The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with non-aphakic eyes who require extended wear, for whom extended wear is medically necessary, and has been aspherized to control the longitudinal spherical aberration of the lens.

The physical/optical properties of the lenses:
- Refractive Index: 1.41
- Light Transmittance: 97%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability: 19.6 x 10^{-11} (cm^2/sec) (ml O2/ml x mm Hg) at 35°C
- Center Thickness: 0.025 mm to 0.40 mm
- Power: -6.00 to +20.00 D
- Visual Angle, Distance

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are available as an aphakic 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 (Soft) Hydrophilic Contact Lens contains vinyl blue dye from edge using VAT (Vat Blue 6) which is added in monomer prior to polymerization to make the lens more visible for patients.

The BIOMEDICS® 55 ASPHERE (ocufilcon D Soft) Hydrophilic Contact Lens contains a benzenophene 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: 12.00 mm to 18.00 mm
- Base Curve: 8.50 mm to 12.88 mm
- Center Thickness: 0.025 mm to 0.40 mm
- Powers: -6.00 to +20.00 D
- Visual Angle, Distance

The visibility tinted BIOMEDICS® 55 ASPHERE (ocufilcon D Soft) Hydrophilic Contact Lenses 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) will absorb 49% of UV radiation and UV radiation average across the spectrum of the lens.

The transmission of harmful UV radiation to the cornea and into the eye.

Harmful UV radiation to the cornea and into the eye.

Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.

1. Lerner, S., Radiant Energy and the Eye (New York: Macmillan, 1960), p. 58, Figure 2-21.

Typical Transfer Profile of  -8.00D ocufilcon D hydrophilic contact lens with UV blocker versus a human cornea and a human crystalline lens.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV absorbing sunglasses. It is recommended that patients reapply sunglasses or lenses after they have completely covered the eye and the surrounding area. You should continue to use protective sunglasses or lenses when outdoors.

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 (-2.00 to -10.00 D) for 49% of UV radiation and UV radiation average across the spectrum of the lens.

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The visibility tinted BIOMEDICS® 55 ASPHERE (ocufilcon D Soft) Hydrophilic Contact Lenses allow the lens to become visible to the wearer when the lens is not on the eye.
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 remeasured, a lens must 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 removals for cleaning and disinfection prior to reinsertion.

*BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens Fitting Guide* provides detailed fitting information for fitting BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses. Cooperative methods of fitting apply to these lenses. Prescribing eye-care practitioners should review with appropriate instructions. Wearing Schedule, removing and replacing their lenses, and patients must fully understand all handling and lens-care instructions. For complete information, refer to the Patient Information Booklet for the appropriate Patient Information Booklet (either for the Disposable Wear Program of the Scheduled Replacement Program).

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

CooperVision
711 North Road
Scarsdale, NY 10583
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, is 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 their 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 remeasured, a lens must 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 removals for cleaning and disinfection prior to reinsertion.

**LENS CARE & REMEDIES**

Eye-care practitioners should provide their patients with appropriate and adequate instructions and warnings for lens care and handling, and practitioners should prescribe 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.

**COOPERVISION® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens practitioner Fitting Guide**

The prescribing practitioner should remove the lenses from the lens case, to prevent contamination, and to avoid any serious eye injury, the patient should always avoid and remove the lenses when they are removed and have replacement lenses or spectacles available.

**WEARING SCHEDULES**

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 remeasured, a lens must 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 removals for cleaning and disinfection prior to reinsertion.

**LENS CARE & REMEDIES**

Eye-care practitioners should provide their patients with appropriate and adequate instructions and warnings for lens care and handling, and practitioners should prescribe 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, see the Patient Information booklet for the Scheduled Replacement Program.

**CARE FOR A DEHYDRATED LENS**

If the lens is dry, it may not be easy to remove, and the patient should follow the instructions as given in the patient information booklet. Items not to use include:

- Cigarette smoke
- Wind
- Dust
- Sunlight
- Water
- Soap
- Snake oil
- Grease
- Cream
- Petroleum-based ointment
- Vigorous eye rubbing

**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.

**PRACTITIONER FITTING GUIDES AND PATIENT INFORMATION BOOKLETS**

The BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses practitioner Fitting Guide provides detailed fitting information for fitting BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses. Cooperative methods of fitting apply to these lenses. Prescribing eye-care practitioners should review with appropriate instructions. Wearing Schedule, removing and replacing their lenses, and patients must fully understand all handling and lens-care instructions. For complete information, refer to the Patient Information Booklet for the appropriate Patient Information Booklet (either for the Disposable Wear Program of the Scheduled Replacement Program).