Part Number: PI01018  Page 1 of 2

**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 their prescribed lenses.

**SYMBOLS KEY**

The following symbols may appear on the label or carton:

- **Caution:** Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner
- **Use by Date (expiration date)**
- **Batch Code**
- **Sterile using Steam Heat**
- **Authorized representative in the European Community**
- **Do not use if package is damaged**
- **Consult instructions for use or consult electronic instructions for use**
- **Date of manufacture**

**DESCRIPTION**

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes which manifest myopia (nearsighted), hyperopia (farsighted) and astigmatic correction lower than –2.00 diopters that does not require a device to sale by or on the order of a licensed practitioner.

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

**INDICATIONS (USES)**

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

The lens material for BİOMEDICS® 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 a benzocatechophene UV absorbing monomer which is used to block UV radiation.

The physical/ optical properties of the lenses are:

- **Diameter:** 12.0mm to 18.0mm
- **Base Curve:** 8.60 to 8.88mm
- **Center Thickness:** 0.025 mm to 0.40 mm
- **Powers:** +0.00 to -10.00 D

**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.

**Water Content:** 55%

**Refractive Index:** 1.41

**Light Transmittance:** 97%

**Surface Texture:** Hydrophilic

**Oxygen Permeability:** 19.6 x 10 -11 (cm 2/sec) (ml O2/ml x mm Hg) at 35oC

**Whitewater Content:** 55%

**Use of medication that is contraindicated, including eye medications.**

- **Patient history (I.) of recurring eye or eyelid infections, including sties, (II.) of adverse effects associated with contact lens wear; or (III.) of intolerance or abnormal ocular response to contact lens wear.**

**WARNINGS**

Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and with using a number of factors such as environmental stress (altitude, geography, cloud cover) and personal factors (extent and nature of the outdoor activities performed). Problems associated with contact lens wear include:

- **Acute and sub-acute infection or inflammation of the anterior chamber of the eye**
- **Abnormality that may be incurred by the eye environment, corneous, conjunctival and corneal**
- **Severe insufficiency of lacrimal secretion (dry eye)**
- **Corneal hypopea (reduced corneal sensitivity)**
- **Any syndrome that may affect the eye or be exagerrated by wearing contact lenses**
- **Allergic reactions of outer surfaces or adversity that may be induced or exaggerated by wearing contact lenses or use of contact lens solution.**
- **Allergy to any ingredient, such as thimerosal, mercury or chlorhexidine, in a solution in which it is to be used for care of the lens.**
- **Use of medication that is contraindicated, including eye medications.**
- **Patient history (I.) of recurring eye or eyelid infections, 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 regimens and removal schedules; improper wear or use of contact lens units.**
- **Patient inability or unwillingness, because of age, illness, or other physical or mental conditions, or because of an adverse wearing or lens wearing, to understand or comply with any warnings, precautions, restrictions, or directions.**
- **Patients who require only vision correction and (i.) who would not, or could not, adhere to a recommended care regimen; or (ii.) of intolerance or abnormal ocular response to contact lens wear.**

Since eye injury can develop rapidly, it is most important that eye care practitioners instruct their patients to 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 contact their eye-care practitioner if they experience any such signs or symptoms (including those listed below underlying each warning). In addition, eye-care practitioners should assume the patients presenting with these symptoms should see below in “Practitioner Fitting Guides and Patient Information Booklet.”

Researchers have shown that the risk of ulcerative keratitis is greater among users of extended wear contact lenses. Therefore, after a thorough eye examination, including appropriate medical background, the prescribing practitioner can fully acquaint patients with contact lens wear. To minimize these risks, the practitioner must emphasize to the patient the need for strict compliance with care regimens and cleaning of the lens case, (if applicable); specific lens replacement schedule; wearing restrictions; wearing, and follow-up visit schedule. See the considerations listed under “Contraindications” and “Precautions.”

The reversibility of endothelial effects associated with contact lens wear has not yet been established. Consequently, eye-care practitioners’ views of extended wearing periods, and with the current increases in the number of patients using extended wear contact lenses, the risk among extended-wear lens-wearing patients increases with the number of consecutive days that the patient wears the lenses, beginning with the first overnight use. Some researchers believe that these complications are cause by one or more of the following: a worsening of the cornea’s resistance to infections, particularly during a closed-eye condition, as a result of a hypoxic; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when the patient does not adhere to a regular and periodic lens removal and disinfection or disposal schedule; improper lens disinfection or cleaning by the patient; contamination of the lenses through handling, cleaning, or storing of lens deposit; damage to the cornea; 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 lens, extended wear of lenses is as is 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 periods, and with the current increases in the number of patients using extended wear contact lenses, the risk among extended-wear lens-wearing patients increases with the number of consecutive days that the patient wears the lenses, beginning with the first overnight use. Some researchers believe that these complications are cause by one or more of the following: a worsening of the cornea’s resistance to infections, particularly during a closed-eye condition, as a result of a hypoxic; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when the patient does not adhere to a regular and periodic lens removal and disinfection or disposal schedule; improper lens disinfection or cleaning by the patient; contamination of the lenses through handling, cleaning, or storing of lens deposit; damage to the cornea; 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.

