LENS INSTRUCTIONS FOR USE

- 1. Choose the appropriately powered lens for the desired magnification and laser spot size.
- 2. Insure lens is properly cleaned and if neces sterilized prior to usage; see cleaning / sterilization instructions as needed.
- 3. Hold lens with thumb and pointer finger Indirect BIO Lens

4. Place lens the appropriate distance away from the patience's cornea to view the desired region of the

- eye using an illuminated binocular indirect ophthalmoscope (BIO); see BIO manufacturer's instructions for use if required.
- 5. If necessary, to steady the hand while viewing the retina, rest the palm and/or remaining fingers on the patience's face or brow.
- 6. The lens can be dynamically moved and/or tilted to change the magnification and field of view or reduce reflections. Moving the lens closer to the cornea increases the magnification, decreases the field of view. Moving the lens further from the cornea decreases the magnification, increases the field of

Indirect Non-Contact Slit Lamp Lens

- Instruct the patient to look in the desired direction and with a narrowed slit lamp beam, focus the slit lamp microscope beam on the patient's cornea; see slit lamp microscope manufacturer's instructions for use if required.
- 5. Place lens the appropriate distance away from the patience's cornea to view the desired region of the
- 6. Using the slit lamp's joystick, pull the slit lamp microscope back until the retinal image comes into
- Manipulate the joystick, microscope magnification and slit lamp illumination axis, width, and intensity to scan the retina and minimize reflections.
- 8. The lens can be dynamically moved and/or tilted to change the magnification and field of view or reduce reflections. Moving the lens closer to the cornea increases the magnification, decreases the field of view. Moving the lens further from the cornea decreases the magnification, increases the field of

Indirect Contact Slit Lamp Lens

- 4. Anesthetize the patient's cornea with topical ophthalmic anesthetic prior to inserting the lens.
 Inspect the concave contact surface and insure it is clean and chip/scratch free. Apply methylcellulose, or similar interface solution, to a flanged lens or verify the normal tear film is present on the patient's cornea or apply a drop of non-preserved saline solution, or similar interface solution, to a non-flanged lens, on the concave contact lens surface. Try to avoid producing bubbles in the interface solution.

 5. Instruct the patient to look forward and with a
- narrowed slit lamp beam, focus the slit lamp microscope beam on the patient's cornea:

- see slit lamp microscope manufacturer's instructions
- 6. Carefully apply the Indirect Contact Slit Lamp Lens to the patient's cornea. As a suction effect will occur, applying slight pressure to keep the lens in contact with the cornea and globe is required.
- 7. Manipulate the lens to eliminate any air bubbles in the interface solution. If the air bubbles are too prevalent and obstruct the view, carefully remove the lens from the patient's cornea, clean off, and reapply the interface solution to the concave contact lens surface before reapplying the lens to patient's
- 8. Raise the lens near or against the patient's eyebrow to optimize fundus visualization
- Using the slit lamp's joystick, pull the slit lamp microscope back until the retinal image comes into focus.
- 10. Manipulate the joystick, microscope magnification and slit lamp illumination axis, width, and intensity to scan the retina and minimize reflections.
- 11. The lens can be dynamically tilted to bring different fields into view. Avoid over tilting the lens and compromise the cornea to lens airtight interface.
- Direct & Mirrored Contact Slit Lamp Lens 4. Anesthetize the patient's comea with topical ophthalmic anesthetic prior to inserting the lens
- 5 Inspect the concave contact surface and insure it is clean and chip/scratch free. Apply methylcellulose, or similar interface solution, to a flanged lens or verify the normal tear film is present on the patient's cornea or apply a drop of non-preserved saline solution, or similar interface solution, to a non-flanged lens, on the concave contact lens surface. Try to avoid
- producing bubbles in the interface solution 6. Instruct the patient to look forward and with a narrowed slit lamp beam, focus the slit lamp microscope beam on the patient's cornea; see slit lamp microscope manufacturer's instructions for use
- 7. Carefully apply the Direct or Mirrored Contact Slit Lamp Lens to the patient's comea. As a suction effect will occur, applying slight pressure to keep the lens in contact with the cornea and globe is required.
- 8. Manipulate the lens to eliminate any air bubbles in the interface solution. If the air bubbles are too prevalent and obstruct the view, carefully remove the lens from the patient's cornea and clean off then reapply the interface solution to the concave contact surface before reapplying the lens to patient's cornea
- 9. Raise the lens near or against the patient's eyebrow to optimize fundus visualization.
- 10. Using the slit lamp's joystick, pull the slit lamp microscope back until the retinal, anterior chamber, iris, or lens capsule image comes into focus.

