BIOMEDICS® 55 ASPHERE
(ocufilcon D) Soft (Hydrophilic) Contact Lenses

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

SYMBOLS KEY

The following symbols may appear on the label or carton:

SYMBOL	DEFINITION	Reference
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner	81 FR 38911
	Caution / See Instructions for Wearers	BS EN ISO 15223-1 Table 1, Symbol 5.4.4
	Use by Date (expiration date)	BS EN ISO 15223-1 Table 1, Symbol 5.1.4
LOT	Batch Code	BS EN ISO 15223-1 Table 1, Symbol 5.1.5
STERILE	Sterile using Steam Heat	BS EN ISO 15223-1 Table 1, Symbol 5.2.5
	Manufacturer	BS EN ISO 15223-1 Table 1, Symbol 5.1.1
EC REP	Authorized representative in the European Community	BS EN ISO 15223-1 Table 1, Symbol 5.1.2
	Do not use if package is damaged	BS EN ISO 15223-1 Table 1, Symbol 5.2.8
	Consult instructions for use / consult electronic instructions for use	BS EN ISO 15223-1 Table 1, Symbol 5.4.3
	Date of manufacture	BS EN ISO 15223-1 Table 1, Symbol 5.1.3

INDICATIONS (USES)

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with not-aphakic, non diseased eyes which manifest myopia (nearsighted), hyperopia (farsighted) and astigmatic correction lower than –2.00 diopters that does not interfere with visual acuity.

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses may be prescribed for daily wear or for extended wear from one to seven days between removals. The eye-care practitioner may prescribe the BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) contact lenses for single use disposable wear or for scheduled replacement wear, with cleaning, disinfection, and scheduled replacement (see Patient Information Booklet for the Scheduled Replacement Program). When prescribed for scheduled replacement the lens may be disinfected using a chemical (no heat) or hydrogen peroxide disinfecting systems.

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

DECSRIPTION

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are available as an asphere lens design.

The lens material for BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens is a random copolymer of 2-hydroxyethylmethacrylate and methacrylic acid. The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses contain visibility blue tint from edge to edge using (VAT Blue 6) which is added in-monomer prior to polymerization to make the lens more visible for handling. The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses contain a benzophenone UV absorbing monomer which is used to block UV radiation.

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are hemispherical shells of the following dimensions:

- Diameter: 12.0mm to 18.0mm
- Base Curve: 6.50mm to 12.80mm
- Center Thickness: 0.025 mm to 0.40 mm
- Powers: +6.00D to -10.00D

The physical/optical properties of the lens are:

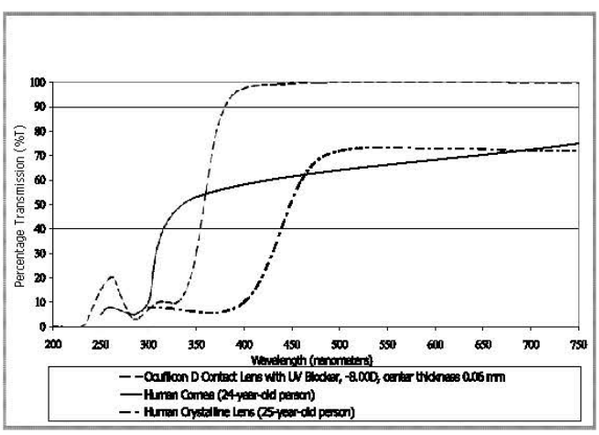
- Refractive Index: 1.41
- Light Transmittance: 97%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability: 19.6 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35°C

DESIGN

The BIOMEDICS® 55 ASPHERE Soft (Hydrophilic) Contact Lenses are hemispherical flexible shells which cover the cornea and may cover a portion of the adjacent sclera.

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens has a spherical posterior surface. The anterior (convex) surface is constructed in lenticular form to provide optimum edge thickness and contour. The front optical surface allows for correction of visual acuity in non-aphakic persons with non-diseased eyes and has been aspherized to control the longitudinal spherical aberration of the lens.

Typical Transmittance Profile of –8.00D ocufilcon D hydrophilic contact lens with UV blocker versus a human cornea and a human crystalline lens



1. Lerman, S., *Radiant Energy and the Eye* (New York: MacMillan, 1980), p. 58, Figure 2-21. Transmittance profile of the human cornea of a 24-year-old person.
2. Waxler, M., and V. M. Hitchens, *Optical Radiation and Visual Health* (Boca Raton: CRC Press, 1986), p. 19, Figure 5. Transmittance profile for the human crystalline lens of a 25-year-old person.

