ENGLISH: Instructions for Use for 2mm Research Lenses

<table>
<thead>
<tr>
<th>Product</th>
<th>Image Magnification</th>
<th>Mirror Angles</th>
<th>Laser Spot Magnification Factor</th>
<th>Contact Diameter</th>
<th>Contact Design</th>
<th>Contact Coating</th>
</tr>
</thead>
<tbody>
<tr>
<td>2mm Research Gonio Lens</td>
<td>1.00</td>
<td>62° (X4)</td>
<td>N/A</td>
<td>2.0 mm</td>
<td>No Flange</td>
<td>No Coating</td>
</tr>
<tr>
<td>2mm Research Fundus Lens</td>
<td>1.00</td>
<td>N/A</td>
<td>N/A</td>
<td>2.0mm</td>
<td>No Flange</td>
<td>Broadband</td>
</tr>
</tbody>
</table>

NOT FOR HUMAN USE

WARNING

CONTACT DESIGN

Methylcellulose or other similar interface solution to be applied to the concave contact surface.

PROTOCOL

For use in research procedures:

1. Inspect the contacting surface(s) to make sure they are free from any chips or scratches.

WARNING

DO NOT USE THE LENS WHEN THE CONTACTING SURFACE(S) SHOW(S) ANY SIGNS OF CHIPPING OR SCRATCHING

2. Apply appropriate amount of sterile viscous, tear-like coupling fluid to the concave contact surface, or verify the normal tear film is present or apply a drop of non-preserved saline solution to the concave contact surface.

WARNING

DO NOT ATTEMPT TO USE THE LENS UNLESS AN ADEQUATE TYPE AND AMOUNT OF COUPLING FLUID IS PRESENT BETWEEN THE CORNEA AND THE CONTACTING LENS SURFACE

3. Use the biomicroscope according to manufacturer’s instructions.

WARNING

DO NOT ATTEMPT TO USE THE LENS IF, FOR ANY REASON, THE IMAGE IS UNCLEAR OR UNFOCUSED

REPROCESSING

Warnings:
1. A thorough, manual cleaning process is recommended.
2. Corrosive cleaning agents (e.g., acids, alkalines, etc.) are not recommended. Detergent cleaning agents with neutral pH are recommended.

Reprocessing Limitations: Repeated cleaning, disinfection and sterilization have minimal effect on Research lenses when processed according to instructions. End of life is normally determined by wear and damage due to use.

Preparation at the Point of Use:
1. New or used, contaminated lenses must be cleaned.
2. Fluids should not be allowed to dry on the unit prior to cleaning. Remove excess fluids.
3. Universal precautions for handling contaminated materials should be observed.
4. Instruments should be cleaned as soon as possible after use to minimize the drying.

Preparation before cleaning: The following instructions are aided by not allowing contamination to dry on the lenses. When possible place the lenses in water or cover them with a damp cloth.

CAUTION

TO AVOID RISK OF INFECTION, CLEAN AND DISINFECT PRODUCT BEFORE USE.

CLEANING, DISINFECTION, STERILIZATION

CLEANING: SELECT THE APPROPRIATE METHOD OF CLEANING FROM THE TABLE BELOW. IF THE LENS IS TO BE SUBSEQUENTLY STERILIZED PRIOR TO ITS RE-USE, VOLK RECOMMENDS THAT IT FIRST BE PROCESSED USING CLEANING METHOD C LISTED BELOW.

Method A: Wash with a mild cleaning solution (diluted dishwashing liquid) and a clean soft cotton cloth or swab.

Method B: Clean entire lens surface with Volk Precision Optical Lens Cleaner (POLC).

Method C: Prepare fresh enzymatic cleaner (e.g. Enzol) solution
1. Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30-43°C) tap water.
2. Soak each device in solution for 20 minutes.
3. After soaking, brush injured surface of housing with a soft bristle brush and wipe lens portion with a soft cloth until all traces of cleaner and soil are removed. Pay special attention to all crevices and other hard to-reach areas. Note: Do not brush lens portion to avoid scratching; use soft cloth.
4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.
5. Transfer the devices to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes.
6. After sonication, thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.
7. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.

Disinfection:

DISTINCTION PROCEDURE TO BE USED FOR ALL DIAGNOSTIC AND THERAPEUTIC LENSES THAT CONTACT THE EYE

1. Follow the cleaning instructions for Method A.
2. Select one of the solution types from the table below:

<table>
<thead>
<tr>
<th>Solution Type</th>
<th>Concentration</th>
<th>Soak Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>2% aqueous solution</td>
<td>20 minutes</td>
</tr>
<tr>
<td>CIDEX® OPA</td>
<td>Per manufacturer</td>
<td>12 minutes</td>
</tr>
</tbody>
</table>

3. Position the lens on its side, then immerse the entire lens in the selected solution type and concentration for the listed soak time.
4. Remove the lens from the solution and thoroughly rinse with room temperature water, then dry with a soft lint free cloth.

Using CIDEX® OPA:
1. Follow the cleaning instructions.
2. Immerse device completely, filling all lumens or other hard-to-reach areas and eliminating air pockets, in CIDEX® OPA Solution for a minimum of 12 minutes at a minimum of 20°C.
3. Rinse thoroughly in a room temperature (minimum of 20°C) water bath. Rinse by immersing device completely for a minimum of one minute. Manually flush all lumens or other hard-to-reach areas with water. Agitate device under water, bring above water level, then re-immers.
4. Repeat rinse procedure two additional times using fresh water.

Sterilization:

STERILIZATION TO BE CONDUCTED ON LENSES AND EQUIPMENT USED IN AN OPERATING ROOM OR OTHER STERILE ENVIRONMENT

1. Lenses may be sterilized using the ethylene oxide sterilization process. Sterilize using a 2 hour cycle with a temperature of 130°F and a concentration of 600 mg/L.

Storage: Sterile instruments should be stored in an area that provides protection from loss of sterility.

CAUTION

TO AVOID PRODUCT DAMAGE, NEVER AUTOCLAVE OR BOIL LENSES.

See website or catalogue for warranty information.