 11. Manipulate the joystick, microscope magnification
- and slit lamp illumination axis, width, and intensity to scan the retina or anterior segment and minimize

- 12. The lens can be dynamically tilted or in mirrored lenses, the lens can be rotated, to change the field of view. As a reminder, the images are reversed for mirrored lenses. Avoid over tilting the lens and compromise the cornea to lens airtight interface.
- 13. When viewing the anterior chamber, avoid excess pressure on the cornea to reduce dynamic effects to the angle structure.

Direct Suture Lysis Contact Slit Lamp Lens

- Instruct the patient to position the eye where the suture can be seen through the slit lamp microscope.
- 5. Position the Suture Lysis lens on the suture that is to be treated.
- 6. Using the slit lamp's joystick, manipulate the slit lamp microscope until the suture image comes into focus; see slit lamp microscope manufacturer's instructions

Surgical Lenses Contact Slit Lamp Lens

- 4. Inspect the concave contact surface and insure it is clean and chip/scratch free. Apply methylcellulose, or similar interface solution, to the concave surface.
- 5. Carefully apply the Surgical Lens to the patient's cornea. Manipulate the lens to eliminate any air bubbles in the interface solution.
- Adjust the surgical microscope's magnification and light source, if applicable, to obtain a retinal image.
- Cleaning Instructions

 1. As all ion VISion, INC. lens components are completely glass, it is possible to clean the contact element's concave surface or coated imaging lens with alcohol, peroxide, or acetone. If these cleaning solutions are unavailable or further cleaning is desired, then proceed with these additional cleaning
- 2. Immediately upon removal from patient's eye or use, thoroughly rinse the entire lens in cool or tepid water.
- 3. Place a few drops of mild cleaning solution, such as diluted liquid dish soap, or similar on a clean moistened 100% cotton cloth, ball, or swab depending on the cleaning area.
- 4. Gently clean the entire lens, insuring the contact concave surface and/or convex surfaces have been thoroughly cleaned to remove any debris, dirt, film, fingerprints or residue. Do not apply excessive pressure as this may cause scratching of the glass lens and/or coating.

 5. Rinse entire lens thoroughly in cool or tepid water
- Dry the lens by using a clean 100% cotton cloth, ball, or swab or non-linting cotton tissue insuring to remove all water droplets from the imaging surfaces.
- 7. Proceed with disinfecting or sterilization instructions as required.

Disinfecting Instructions

- Two methods of disinfection are recommended To avoid lens damage, do not exceed recommended exposure time:
 - ☐ Glutaraldehyde: 2% or 3.4% aqueous solution. Temperature per manufacturer's instructions. Recommended exposure time 20-25 minutes.
 - ☐ Sodium hypochlorite / Bleach: 10% solution mixed at 1 part bleach to 9 parts water Recommended exposure time 10-12 minutes.

 Immerse the lens entirely in the chosen solution for
- the recommended exposure time. Either place lens on its side or insure all air hubbles are removed from under the lens for complete
- Remove lens from the solution after recommended exposure time and rinse lens thoroughly with cool or tepid water to remove all disinfection solution with at least 3 rinse cycles of 1 minute duration.
- Dry the lens by using a clean 100% cotton cloth ball, or swab or non-linting cotton tissue insuring to remove all water droplets from the imaging surfaces.
- Store in a dry storage case.

