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Volk Optical Binocular Indirect Ophthalmoscope (BIO) Lenses

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

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

INDICATIONS FOR USE

- To be used by a licensed physician in a method consistent with other binocular indirect fundus lenses.
- 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.
- 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).
- Volk's UHE Anti-Reflective Laser Coating is optimized for diagnostic imaging and visible wavelength laser procedures only (e.g. argon).
- When calculating the spot size at the retina, the laser spot setting should be multiplied by the appropriate *Laser Magnification Factor*. Refer to the Specifications table to find the appropriate Laser Magnification Factor for the lens you are using.

⚠ CAUTION:

ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO THE DEVICE SHOULD BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED.

REPROCESSING

⚠ WARNING:

- A THOROUGH, MANUAL CLEANING PROCESS IS RECOMMENDED.
- 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:

- New or used, contaminated lenses must be cleaned.
- Body fluids should not be allowed to dry on the device prior to cleaning. Remove excess body fluids.
- Universal precautions for handling contaminated materials should be observed.
- Instruments should be cleaned as soon as possible after use to minimize the drying of contaminants to the surface.
- 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).
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:	<ol style="list-style-type: none"> Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water. Soak each device in solution for 20 minutes. 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 cleaner and soil are removed. Clean lens surface in a clockwise direction. Pay special attention to all crevices and other hard-to-reach areas. NOTE: Do not brush lens portion to avoid scratching; use soft cloth. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes. After sonication, thoroughly rinse device(s) in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.



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DISINFECTION:

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

DISINFECTANT	CONCENTRATION	MIN SOAK TIME	MAX SOAK TIME
Glutaraldehyde	2% aqueous solution	25 minutes	N/A
Sodium hypochlorite (5000 ppm NaClO)	9-parts water:1-part household bleach (5.25% NaClO)	25 minutes	25 minutes
Cidex OPA	See Manufacturer's Instructions	12 minutes	N/A

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 ENTIRITY 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.

DEVICE DISPOSAL

Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Do not dispose the lens as unsorted municipal waste. When disposing of this product, please follow the procedure which conforms with the laws and regulations applicable to your area.



Consult the Instructions for Use for important cautionary information

LOT

Lot number

REF

Reference number



Manufacturer

EC REP

Authorized representative in the European Community



Date of manufacture

MD

Medical Device