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 the surrounding area. You should continue to use absorbing eyewear as directed.

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses may be prescribed for daily wear or for extended wear in the Disposable Wear Program or Scheduled Replacement Program.

In the Disposable Wear Program patients should wear BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses as prescribed by their eye-care practitioners from one to seven days/six nights. Patients are instructed to dispose of the lenses at each removal and to use lens care products only on an emergency basis.

In the Scheduled Replacement Program patients should wear BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses as prescribed by their eye-care practitioners from one to seven days/six nights. Each time the patient must remove his or her lenses before the prescribed replacement time period has elapsed, the patient must clean and disinfect the lenses before replacing them on the eyes. The eye care practitioner is encouraged to determine a lens replacement schedule based upon the response of the patient.

ACTIONS

When placed on the cornea in its hydrated state, the BIOMEDICS® 55 ASPHERE (Ocufilcon D) Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

The visibility tinted BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens allow the lens to become visible to the wearer when the lens is not on the eye.

The thinnest BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens (-2.00 to -10.00 D) blocks 70% of UVA radiation and 96% UVB radiation average across the spectrum. The radiation blockage of the BIOMEDICS 55® ASPHERE lenses will increase for thicker lenses (Please refer to accompanying transmittance curve graph).

Note: Long term exposure to the 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 the 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 eye care practitioner for more information.

CONTRAINDICATIONS (REASONS NOT TO USE)

PATIENTS SHOULD DO NOT USE the BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens when any of the following conditions exist:

- Acute and sub-acute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Severe insufficiency of lachrymal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- 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 thimerosal, mercury or chlorhexidine, in a solution which is to be used to care for the lens
- Use of medication that is contraindicated, including eye medications.
- Patient history (i.) of recurring eye or eyelid infection, including sties; (ii.) of adverse effects associated with contact lens wear; or (iii.) 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 because of an adverse working or living environment, to understand or comply with any warnings, precautions, restrictions, or directions. Additionally, patients who require only vision correction and (i.) who would not, or could not, adhere to a recommended care system for lenses; or (ii.) who are unable to place or remove lenses should not be provided with them.

WARNINGS

Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and with using contact lens-care products. Therefore, after a thorough eye examination, including appropriate medical background, the prescribing practitioner must fully apprise patients of all risks associated with contact lens wear. To minimize these risks, the practitioner must emphasize to the patient the need for strict compliance with care regimen (including cleaning of the lens case, if practitioner prescribes scheduled replacement); wearing restrictions; wearing schedules; and follow-up visit schedule. (See the considerations list under "Contraindications" and "Precautions.").

Since eye injury can develop rapidly, it is most important that eye care practitioners instruct their patients as to the possible signs or symptoms of problems associated with contact lens wear. Further, eye-care practitioners should advise their patients to remove their lenses immediately and be examined by the prescribing practitioner or by a corneal specialist in the vent they experience any such signs or symptoms (including those listed below under "Adverse Effects"). (Practitioners examining patients presenting such symptoms should see below in "Practitioner Fitting Guides and Patient Information Booklets.")

Research has shown that the risk of ulcerative keratitis is greater among users of extended-wear contact lenses than it is among users if daily-wear contact lenses. The risk among extended-wear lens-wearing patients increases with the number of consecutive days that the patient wears the lenses between removals, beginning with the first overnight use. Some researchers believe that these complications are cause by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conductive to the growth of bacteria and other microorganisms, particularly when the patient has not adhere to a regular and periodic lens removal and disinfection or disposal schedule; improper lens disinfection or cleaning by the patient; contamination of lens-care products; accumulation of lens deposits; damage to the lenses; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. Additionally, smoking increases the risk of ulcerative keratitis in contact lens-wearing patients.

While the great majority of patients successfully wear contact lenses, extended wear of lenses is also reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates and endothelial polymegathism, which require consideration of discontinuation of lens wear.

The reversibility of endothelial effects associated with contact lens wear has not yet been established. Consequently, eye-care practitioners' views of extended wearing schedules vary; some practitioners do not prescribe extended wearing schedules at all, while others prescribe flexible wearing schedules to certain patients, which vary from occasional contact lens wear to extended wearing periods ranging from one to seven days/six nights with specified intervals of no lens wear. Ultimately, the prescribing eye-care practitioner should determine the appropriate replacement schedule. Additionally, the practitioner should determine the patient's lens-care regimen (if appropriate) and schedule for follow-up visits.