Ethylene Oxide Sterilization Instructions Use the standard hospital ETO time, temperature, and

aeration for instrumentation or: Minimum Time: 60 minutes Temperature: 130°F (54°C), do not exceed Aeration Time: 12 hours

Vacuum Steam Sterilization Instructions SurgiView Lenses ONLY

Follow the standard hospital vacuum steam sterilization procedures for instruments or use these as guidelines"

Prep: Place SurgiView lenses in a protective sterilization case.

Process: Standard Cycle (wrapped) Temperature: 270°F (134°C) Time: 15 minutes minimum

Temperature: 250°F (121°C) Time: 30 minutes minimum

CAUTION: Do not boil lenses. Do not autoclave (vacuum steam sterilize) lenses except for SurgiView lenses. Do not disassemble lenses for any reason. Insure contact surface is chip/scratch free and do not use a lens that has a chip or scratch on contact surface. Insure all lens surfaces are clean prior to diagnosis and do not treat / use a laser through a non-clean surface.

oduct Specification Chart

| Lens Name | FOV | Image Mag | LSF |
|---------------------------------------|--------------|-----------------------------|---------------|
| | | | |
| | | PTHALMOSCOPE LI | |
| eZView 14D eZView 15D | 47° 47° | 4.30x | .23x |
| eZView 15U eZView 20D | | 4.11x | |
| SurgiView 20D | 60° | 3.08x | .32x |
| eZView 22D | 73° | 2.68x | .37x |
| eZView 25D | 68° | 2.54x | .39x |
| eZView 28D | 69° | 2.27x | .44x |
| SurgiView 28D eZView 30D | 75° | 2.15x | .47x |
| eZView 40D | 90° | 2.15X 1.67x | .47X |
| | | ACT INDIRECT LEN | |
| eZView 60D | 81° | 1 15X | .87x |
| eZView 78D | 97° | .93x | 1.08x |
| eZView 90D | 89° | .76x | 1.32x |
| eZView 95 | 96° | 1.0x | 1.0x |
| eZView 115 | 116° | .76x | 1.3x |
| eZView 125 | 124° 124° | .57x | 1.75x |
| eZView 124 SP i3D HiMag | 124° | .45x 1.0x | 2.22x 1.0x |
| i3D WideField | 117° | 0.76x | 1.32x |
| i3D Ultra WideField | 125° | 0.57x | 1.75x |
| i3D UltraWide Non- | 125° | 0.45x | 2.22x |
| Myd i3D Elite Mag | 49° | 3.89x | .26x |
| i3D Elite Wide | 72° | 2.79x | .36x |
| i3D Elite | 70° | 1.30x | .77x |
| StereoMag | 72° | 1.0x | 1.0x |
| i3D Elite Stereo1x i3D Elite Field | 125° | 1.0x .72x | 1.0x 1.39x |
| | | CONTACT LE | |
| OmniView 165 | 165° | .5x | 2.0x |
| OmniView 145 | 144° | .51x | 1.97x |
| OmniView 137 | 137° | .44x | 2.27x |
| OmniView 135 | 137° | .66x | 1.50x |
| OmniView 85 | 84° | 1.06x | .94x |
| | | CONTACT LEN | |
| DirectView Fundus 1.0x | 35° | 1.0x | 1.0x |
| DirectView Iridotomy DirectView | N/A | 1.5x | 0.67x |
| Capsulotomy | N/A | 1.5x | 0.67x |
| DirectView Suture Lysis | N/A | 1.25x | 1.0x |
| DirectView Suture Lysis TS & TST | N/A | 1.5-2.0x | 1.0x |
| DirectView 1 Mirror | N/A | Mirror 1.0x | 1.0x |
| Directives I will of | IWA | Central 1.5x | 0.67x |
| DirectView 1 Mirror SLT | N/A | Mirror 1.0x Central 1.5x | 1.0x 0.67x |
| DirectView 2 Mirror | N/A | Mirror 1.0x | 1.0x 0.67x |
| DirectView 3 Mirror | N/A | Central 1.5x 1.0x | 1.0x |
| DirectView 4 Mirror | 360° | 0.9x | 1.1x |
| DirectView 4 Mirror 1.5x | 360° | Mirror 1.0x | 1.0x |
| | | Central 1.5x | 0.67x |
| SurgiView Direct 0.5 | 48° | 0.5x | N/A |
| SurgiView Direct 0.75 | 46° | 0.5X 0.8X | N/A N/A |
| SurgiView Direct 1.0 | 36° | 1.0x | N/A |
| SurgiView Direct 1.5 | 36° | 1.5x | N/A |
| SurgiView Direct 20° | 44° | 0.58x | 1.72x |
| Prism SurgiView Direct 30° | 33° | 1.0x | 1.0x |
| Prism | | | |
| SurgiView Central SurgiView Wide | 88° 127° | 0.7x 0.4x | N/A N/A |
| ourgiview WIDB | 141 | U.4X | N/A |

