

# MASTEL

PRECISION SURGICAL INSTRUMENTS, INC.  
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## ILLUMINATED SURGICAL KERATOSCOPE ORDER # VARL IK

Designed in conjunction with:

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***Congratulations on your purchase of a Mastel Illuminating Surgical Keratoscope (ISK):***

Your keratoscope is designed to provide accurate centration with a flashing fixation target and three concentric rings of illuminating LED's. These LED's are arranged every 10 degrees. We have targeted the corneal reflection at a normal surgical microscope working distance of 175mm, to represent corneal mires starting at 2.5mm ranging out to 3.5mm. Adjusting your microscope with a closer working distance will allow visualization of a larger diameter optical zone.

## ***Installing your Illuminated Surgical Keratoscope:***

The illuminating keratoscope is mounted to the objective lens of your surgical microscope with the correctly sized mounting ring. These rings are available in 48mm, 65mm, 70mm, and 82mm currently. The mounting rings listed are intended to be used on objectives that are equal to or smaller than the ring size listed. These rings will tighten down approximately two to three millimeters. Please measure your objective lens barrel's outside diameter and choose the appropriate sized mounting ring. If the correct ring is not available, custom adaptors are available for purchase.

We ship your ISK with the mounting ring specified during ordering. If you need to change your mounting ring, please refer to the following pictures and sequence to remove and reassemble the correct mounting ring. This is easily done with a hex key wrench and three screws.





### ***Changing your ring:***

Three screws secure the mounting ring to the ISK. If it is necessary to change your mounting ring simply remove these screws and re-secure the new mounting ring. The new mounting ring will come with the security strap. The security strap is not designed to be removed.

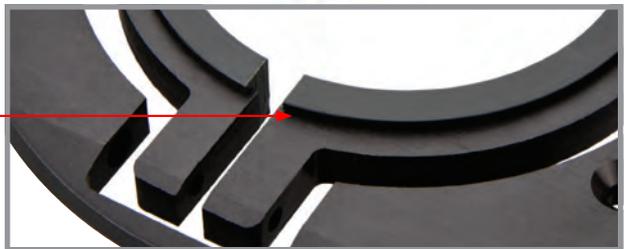
*Torque screws using caution to not over-tighten.*

### ***Custom Adaptors:***

These adaptors are available upon request and will require a lead time along with additional fees.

They are created to provide a solution when unique scope objective sizes are not accommodated by our standard mounting rings.

*These adaptors snap into a standard mounting ring.*



When mounting your ISK to your surgical scope, please note that the fixation light tube is intended to be positioned between the stereo objectives. Please use caution not to scratch the scope's objective lens and avoid bending the fixation tube. Observe that the fixation target is located precisely between the lenses for optimum patient centering. Tighten the thumb knob at the back of the ISK. *Turn the thumb screw clockwise to tighten and counterclockwise to loosen.*

### **Ordering New Adaptor Rings:**

Standard Sizes:

- 48mm - Order # VARL IR48
- 65mm - Order # VARL IR65
- 70mm - Order # VARL IR70
- 82mm - Order # VARL IR82



### **Safety Strap for your Illuminated Surgical Keratoscope:**

The ISK should be firmly in place and then route the safety strap over the top of the scope, fasten the buckle and pull the 3/8" nylon strap until snug to prevent any possible movement of the ISK if it were to become loose. You may choose to remove excess strap\* once you are certain the variety of the surgical microscopes this device will be used with. Do not remove more strap than necessary so that there is enough to be confident the buckle will function properly.



## ***Powering your Illuminated Surgical Keratoscope:***

Your keratoscope is powered by a medical grade 10v DC supply. The power cord utilizes a unique plug that latches when pushed into the jack at the back side of the ISK. To unplug the device from the power source, simply grasp the large barrel portion of the plug and pull gently. The plug releases and detaches as the barrel slides away from the device.



## ***Using your Illuminated Surgical Keratoscope:***

Your new keratoscope is equipped with a control switch with variable illumination. This control knob is designed to firmly accommodate the Zeiss autoclavable sleeve (see page 10). Clockwise rotation turns the device on, providing initial illumination of the flashing LED fixation target. The bright orange flashing LED can be used for any procedure that aids the surgeon's request for the patient to fixate on a target. When the control is turned further clockwise the full ring light array begins to illuminate at its lowest level. With continued rotation the array will achieve full brightness. You will find the lower limit of illumination works best for most needs. This device was not designed with the intent to replace your coaxial light source during intraocular surgery.

