





**BIOMEDICS® TORIC 1 Day (ocufilcon D)
HYDROPHILIC CONTACT LENSES
PACKAGE INSERT**

IMPORTANT: Please read carefully and keep this information for future use. This package insert is directed to eye-care practitioners. Please provide patients with the appropriate patient information booklet for the patient's lenses.

Symbol	Description
	CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a licensed practitioner.
	See Instruction Leaflet
6	Use by date (expiration date)
	Batch code
	Sterile using steam heat

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

DESCRIPTION:

The **BIOMEDICS® Toric 1 Day** (ocufilcon D) hydrophilic contact lens is designed as a daily wear lens which is disposed at the end of each day. It is manufactured with a hydrophilic polymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). The lenses are tinted for easy handling.

Lens features:

- Chord diameter: 12.5 mm to 18.0 mm
- Center thickness: 0.025 mm to 0.270 mm, depending on power
- Inside Spherical Radius: 6.50 mm to 10.8 mm
- Spherical Powers: +10.00D to -10.00D
- Cylinder Powers: -0.25D to -10.00D
- Axis: 0° to 180° in 10° increments

The physical properties of the lens are:

- Refractive Index: 1.41
- Surface Character: Hydrophilic
- Water Content: 55.0%
- Oxygen Permeability (Dk)*: 19.7 x 10⁻¹¹ (cm²/sec)ml O₂/ml x mm Hg at 35°C (Fatt Method)
- Light Transmittance: 90% to 97%, depending on tint type.

ACTIONS:

When placed on the human cornea, the hydrated lens acts as a corrective refracting medium to focus light rays on the retina.

The visibility tinted **BIOMEDICS® Toric 1 Day** (ocufilcon D) hydrophilic contact lenses allow the lens to become readily visible to the wearer when not on the eye.

INDICATIONS:

BIOMEDICS® Toric 1 Day (ocufilcon D) hydrophilic contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

CONTRAINDICATIONS (Reasons Not To Use):

BIOMEDICS® Toric 1 Day (ocufilcon D) hydrophilic contact lenses are contraindicated when any of the following conditions exist:

- Inflammation in the anterior chamber of the eyes.
- Active disease, injury or abnormality affecting the cornea, conjunctiva or eyelids.
- Microbial infection of the eye.
- Insufficiency of lacrimal secretion.
- Corneal hypoesthesia.
- Use of a medication that is contraindicated, including eye medications.
- Patient history of recurring eye or eyelid infections including sties, or of adverse effects associated with contact lens wear, or of intolerance or abnormal ocular response to contact lens wear.
- History of patient non-compliance with contact lens care and disinfection regimens, wearing restrictions, wearing schedule or follow-up visit schedule.
- Patient inability or unwillingness, because of age, infirmity or other mental or physical conditions, or an adverse working or living environment, to understand or comply with any warnings, precautions, restrictions, or directions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which must be used to care for the lens.
- Patients who require only vision correction and who would not, or could not, adhere to a recommended care system for lenses, or who are unable to place and remove lenses should not be provided with them.

WARNINGS

Patients were not studied who exceed the conditions characterized by any of the following diagnostic characters:

- Rose Bengal staining > 12 on a scale of 18
- Fluorescein staining > 12 on a scale of 15
- Meibomian gland dysfunction > 8 on a scale of 0 – 4

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 eye care practitioner's 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 reactions 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 the lenses and promptly contact his or her eye care practitioner.

PRECAUTIONS

In prescribing contact lenses, the Precautions should be carefully observed. It is also strongly recommended that the practitioner review with the patient the appropriate Patient Information Booklet (the Frequent Replacement Information Booklet) prior to dispensing the lenses and assure that the patient understands its contents.

- Contact lens wear may not be suitable for certain occupations, or, in other instances, may require eye protection equipment.
- Environmental fumes, smoke, dust and vapors, and windy conditions, must be avoided, in order to minimize the chances of lens contamination or physical trauma to the cornea.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Eye injury from irrigation or infection and damage to lenses may result if cosmetics, lotion, soaps, creams, hair sprays or deodorants come in contact with lenses.
- Eye injury from irrigation or infection may result from lens contamination.
- Tweezers or other tools should not be used by patients to remove a lens from the lens container. The lens should be poured into the hand.
- Patients should be instructed on and demonstrate the ability of prompt removal of the lenses.
- Fluorescein should not be used while the lenses are on the patient's eye. The lenses absorb this dye and become discolored. Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in-eye use; and a new lens should be reinserted only after at least one hour.
- A lens must move freely on the eye for a proper fit. For further information, see the **BIOMEDICS® Toric 1 Day** (ocufilcon D) hydrophilic contact lenses Fitting Guide. 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 eye care practitioner.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- The patient should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eye-care practitioner before using any medication in the eye.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision. Should these conditions exist proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing the lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- 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 following symptoms may occur:

- eye pain
- eyes sting, burn or itch (irritation)
- comfort is less than when lens was first placed on eye
- feeling of something in the eye (foreign body, 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
- change in sensitivity to light (photophobia)
- feeling of dryness

The patient should be instructed that if any of the above symptoms occur:

- **Immediately** remove the lenses.
- If the discomfort or problem stops, then look closely at the lens.
- If the lens has dirt, an eyelash or other foreign body on it, or the problem stops, clean, disinfect and reinsert the lens if in the Scheduled Replacement Program; or discard the lens and replace it with a new **BIOMEDICS® Toric 1 Day** lens.
- If the lens is in any way damaged, **DO NOT** put the lens back on the eye. Discard the lens.
- If the above symptoms continue after removal of the lens or upon reinsertion of a lens or upon insertion of a new lens, the new lenses should be removed immediately and the patient should immediately contact his eye-care practitioner or a physician, who must determine the need for examination, treatment or referral without delay. A serious condition such as infection, corneal ulcer, corneal vascularization or iritis may be present, and may progress rapidly. Less serious reactions, such as abrasions, epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications.

CARE FOR A DEHYDRATED LENS

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. Simply dispose of the lens and use a new one.

CARE FOR A STICKING LENS

If the lens sticks (stops moving), the patient should be instructed to apply several drops of the recommended lubricating 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 several minutes, the patient should be instructed to immediately consult the eye-care practitioner.

PRACTITIONER FITTING SETS

All lenses that have been opened must be discarded after each fitting.

HOW SUPPLIED

Each **BIOMEDICS TORIC 1 DAY** (ocufilcon D) contact lens is supplied sterile in a container with a normal buffered saline solution. Several containers are packaged in a multi-pack, both of which are marked with the manufacturing lot number of the lens, the diameter, the dioptric power, the lens tint, the base curve or series, and the expiration date.



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