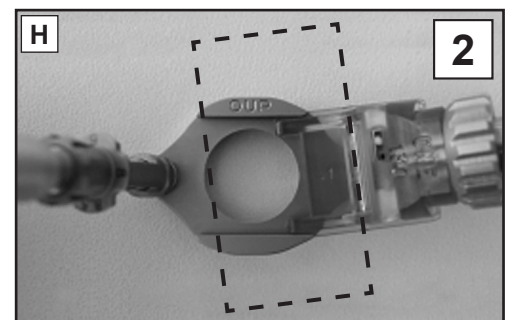
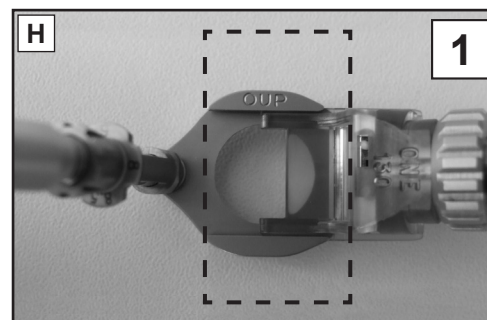
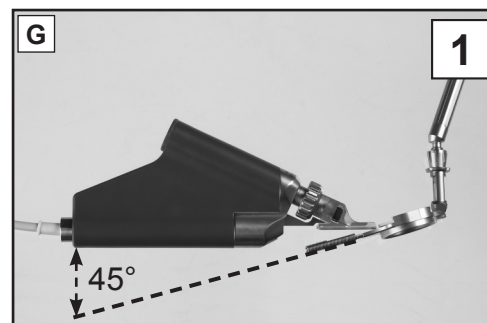
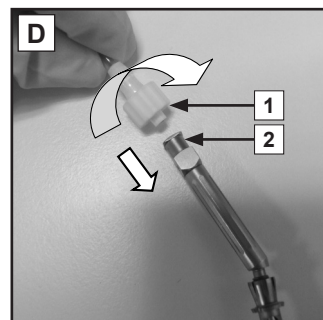
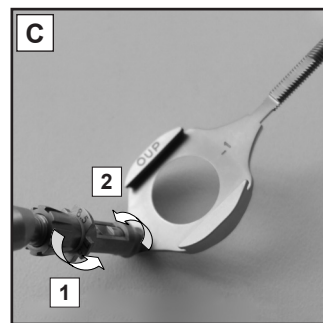
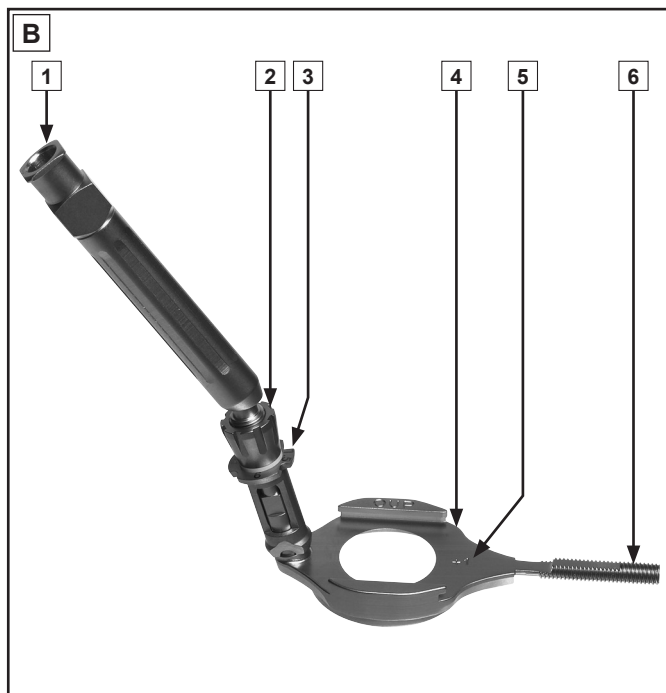
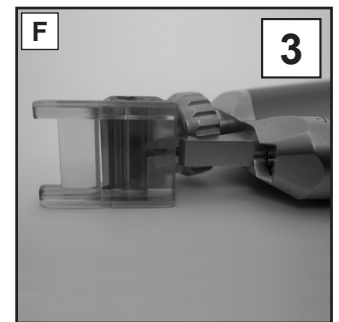
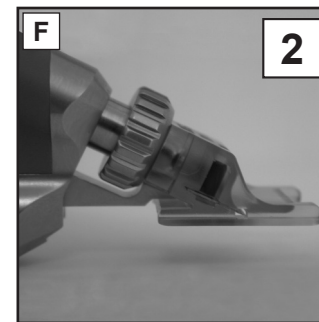
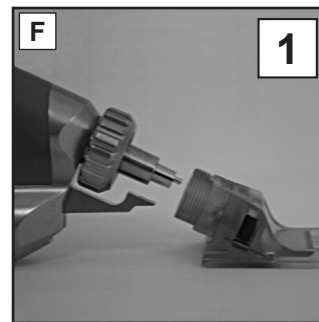
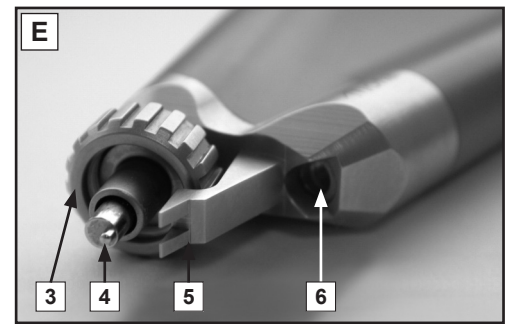
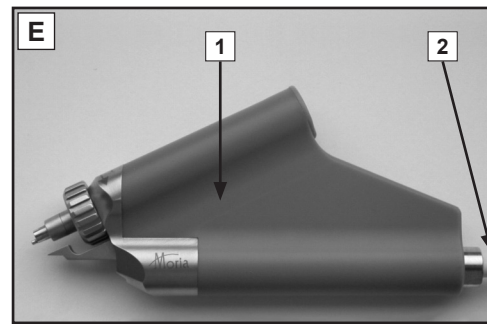
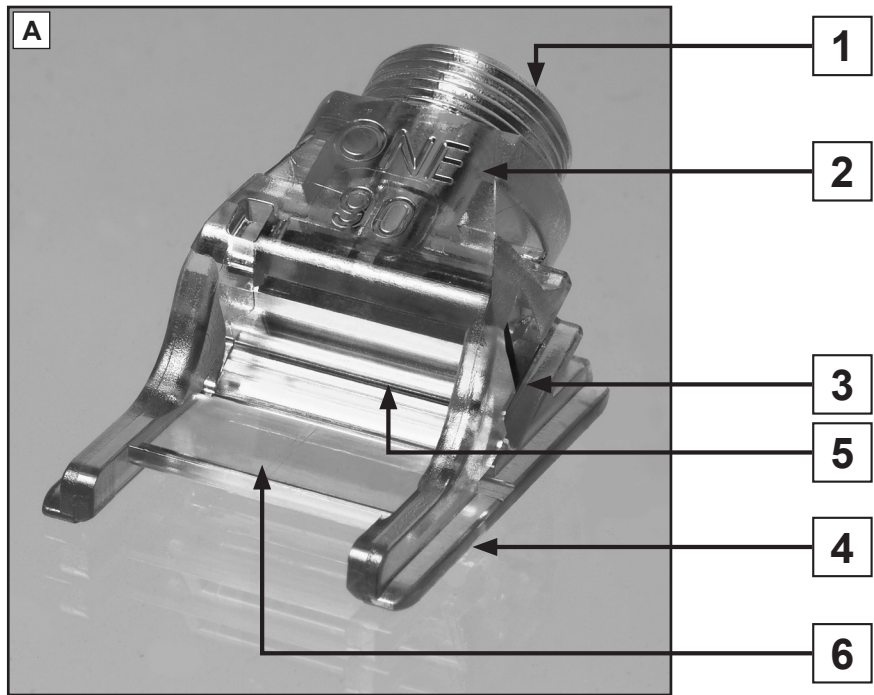


