORIA shall not be held liable for any malfunction or damage to the apparatus, poor results, or surgical complications due to maintenance having been carried out by an unqualified operator or third party.

Any such unauthorised intervention shall render the guarantee and any maintenance contract null and void.

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