*Rotate to illuminate the array*



*Rotate switch to activate the "Jones SteadyPulse" LED*

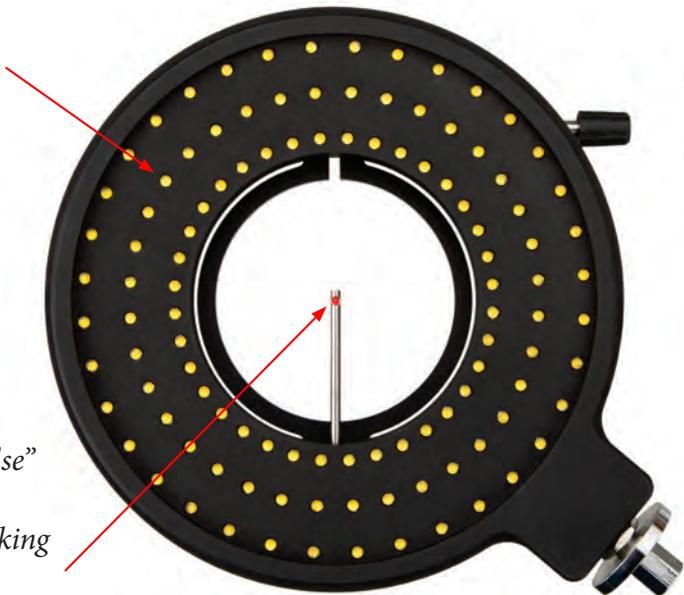
Utilizing the benefits of the flashing fixation LED maximizes the patient's ability to cooperate during surgery when it is necessary for them to move their eye centrally for the procedure. In addition, while the surgeon is performing any crucial alignment steps the patient is able to center his or her visual axis so these procedures can optimize the patient's optical alignment.

The array provides visualization of magnitude and location of corneal aberrations, more specifically, astigmatism. These LED placido rings show the surgeon corneal astigmatism down to one diopter or less. This improves the confidence of superior outcomes and minimizes errors when aligning TORIC IOLs, performing LRI's and procedures such as tensioning sutures during corneal transplantation (keratoplasty).

Not all applications that may benefit from this device focus on cylindrical aberrations. Multi-focal IOLs are centered more precisely as well when aligning the concentric rings of the IOL and the concentric reflections in the cornea while the patient is focusing on the fixation target.

The majority of your precision diagnostic instruments (i.e. topographers and aberrometers) utilize a fixation target so the patient's visual axis is taken into full consideration.

*The LED Array*



*"Jones SteadyPulse"*

*The Orange Blinking  
Fixation LED*

### ***TORIC IOL Alignment:***

With the IOL in place reduce or switch off the coaxial lighting, allowing the reflections off the IOL to appear. The surface reflections of the array off of the cornea appear the brightest. Any astigmatism present will be aligned with the steepest region (the shorter cross section of the dotted mires) with your surgical pre-marks. Reflections from the IOL will appear larger, dimmer and slightly different in color (possibly a slight green/blue tint if chromophore is present).

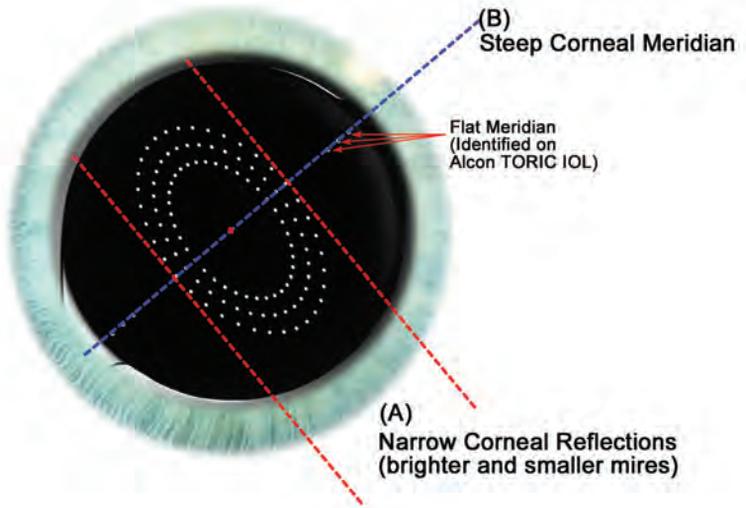
The narrow corneal reflections (A) must align with the steep meridian marks (B). Asking the patient to fixate on the blinking LED, you should attempt to align your scope as close to perpendicular as possible with the patients visual axis. This will provide the most accurate results. You should be able to view the reflections off the IOL and begin your alignment procedure. With the IOL properly placed the reflex of the fixation target should be as centered as possible with regard to the cornea and the IOL (the flashing dots should align with one another). With viewable amounts of cylinder the IOL should be placed with reflections off the IOL (C) aligned 90 degrees from the reflections from the brighter and smaller corneal surface.

This device was not intended as a sole indication of absolute alignment rather a compliment to an entire systematic approach to accurate IOL alignment. The result should instill confidence that the IOL is centered accurately with no concern of being 90 degrees off axis. With refined use, the surgeon will adapt to a system that greatly improves the accuracy of alignment and patient outcomes.