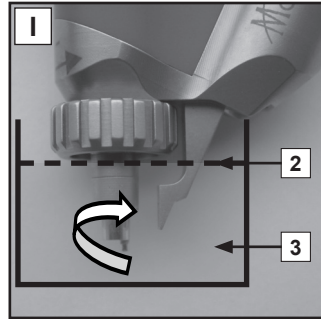
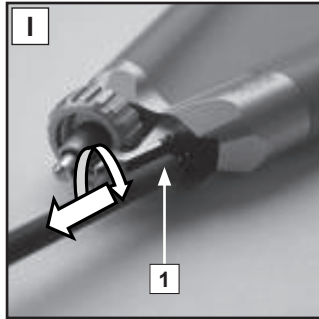
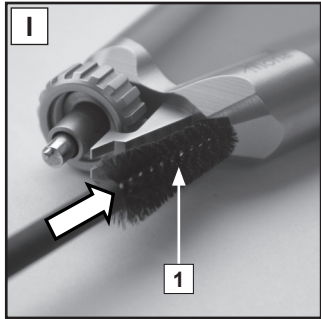
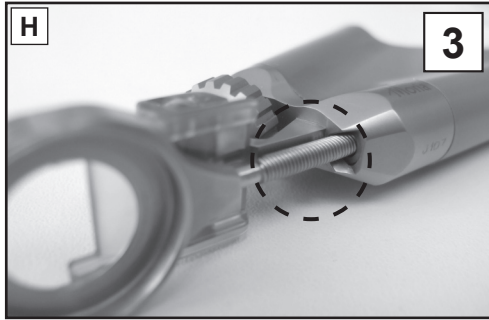
**Ref.: 65040**

Année de première mise sur le marché : 2004



MORIA S.A. – 27, rue du Pied de Fourche - 03160 Bourbon  
L'Archambault – France #65040-H-05.2023





## CONTENTS

<b>1</b>	<b>DISCLAIMER .....</b>	<b>2</b>
1.1	MAINTENANCE AND WARRANTY .....	2
1.2	USE OF GENERIC PRODUCTS AND REUSE OF SINGLE-USE CONSUMABLES .....	2
1.3	HEAD CALIBRATION VALUE AND FLAP THICKNESS .....	2
<b>2</b>	<b>REGULATORY INFORMATION.....</b>	<b>3</b>
<b>3</b>	<b>LIST OF EQUIPMENT, ACCESSORIES AND LABELING.....</b>	<b>3</b>
3.1	EQUIPMENT LIST AND PRIMARY ACCESSORIES LIST .....	3
3.2	SECONDARY ACCESSORIES LIST .....	4/5
3.3	LABELING .....	4/5
<b>4</b>	<b>LABELING INFORMATION .....</b>	<b>6</b>
<b>5</b>	<b>IMPORTANT INFORMATION .....</b>	<b>7</b>
5.1	DESCRIPTION .....	7
5.2	INDICATIONS.....	7
5.3	CONTRAINDICATIONS .....	7
5.4	WARNINGS .....	7
5.5	POTENTIAL ADVERSE EVENTS .....	8
5.6	PRECAUTIONS.....	8
5.7	PRODUCT COMPLAINTS .....	9
5.8	PACKAGING .....	9
<b>6</b>	<b>INSTALLATION AND CONNECTION.....</b>	<b>9</b>
<b>7</b>	<b>OPERATION .....</b>	<b>10</b>
<b>8</b>	<b>TROUBLESHOOTING .....</b>	<b>11</b>
<b>9</b>	<b>CARE &amp; MAINTENANCE .....</b>	<b>11</b>
9.1	INTRODUCTION .....	11
9.2	INITIAL TREATMENT AND STORAGE .....	11
9.3	CLEANING-DISINFECTION-STORAGE OF THE HANDPIECE AND ELECTRICAL CABLE .....	12
9.4	CLEANING-DISINFECTION-STERILIZATION-STORAGE OF THE SUCTION RINGS .....	13
<b>10</b>	<b>WARRANTY .....</b>	<b>14</b>
10.1	SCOPE OF WARRANTY.....	14
10.2	NON-APPLICATION OF WARRANTY .....	14
10.3	WARRANTY PERIOD .....	14
10.4	LIABILITY .....	14
<b>11</b>	<b>DRAWINGS.....</b>	<b>15</b>