ion VISion, INC. Policy Statements

Warranty

ion VISion, INC, ("IVI") takes tremendous pride in designing, developing, manufacturing, distributing, and supporting high quality ophthalmoscopic lenses (the "Product"). If for any reason a Product does not meet or exceed your expectations, you may return it to IVI within 30 days of purchase for a full refund of the purchase price, less shipping. IVI warrants all of its products against defects in materials and workmanship for 1 year from the invoice date. Warranty service will not be provided without receipt or proof of purchase from IVI or an authorized distributor of IVI. Warranty repairs will include all labor, adjustments and replacement parts. The Warranty does not cover shipping damage from the returning party and it is the returning party's responsibility to properly package, insure, and track the product throughout the return shipping process. The Warranty does not cover any damages to the product caused in whole or in part by the customer's failure to follow the recommended cleaning, disinfection and sterilization instructions and/or precautions contained in the Instruction For Use, which shall be determined solely by IVI. The Warranty also does not cover service required because of disassembly, unauthorized modifications or service, defacing, misuse, abuse, droppage, etc. unrelated to the design and manufacturing processes of IVI, as determined solely by

Except for the above express warranty, no other warranties, express or implied (including merchantability or fitness for any particular purpose), are made or applicable to this agreement. IVI will not be liable to purchaser or any third party for consequential, incidental or special damages arising directly or indirectly from the manufacture, sale or use of IVI's products, including ophthalmoscopic lenses, and in no event will IVI's liability under this agreement exceed the amount of the purchase price received by ion vision for the product.

Product Return PolicyAll returned Products must be accompanied by a Return Authorization Number to qualify for a refund. Please contact IVI's Customer Service Department prior to returning the Product to obtain a Return Authorization Number. Customers shall be responsible for returning Products for warranty service or returned goods to ion VISion, INC. IVI recommends that all shipments to IVI be made via UPS, prepaid and insured for full value. Products damages during return shipping do not qualify for a refund or the warranty. Please clean and disinfect all Products prior to returning them to IVI or they will be returned.

If you have questions regarding or ion VISion, INC.'s Policy Statements, please contact ion VISion, INC.

Telephone: 1.760.814.7099 1.760.494.4454 Fax: Email: sales@ion-vision.com Website: www.ion-vision.com

ion VISion, INC. Instructions For Use written in conjunction with:

Peter K. Kaiser, MD Cole Eye Institute, Cleveland Clinic Foundation



ion VISion, INC. **Instructions For Use**

(L-0100)



EEC Representative

M Gourlay 7 Kirby Way Southbourne Bournemouth BH6 3HZ 01202 434022

NON-STERILE, No estéril, Unsteril, Non-stérile, Non sterile, 非滅菌



ion VISion, INC.

1.760.814.7099 1 760 494 4454 fax sales@ion-vision.com www.ion-vision.com

©2016 ion VISion, INC. L-0100 REV. E 12/16