**WARNNG:** UV- absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing gogglies 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/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 for one to seven days/nights. Patients are instructed to dispose of the lenses at each removal and to use lens care products only on an emergency basis.

**CONTRAINDICATIONS (REASONS NOT TO USE)**

**WARNINGS**

Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and with using a number of factors such as environmental stress (altitude, geography, cloud cover) and personal factors (extent and nature of the outdoor activities performed). Problems associated with contact lens wear include:

- **Acute and sub-acute infection or inflammation of the anterior chamber of the eye**
- **Abnormality that may be incurred by the eye environment, corneous, conjunctival and corneal**
- **Severe insufficiency of lacrimal secretion (dry eye)**
- **Corneal hypopea (reduced corneal sensitivity)**
- **Any syndrome that may affect the eye or be exagerrated by wearing contact lenses**
- **Allergic reactions of outer surfaces or adversity that may be induced or exaggerated by wearing contact lenses or use of contact lens solution.**
- **Allergy to any ingredient, such as thimerosal, mercury or chlorhexidine, in a solution in which it is to be used for care of the lens.**
- **Use of medication that is contraindicated, including eye medications.**
- **Patient history (I.) of recurring eye or eyelid infections, 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 regimens and removal schedules; improper wear or use of contact lens units.**
- **Patient inability or unwillingness, because of age, illness, or other physical or mental conditions, or because of an adverse wearing or lens wearing, to understand or comply with any warnings, precautions, restrictions, or directions.**
- **Patients who require only vision correction and (i.) who would not, or could not, adhere to a recommended care regimen; or (ii.) of intolerance or abnormal ocular response to contact lens wear.**

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 contact their eye-care practitioner if they experience any such signs or symptoms (including those listed below underlying each warning). In addition, eye-care practitioners should assume the patients presenting with these symptoms should see below in “Practitioner Fitting Guides and Patient Information Booklet.”

Researchers have shown that the risk of ulcerative keratitis is greater among users of extended wear contact lenses. Therefore, after a thorough eye examination, including appropriate medical background, the prescribing practitioner can fully acquaint patients with contact lens wear. To minimize these risks, the practitioner must emphasize to the patient the need for strict compliance with care regimens and cleaning of the lens case, (if applicable); specific lens replacement schedule; wearing restrictions; wearing, and follow-up visit schedule. See the considerations listed under “Contraindications” and “Precautions.”
The patient should be informed that the following problems may occur when wearing contact lenses: 

**PRECAUTIONS**

Care practitioners must supply their patients with appropriate instructions for wearing, removing, and (Hydrophilic) Contact Lenses. Conventional methods of fitting apply to these lenses. Prescribing eye-care practitioners should observe these precautions carefully. It is also strongly recommended that practitioners review with their patients the appropriate Patient Understands its contents.

- 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 on a daily-wear schedule to remove their lenses before sleeping.
- In the Disposable Wear Program, CooperVision, Inc., recommends the use of sterile lens-care solutions and should discard such solutions after the time specified in their label directions.
- If the lens does not become softer after soaking, the lens should not be used until it is hydrated. If the lens is adhering to a surface such as a counter top, apply sterile saline before handling the lens.
- The lens should not be used until it is hydrated. It is important that the patient always has a pair of replacement lenses available.
- Patients in the Disposable Wear Program should remove their lenses each day. If replacement lenses are not available, the patient should refer to the emergency lens care 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 lens.

**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 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 more lenses): 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/or disinfect them or replace them with fresh, new lenses as directed by the eye-care practitioner. Once extended wear is initiated, the maximum recommended extended wearing time is 7 days/6 nights/7 days between removal for cleaning and disinfection prior to reinsertion.

**LENSES CARE DICTIONS**

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 lens.

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 stare/able. 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, the lens may become dehydrated, the patient should remove that lens, and clean and/or disinfect 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 practitioner. Alternatively, if the patient is wearing a lens in the Disposable Wear Program, after removal of the lenses from the lens case, to prevent contamination and to avoid serious eye injury, the patient should always and empty and replace the lens before the lens becomes dehydrated. The patient should then discard it, replace it with a fresh, new lens, and patients should be able to demonstrate the ability to do so. As oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.

IF THE LENS STICKS, apply sterile saline or the particular characteristics of the patient.

**PRACTITIONER 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 lens configuration (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 Lens) or experienced with any lenses should be reported to:

**PRACTITIONER FITTING GUIDE AND PATIENT INFORMATION BOOKET**

The BIOMEDICS® 55 ASPHERE (ocufilcon D Soft) (Hydrophilic) Contact Lenses Practitioner Fitting Guide provides instructions for fitting BIOMEDICS® 55 ASPHERE (ocufilcon D Soft) (Hydrophilic) Contact Lenses. Conventional methods of fitting apply to these lenses. Prescribing eye-care practitioners should provide their patients with appropriate instructions for wearing, removing, and replacing their lenses, and patients must fully understand all handling and lens-care instructions.

Additionally, it is very important for eye-care practitioners to provide their patients with appropriate Patient Information Booklet (either for the Disposable Wear Program for the Scheduled Replacement Program).