## 1 DISCLAIMER

### 1.1 MAINTENANCE AND WARRANTY

The One Use-*Plus* system has been designed for optimal operation, provided that the recommendations listed in this user manual are followed carefully. If, for any reasons, the system does not perform properly, have it checked immediately by MORIA. In order to maintain the original performance of your system, reusable items must be checked by MORIA on a yearly basis as a preventive maintenance.

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 being 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.

### 1.2 USE OF GENERIC PRODUCTS AND REUSE OF SINGLE-USE CONSUMABLES

The materials used in the microkeratome blade, blade holder and head have been selected for their sliding characteristics. The dimensions and tolerances of the blade have been determined in consideration of the dimensions and tolerances of the head of the keratome. MORIA's manufacturing and inspection procedures guarantee there is no conflict in dimensions between head and blade, and that the blade will slide smoothly in the head.

**Single-use devices must not be re-used. Reuse affects their mechanical and biological features, their clinical performances, causes device failures and exposes the patient to adverse events such as contamination, bacterial infection, inflammation, irritation or minor eye lesion.**

**The reuse of single-use products, or the use of consumables other than those supplied by MORIA, entails serious surgical consequences for the patient and damages the microkeratome.**

MORIA shall not be held liable in the event of a malfunction or damage to the microkeratome, poor results or surgical complications due to the reuse of a single-use product or the use of consumables other than those supplied by MORIA.

**MORIA handpieces must only be connected to MORIA devices (console unit, heads, suction rings, etc.).**

All warranties become null and void if the microkeratome degrades or malfunctions due to such practices.

### 1.3 HEAD CALIBRATION VALUE AND FLAP THICKNESS

Flap thickness is a key factor for both LASIK and lamellar keratoplasty. Multiple parameters affect flap thickness and standard deviation. Numerous scientific studies have demonstrated that flap thickness is influenced by several patient-related factors such as keratometry (K) readings, corneal anatomy, preoperative pachymetry and refraction, intraocular pressure (IOP), and also by surgery-related factors, such as corneal hydration and the speed of the pass (when using manual microkeratomers).

Ultrasonic pachymetry measurements are not always accurate and reproducible, and results may also vary with surgeons' techniques and calibration of the device. Thus, at Speed 2, a MORIA One Use-*Plus* head labeled:



- "90" (SBK head) cuts, on average, a 100-micron flap with variations around this average.
- "130" cuts, on average, a 130-micron flap with variations around this average.

MORIA can only guarantee the dimensional characteristics of the head, not the surgical result.

For the EVOLUTION 3E console, refer to the related instruction manual (#65060/INTL).

The most recent version of this user guide and additional information on your keratome are available on the MORIA website: <http://www.moria-surgical.com>.

## 2 REGULATORY INFORMATION

	MORIA S.A. 27, rue du Pied de Fourche-03160 Bourbon L'Archambault - France Phone +33 (0) 146 744 674 Fax +33 (0) 146 744 670 <a href="mailto:moria@moria-int.com">moria@moria-int.com</a> <a href="http://www.moria-surgical.com">http://www.moria-surgical.com</a>
Customer Service Information	Contact your local dealer or MORIA
EUROPE	CE 0459 CLASS IIA according to MDD 93/42/CEE
USA	Product registered at the Food and Drug Administration (FDA): 510(k) K040297 Caution USA only: Federal law restricts the use of this device to physicians or licensed practitioners.
Electrical Safety Standard	IEC 60601
	For EU customers only: this symbol indicates that within the European Union, the product must be discarded in a separate collection bin at the end of its useful life. This applies not only to this device, but also all accessories, including the footpedal and electrical motors, regardless of whether those accessories are marked with the symbol. Do not dispose as unsorted municipal waste. For users out of European Union: please refer to local environmental regulatory regarding waste of electrical and electronic equipment.

