ML7® Donor Cornea System

OPERATION MANUAL

MED-LOGICS®

1627 Enterprise Street
Athens, TX 75751, USA
Phone: +1(949) 582-3891
E-mail: info@mlogics.com
Web Site: www.mlogics.com

EC REP
E C Rep Ltd,
5 Fitzwilliam Square East,
Dublin 2, D02 R744, Ireland
Tel: +353-89-225-1951
E-mail: info@ecrep.ie

UK REP
Responsible Person Ltd,
Summit House, 4-5 Mitchell Street,
Edinburgh, EH6 7BD, UK
Tel: +44-7543-672-888
E-mail: info@responsible-person.co.uk

Table of Contents

Indications for Use 4

System Description 4

Additional Equipment: 4

System Features and Benefits 5

Maintenance Procedure 10

Cleaning Instructions (Immediately After Use) 14
Drying Process of the Handpiece 15

Sterilization Protocol 15

Initial Installation Procedure 17

Using the Motorized Handpiece with the AAC 27
Handling the Flap during Procedure 27

Troubleshooting Guide for ML7 DSAEK Donor Cornea System 29

Maintenance 32

Fuses 32

Battery 32

Warranty 33

Specifications 34

Environmental Conditions 35

Indications for Use

The ML7 Donor Cornea System is considered laboratory equipment that is indicated for use in the sectioning of cornea tissue from donor eyes. **This is not considered a medical device.**

Do not attempt to use the ML7 Donor Cornea System without having adequate understanding of all its components, functions, controls, and limitations.

MED-LOGICS offers training assistance if necessary. ML7 Donor Cornea System users who wish to participate in a training session provided by a representative of MED-LOGICS before using the system should contact MED-LOGICS at (949) 582-3891 to schedule a training session.

System Description

The ML7 Donor Cornea System is a precision instrument designed for performing lamellar corneal resections.

Never modify any ML7 or its components.

Contact MED-LOGICS prior to any modifications. MED-LOGICS is not responsible for any injury or damage caused by the device modification.

System Essential Components:

- Console and Power Cord
- Digital Pressure Gauge
- Footswitch
- Motorized Handpiece
- Heads (100, 200, 250, 300, 350, 400, 450, 500, 550, & 600-micron options)
- Artificial Anterior Chamber (AAC) with Threaded Fixation Ring
- Cornea Fixation Caps

The system Requires the use of the following
Disposables:

1. Calibrated Blades & Shuttle (ML7100 options: +20, +10, Plano, -10, -20, and -30)
2. Infusion Tubing & Syringe Set (ML9700D and ML9701D)
3. Motorized Handpiece Sterile Sleeve (S001 and S002)

Additional Equipment:

- Cart
- Carrying Case
- Eye Marker (no picture)
- Cleaning Brush (no picture)
- Handpiece Dryer (no picture)

System Features and Benefits

The ML7 Donor Cornea System is a precision-manufactured instrument designed to create precise tissue sections from human donor corneas.

The ML7 is used to perform lamellar keratoplasty procedures. This procedure is performed by either a technician or ophthalmic surgeon to create a thin membrane of tissue for transplantation.

Equipment Features and Benefits

Reusable

Console
Product Code: 1700ML7

The ML7 is equipped with a battery backup power supply. In the event of a power loss, the battery backup power supply will automatically engage, and the device will function without interruption. It is not recommended that you use the ML7 while on battery backup mode for an extended period of time. The battery backup is for emergency power supply.

Console Power Cord

The ML7 console features quick-connect and disconnect plugs and cords.

Model Number	Power Cord Type	Country/Region
1600PC	Type B	North America
1601PC	Type D	Hong Kong, India, South Africa
1602PC	Type E/F	Europe
1603PC	Type G	United Kingdom
1604PC	Type H	Israel
1605PC	Type I	Australia
1606PC	Type J	Switzerland
1607PC	Type L	Italy
1609PC	Not Specified	Brazil

ML7 Footswitch *Product Code: 1800ML7* The ML7 Footswitch is simple and robust. Two foot pedals on the Footswitch control the forward and reverse and a simple button in the center controls vacuum activation. The ML7 software allows the user to simply hold down on the forward pedal to make a complete forward reverse pass when vacuum is activated.	
Digital Pressure Gauge *Product Code: 9600D* This patented pressure gauge allows the user to know what pressure is being applied to the corneal tissue. This increases repeatability and allows the Eye Bank to find the optimum pressure to apply to the tissue during the procedure.	
Motorized Handpiece *Product Code: 1400ML7* The Motorized Handpiece is ergonomic and lightweight. The handpiece has two motors that individually control oscillation and transition across the donor cornea. The software monitors each motor every 50 milliseconds that results in a load compensation function to maintain constant blade oscillation and translation across the donor cornea.	