PRECAUTIONS

In prescribing contact lenses, eye-care practitioners should observe these precautions carefully. It is also strongly recommended that practitioners review with their patients the appropriate Patient Information Booklet (either for the Disposable Wear Program or for the Scheduled Replacement Program), available from CooperVision, Inc., prior to dispensing the lenses and ensure that patients understands its contents.

- In the Disposable Wear Program, BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses should be discarded upon removal from the patient's eye. Therefore, prescribing practitioners should instruct their patients always to have a pair of replacement lenses available. In the event a patient must remove a lens from the eye because of dust, a foreign body, or some other contaminant gets on the lens, or because the lens becomes dehydrated, the patient should remove that lens, discard it, replace it with a fresh, new lens. If replacement lenses are not available, the patient should refer to the emergency lens care directions
- In the Scheduled Replacement Program, in the event a patient must remove an BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens from the eye because of dust, a foreign body, or some other contaminant gets on the lens, or because the lens becomes dehydrated, the patient should remove that lens and clean and disinfect it before replacing it on the eye. If a lens becomes dehydrated, the patient should follow the lens care instructions for "Care for a Dehydrated Lens".
- Contact lens wear may not be suitable for those in certain occupations, or, in other instances, such persons may require protection equipment.
- In order to minimize the likelihood of lens contamination or of physical trauma to the cornea, lens-wearing patients should avoid environmental fumes, smoke, dust, vapors, and windy conditions.
- In the Scheduled Replacement Program, or in the event of emergency lens care in the Disposable Wear Program, CooperVision, Inc., recommends the use of sterile lens-care solutions. If a particular patient is allergic to preservatives, that patient should use sterile non-preserved solutions and should discard such solutions after the time specified in their label directions.
- Eye injury from irritation or infection and damage to contact lenses may result from lens contamination. Patients should take care to prevent cosmetics, lotions, soaps, creams, hair sprays, or deodorants from coming into contact with their lenses.
- Tweezers or other tools should not be used by patients to remove lenses from lens containers; rather, the contents of lens container should be poured into the hand.
- Practitioners should instruct their patients as to the proper manner to promptly remove their lenses, and patients should be able to demonstrate the ability to do so.
- Fluorescein should not be used while BIOMEDICS® 55 55 lenses are on the patient's eye. The lenses absorb this dye and become discolored. In the event fluorescein does come in contact with the lenses while they are on the patient's aye, the eyes should be flushed thoroughly with a sterile saline solution recommended for in-eye use, and new lenses should be inserted only after at least one hour.
- A lens must move freely on the eye for a proper fit. For further information, see the BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens Practitioner Fitting Guide.
- Some patients will not be able to tolerate extended wear even if they are able to tolerate the same or another lens on a daily-wear basis. Eye-care practitioners should carefully evaluate their patients for extended wear prior to prescribing and dispensing and should conduct early and frequent follow-up examinations to determine ocular response to extended wear.
- In the Scheduled Replacement Program, or in the event of emergency lens care in the Disposable Wear Program: After removal of the lenses from the lens case, to prevent contamination and to help avoid serious eye injury, the patient should always empty and rinse the lens case with fresh rinsing solution and allow it to air-dry between each lens disinfection cycle.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Contact lens-wearing patients should be instructed to inform their physicians that they wear contact lenses; further, patient's physicians should consult their eye-care practitioners before using any medication in the eye.
- Certain medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and medications 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, such measures 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 medications are being used.
- As with any contact lens, follow-up visits are necessary to better ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Practitioners should caution their patients wearing BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens on a daily-wear schedule to remove their lenses before sleeping.

ADVERSE EFFECTS

The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may be painful or may burn, or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering (tearing), unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows, or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn for too long a time.
- If the patient reports any problems, including, but not limited to, the foregoing, he or she should be instructed to **IMMEDIATELY REMOVE THE LENS**.
- If the discomfort or problem stops, the patient should then look closely at the lens.
- If the lens has dirt, an eyelash, or other foreign body on it, the patient should be instructed as follows:
  If the patient is in the Disposable Wear Program, he or she should dispose of the lens and replace it with a fresh, new lens.
  If the patient is in the Scheduled Replacement Program, and if the lens appears undamaged, he or she may clean, disinfect, and reinsert the lens.
- If the lens is or appears in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and insert a fresh, new lens on the eye.
- If the patient's problem continues, the patient SHOULD NOT put the lens back on the eye; but rather he or she should immediately consult his or her eye-care practitioner or a physician, who must determine the need for examination, treatment, or referral without delay.
- The patient should be advised that when any of the aforementioned symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present and may progress rapidly. The patient should seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage. Less serious reactions, such as abrasions, epithelial staining, and bacterial conjunctivitis, should be treated appropriately to avoid complications.

