CAUTIONS

The **ML7061 Metal Head** must be cleaned immediately after use. Salt from the saline solutions can cause rust or corrosion to occur if they are not quickly cleared from the head; see additional information in this document under Section 3: Cleaning and Drying.

Ensure the head is thoroughly dry before putting it away for storage; see additional information in this document under Section 6: Sterilization and Section 7: Storage.

WARNINGS

Reusable instruments are not delivered sterile and must be cleaned and sterilized before first use.

MED-LOGICS does not define an appropriate maximum number of uses for the ML7061 Head. See Section 9: Limitations and Restrictions on Reprocessing for additional information.

Verify the model of the ML7061 Metal Head (R100M or R130M) to ensure that the correct cutting depth has been selected prior to use. Failure to do so could result in a less-than-optimal flap thickness.

Verify that the bottom of the ML7061 Metal Head is free of scratches or other damage before use. Such damage could injure the patient's epithelium if used. See additional information in this document under Section 4: Inspection and Maintenance.

Calibration

Each head is labeled with the nominal value (e.g., 100 or 130) on top of the adaptation plate. This value is the average flap thickness that will be cut by the head, with variations around the average value due to a variety of factors, such as corneal thickness, keratometry, IOP, and surgical technique. MED-LOGICS certifies the dimensional characteristics of the head.

Flap thickness measurements in LASIK have been reported in a large number of published articles. The standard deviation of flap thickness increases as the nominal flap target increases. With a target flap of 100–130 microns, the typical standard deviation is 10–20 microns.

Flap diameter and hinge width are not controlled by the head. See the Moria® M2 Operator's Manual for additional information.

Using the ML7061 Metal Head

The ML7061 Metal Head is intended for use only with the Moria® OUP Microkeratome Handpiece and the MED-LOGICS ML7061 Calibrated LASIK Blade (CLB®).

Reference the Moria® OUP Microkeratome Operator's Manual for instructions on use of the microkeratome.

Product Warranty and Limitations of Liability

MED-LOGICS warrants that the ML7061 Metal Head will conform to MED-LOGICS's then current version of the product specifications for such products in all material respects and shall be free from defects in material or workmanship for a period equal to one year from the date of purchase. Above and aside from the foregoing, no warranties, express or implied, are provided under this warranty. Using non-Calibrated LASIK Blades (CLB®) in these precision heads can cause damage to the ML7061 Metal Head. Such damage is not covered under this warranty.

MED-LOGICS excludes all other warranties, whether expressed, implied, or by operation of law, including but not limited to any implied warranties of merchantability or fitness. MED-LOGICS shall not be liable for any incidental, consequential or exemplary loss, damage or expenses, directly or indirectly resulting from the use of this product even if MED-LOGICS has been advised of the possibility of such loss, damage or expenses.

Trademark and Affiliation Information

- The OUP Microkeratome is a product of Moria® and is a registered trademark of Moria Surgical, S.A.
- MED-LOGICS, Inc. is not affiliated with Moria Surgical, S.A.
- The CLB® is a registered trademark of and a product of MED-LOGICS, Inc. For additional information about the CLB®, contact MED-LOGICS, Inc. using the contact information on this sheet.

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Symbols Used on Labeling

REF	Catalog Number	EC REP	Authorized Representative in the EU
LOT	Lot Number	UK REP	Authorized Representative in the UK
CE 2797	CE Mark & Notified Body No.	UDI	Unique device identifier
CC	Date of Manufacture (YYYY-MM-DD) & Country of Manufacture		Consult Instructions for Use
MD	Medical Device		Manufacturer
Rx ONLY	For use by, or on the order of, a physician		

NOTICE:

Any serious incident that has occurred in relation to the ML7061 Head should be reported to MED-LOGICS and the competent authority of the Member State in which the user and/or patient is established.

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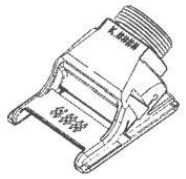
MED-LOGICS, INC.®



ML7061 Metal Head

Replacement Metal Head to fit
the Moria® One Use Plus (OUP) Microkeratome

The MED-LOGICS® ML7061 Metal Head is designed for use on the Moria® OUP Microkeratome Handpiece. Please read and follow the microkeratomes operator's manual prior to use.

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1. Pre-Requisites Before Use and Instructions for Use

Warning: Reusable ML7061 Heads are not delivered sterile and must be cleaned and sterilized before first use.

Preliminary precautions:

- Do not expose the ML7061 Metal Head to temperatures above 134 °C (273 °F). The ML7061 Metal Head can be damaged by overheating.
- During sterilization, verify that the instruments are positioned correctly without overloading and that the components do not touch each other during the process.

MED-LOGICS, INC.®

ML7061 Metal Head

Replacement Metal Head to fit
the Moria® One Use Plus (OUP) Microkeratome

The MED-LOGICS® ML7061 Metal Head is designed for use on the Moria® OUP Microkeratome Handpiece. Please read and follow the microkeratomes operator's manual prior to use.

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1. Pre-Requisites Before Use and Instructions for Use

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2. Point of Use

Immerse in cleaning solution[1] at least 3 minutes before the first use and immediately after surgery.