Heads *(100, 200, 250, 300, 350, 400, 450, 500, 550 & 600-micron options)* The Heads are made from a Stainless Steel that is coated with a special material 5 microns thick to provide improved lubricity as the head passes over the donor cornea. The Heads feature extremely tight tolerances and offer interchangeability between components.	
Artificial Anterior Chamber (AAC) *Product Code 9000D* A precision set of two components that ensure ideal seal stability consisting of two sets of circular ridges that are designed to maintain constant pressure during procedure.	
Fixation Cap *Product Codes:* *9.0mm Opening: 9090FCD* *10.0mm Opening: 9100FCD* *11.0mm Opening: 9110FCD* The Cornea Fixation Cap is made from durable, stainless steel. Elevated linear rails provide smooth movement of the head across the donor's cornea and allow for tight tolerance and improve accuracy. Offering 3 different sizes for the Fixation Cap, 9.0mm, 10mm, and 11.0mm opening, allowing the Eye Bank a range of options	
Sterile - Disposables	
ML7100 Calibrated LASIK Blade (CLB®) and Blade Shuttle *Product Code: ML7100* *(Plano, -10, -20, -30, +10 & +20 options)* The Calibrated LASIK Blade is manufactured to critical dimensions of +/- 5 microns and comes in 6 different sizes to accommodate a variety of cornea thickness.	

Infusion Tubing & Syringe Set
Product Code: 9700D or 9701D

MED-LOGICS manufactures two different types of DSAEK tubing to suit the user's preference.

9700D
With a four-way stopcock as shown below:

9701D
With a one-way stopcock as shown below:

Handpiece Sleeve
Product Code: S001 or S001-S)

The Handpiece Sleeve conveniently covers the handpiece and the cord, ensuring a sterile barrier during the tissue separation.

Additional Reusable Equipment	
ML7 Cart Product Code: 1900ML7 This durable cart comes with an articulating tray and a component basket for convenient storage, making this a desirable option for the ML7 Microkeratome.	
Carrying Case Product Code: 2000ML7 This rugged Pelican Case can take the portable ML7 Console anywhere safely. Its robust design and compartments can hold the system and keep it safe in transit from one site to another.	
Handpiece Case *Product Code: 2001ML7* The handpiece case protects the handpiece while stored between procedures.	

Maintenance Procedure

Proper care and maintenance of the ML7 is required to ensure the optimal operation of the system and the removal of all bioburdens, biofilms, or contaminants.

Console & Power Cord:

Make sure the ML7 Console is powered off before unplugging the power cord from the electrical outlet. Using a damp alcohol wipe, clean the surface of the ML7 Console and Power Cord. Do not immerse the ML7 Console in any fluid. Avoid drawing fluid through the vacuum inlet on the front of the ML7 Console. Never open the ML7 Console without first consulting a MED-LOGICS representative.

Footswitch:

Unplug the footswitch from the ML7 Console before using a damp alcohol wipe or cloth to clean the outside surface of the footswitch. Do not immerse the Footswitch in any fluid.

Motorized Handpiece:

Do not immerse the Motorized Handpiece in any fluid at any time. Do not use any form of sterilization for the Motorized Handpiece, as this can cause damage to the motors. Do not attempt to lubricate the motors. If the Motorized Handpiece is damaged, contact MED-LOGICS for service at (949) 582-3891 or info@mlogics.com

Unplug the Motorized Handpiece from the Console to perform clean process.
Position the handpiece drive shaft with the shaft pointing down and the cable facing up, and with the use of a damp alcohol cloth carefully wipe the outside surface of the Motorized Handpiece.

Keep the Handpiece in the same position and clean the motor shaft with a PVA eye spear lightly moistened with a small amount of alcohol or a dry soft bristled brush.

For the most effective dryness of the Handpiece, MED-LOGICS recommends the use of the 1420ML7 Handpiece Dryer.

Heads:

Using a soft bristled brush and a cleaning solution, such as Opti-Cide and Opti-Lube or equivalent, clean all surfaces of the Head thoroughly, including the blade holder cavity, blade exit cavity, and side rails.

After brushing the head, **we strongly recommend that it undergo ultrasonic cleaning for 3 minutes between procedures and for 10 minutes at the end of the day** because they contain several small and difficult to reach surfaces and cavities. **Only use ultrasonic cleaning devices that utilize plastic baskets because metal baskets can damage components and cannot be used.** Rinse the head with distilled water and completely dry using a lint-free instrument wipe, or instrument dryer. Place the head back into the sterilization tray or container for storage.

AAC Base & Components:

Using a soft-bristled brush and a cleaning solution, such as Opti-Cide and Opti-Lube or equivalent, thoroughly clean all surfaces of the AAC base and dome, threaded fixation ring, and cornea fixation cap. After brushing these components, we strongly recommend they undergo ultrasonic cleaning for 10 minutes after each use because they contain several small and difficult to reach surfaces and cavities. Only use ultrasonic cleaning device that utilizes a plastic basket. Thoroughly rinse these components with distilled water and completely dry them using a lint-free instrument wipe, or instrument dryer. Place it back into the sterilization case for storage.

Digital Pressure Gauge:

Use a damp alcohol wipe to clean the surface of the digital pressure gauge. Do not immerse the Digital Pressure Gauge in any fluid. Avoid drawing fluid through the pressure inlet on the side of the Digital Pressure Gauge.

> WARNING: There is a risk of electrical shock if the ML7 Donor Cornea System is exposed to or immersed in fluid. Do not operate if console is wet or exposed to fluids. Contact MED-LOGICS at (949) 582-3891 or email at info@mlogics.com for service.

Cleaning Procedure for MED-LOGICS Stainless Steel DSAEK Components

To ensure thorough cleaning and maintenance of MED-LOGICS stainless steel DSAEK components, preserving their integrity and sterility for safe surgical use.

This procedure applies to all stainless steel DSAEK components used in corneal transplantation procedures.

