

PACKAGE INSERT

IMPORTANT - Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION - Federal Law Prohibits Dispensing Without a Prescription.

HYDRO₂[®] (filofocn A)

RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR

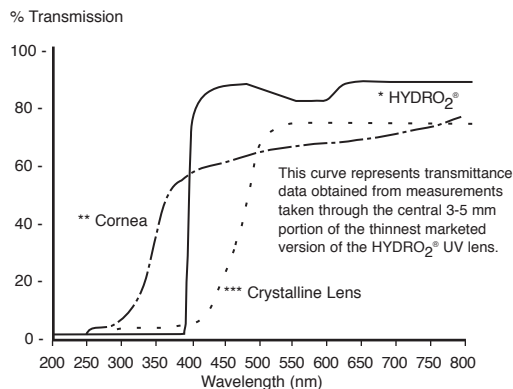
Spherical, Aspheric Lenses for:
Nearsightedness (Myopia),
Farsightedness (Hyperopia),
After Cataract Surgery (Aphakia),

Astigmatic (Toric) Lenses for Astigmatism
Bifocal/Multifocal Lenses for Presbyopia

DESCRIPTION:

The HYDRO₂[®] (filofocn A) Rigid Gas Permeable Contact Lens is available as spherical, aspherical, and as an astigmatic (toric) lens. The lens material, (filofocn A), is a copolymer derived from fluorosilicone acrylate monomers.

The HYDRO₂[®] Contact Lens is available in a light blue tint containing the color additive D & C Green No. 6. Ultra -Violet light absorbing lenses contain the additive Uvinul D-50 which effectively blocks all light in the 200nm to 400nm range.



*HYDRO₂[®] -5.00D power, .10mm center thickness, Clear

**Cornea Human cornea from a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, New York, 1980, p.58, figure 2-21

*** Crystalline Lens Human crystalline lens from a 25 year old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, figure 5

NOTE: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eyecare practitioner for more information.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

The HYDRO₂[®] Contact Lens is a hemispherical shell of the following dimensions:

Chord Diameter:7.0 to 11.5mm
Center Thickness:08 to 1.0mm
Base Curve:6.00 to 10.00 mm
Powers: sphere:+20.00 to -20.00 Diopters
cylinder:up to 7.00 Diopters (torics only)
axis:0 to 180 Degrees (torics only)
Eccentricity:<1 (low eccentric aspherics only); >=1 (multifocals)
Bifocal/Multifocal Add Powers:+25 to +4.00 Diopters

The physical properties of the HYDRO₂[®] lens are:

Specific Gravity:1.146 gm/ml at 25°C
Refractive Index:1.463
Light Transmittance: (Average Level)91% Lt Blue
Wetting Angle:11.3 (Captive Bubble) ANSI Z80.20 - 1998, 8.11.2
Water Content:1.04% (Gravimetric) ANSI Z80.20 - 1998, 8.22
Oxygen Permeability (Dk):40 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg) @ 35°C (Corrected Polarographic) ANSI 80.20-1998, 8.18.2
Material Hardness:85 ANSI Z80.20-1998, 8.16.1.2

ACTIONS:

The HYDRO₂[®] lens when placed on the human cornea acts as a refracting medium to focus light rays on the retina. The toric lens also provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS FOR USE:

The HYDRO₂[®] (filofocn A) rigid gas permeable spherical, aspheric or toric contact lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes.

The bifocal/multifocal designs of the HYDRO₂[®] (filofocn A) contact lens are indicated for daily wear correction of visual acuity in non-aphakic persons with non-diseased presbyopic eyes that are myopic or hyperopic.

The lens may be disinfected with chemical disinfection only.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the HYDRO₂[®] lens when any of the following conditions are present:

- Acute and subacute inflammation or infection of the interior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic
- Any systemic disease that may affect the eye or be exaggerated by wearing a contact lens
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the HYDRO₂[®] Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS:

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioners directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reaction is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences **eye discomfort**, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eyecare practitioner.

PRECAUTIONS:

CAUTION: Non-sterile. Clean and condition lenses prior to use.

Special precautions for Eyecare Practitioners:

- Due to the small number of patients enrolled in the clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of

the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

- Aphakic patients should not be fitted with HYDRO₂[®] Contact Lenses until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, may be used with the HYDRO₂[®] Contact Lens. The presence of an UV absorber in the HYDRO₂[®] lens may require the use of a Kodak Wratten #12 Filter to visualize fluorescein patterns adequately using a slit lamp.

