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Volk Binocular Indirect Ophthalmoscope (BIO) and Non-Contact Indirect Slit Lamp Cielo Lenses

- FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

ENGLISH: INSTRUCTIONS FOR USE

INDICATIONS FOR USE

The Volk BIO Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a binocular indirect ophthalmoscope. The Volk Non-Contact Indirect Slit Lamp Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a slit lamp.

SPECIFICATIONS

Product	Magnification	Field of View	Laser Spot Magnification Factor	Working Distance	Anti-Reflective Laser Coating
Cielo 20D (C20)	3.13	45° / 58°	0.32	47 mm	Yes
Cielo 28D (C28)	2.27	54° / 70°	0.44	30 mm	Yes
Cielo 78D (C78)	0.93	81° / 97°	1.08	8 mm	Yes
Cielo 90D (C90)	0.76	77° / 93°	1.32	6.5 mm	Yes



WARNINGS

- Inspect the optical surface(s) to make sure it is free from any damage (e.g. chips, scratches, etc.). Do not use or repair if the device is damaged.



PRECAUTIONS

- Do not attempt to use the Volk Binocular Indirect Ophthalmoscope (BIO) and Non-Contact Indirect Slit Lamp Cielo Lenses prior to completely reading and understanding these instructions for use.
- To be used by a licensed physician in a method consistent with other indirect image binocular and slit lamp lenses.
- Volk Binocular Indirect Ophthalmoscope (BIO) and Non-Contact Indirect Slit Lamp Cielo Lenses are not rated for sterilization. Do not sterilize the Volk Binocular Indirect Ophthalmoscope (BIO) and Non-Contact Indirect Slit Lamp Cielo Lenses.
- Corrosive cleaning agents are not recommended. Cleaning detergents / agents with neutral pH are recommended.
- To avoid lens surface damage, do not clean the device with hydrogen peroxide or acetone.

SUGGESTED DIRECTIONS FOR USE

- A thorough manual cleaning process is recommended prior to use.
- Always use the Volk Binocular Indirect Ophthalmoscope (BIO) Cielo Lenses in combination with a binocular indirect ophthalmoscope.
- Always use the Volk Non-Contact Indirect Slit Lamp Cielo Lenses in combination with an ophthalmic slit lamp biomicroscope.
- Carefully position the lens at the appropriate working distance from the cornea, and adjust to view the fundus.
- When calculating the spot size at the treatment site, 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 that is being used.

CLEANING AND DISINFECTION

- Follow the Method A cleaning instructions. If disinfection is also performed, Method A cleaning instructions are recommended prior to disinfection.

Cleaning Method	Instructions
A	Clean with a mild detergent and a clean soft cotton cloth or swab. Do not use detergent with any type of emollients.
B (optional)	Clean the optical surface(s) with Volk Precision Optical Lens Cleaner (POLC) or a Volk LensPen®. Clean lens surface in a clockwise direction.

NOTE: Disinfection is not required; however, if performed, disinfection should be performed as prescribed below.

- Select one of the solution types from the table below following the Method A cleaning instructions.

Disinfectant	Concentration	Minimum Soak Time	Maximum Soak Time
Sodium hypochlorite (5.25% NaClO; household bleach)	9 parts water, 1 part bleach	10 minutes	25 minutes
Cidex OPA	Refer to manufacturer's instructions	12 minutes	N/A

- 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.
- 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-immerses. Repeat rinse procedure two additional times using fresh water.
- Dry with a soft, lint-free cotton cloth.



Consult the Instructions for Use for important cautionary information

LOT

Lot number

REF

Reference number



Manufacturer

EC REP

Authorized representative in the European Community