Required Materials

a) Personal Protective Equipment (PPE) (gloves, masks, eye protection)
b) Neutral pH or Enzymatic Detergent (as recommended by MED-LOGICS)
c) Soft-Bristled Brushes (for delicate cleaning)
d) Sterile Lint-Free Cloths
e) Distilled or Deionized Water
f) Ultrasonic Cleaner
g) Autoclave or Sterilizer ***Only for Heads Artificial Anterior Chamber (AAC and fixation cap)***

Cleaning Component Procedure

Pre-Cleaning (Immediately After Use)

- Rinse components with cold or lukewarm distilled water to remove visible debris.

Manual Cleaning

Prepare a diluted Concentrated Surgical Instrument Cleaner solution as per manufacturer's instructions.

a) Submerge DSAEK components in the solution.
b) Use a soft-bristled brush to gently clean all surfaces, ensuring no residue remains in grooves or edges

DSAEK System Head:

Brush the Metal Head

- Thoroughly brush the entire metal head using a soft-bristled brush.
- Pay special attention to the **linear bearings (rails)** to ensure the removal of debris and residue.

Clean the Blade Holder Cavity

- Clean the area where the microkeratome blade is inserted and removed **between cases**.
- Use a soft-bristled brush and **diluted Concentrated Surgical Instrument Cleaner** to ensure proper sanitation.

Clean the Blade Exit Cavity

- Thoroughly clean the blade exit cavity **between cases**.
- Use a soft-bristled brush and **diluted Concentrated Surgical Instrument Cleaner** to remove any contaminants.

Cleaning the Fixation Cap

a) Thoroughly clean the linear railing on the fixation cap using a soft-bristled brush.
b) Use a cleaning solution, such as Opti-Cide and Opti-Lube or an equivalent product, to ensure proper sanitation and functionality.

Rinsing Components

Rinse thoroughly with distilled or deionized water to remove all cleaning solution.

Important Note:

Brushes must be replaced when they show wear

Ultrasonic Cleaning

The components are **required** to undergo ultrasonic cleaning

Important Notes

- Use an Ultrasonic Cleaner with a Plastic Basket (similar to the one shown).
- Do not leave components in the ultrasonic cleaner overnight, as moisture may cause corrosion.

1. Preparation
   - Place components in an ultrasonic cleaner filled with enzymatic detergent.
   - Ensure components are fully submerged and arranged without overlapping.
2. Cleaning Cycle
   - Run the ultrasonic cleaner for 3 minutes between procedures and 10 minutes at the end of the day to ensure thorough cleaning of small and hard-to-reach surfaces and cavities.
3. Rinsing
   - After each cycle, rinse components thoroughly with distilled water.
   - At the end of the day, ensure components are completely dried before storage.

Dry Components

NOTE: It is critically important to COMPLETELY DRY ALL COMPONENTS at the end of the surgical schedule to ensure components don't corrode over time.

Properly Dry Components

- Use **lint-free sterile cloths** to dry all components thoroughly.
- Place clean instruments and components on a lint-free disposable instrument pad or dry towel. Ensure all instruments are completely dry.

Instrument Dryer (Recommended)

- For best results, use an instrument dryer at the end of each day. This ensures thorough drying and improves efficiency.
- When using the instrument dryer, hold all components securely. The dryer's power and speed may cause parts to slip or fall if not held tightly.

Important: Failure to fully dry the Stainless Steel components before storage may lead to corrosion.

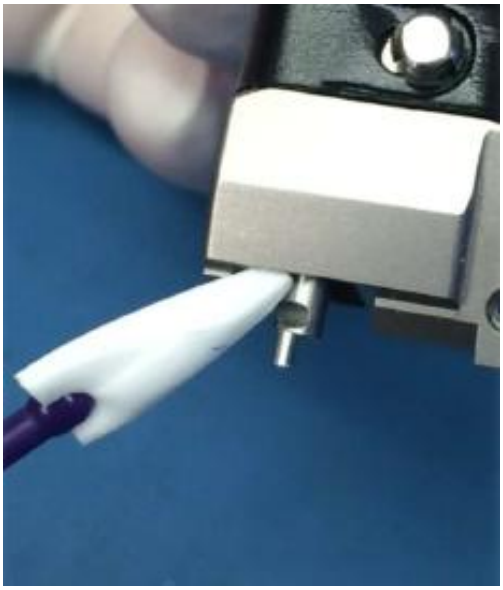
Do not use the instrument dryer to dry the handpiece.

Handpiece Cleaning and Drying Process

Unplug The Motorized Handpiece from the Console To Perform Clean Process.

Cleaning Instructions (Immediately After Use)

1. **Position the Handpiece:** Place the handpiece drive shaft with the shaft pointing downward and the cable facing upward.
2. **Wipe the Exterior:** Use a lightly alcohol-dampened cloth to carefully wipe the outside surface of the motorized handpiece.
3. **Clean the Motor Shaft:** Keeping the handpiece in the same position, use a PVA eye spear lightly moistened with alcohol or a dry, soft-bristled brush to clean the motor shaft. Remove any debris from the motorized handpiece drive pin. **It is essential to maintain the drive pin in a downward position to prevent fluid from entering the handpiece.**



Drying Process of the Handpiece	
To effectively eliminate humidity inside the handpiece, MED-LOGICS recommends using the 1420ML7 Handpiece Dryer. This specialized dryer is designed to ensure thorough drying, helping to maintain the performance and longevity of the handpiece by preventing moisture buildup.	