## 3 LIST OF EQUIPMENT, ACCESSORIES AND LABELING

### 3.1 EQUIPMENT LIST AND PRIMARY ACCESSORIES LIST

Description	Regulatory designation	MORIA reference
One Use- <i>Plus</i> handpiece (blue color)	ONE USE PLUS MOTOR	19345
One Use- <i>Plus</i> One-Handed handpiece (blue color)	ONE HAND ONE USE PLUS HANDPIECE	19345OH
Wrench	WRENCH	19345C
One Use- <i>Plus</i> ring sterilization box	ONE USE PLUS RING STERILIZATION BOX	22519513
Polymere box for One Use- <i>Plus</i> handpiece	ONE USE PLUS STERILIZATION BOX	22519514
EVOLUTION 3E Console (S/N above 5000)	EVOLUTION 3E CONTROL UNIT	19380
EVOLUTION 3-3E Control Footpedal	FOOTPEDAL FOR EVOLUTION	19361
EVOLUTION 3E Control Footpedal Epi-K™	EVOLUTION 3E FOOTSWITCH	19381
EVOLUTION 3E Footswitch - China	EVOLUTION 3E FOOTSWITCH	19381C
EVOLUTION 3E Footswitch - Japan	EVOLUTION 3E FOOTSWITCH	19381J
EVOLUTION 3 Supply Cords (CEE) (2.50m) / Cable (CEE)	EVOLUTION 3 SUPPLY CORD (EEC)	19362
EVOLUTION 3 Supply Cords (USA) (2.50m) / Cable (USA)	EVOLUTION SUPPLY CORD (USA)	19363
EVOLUTION 3 Supply Cords (UK) (2.50m) / Cable (UK)	EVOLUTION 3 SUPPLY CORD (UK)	19364
EVOLUTION 3 Supply Cords (China) (2.50m) / Cable (China)	EVOLUTION 3 SUPPLY CORD CHINA	19516
EVOLUTION 3 Supply Cords (Brazil) (2.50m) / Cable (Brazil)	EVOLUTION 3 SUPPLY CORD BRAZIL	19521
Supply cord USA	SUPPLY CORD (USA)	19451
Carrying Case	N/A	19511
Aspiration tubing	EVOLUTION 2-3-3E TUBING X10	19138
Aspiration tubing - China	EVOLUTION 2-3-3E TUBING X10	19138C



















### 3.2 SECONDARY ACCESSORIES LIST

Description	Regulatory designation	MORIA reference	User manual
One Use- <i>Plus</i> : ring -1 and Head SBK (90) or 130	ONE USE PLUS SBK SET (90/-1)	19336/90	65039
	ONE USE PLUS SET (130/-1)	19336/130	
One Use- <i>Plus</i> : ring 0 and Head SBK (90) or 130	ONE USE PLUS SBK SET (90/0)	19337/90	
	ONE USE PLUS SET (130/0)	19337/130	
One Use- <i>Plus</i> : ring -1 Large Cut and Head Large Cut 110L and 130L	ONE USE PLUS 110 LARGE CUT SET	19354/110	65039 - 65040
	ONE USE PLUS 130 LARGE CUT SET	19354/130	
One Use- <i>Plus</i> Large cut reusable metal ring size -1, 0 with stops at 7.5 - 8.0 - 8.5 - 9.0 (mauve color)	OUP LC -1 REUSABLE SUCTION RING	19519/-1	65040
One Use- <i>Plus</i> reusable metal ring size -1, 0 with stops at 7.5 - 8.0 - 8.5 - 9.0 (blue color)	OUP REUSABLE SUCTION RING -1	19391/-1	
	OUP REUSABLE SUCTION RING 0	19391/0	
One Use- <i>Plus</i> reusable metal ring size +1, +2, +3 with stops at 7.0 - 7.5 - 8.0 - 8.5 (yellow color)	OUP REUSABLE SUCTION RING 1	19391/1	
	OUP REUSABLE SUCTION RING 2	19391/2	
	OUP REUSABLE SUCTION RING 3	19391/3	
One Use- <i>Plus</i> reusable metal oval rings size +1, +2, +3, with stops at 7.0 - 7.5 - 8.0 - 8.5 (grey color)	OVAL FLAP OUP METAL SUCTION RING +1	19391/1/OV	
	OVAL FLAP OUP METAL SUCTION RING +2	19391/2/OV	
	OVAL FLAP OUP METAL SUCTION RING +3	19391/3/OV	
Box of 10 sterile heads One Use- <i>Plus</i> SBK (90) or 130	ONE USE PLUS SBK HEAD	19393/90	
	ONE USE PLUS 130 HEAD	19393/130	
Box of 80 sterile heads One Use- <i>Plus</i> SBK (90) (China)	ONE USE PLUS SBK HEAD X80 (CHINA)	19393/90C5	
Disposable brush	BRUSH	19149	-
Tonometer	BARRAQUER AUTOCLAVABLE TONOMETER	19042	-
Sterilization box for autoclave tonometer	BARRAQUER AUTOCLAVABLE TONOMETER STERILIZATION BOX	22519049	-

### 3.3 LABELING

Description	Regulatory designation	MORIA reference
One Use- <i>Plus</i> metal ring user manual	N/A	65040
One Use- <i>Plus</i> metal ring nomogram (-1 Large-Cut, -1, 0, +1, +2, +3)	N/A	65067
One Use- <i>Plus</i> -1 Large-Cut metal ring nomogram	N/A	65074XX
One Use- <i>Plus</i> metal ring nomogram for Asian eyes	N/A	65075XX
One Use- <i>Plus</i> Oval metal ring nomogram	N/A	65077EN 65077XX
Instruction for use for the setting of the One Use- <i>Plus</i> single-use head	N/A	65055
One Use- <i>Plus</i> & Epi-K™ Operator's cleaning-disinfection-sterilization-storage instructions (extract from One Use- <i>Plus</i> metal ring user manual)	N/A	65096 65096XX
EVOLUTION 3 console user manual	N/A	65038
EVOLUTION 3E console user manual (serial number below 5000)	N/A	65051
EVOLUTION 3E console user manual (serial number 5000 and above)	N/A	65060/INTL
EVOLUTION 3E console user manual (serial number 5000 and above) - China	N/A	65060ZH
EVOLUTION 3E console user manual (serial number 5000 and above) - Brazil	N/A	65060BR
EVOLUTION 3E console user manual (serial number 5000 and above) - Japan	N/A	65060JA
Annexe "Guidance and manufacturer's declaration: electromagnetic emissions and immunity"	N/A	65073