Eyecare Practitioners should carefully instruct patients about the following care regimens and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package insert for the use of contact lens solutions.
 - Use only a chemical lens care system. Use of a heat (thermal) care system can permanently damage the HYDRO₂[®] Contact Lenses by distorting its optics and/or physical shape.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubrication or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on make-up. Water base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storage and wearing instructions in the Patient Instruction for the HYDRO₂[®] Contact Lens and those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses gently and avoid vapors and fumes while wearing lenses.

- Inform the doctor (health care practitioner) about being a contact lens wearer.

- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

- Do not touch the lens with fingernails.

- Always contact the eyecare practitioner before using any medicine in the eyes.

- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE EFFECTS:

The Patient should be informed that the following problems may occur:

- Eyes stinging, burning or itching (irritation), or other eye pain

- Comfort is less than when lens was first placed on the eye

- Feeling that something is in the eye such as a foreign body or scratched area

- Excessive watering (tearing) of the eyes

- Unusual eye secretions

- Redness of the eyes

- Reduced sharpness of vision (poor visual acuity)

- Blurred vision, rainbows or halos around objects

- Sensitivity to light (photophobia)

- Dry eyes

If patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**

- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or if the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eyecare practitioner.**

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be

present. The patient should be instructed to **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING:

Conventional methods of fitting rigid contact lenses apply to the HYDRO₂[®] Contact Lens. For a detailed description of the fitting techniques, refer to the HYDRO₂[®] Professional Fitting and Information Guide, copies of which are available from: InnoVision, Inc., 3125 South 61st Avenue, Omaha, Nebraska 68106-3675.

PREPARING AN RGP LENS FOR FITTING:

The HYDRO₂[®] Contact Lens is shipped from the manufacturer in an unhydrated (dry) state. To prepare the lens for fitting and dispensing to the patient, clean the lens with the recommended lens cleaner, rinse the lens thoroughly with saline solution, replace the lens in the lens case and add the recommended disinfection solution. Store the lenses in the closed case at least 12 hours to hydrate until ready to fit or dispense.

WEARING SCHEDULE:

The wearing and replacement schedules should be determined by the eyecare practitioner. Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The HYDRO₂[®] Contact Lens is indicated for daily wear. The maximum suggested wearing time for the lens is:

Day	Hours
1	4
2	5
3	6
4	7
5	8
6	9
7	10
8	11
9	12
10 and after	All Waking Hours

Studies have not been completed to show that the HYDRO₂[®] Contact Lens is safe to wear during sleep.

LENS CARE DIRECTIONS:

Eyecare practitioners should review lens care directions with the patient, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions.

- Use the recommended lens care system and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.

- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.

- Always remove, clean, rinse, enzyme (as recommended by the eyecare practitioner) and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**

- The lens care products listed below are recommended by InnoVision, Inc. for use with the HYDRO₂[®] Contact Lens. Eyecare practitioners may recommend alternative solutions that are appropriate for the patient's use with his or her lenses.

Lens Care Table:

Manufacturer	Lens Care System	Solution Purpose
LOBOB	Optimum Extra Strength Cleaner	Clean
	Optimum Cleaning/Disinfection/ Storage Solution	Disinfect
	Optimum Wetting/Rewetting Drops	Lubricate
ALCON	Opti-Free Daily Cleaner	Clean
	Opti-Soak Conditioning Solution	Disinfect
	Opti-Soak Soothing Drops	Lubricate
ALLERGAN	Gas Permeable Daily Cleaner	Clean
	Profree/GP Weekly Enzymatic Cleaner	
	Comfort Care G.P. Wetting/Soaking	Disinfect
	Wet-N-Soak Rewetting Drops, Gas Permeable Comfort Drops	Lubricate

- Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- **Clean** one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfection solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, **disinfect** lenses using the system recommended by the eyecare practitioner.

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses.

- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals.

- Eyecare practitioners may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

- HYDRO₂[®] Contact Lenses cannot be heat (thermally) disinfected.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. The deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfection. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE:

Contact Lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals.

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stops moving), the patient should be instructed to apply 2 or 3 drops of the recommended lubrication or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If nonmovement of the lens continues after 15 minutes, the patient should **immediately** consult the eyecare practitioner.

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:

The HYDRO₂[®] Contact Lens is supplied unhydrated (dry) in a polypropylene contact lens case. The lens specifications will be marked on the back of the lens case or accompanied with the lens. Single cut spherical lenses will specify base curve, diopter power, diameter, center thickness, optic zone, lot number, color, and UV-absorber (if applicable). In addition to the above, lenticular field, prism diopter, prism axis, truncation and eccentricity may also be listed for lenticular, toric and aspheric lens designs.

REPORTING OR ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing HYDRO₂[®] Contact Lenses or experienced with the lenses should be reported to:

InnoVision, Inc.
3125 South 61st Avenue
Omaha, Nebraska 68106-3675
1-(800)-232-7985