Sterilization Protocol

The following matrix indicates which sterilization or sanitization methods are safe and acceptable for each individual component.

The ML7 DSAEK components indicated below sterilized before each use.

Component	Autoclave[(a)]	Alcohol Wipe	Drying Method
Console & Power Cord	No	Yes	Dry Cloth Wipe
Footswitch	No	Yes	Dry Cloth Wipe
Cornea fixation cap[(a)]	Yes	No	Instrument Dryer
Head[(a)]	Yes	No	Instrument Dryer
Motorized Handpiece	No	Yes	Dry Cloth Wipe

(a)	The ML7 DSAEK components shall be sterilized in an autoclave (moist heat sterilizer) at **134°C** at least 27psi for 18 minutes before each use. NOTE: *Leaving components in the sterilizer overnight may cause corrosion due to residual moisture. It is recommended that the components are sterilized on the day of use.*
(b)	Alcohol does not constitute a sterilization procedure and will damage plastic and acrylic parts.
(c)	Do not attempt to sterilize the motorized Handpiece as this will damage the motors inside the handpiece.

Proper System Storage and Component Sterilization

1. **Use Protective Trays:** Place all instruments and components into their protective tray for future storage. Store in sterile, dry, and dust-free conditions until the next use.
2. **Autoclaving Recommendations:** It is recommended to **autoclave the components** on the day of use. Avoid autoclaving them before storage to prevent corrosion. DO NOT place Handpiece into the Autoclave.
3. **High-Temperature Dry Heat Sterilization:** If using a high-temperature dry heat sterilizer, do not use the plastic sterilization tray during this process.

Continue to next page

Initial Installation Procedure

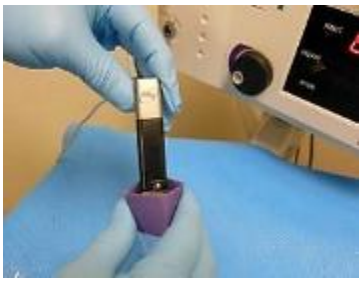
Fully read following instructions to ensure proper setup, usage, and maintenance of the ML7 DSAEK Console power system.

Notes:

- Ensure the power outlet is functional and meets the required voltage specifications for the ML7 Donor Cornea Console.
- Regularly check the power connections for any signs of wear or damage.
- Keeping the console plugged in when not in use helps maintain the longevity of the internal battery.

1. Connecting Power:
   a. Plug the Power Cord into a power outlet.
   b. Connect the opposite end of the Power Cord into the back of the ML7 Console.
   c. Turn on the rear and front power switches.
2. Charging the Internal Backup Battery:
   a. Once powered on, the internal backup battery will begin charging.
   b. It is recommended to keep the Console plugged in and charging when not in use to maintain battery health.
3. Extended Periods of Non-Use:
   a. If the system is not used for an extended period, turn off the rear panel power switch.
   b. Disconnect the Power Cord from the wall outlet to prevent unnecessary power consumption and potential electrical hazards.
4. Connecting the Footswitch:
   a. Connect the Footswitch to the Console.
   b. Note the keyed design on the Footswitch connector, which eliminates incorrect connection.
   c. Screw on the Footswitch connector and hand tighten until secure.
   d. Place the Footswitch on the floor in a convenient location for use during the procedure.
5. Connecting the Motorized Handpiece:
   a. Connect the Motorized Handpiece to the Console by lining up the red dots on the handpiece and the mating connector on the Console.
   b. There should be a “click” when the handpiece is properly inserted.

6. Inserting the Handpiece into the Sterile Sleeve:
   a. While using proper sterile technique, insert the handpiece into the Sterile Handpiece Sleeve.
   b. Peel off the tape and secure the distal end of the sleeve to the distal end of the handpiece as shown below.

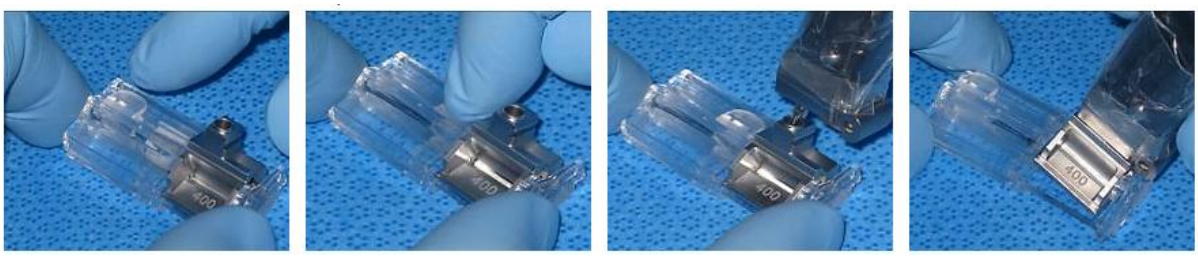


Reference https://mlogics.com/videos/ to find available training video ML7 DSAEK

7. Assembling the Handpiece, Head, and Blade:

   Blade Placement:
   a. While using a proper sterile technique, load the Head into the Blade Shuttle as shown on the next page.
   b. Push the tab to move the blade into the Head.
   C. Move tab back to the original position to prevent it from obstructing removal of head from Blade Shuttle.

   Mount the Motorized Handpiece onto the Head.
   a. Gently mount the Motorized Handpiece onto the Head.
   b. Listen for a click to confirm proper mounting. This indicates that the handpiece is securely attached.