## 4 LABELING INFORMATION

 xxxxxx	CATALOGUE REFERENCE
	QUANTITY
 YYYY/MM/DD	USE BY DATE
 xxxxxx	BATCH CODE
	STERILIZED USING ETHYLENE OXIDE
	DO NOT REUSE
 xxxxxxxx	MANUFACTURER
 YYYY/MM/DD	DATE OF MANUFACTURE
 xxxxxx	CAUTION : CONSULT ACCOMPANYING DOCUMENT(S)
 xxxxxx	CONSULT OPERATING INSTRUCTIONS
	DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTION FOR USE
	NON-STERILE
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	DISCARD IN A SEPARATE COLLECTION BIN
	CAUTION for USA only: US federal laws restrict this device to sale by, or on the order of, a physician.
	MEDICAL DEVICE
	UNIQUE STERILE BARRIER SYSTEM WITH INNER PROTECTIVE PACKAGING

## 5 IMPORTANT INFORMATION

### 5.1 DESCRIPTION

The One Use-*Plus* microkeratome is used to create corneal, lamellar, hinged flaps (keratectomy). The One Use-*Plus* microkeratome is an automated, mechanical, linear microkeratome designed to create nasal-hinged flaps. It has three components:

- a handpiece (#19345), containing 2 independent motors: one for advancement, and one for oscillation.
- a metallic suction ring ((#19391/xx or #19391/x/OV).
- a single-use sterile plastic head (#19393/xx) encasing a pre-inserted blade.

The One Use-*Plus* microkeratome operates with the EVOLUTION 3 and 3E control units (#19360, 19380). Please refer to user guide: #65060/INTL (EVOLUTION 3E serial numbers 5000 and above).

The EVOLUTION 3E control unit and the electrical motors / turbines must follow the following conditions:

	Temperature	Humidity rate (without condensation)	Atmospheric pressure
Transportation	5 - 45°C / 41°F – 113°F	30 - 90%	
Storage	10 - 40°C / 50°F – 104°F	30 - 75%	
Normal conditions of use	10 - 40°C / 50°F – 104°F	30 - 75%	70 - 106 kPa

### 5.2 INDICATIONS

The One Use-*Plus* microkeratome is indicated for the creation of lamellar nasal-hinged flaps in corneas with preoperative pachymetry of 500 microns or greater, and keratometry between 39 D and 49 D. During laser in-situ keratomileusis (LASIK), the flap is then lifted to enable photoablation of the stroma with an excimer laser.

### 5.3 CONTRAINDICATIONS

Patients who are not candidates for LASIK.

Note: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to determine the risk/benefit ratio. Particular attention must be given before performing a keratectomy on a patient with any of the following conditions:

- preoperative pachymetry under 500 microns
- keratometry under 39 D
- keratometry over 49 D
- inability to withstand a transient rise in intraocular pressure.

### 5.4 WARNINGS

- **Design of this medical device does not allow its reuse. Reuse may affect its mechanical and biological features, its clinical performances, may cause device failures and may expose the patient to adverse events such as contamination, bacterial infection, inflammation, irritation or minor eye lesion.**
- Do not mix One Use-*Plus* heads with Epi-K™ heads.
- Do not use disposable materials and/or components or a brand other than MORIA with the One Use-*Plus* microkeratome.
- The heads must only be screwed on by hand. Dismantling should be done only with the provided wrench (#19345C) or by hand. Never use any tools or other spanners. Incorrect assembly may cause incomplete or uneven cuts due to lack of blade oscillation.
- Never pull on the cable connected to the handpiece, and never hold the motor by the cable.

## 5.5 POTENTIAL ADVERSE EVENTS

As with any surgical procedure, there is risk involved. LASIK surgery requiring the use of a microkeratome that cuts a corneal flap, potential side effects of laser refractive surgery may include but are not limited to: visual anomalies, dry eye and flap related complications (free cap, incomplete flap, buttonhole, epithelial defect, flap dislocation, flap striae, wrinkles, etc.).

Inappropriate use, deterioration of microkeratome and/or non-respect to contraindications (§ 5.3) and warnings (§ 5.4) expose patient at higher risk to adverse events.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

Any serious incident occurring in conjunction with these instruments must be reported to the manufacturer and the competent authority of the user's and/or patient's Member State.

## 5.6 PRECAUTIONS

- The keratotomy must be performed only by experienced refractive surgeons with specific training in the use of the One Use-*Plus* microkeratome.
- Preoperative and operative procedures, including knowledge of surgical techniques, proper head and ring selection, and assembly and placement of the microkeratome are important considerations in the successful use of the system by the surgeon. Furthermore, proper patient selection and compliance will greatly affect the results.

### For USA only

**CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

Other preoperative, intraoperative and postoperative warnings and precautions are as follows:

### PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Care should be used in the handling and storage of the microkeratome components. They should not be scratched or otherwise damaged. Handpiece should be protected during storage, especially from corrosive environments.
- Check the label and expiration date on the unopened package for head.
- After opening the package, verify that head information is consistent with information on outer package labeling.
- The head, suction ring, handpiece and the control unit should be fully inspected prior to use. The pre-inserted blade should be inspected on both sides under a microscope.
- The surgeon should be familiar with the various components before using the microkeratome and verify that all parts and necessary instruments are present and properly assembled before the surgery begins. Additional sterile components should be available in case of an unexpected need.
- The selection of the proper head, ring and stop position for each eye is crucial to the success of the procedure: see MORIA nomogram.

### INTRAOPERATIVE

- Breakage, slippage, or misuse of microkeratome and its components may cause injury to the patient or operating personnel.
- Before any usage, lubricate the eye, the suction ring, the head and the blade with a physiological saline solution or another appropriate ophthalmic solution that is compatible with the One Use-*Plus* components.

### POSTOPERATIVE

- The surgeon's postoperative instructions to the patient and the corresponding patient compliance are extremely important.