### ***In Summary:***

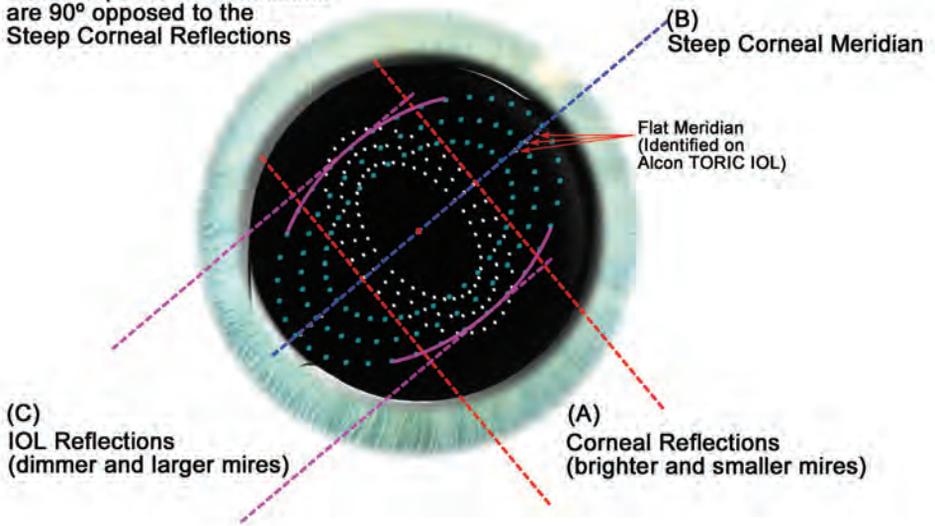
The narrow cross-section of corneal mires aligns with the steep meridian. The wide cross-section of the TORIC IOL is aligned with the steep corneal meridian marks.

*Astigmatic Corneal Reflection Diagram:*



*TORIC IOL Reflection Diagram:*

The Steep TORIC Reflections are 90° opposed to the Steep Corneal Reflections



### ***Multi-Focal IOL Alignment:***

As with TORIC alignment reduce the coaxial lighting so that the reflection off the cornea and the IOL can be seen. With the surgical microscope aligned as perpendicular as possible ask the patient to locate and fixate on the flashing LED. Align the concentric rings of the corneal reflection and those of the IOL. Align the reflections so all become concentric with the flashing fixation light. Confirm alignment by asking the patient to fixate on the fixation target and validate the IOL has been centered properly with the patient's visual axis.



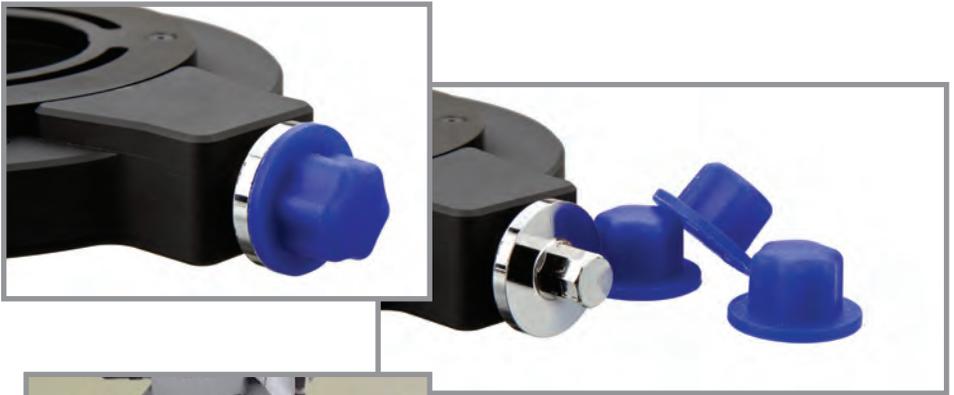
*Autoclavable Sleeves:*

*The ISK is shipped with three standard Zeiss autoclavable sleeves. You may purchase sleeves from:*

*Mastel Precision      Part # RLIK Z3      (package of 3)*

*or*

*Direct from Zeiss      Part # 305810 9002 000      (package of 6)*



# WARRANTY

Mastel Precision non-handheld products are warranted to be free from defects in materials or workmanship for one year from the date of purchase. Within this period, Mastel will, at its sole option, repair or replace any components which fail in normal use. Such repairs or replacement will be made at no charge to the customer for parts or labor, provided that the customer shall be responsible for any transportation cost. This warranty does not cover failures due to abuse, misuse, accident or unauthorized alterations or repairs.

Note: Repairs have a 90 day warranty. If the unit sent in is still under its original warranty, then the new warranty is 90 days or to the end of the original one year warranty, depending upon which is longer.

The warranties and remedies contained herein are exclusive and in lieu of all other warranties, whether expressed, implied or statutory, including any liability arising under any warranty of merchantability or fitness for a particular purpose, statutory or otherwise. This warranty gives you specific legal rights, which may vary from state to state.

In no event shall Mastel be liable for any incidental, special, indirect or consequential damages, whether resulting from the use, misuse or inability to use the product or from defects in the product. Some states do not allow the exclusion of incidental or consequential damages, so the above limitations may not apply to you.

Mastel retains the exclusive right to repair or replace the product or offer a full refund of the purchase price at its sole discretion.



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