Removing the Assembled Unit:

a) Push the tab back to its original position.
b) Open the shuttle tray carefully.
c) Gently remove the assembled handpiece/Head/Blade from the shuttle, ensuring not touch any non-sterile surfaces.

Reference https://mlogics.com/videos/ to find available training video ML7 DSAEK

Footswitch Operation

Footswitch Operation and Blade Engagement Verification:

a) Depress the Footswitch to activate the handpiece.
b) Observe the blade movement:
c) If the blade is properly engaged, it will move back and forth.
d) This movement can be observed by looking at the plastic blade holder or the actual blade itself. The blade should move back and forth if properly engaged.

Pressure Gauge Setup

a) Position the Digital Pressure Gauge on top of the console or another convenient location.
b) Ensure the gauge is elevated at least 6 inches (15 centimeters) above the base of the console.

Connecting the Gauge: a) Attach the female luer connector on the long tubing line (near the canister) to the inlet of the Digital Pressure Gauge.	
Infusion Tubing Connection	
a) Connect the infusion tubing to the Artificial Anterior Chamber (AAC) and the syringe while maintaining proper sterile technique.	

Continue to next page

Surgical Set-Up for Donor Cornea Sectioning

Preparation Overview
This section serves as a guideline for preparing a donor cornea for sectioning. Please follow your facility's established protocols and guidelines.

Prepare the Media Solution:

a) Ensure that the media solution in the syringe is sterile and ready for use.
b) Remove the cap from the syringe and attach the appropriate connector to the AAC line.

Prime the Lines:

a) **Insert the Syringe**: Place the syringe filled with media solution connector onto the AAC.
b) **Ensure Removal of Air Bubbles**: Slowly push the plunger of the syringe to expel the media solution into the AAC line, ensuring that all air bubbles are removed.

Continue Priming the AAC:

a) After the initial priming, maintain the connection with the syringe containing the media solution.
b) Slowly and steadily push the plunger of the syringe to continue infusing the media solution into the AAC line.

Observe for Meniscus Fluid Dome:

a) As you continue to prime, watch the AAC line closely for the formation of a meniscus fluid dome.
b) The meniscus should appear as a rounded dome shape at the tip of the AAC line, indicating that the line is completely filled with the media solution.

Float the Cornea:

Slowly lower the donor cornea onto the fluid meniscus dome, allowing it to "float" on the surface of the fluid.
Avoid pressing down on the cornea at this stage, as it should rest gently on the meniscus.

Inject Additional Fluid if Necessary:

If necessary, inject additional media solution to help maintain the dome in shape.

Carefully observe the area around the cornea as additional fluid is injected.

This step is crucial for reducing the chance of capturing air underneath the cornea, which could compromise the surgical procedure.

Prevent Air Capture:

Ensure that the cornea remains elevated above the meniscus dome and that no air bubbles are trapped underneath.

Adjust the position of the cornea as needed, using the fluid injection to keep the dome stable and prevent air from being captured.

Center the cornea on the (AAC).

Once the cornea is properly floated over the meniscus dome, confirm that it is centered and correctly positioned for the surgical procedure.

Placing the Cornea Fixation Cap on the AAC

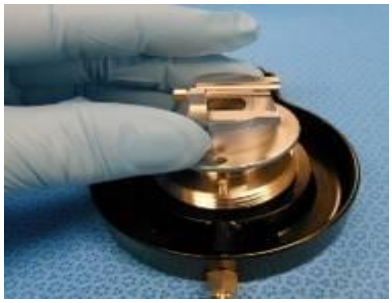
Place the Sterilized Cornea Fixation Cap over the AAC, noting the position of the pin on the base of the AAC and the pin receptacle on the Cornea Fixation Cap Prepare the Cornea Fixation Cap:

Identify the Pin:

a) Locate the position of the pin on the base of the AAC system. This pin is crucial for aligning the Cornea Fixation Cap properly. Identify the pin receptacle on the base of the Cornea Fixation Cap that corresponds to the AAC pin.

Align the Cornea Fixation Cap:

a) Position the Cornea Fixation Cap over the AAC, ensuring that the pin receptacle aligns directly with the pin on the AAC base.



b) Be mindful of the orientation, ensuring that the cap is positioned correctly to fit securely onto the AAC.

c) Lower the Cornea Fixation Cap:

d) Gently lower the Cornea Fixation Cap onto the AAC, ensuring that the pin enters the receptacle smoothly.

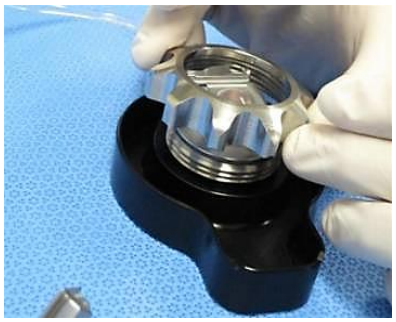
e) Do not force the cap down; if it does not fit easily, double-check the alignment.

Secure the Cap:

a) Once the pin is properly seated in the receptacle, press down gently on the Cornea Fixation Cap to ensure it is securely in place.

b) Verify that the cap is stable and does not move when lightly touched.

c) Ensure there are no visible gaps between the cap and the AAC, and that the cornea remains centered.