## 5.7 PRODUCT COMPLAINTS


Health care professionals (e.g., customers or users of this device) having any complaints about or dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify MORIA or its distributor by telephone, fax or written correspondence, and have the products checked by MORIA.


When filing a complaint, please provide the component(s) name(s), reference(s), batch number(s), as well as your name and address, the nature of the complaint, and the relevant patient data. Also disinfect and return the components.

## 5.8 PACKAGING


Packages of each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness, and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used and should be returned to MORIA. Do not use single-use products if package is open or torn.


## 6 INSTALLATION AND CONNECTION

Steps	What to do	 IMPORTANT WARNINGS	Related picture
1	Select the suction ring and the head according to the One Use- <i>Plus</i> nomogram	<ul style="list-style-type: none"><li>The disposable head (#19393/xx) is supplied sterile and for single use only.</li><li>Check that package is undamaged, unopened and within the expiration date.</li></ul>	A, B
2	Assemble the head onto the handpiece	<ul style="list-style-type: none"><li>Open the package containing the disposable head (#19393/xx).</li><li>Screw the head clockwise onto the threaded motor shaft.</li><li>Check that the head is screwed on tightly to the motor. There should be no rotation of the head.</li><li>If the head is not screwed completely onto the motor, the shaft will not drive the blade holder, and the blade will not move. Poor or irregular resections can result from incorrect assembly.</li><li>Do not use the wrench (#19345C) or other tools to assemble it. The wrench should be used for disassembly only.</li></ul>	E, F
3	Carefully inspect the keratome head after assembly	<ul style="list-style-type: none"><li>The disposable head must be perfectly clean inside and outside and free from debris, particles, oxidation and deposits. There should be no scratches on the plates. If any, replace the head.</li><li>After assembly and using a microscope, carefully inspect the blade under high magnification to ensure that it is not damaged.</li></ul>	A
4	Check for blade oscillation	<ul style="list-style-type: none"><li>Start the motor to check proper blade oscillation</li><li>Do not use the One Use-<i>Plus</i> system if the oscillation is not smooth, regular and uninterrupted.</li></ul>	
5	Inspect the suction ring	<ul style="list-style-type: none"><li>The suction ring must be carefully inspected prior to use; it must be perfectly clean, free from debris, particles and deposits.</li><li>Carefully check that the suction port is not obstructed.</li></ul>	B

Steps	What to do	 <b>IMPORTANT WARNINGS</b>	Related picture
6	Set the stopper	<ul style="list-style-type: none"> <li>Refer to the indicative nomogram for the selection of the ring and stop.</li> <li>The adjustable stop pin is pre-mounted on the suction ring and used to determine the size of the hinge. The hinge will be placed in a nasal position.</li> <li>To configure the stop, follow these steps: <ul style="list-style-type: none"> <li>unscrew the stop setting screw</li> <li>lift it up then turn the stop to the appropriate value</li> <li>the value of the stop selected must line with the etched ring size</li> <li>screw the stop setting screw.</li> </ul> </li> </ul>	
7	Connect the suction ring to the aspiration tubing	<ul style="list-style-type: none"> <li>The aspiration tubing (#19138) is supplied sterile and for single use only.</li> <li>Check that package is undamaged, unopened and within the expiration date.</li> <li>Inspect the aspiration tubing and in case of kinks or obstructions, replace it.</li> </ul>	D

## 7 OPERATION

Steps	What to do	 <b>IMPORTANT WARNINGS</b>	Related picture
1	Preliminary check before any usage	<ul style="list-style-type: none"> <li>It is imperative to verify that the devices are perfectly clean and free of any organic or other residues.</li> <li>Refer to EVOLUTION 3E user manual (#65060/INTL) for operations prior use. The operator should be familiar with the functioning of the EVOLUTION 3E control unit (#19380).</li> <li>If you have additional questions, consult MORIA website or your MORIA distributor.</li> </ul>	
2	Connect the motor to the control unit, select One Use-Plus and the speed, then check vacuum prior use	<ul style="list-style-type: none"> <li>Refer to EVOLUTION 3E user manual (#65060/INTL) for operations prior use.</li> <li>Refer to the indicative nomogram for the selection of the speed, ring and stop.</li> </ul>	
3	Insert the head in the rails of the suction ring	<ul style="list-style-type: none"> <li>When inserting the head in the rails of the suction ring, the handpiece must be at a 45° angle from the threaded shaft of the ring, to avoid any blade damage</li> <li>If the bottom of the head (the area where the blade edge protrudes) is in contact with the threaded shaft of the suction ring, inadvertent damage to the blade may occur. Release vacuum and change to a completely new set to avoid the possibility of irregular cut.</li> <li>Once the head properly inserted, slightly reduce the angle from 45° to 0°.</li> <li>Carefully engage the head into the ring.</li> <li>The shaft of the ring must be aligned with the motor.</li> </ul>	G, H
4	Check for keratome translation prior to use (forward and backward pass)	<ul style="list-style-type: none"> <li>Press vacuum ON, make forward then backward movements using footpedals, then press vacuum OFF. Refer to EVOLUTION 3E user manual (#65060/INTL) for operations prior use.</li> <li>Do not use the One Use-Plus system if the forward pass is not smooth, regular and uninterrupted.</li> </ul>	
5	Position the suction ring on the eye. Activate vacuum by pressing the "Vacuum" footswitch once.	<ul style="list-style-type: none"> <li>Verify that the device will not interfere with any other medical devices used during the procedure.</li> </ul>	

