ENGLISH: INSTRUCTIONS FOR USE

INTENDED USE
The Volk Optical BIO Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a binocular indirect ophthalmoscope.

SPECIFICATIONS

<table>
<thead>
<tr>
<th>Product</th>
<th>Magnification</th>
<th>Field of View</th>
<th>Working Distance</th>
<th>Laser Spot Magnification</th>
<th>Diameter</th>
<th>Anti-Reflective Laser Coating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macula Plus® 5.5</td>
<td>5.50</td>
<td>36° - 43°</td>
<td>80 mm (w/ Extension) 39 mm (w/ Extension)</td>
<td>0.18</td>
<td>58 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>14D</td>
<td>4.3</td>
<td>36° - 47°</td>
<td>75 mm</td>
<td>0.23</td>
<td>52 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>15D</td>
<td>4.11</td>
<td>36° - 47°</td>
<td>72 mm</td>
<td>0.24</td>
<td>52 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>20D</td>
<td>3.13</td>
<td>46° - 60°</td>
<td>50 mm</td>
<td>0.32</td>
<td>50 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>Pan Retinal® 2.2</td>
<td>2.68</td>
<td>56° - 73°</td>
<td>40 mm</td>
<td>0.37</td>
<td>53 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>25D</td>
<td>2.54</td>
<td>52° - 68°</td>
<td>38 mm</td>
<td>0.39</td>
<td>45 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>28D</td>
<td>2.27</td>
<td>53° - 69°</td>
<td>33 mm</td>
<td>0.44</td>
<td>41 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>30D</td>
<td>2.15</td>
<td>58° - 75°</td>
<td>30 mm</td>
<td>0.47</td>
<td>43 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>30D Small</td>
<td>2.09</td>
<td>44° - 57°</td>
<td>30 mm</td>
<td>0.48</td>
<td>31 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>40D</td>
<td>1.67</td>
<td>69° - 90°</td>
<td>20 mm</td>
<td>0.60</td>
<td>40 mm</td>
<td>BBAR</td>
</tr>
<tr>
<td>Digital ClearField</td>
<td>2.79</td>
<td>55° - 72°</td>
<td>37 mm</td>
<td>0.36</td>
<td>48 mm</td>
<td>UHE</td>
</tr>
<tr>
<td>Digital Clearflag</td>
<td>3.89</td>
<td>38° - 49°</td>
<td>60 mm</td>
<td>0.26</td>
<td>48 mm</td>
<td>UHE</td>
</tr>
</tbody>
</table>

INDICATIONS FOR USE
1. To be used by a licensed physician in a method consistent with other binocular indirect fundus lenses.
2. Using the Specifications above, carefully position the lens to the appropriate working distance from the cornea. The silver rim on the ring is to be positioned towards the patient.
3. Volk’s BBAR Anti-Reflective Laser Coating is optimized for diagnostic imaging, as well as visible and near-infrared wavelength laser procedures (e.g. argon & diode).
4. Volk’s UHE Anti-Reflective Laser Coating is optimized for diagnostic imaging and visible wavelength laser procedures only (e.g. argon).
5. When calculating the spot size at the retina, the laser spot setting should be multiplied by the appropriate magnification factor. Refer to the Specifications table to find the appropriate Laser Magnification-Factor for the lens you are using.

REPROCESSING

WARNING:  
1. A THOROUGH, MANUAL CLEANING PROCESS IS RECOMMENDED.
2. CORROSIVE CLEANING AGENTS (I.E. 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 Volk Non-Contact BIO Lenses when processed according to instructions. End of the product’s life cycle 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. Body fluids should not be allowed to dry on the device prior to cleaning. Remove excess body 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 of contaminants to the surface.
5. Devices should always be handled in an appropriate method to ensure contamination is not introduced to a recently cleaned, disinfected, and/or sterilized device.

PREPARATION BEFORE CLEANING:
The following cleaning, disinfection, and sterilization instructions are aided by not allowing contamination to dry on the lens surface. When possible place the lenses in water or cover them with a damp cloth.

CLEANING, DISINFECTION, STERILIZATION
CLEANING:
Select the desired method of cleaning:

Method A: Clean with a mild detergent and a clean soft cotton cloth or swab. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing. Do not use detergents containing Emollients (moisturizers). CAUTION: Do not reach beyond the retaining ring. Method B: Clean the glass element with Volk Precision Optical Lens Cleaner (POLC) or a Volk LensPen®. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing. CAUTION: Do not use Volk’s POLC, or the Volk LensPen® on surfaces that contact the eye.

Method C: 1. Prepare fresh enzymatic solution (~2 ounces per gallon using warm (~50 - 45°C) tap water. 2. Soak each device in solution for 20 minutes. 3. After soaking, brush knurled surface on device ring with a soft bristle brush and wipe lens portion with a soft cloth until all traces of debris are removed. 4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. 5. After sonication, thoroughly rinse device(s) in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. 6. After sonication, thoroughly rinse device(s) 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:
1. Follow the Method A or Method C cleaning instructions.
2. Select one of the solution types from the table below:

<table>
<thead>
<tr>
<th>DISINFECTANT</th>
<th>CONCENTRATION</th>
<th>MIN SOAK TIME</th>
<th>MAX SOAK TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>2% aqueous solution</td>
<td>25 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium hypochlorite</td>
<td>9 parts water:1 part household bleach (5.25% NaClO)</td>
<td>10 minutes</td>
<td>25 minutes</td>
</tr>
<tr>
<td>Cidex OPA</td>
<td>See Manufacturer’s Instructions</td>
<td>12 minutes</td>
<td>N/A</td>
</tr>
</tbody>
</table>

3. Position the lens on its side, and then immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C). Ensure to fill all lumens, hard-to-reach areas, and eliminate air pockets.
4. Rinse thoroughly in a room temperature water bath (minimum of 20°C). 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. Repeat rinse procedure two additional times using fresh water.
5. Dry with a soft, lint-free cotton cloth.

CAUTION:
1. Ensure the device is completely submerged in the disinfectant solution for the entirety of the recommended or desired soak time. Do not allow the device to become unsubmerged from the disinfectant solution.
2. Extended exposure and/or exposure to higher concentrations of sodium hypochlorite will result in accelerated degradation of the product.

STERILIZATION:
1. Follow the Method C cleaning instructions.
2. Ethylene oxide sterilization is the preferred method of sterilization. Sterilize using a 2 hour cycle with a recommended temperature of 130°F (not exceeding 150°F) and a concentration of 600 mg/L.
3. Do not sterilize lenses within standard (black leatherette) lens cases as they are not meant for use in sterilization systems.

CAUTION:
To avoid product damage, never autoclave or boil lenses or adapters.

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

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