PRACTITIONER FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens Practitioner Fitting Guide provides detailed fitting information for fitting BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses. Conventional methods of fitting apply to these lenses. Prescribing eye-care practitioners must supply their patients with appropriate instructions for wearing, removing, and replacing their lenses, and patients must fully understand all handling and lens-care instructions. In addition, it is very important for practitioners to provide their patients with appropriate Patient Information Booklet (either for the Disposable Wear Program of for the Scheduled Replacement Program).

Practitioner Fitting Guide and the Patient Information Booklet are available from:

CooperVision
711 North Road
Scottsville, NY 14546
1-800-341-2020
www.coopervision.com

WEARING SCHEDULES

It is recommended that a contact lens wearing patient see his or her eye-care practitioner twice each year or, as so directed, more frequently. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

Daily wear: Patients tend to over wear the lenses initially. Therefore, practitioners should stress to these patients the importance of adhering to a proper initial daily wearing schedule. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

Extended wear (greater than 24 hours or while asleep): The prescribing practitioner should determine the appropriate wearing schedule and replacement schedule for each individual patient based upon a full examination and patient history, as well as the practitioner's experience and professional judgement. CooperVision, Inc., recommends beginning extended-wear patients with the recommended initial daily-wear schedule, followed by a period of daily wear, and then the gradual introduction of extended wear, one night at a time, unless individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear to determine corneal response. Patients should remove their lenses and clean and disinfect them or replace them with fresh, new lenses as directed by the eye-care practitioner. Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye-care practitioner. The maximum recommended extended wearing time is 7 days/6 nights between removal for cleaning and disinfection prior to reinsertion.

LENS CARE DIRECTIONS

Eye care practitioners should provide their patients with appropriate and adequate instructions and warnings for lens care and handling, and practitioners should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens-wearing schedule and care system selected by the practitioner, the specific instructions for such products, and the particular characteristics of the patient.

For patients in the Disposable Wear Program: Eye-care practitioners should review with patients that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.
For complete information concerning emergency lens care, refer to the Patient Information Booklet for patients in the Disposable Wear Program. Emergency lens care does not apply to lenses worn on a daily-wear basis.

For patients in the Scheduled Replacement Program: For complete information concerning the care cleaning and disinfecting of BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses, patients should refer to the Patient Information Booklet for the Scheduled Replacement Program.

CARE FOR A DEHYDRATED LENS

For patients in the Disposable Wear Program: If a soft contact lens is off the eye and is exposed to air for a significant period of time, it may become dry and brittle. If this should occur, patients should discard the lens and use a fresh, new one; dehydrated lenses should not be re-hydrated. It is important that the patient always have a pair of replacement lenses available.

For patients in the Scheduled Replacement Program: If a soft contact lens is off the eye and is exposed to air for a significant period of time, it may become dry and brittle and need to be re-hydrated. If the lens is adhering to a surface such as a counter top, apply sterile saline before handling the lens.
Eye-care practitioner should review the following information on re-hydrating the lens with the patient:

- Handle the lens carefully.
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state.
- Clean and disinfect and re-hydrate lens using a recommended lens-care system.
- If the lens does not become softer after soaking, the lens should not be used until it is examined by the eye-care practitioner

CARE FOR A STICKING LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply a few 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 non-movement of the lens continues after a few minutes, the patient should **immediately** consult the eye care practitioner.

PRACITIONER FITTING SETS

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

HOW SUPPLIED

BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens is supplied sterile in a container with a phosphate buffered saline solution containing 0.005% poloxamer. Several containers are packaged in a multi-pack arrangement, each of which is marked with the manufacturing lot number of the lens, the dioptric power, the base curve or series, the diameter, and the expiration date.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing the BIOMEDICS 55® ASPHERE (ocufilcon D) Contact Lenses or experienced with any lenses should be reported to:

CooperVision
711 North Road
Scottsville, NY 14546
1-800-341-2020