Steps	What to do	 <b>IMPORTANT WARNINGS</b>	Related picture
6	Check the intraocular pressure with the tonometer	<ul style="list-style-type: none"> <li>The tonometer (#19042) must be perfectly dry and used only on dry eyes. If the pressure is below 65 mmHg, do not proceed with the surgery.</li> </ul>	
7	<b>Lubricate the suction ring, the head and the blade</b>	<ul style="list-style-type: none"> <li><b>Prior to use, lubricate the rails of suction ring, head, and blade with balanced salt solution or another appropriate solution.</b></li> <li><b>The device should not be placed in contact with solutions for which the potential interactions are unknown.</b></li> </ul>	
8	Once the One Use-Plus system is in position, activate the motor by pressing the "Forward" footswitch. When the microkeratome head touches the stop, immediately release the "Forward" footswitch. Reverse by pressing the "Backward" footswitch.	<ul style="list-style-type: none"> <li>See EVOLUTION 3 or 3E console user manual (#65038, 65051, 65060/INTL).</li> <li>Hold the suction ring by its handle; check that your fingers do not hinder the forward movement of the device.</li> <li>Check nothing prevents or modifies head movement in the rails of the suction ring</li> <li>Ensure that there are no obstructions (speculum, eyelashes, eyelids, etc.) in its path.</li> </ul>	
9	Release the "Vacuum" footswitch by pressing once. Remove the suction ring.	<ul style="list-style-type: none"> <li>Discard the disposable head and aspiration tubing after each procedure in an appropriate container.</li> </ul>	

## 8 TROUBLESHOOTING

For any further information and description, refer to EVOLUTION 3E user manual (#65060/INTL) for operations prior use.  
In case of defective handpiece, contact your MORIA representative or distributor for repairing.

## 9 CARE & MAINTENANCE

The recommendations for cleaning, disinfection and sterilization are updated and available on MORIA's website: <http://www.moria-surgical.com>.

### 9.1 INTRODUCTION

In case of unusual vibrations or noises, do not use the unit and contact your distributor.  
Please contact MORIA for any other servicing.

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.

MORIA recommends:


- not to touch potentially contaminated areas,
- use gloves during cleaning and decontamination operations

### 9.2 INITIAL TREATMENT AND STORAGE

To avoid risks of condensation inside the packaging, unpack and store the devices in a clean, dry environment. Do not store the instruments in an environment or next to other products that may possibly have a corrosive or magnetic effect. Avoid any contact between devices, especially those comprised of different materials. The device should be damage free and have no scratches or other surface defects.


Fragile devices or those requiring particular manipulation must be handled separately, taking special care to protect delicate parts.

### 9.3 CLEANING-DISINFECTION-STORAGE OF THE HANDPIECE AND ELECTRICAL CABLE

Steps	What to do	 IMPORTANT WARNINGS	Related picture
1	<b>Cleaning</b> <ul style="list-style-type: none"> <li>To clean the screw core of the motor and metallic parts, use the disposable brush (#19149) moistened with cleaning solutions.</li> <li>Dip the blade oscillation shaft of the motor in a sterile distilled water bath and run the motor back and forth 10 times.</li> <li>Remove the motor from the cup, unplug it from the console, and wipe the oscillation shaft of the motor with a lint-free cloth.</li> <li>Air-dry the shaft of the motor with clean, filtered compressed air.</li> <li>Cable can be cleaned with a lint-free cloth moistened with cleaning solutions.</li> <li>Air-dry the shaft of the motor with clean, filtered compressed air (medical compressed air).</li> </ul>	<ul style="list-style-type: none"> <li><b>The handpiece must be carefully cleaned after each surgical procedure.</b></li> <li>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.</li> <li>Do not immerse the motor in the sterile distilled water bath.</li> <li>To prevent damaging the connectors and to ensure proper functioning of the motor, never pull on the cables and never hold the motor by its cable.</li> </ul>	I
2	<b>Disinfecting &amp; Drying</b> <ul style="list-style-type: none"> <li>Wipe each part of the motor with a lint-free cloth moistened with disinfecting solutions.</li> <li>Use appropriate disinfecting solutions (spray or wipe clean disinfectant) according to the manufacturers' instructions.</li> <li>Dry carefully with disposable instrument cleaner (lint-free) then with clean, filtered, compressed air.</li> </ul>	<ul style="list-style-type: none"> <li>It is imperative to verify that the devices are perfectly clean and free of any organic or other residues.</li> <li>Do not gas sterilize (ETO) the motor.</li> <li>Do not autoclave the motor.</li> <li>No current sterilization process is compatible with MORIA motors.</li> </ul>	
3	<b>Storage</b>	<ul style="list-style-type: none"> <li>Failure to completely dry the inside of the motor can result in oxidation.</li> <li>Do not store products that are not completely dry; doing so may create rust and result in irregular corneal resection.</li> <li>When not in use, the One Use-Plus system should be kept in its storage box (#22519514) in a dry atmosphere.</li> </ul>	