Lower the Cornea Fixation Cap: Gently lower the Cornea Fixation Cap as far down as possible to ensure proper positioning.	
Place the Threaded Fixation Ring: Carefully place the (AAC) Threaded Fixation Ring over the assembly. **Secure the Fixation Ring**: Tighten the ring until it is secure.	
Wait Period: Allow the assembly to rest for 15-30 seconds. This waiting period is crucial to prevent pressure leaks caused by tissue compression. **Final Tightening**: After the wait, tighten the ring again to ensure a secure fit. **Verification**: Verify that the ring is tight to confirm proper assembly and prevent any potential leaks.	

Pressurizing the System with Syringe

1. **Open the Stopcock**: Turn the stopcock to the open position.
2. **Pressurize the System:** Use a syringe to gradually pressurize the system while observing the Digital Pressure Gauge on top of the console.

Recommended Pressure Setting:
The ideal pressure range is 125 to 135 mmHg.

- **For the 9700D**, once the desired pressure is reached, turn the stopcock to all "OFF" position.
- **For the 9701D** - Set the Digital Pressure Gauge to approximately 130 mmHg or your facility's protocol. Once the desired pressure is reached, close the stopcock at both locations.

Note: Maintaining consistent pressure in subsequent procedures is crucial for establishing an accurate nomogram.

Sealing the System:

1. **Close Off the AAC Tube:** Once the desired pressure is reached, turn the stopcock to close off the tube leading to the Artificial Anterior Chamber (AAC). *Refer to Stopcock Instructions Below.*

Using the 4-Way Stopcock (9700D Set)
The four-way stopcock controls fluid flow by closing off one tube at a time.

Instructions for Use:

1. **Adjusting Pressure:** Use a **syringe** to increase or decrease pressure to the desired level.
2. **Open Position:** While adjusting the pressure, ensure the stopcock is in an **open position** (see image below).

Current Version Stopcock

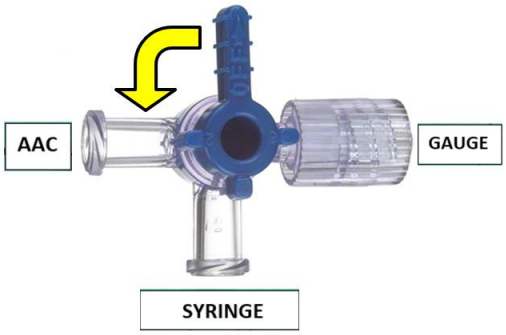
Stopcock Versions

- **9700 D Legacy** (White Handle) – Older model, same function.
- **9700 D Current** (Blue Handle) – New model, same operation.

- **9701D** (2-Way Stopcock) – Follow facility protocol for pressure adjustments.

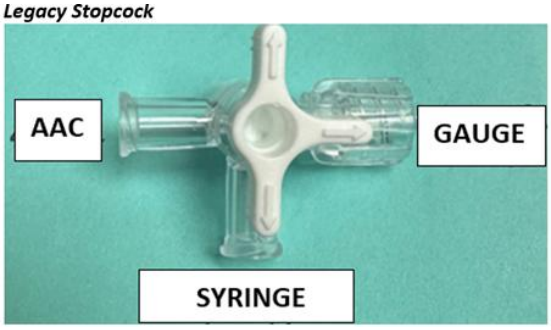
Legacy Stopcock

3. **Sealing the AAC:** Once the desired pressure is reached, rotate the stopcock to close off the tube leading to the Artificial Anterior Chamber (AAC) (see image below).



Current Version Stopcock

Legacy Stopcock



Important: Always verify the stopcock position to maintain proper pressure and prevent unintended flow.

Using the Motorized Handpiece with the AAC

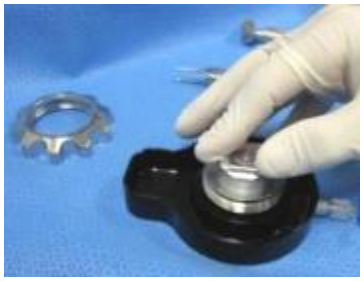
1. **Place the Handpiece**: Position the Motorized Handpiece on the assembled Artificial Anterior Chamber (AAC).
2. **Verify Engagement**: Ensure that the handpiece is properly seated in the tracks and that the helical drive is engaged with the handpiece. At this point, it is ready for the pass.
3. **Initiate Forward Movement**:
   - Press the **"FORWARD"** pedal on the Footswitch.
   - Continue to hold the pedal down until the handpiece stops moving forward.
4. **Reverse Movement**:
   - Press and hold the **"REVERSE"** pedal on the Footswitch.
   - Continue reverse movement until the Hand Piece reaches the end of the helical drive and then remove the Handpiece.

Handling the Flap during Procedure

1. **Check the Flap Position:**
   - If the flap remains on the front angled wall of the Head, proceed to remove it according to your facility's protocol.
   - After removal, carefully replace the flap back onto the cornea.
2. **If the Flap is Connected to the Cornea:**
   - Gently lift the flap to allow for marking or measuring any necessary parameters.
   - Once measurements are completed, carefully replace the flap onto the stromal bed.

Maintaining Pressure During Procedure

1. **Maintain Downward Pressure**: While keeping a steady downward pressure, proceed to the next step.
2. **Open the Stopcock**: Open the stopcock while continuing to apply downward pressure.
3. **Apply Positive Pressure**: Maintain slight positive pressure on the syringe. This action will help ensure that the chamber is properly maintained and will assist in preventing a collapse.