3. Cleaning and Drving

Warning: Do not place the head through an automated washer-disinfector for cleaning. The Manual Cleaning Process describedbelow is the only validated means of cleaning the ML7061 Head. Pre-Cleaning:

- Rinse with tap water (<30˚C) for a minimum of 30 seconds, exposing all surfaces and cavities to flowing water.
- Immerse in cleaning solution[1] (30˚ to 40˚C) for at least 3minutes to loosen debris and soil.
- Remove head from the cleaning solution[1] and scrub allsurfaces and interior cavities of the head using a soft bristlebrush.

Manual Cleaning Process:

Warning: For effective sterilization, verify that the head is free of any residues and all surfaces and cavities are completely clean.

- Immerse the head into an ultrasonic cleaner with a plastic basket filled with cleaning solution[1] (30˚C to 40˚) and sonicate for at least 3 minutes.
- Rinse with tap water (<30˚C) for a minimum of 30 seconds,exposing all surfaces and cavities to flowing water.
- Immerse in demineralized water (30˚C to 40˚C) for at least 1 minute.
- Wipe and dry with filtered air.

4. Inspection and Maintenance

After cleaning and drying:

- Ensure that the head does not show signs of impact and that it is free of marks or signs of wear.
- Verify that the bottom of the head is free of scratches or other damage before use, which could injure the patient's epithelium. Insert a blade into the head and test with the handpiece to confirm function.

5. Packaging

The packaging for sterilization of the ML7061 Head should satisfy the following requirements:
For the packaging of individual heads:

- A single head should be placed in a generic or dedicated sterilization tray/case to protect the instrument. Trays and cases with lids should be double pouched in standard medical grade self-sealing steam sterilization pouches using the AAMI double pouch or equivalent method.

6. Sterilization

Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces:

- Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.

6. Sterilization (Continued)

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle with distilled or deionized water is recommended according to minimum sterilization parameters found in the table below:

- The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust

Cycle Type	Preparation	Exposure Time	Temperature	Minimum Drying Time (in room chamber)
Pre-vacuum	Double Pouched	3 minutes	134 °C / 273 °F	30 minutes

- Refer to manufacturer's cleaning detergent recommendation regarding concentration; see Cleaning Validation study details in Section 11: Product Information Disclosure.
- [2]Gravity autoclaves are not recommended due to variations in steam penetration efficacy based on cycle time parameters.
- Flash (immediate-use) steam sterilization in unwrapped packaging and without the recommended dry time, by exposure at 134˚(/ 273˚F for the exposure time listed in the above table should only be used as an emergency procedure. Heads must be clean and free of soil.

7. Storage

ML7061 Heads must be thoroughly dried prior to storage. Always store the heads in clean, dry conditions in order to prevent risk of condensation inside the packaging.

- Keep the heads stored inside the dedicated sterilization tray.
- Do not store in an environment that may have a corrosive or magnetic effect.
- Avoid contact with other instruments.

8. Transportation

Transportation inside healthcare facility:

- Used devices must be transported to the processing location (i.e. sterile processing) in closed or covered containers to prevent contamination risks.

Transportation outside the healthcare facility:

- Used devices must be transported to MED-LOGICS in closed or covered containers to prevent contamination risks. (Original sterilization tray is recommended)
- Used devices must be cleaned before return for repair.

9. Limitations & Restrictions on Reprocessing

MED-LOGICS does not define an appropriate maximum number of uses for the ML7061 Head. The lifespan depends on several factors including the method and duration of each use and the heads are treated: wear and damage during use, sterile barrier employed, storage manner, environmental, handling, and individual reprocessing conditions. Repeated processing according MED-LOGICS recommendations has minimal effect on the heads.
A visual inspection followed by a functional test before use is the best method to determine when an instrument should be discarded or sent for repair; see Section 4: Inspection and Maintenance.

- Verify that the bottom of the ML7061 Metal Head is free of scratches or other damage before use. Such damage could injure the patient's epithelium if used.

10. Disposal

Unless otherwise mentioned:

- Devices must be disposed of as a medical device in an appropriate biological waste container in accordance with healthcare facility procedures

11. Product Information Disclosure

Instructions for Use - ML7061 Head Care, Cleaning, and Sterilization of Reusable Autoclavable Devices per ISO 17644-1:

Manual Cleaning Validation Study Information: Detergent Ruhof Endozyme at 0.4% (0.5 ounce detergent/ per gallon or 4mL detergent/Liter). See NAMSA Trial Reports: MLE073125CLN.01

Sterilization Validation Study Info:
Sterilization validation has been performed with Steris' AMSCO LAB 250 steam sterilizer, MED-LOGICS' Sterilization Tray ST0278, double pouched using Cardinal Health's Self-Sealing Sterilization Pouches #92713. See NAMSA Trial Report: MLE071125STM.01

Intended Use: Replacement head for the Moria® OUP microkeratome.
Product Description: The ML7061 Heads accept the ML7061 CLB Blade. The devices are intended for re-use and are serialized for traceability.
Indication for Use / Intended User: The intended user is a ophthalmic surgeon and the device is indicated for use on patients aged 18+ and those deemed eligible for refractive surgery by an ophthalmologist.
Contraindications and undesirable side-effects: No contraindications and no undesirable side-effects are known when used as intended.
Clinical Benefits: The clinical benefits of the ML7061 Head are derived from the creation of an accurate corneal flap allowing the patient to undergo further refractive procedures.
Residual Risks: There are no adverse reactions or residual risks associated with the device beyond the warnings contained herein.