### 9.4 CLEANING-DISINFECTION-STERILIZATION-STORAGE OF THE SUCTION RINGS

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

Steps	What to do	 IMPORTANT WARNINGS
1	<b>Double cleaning</b> <ul style="list-style-type: none"> <li>On leaving the operating theatre, immediately immerse the devices in an aldehyde-free detergent/disinfectant solution (e.g.: Alkazyme® / Alkapharm Laboratories) for at least 15 minutes according to manufacturer recommendations.</li> <li>Manual cleaning (or use a machine, provided that it does not recycle the cleaning products, after disassembling the device where appropriate).</li> <li>Rinse the circuit with water.</li> <li>Immerse the device in an aldehyde-free detergent/disinfectant solution (a different bath from the one above).</li> <li>Manual cleaning (or use a machine, provided that it does not recycle the cleaning products).</li> <li>Rinse using filtered distilled or osmosis-treated water.</li> <li>Wipe the device using a non-woven, lint-free, disposable cloth.</li> </ul>	<ul style="list-style-type: none"> <li>Manual cleaning: mechanical cleaning of the medical device using soft brushes (metal brushes and scouring pads are prohibited).</li> <li>IMPORTANT: Change the baths after each use.</li> <li>Incompatibility: <ul style="list-style-type: none"> <li>Do not use bleach</li> <li>Do not apply this protocol to products made of aluminium alloy.</li> <li>Do not apply this protocol to heat-sensitive (motor and turbine).</li> </ul> </li> </ul>
2	<b>Deactivation of NCTAs (Non-Conventional Transmitted Agents)</b> <ul style="list-style-type: none"> <li>On leaving the operating theatre, immediately immerse the devices in an aldehyde-free detergent/disinfectant solution, preferably enzymatic (e.g.: Alkazyme® / Alkapharm Laboratories) for at least 15 minutes according to manufacturer recommendations, and then rinse the devices.</li> <li>Cleaning, disinfectant and rinsing fluids must be stored in sealed containers and disposed of by appropriate procedures for contaminated biological liquid waste.</li> <li>Immerse the device in a soda solution (1 N) for one hour.</li> <li>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.</li> <li>Wipe the device using a non-woven, lint-free, disposable cloth, and reinstall the device in the normal disinfection/sterilization circuit.</li> </ul>	<ul style="list-style-type: none"> <li>Deactivation of NCTAs: for patients with a risk of Creutzfeldt-Jakob disease only – CJD questionnaire (see the Ministry's guide, dated November 05)</li> <li>Note: If the pH is not neutral, perform further rinses until an acceptable pH is reached (close to pH7).</li> </ul>
3	<b>Sterilization</b> Sterilize the sterilization tray using an autoclave (moist heat sterilizer) at a temperature of at least 134°C for 18 minutes.	

#### Bibliography:

- March 2001 – Circular No. DGS/5C/DHOS/E2/138 dated 14 March 2001 on risk management in health establishments
- November 2005 - Guide from the Ministry on the treatment of medical devices for ophthalmology and contactology - <http://www.sante.gouv.fr>.

## 10 WARRANTY

### 10.1 SCOPE OF WARRANTY

Designation	MORIA references
One Use-Plus handpiece (blue color)	19345
Wrench	19345C
Storage box for the One Use-Plus handpiece	22519514
EVOLUTION 3 console (except the battery)	19360
EVOLUTION 3E console (except the battery)	19380
EVOLUTION 3E Footswitch	19361
EVOLUTION 3E Footswitch Epi-K™	19381

- The above items as well as spare parts and labor necessary for their repair are covered by warranty. Any items returned must be sent in their original packaging, after having previously been disinfected.
- The maintenance operations and the replacement of spare parts will be exclusively carried out by technicians authorized by MORIA.
- Any defective part exchanged during the period of warranty becomes property of MORIA.
- Instruments and accessories that cannot be reused are excluded from this warranty.
- Future upgrades and/or improvements on the keratome are not implied by this warranty.

### 10.2 NON-APPLICATION OF WARRANTY

The warranty will not be applicable under any of the following conditions:

- Defects or malfunction that occur out of the warranty period (10.3).
- Normal wear and tear.
- Negligence or usage that does not comply with the specifications in the user manual.
- The use of supplies, spare parts, or accessories other than those supplied by MORIA.
- Any disassembly, modification or intervention carried out on the devices by a person not authorized by MORIA.

### 10.3 WARRANTY PERIOD

- The warranty takes effect on the date the material is dispatched.
- The duration of the warranty is 12 months from the date of effect.

### 10.4 LIABILITY

- The liability of MORIA is limited to the supply of the services mentioned in paragraph 10.1. MORIA will not be held responsible of any direct or indirect damage suffered by the client owing to the interventions within the scope of this warranty.
- For any dispute concerning the interpretation or the execution of the present contract or the present general terms and conditions, the Commercial Court of Nanterre (France) will have sole jurisdiction.

## 11 DRAWINGS

### A. DISPOSABLE HEAD

- 1 Threaded shaft
- 2 Head calibration value
- 3 Blade housing
- 4 Slide
- 5 Blade
- 6 Aplanating plate

### B. SUCTION RING

- 1 Vacuum connection
- 2 Stop setting screw
- 3 Stop
- 4 Guiding
- 5 Ring size
- 6 Threaded shaft

### C. SETTING THE STOPPER

- 1 Step 1: Loosen safety screw
- 2 Step 2: Turn stop to desired value (the desired stop value must face the ring).  
Tighten screw with fingers

### D. CONNECTING THE SUCTION RING TO THE ASPIRATION TUBING

- 1 Aspiration tubing end
- 2 Suction ring end

### E. MOTOR

- 1 Motor housing
- 2 Motor cord
- 3 Threaded ring
- 4 Oscillation motor shaft
- 5 Head alignment guide
- 6 Advance drive

### F. MOUNTING THE HEAD ON THE MOTOR

- 1 Screw the head clockwise onto the threaded motor shaft.
- 2 Check that the head is screwed on tightly to the motor.
- 3 There should be no rotation of the head.

### G. MOUNTING THE HEAD ON THE SUCTION RING

- 1 When inserting the head in the rails of the suction ring, the handpiece must be at a 45° angle from the threaded shaft of the ring
- 2 Once the head properly inserted, slightly reduce the angle from 45° to 0°

### H. ALIGNMENT OF THE HEAD, MOTOR AND SUCTION RING

- 1 Proper assembly
- 2 Incorrect alignment
- 3 Alignment of the threaded shaft with the motor

### I. CLEANING THE MOTOR

- 1 Disposable brush (#19149)
- 2 Maximum submersion
- 3 Sterile distilled water



MORIA S.A. – 27, rue du Pied de Fourche - 03160 Bourbon  
L'Archambault – France #65040-H-05.2023