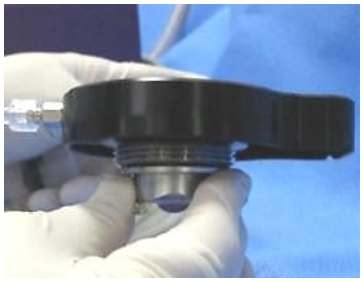


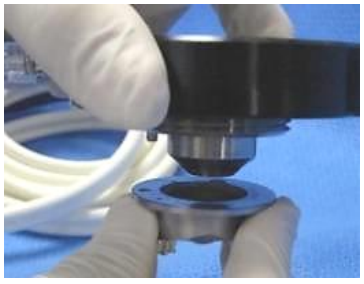
Removing the Cornea Fixation Cap from the AAC

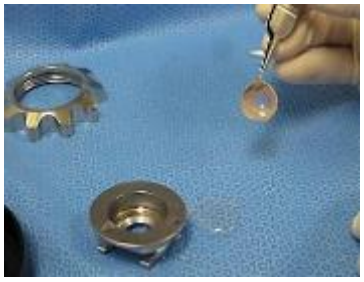
1. **Follow Facility Protocol**: Adhere to your facility's protocol for removing the Cornea Fixation Cap.
2. **Maintain Positive Pressure**: As you begin to remove the Cornea Fixation Cap, ensure that you maintain positive pressure in the chamber. This step is crucial to minimizing the possibility of chamber collapse.
3. **Remove the Cap**:

   Gently continue to remove the Cornea Fixation Cap from the AAC.

   Ensure that positive pressure is maintained throughout this process.
4. **Complete Separation**: Continue to remove the Cornea Fixation Cap until the two components (Cap and AAC) are completely separated.





Removing the Cornea from the Cornea Fixation Cap 1. **Ensure Proper Position**: Confirm that the cornea remains in the Cornea Fixation Cap during the procedure. 2. **Careful Removal**: Take great care when removing the cornea from the Cornea Fixation Cap. 3. **Work the Cornea Free**: o It may be necessary to gently "work" the cornea free from the Cap. o In that case, Use slow and careful movements to avoid damage to the cornea	

Troubleshooting Guide for ML7 DSAEK Donor Cornea System

The ML7 DSAEK Donor Cornea System is designed to alert users of any issues. When a problem occurs, the Console will display error codes on the illuminated front panel to help you identify the issue. Below are the error codes you may encounter:

Error Code	Description
E1	Program memory failure
E2	Footswitch failure
E3	Critical RAM failure
E4	Communications failure
E5	Vacuum error
E6	Blade motor failure
bAT	Low battery voltage

Component Troubleshooting Table

Component	Issue	Possible Cause	Solution
Head	Head not moving smoothly	Damage or debris on the helical drive	Inspect for damage and replace the Cornea Fixation Cap if the helical drive is damaged.
			Remove debris using a soft-bristled brush. To prevent Debris - follow the proper component cleaning process and ensure all components are completely dry before storage.
	Blade is not moving freely	Blade cavity may be dirty	Remove the blade and thoroughly clean the blade cavity using a soft brush and cleaning solution. To prevent a dirty cavity, follow the proper component cleaning process and ensure all components are completely dry before storage.
			Ensure the Blade Shuttle instructions are followed.
Motorized Handpiece	Motor shaft won't rotate	Power issue or disconnected cables	Ensure the power switch is ON and check the Footswitch and handpiece power cord connections. To prevent this issue, follow the proper handpiece cleaning process and ensure all components are completely dry before storage. ***If the issue persists, contact MED-LOGICS and schedule equipment for a Service Appointment.***
	Handpiece won't attach to Head	Quick connect latch malfunction	Test the quick connect latch; if faulty, replace the handpiece or the Head. DO NOT IMMERSE, DROP, OR AUTOCLAVE THE HANDPIECE.
Console	Vacuum readouts are not shown	Power supply issue	Ensure the Front and Rear Console power are ON. Verify the Console power cord is securely connected to the back panel and plugged into a functioning, grounded outlet. If the issue persists, contact MED-LOGICS for service.

Digital Pressure Gauge	Pressure not maintained	Loose or incorrect connections	Check all connections, including the Infusion Tubing Set and Syringe. Ensure all stopcocks are in the correct position. Verify that the cornea is properly affixed in the AAC and that the Threaded Fixation Ring is tight on the Cornea Fixation Cap. Important Note: Make sure to replace the Tubing Set, all pressure tubing sets are single-use products and should not be reused.

Continue to next page

Maintenance

Fuses

If the Power Cord is connected and the Console power switch is turned to the "ON" position, but the Console is not functioning, the fuses inside the Console may need to be replaced. In order to replace the fuses, the following procedure is required:

1. Turn "OFF" both the front and back power switches on the console.
2. Unplug the power cord from the wall outlet.
3. Remove the inlet cover by loosening the screws holding it in place.
4. Disconnect the power cord from the inlet.
5. Pull out the fuse carrier while pushing the outer edge with a flat object, such as a screwdriver.
6. Replace both fuses with the following: 2A/250V 5X20mm Fast Acting Fuse. Remove the inlet cover by loosening the screws holding it in place.

If the fuses fail again, contact an authorized MED-LOGICS distributor/representative or contact MED-LOGICS directly. Attach the fuse carrier in the reverse order of step 5. Verify the fuses following the procedures below:

- Plug the Power Cord into the Console power inlet, and then to the wall outlet.
- Turn the power switch on the Console to an "ON" position and verify that the "POWER" indicator on the Console front panel illuminates.
- Attach the inlet cover in the reverse order of step 3 from above.

Battery

Console: The Console has a single 12 Volt battery inside. It is highly recommended to test the battery at least twice a year and replace the battery every year by a qualified trained Clinic Technician **or** a MED-LOGICS representative **or** at the MED-LOGICS manufacturing facility located in Athens, Texas.

The battery can be tested by unplugging the power cord from the wall outlet while the Console is set to "ON". If the Console's front panel lights indicate "bAT", the battery may need to be recharged or replaced.

Digital Pressure Gauge: The Digital Pressure Gauge has a single 9-Volt battery inside. It is recommended to replace the battery annually or as needed.
If the Digital Pressure Gauge doesn't turn on when the power button on the front is pressed, contact a trained clinic technician or a qualified MED-LOGICS representative to ensure proper battery replacement. If further assistance is needed, please contact MED-LOGICS at (949) 582-3891 or info@mlogics.com.

Warranty

MED-LOGICS warrants that the ML7 Donor Cornea System will conform to the manufacturer's version for the published specifications for the device in all material respects and shall be free from defects in material or workmanship for a period of twelve (12) months from documented receipt date.

The exclusive remedy for any breach of the Warranty shall be at MED-LOGICS's option the repair or replacement of the non-conforming equipment; or part thereof, which is returned to MED-LOGICS. An authorization number (RGA Number) must be obtained by calling MED-LOGICS Customer Service at (949) 582-3891 and must accompany any item and/or equipment returned for any reason. Please print the authorization number on the outside of the shipping box.

MED-LOGICS shall only pay for return shipping expenses for equipment repaired under Warranty. For equipment returned for repair and not under warranty, the standard repair charges of MED-LOGICS, will be in effect.

This Warranty does not apply to normal wear and tear. Any component deemed to have been defective from malfunctions or failures that resulted from abuse, neglect, improper installation or maintenance, alteration, modification, accident or misuse of the equipment will void such warranty.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTEIS OF MERCHANTABILITY OR FITNESS FOR A PARTICLUAR PURPOSE. NO WARRANTY IS GIVEN THAT THE EQUPMENT IS DELIVERED FREE OF THE RIGHTFUL CLAIM OF ANY THIRD PARTY FOR PATENT INFRINGEMENT AND THE LIKE.

The warranty set forth above may not be extended, broadened or otherwise modified by any MED-LOGICS agent or employee, and MED-LOGICS does not assume any liability or make any warranty except as stated above.

Specifications

Handpiece

Forward speed	3.5mm/sec. fixed +/- 10%
Reverse speed	3.5mm/sec. fixed +/- 10%
Oscillation rate	10,500 opm +/- 3%

Head

Material	420 or 17-4 Grade Hardened Stainless Steel	
Head size options	100 microns	200 microns
	250 microns	300 microns
	350 microns	400 microns
	450 microns	500 microns
	550 microns	600 microns

Cornea Fixation Cap

Material	420 Grade Hardened Stainless Steel
Diameter options	10 mm

Artificial Anterior Chamber

Material	Aluminum Base/Stainless Steel Dome & Nut

ML7100 Calibrated LASIK Blade (CLB®)

Material	Stainless Steel
Sterilization method	EtO
Blade options	+20 microns
	+10 microns
	Plano
	-10 microns
	-20 microns
	-30 microns

Console

Material	Steel & Aluminum
Footswitch	
Structure	Waterproof (IP68)
Power source	
Voltage	100-240 VAC
frequency	50/60 Hz
power consumption	40 VA or less
fuses	2A/250V 5X20mm Fast Acting Fuse
Dimensions	12’ X 14’ X 6’
Weight	15 lbs.

Environmental Conditions

Storing Conditions

In Transportation & In Storage	Temperature: +32°F to +104°F (0°C to +40°C) Humidity: 0 to 90% (non-condensation) Air Pressure: 650 to 1070 hPa
In Use	Temperature: +59°F to +77°F (+15°C to +25°C) Humidity: 0 to 70% (non-condensation)

Label Definitions

CONSOLE LABELS

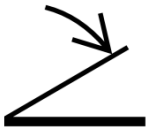
	Catalog or Re-Order Number
	Risk of electric shock
	Caution
	Equipotential Ground
	Fuse Rating
	OFF Switch Position
	ON Switch Position
	Console is classified as a type B system

Manufacturer

Authorized representative in the European Community

Authorized representative in the United Kingdom

Footswitch connection location



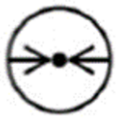
Footswitch connection location

This symbol identifies the handpiece connection location

Vacuum connection location

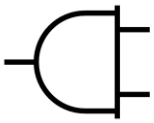
CAUTION: Federal (U.S.) law restricts this device to sale by, or on the order of, a physician

Date and country of Manufacture



Pressure Sensing

Eject



Power Connection Point

DISPOSABLE LABELS

Catalog or Re-Order Number

Caution

Do Not Re-use

Date and Country of Manufacture

Use By / Expiration

Lot Number

Manufacturer Information

This symbol identifies the European Authorized Representative information

This symbol identifies the United Kingdom Authorized Representative information

This symbol means the product has been sterilized using ethylene oxide

This symbol warns that federal (U.S.) law restricts this device to sale by, or on the order of, a physician