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

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

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

DESIGN

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

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

The BIOMEDICS® ASPHERE (ocufilcon D Soft) Contact Lens are hemispherical soft lenses with the following dimensions:

- Diameter: 13.00mm to 18.00mm
- Base Curve: 8.60mm to 12.80mm
- Center Thickness: 0.025 mm to 0.40 mm
- Powers: -6.00D to -10.00D

The physical/optical properties of the lenses are:

- Refractive Index: 1.41
- Light Transmittance: 97%
- Surface Character: Hydrophilic
- Water Content: 95%
- Oxygen Permeability: 16.0 x 10^-11(cm²·O₂·ml·mmHg) (at 35°C)

The BIOMEDICS® ASPHERE (ocufilcon D Soft) Contact Lens has a spherical posterior surface. The anterior (convex) surface is constructed in keratometric form-toprime optimum edge thickness. Many of the front optical surfaces allow for correction of visual acuity in non-
aphasic persons with non-diseased eyes and has been asphantated to the corneal alignment of abrasions.

Typical Transmittance Profiles of -8.00D of 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 eyewear, such as UV absorbing goggles or sunglasses because they do not completely block harmful UV rays in the surrounding area. You should continue to use absorbing eyewear as directed.

The BIOMEDICS® 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 consecutive nights. Patients are instructed to dispose of the lenses at each replacement, 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 consecutive nights or less than one week per interval. When the prescribed replacement time period has elapsed, the patient must clean and disinfect the lenses before replacing them in the eyes. The eye care practitioner is encouraged to determine a lens replacement schedule based upon the response of the patient.

INDICATIONS (USES)

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.

BASE CURVE

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 Lenses have visibility blue tint from edge to edge using (VAT Blue 6) which is added in-monomer prior to polymerization to make the lenses 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 contact lenses with the following dimensions:

- Diameter: 13.00mm to 18.00mm
- Base Curve: 8.60mm to 12.80mm
- Center Thickness: 0.025 mm to 0.40 mm
- Powers: -6.00D to -10.00D

The physical/optical properties of the lenses are:

- Refractive Index: 1.41
- Light Transmittance: 97%
- Surface Character: Hydrophilic
- Water Content: 95%
- Oxygen Permeability: 16.0 x 10^-11(cm²·O₂·ml·mmHg) (at 35°C)
replace it with a fresh, new lens. If replacement lenses are not available, the patient should refer to the emergency lens care directions.

**BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses or experienced with the lenses should be reported to:**

**Care for a Dehydrated Lens**

Eye-care practitioners should review the following information on re-hydrating the lens with the patient:

- **Clean** and disinfected and re-hydrate a 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.**

**PRACTITIONER FITTING GUIDES AND PATIENT INFORMATION BOOKLETS**

**The prescribing practitioner should provide to the patient.**

- The prescribing practitioner, in the event a patient must remove an ASPHERE (Hydrophilic) Contact Lenses or experienced with the lenses should be reported to:**

**HOW SUPPLIED**

- BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses is supplied sterile in a combination of preservative solutions containing 0.001% polyvinyl pyrrolidone. Several containers are packaged in a multi-pack, each of which is marked with the manufacturer's 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 any BIOMEDICS® 55 ASPHERE (ocufilcon D) Contact Lenses or experienced with the lenses should be reported to:

**CooperVision, Inc.**

71 North Road

Scottsville, NY 14546

1-800-341-2020

www.coopervision.com

**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 remedied, 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.

**LENSES CARE DICTIONARY**

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 precautions 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 patients.

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 disposable 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 or experienced with the lenses should be reported to:

**CooperVision, Inc.**

71 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, if appropriate, whenever a change in lens care system may occur. A change of schedule may occur as the result of a change in wearing, removing, and replacing their lenses, and patients must fully understand all handling and lens-care instructions. The practitioner should provide an appropriate Patient Information booklet (either for the Disposable Wear Program of the Scheduled Replacement Program).

**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.**

**Continuous wear**

- BIOMEDICS® 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses or experienced with the lenses should be reported to:**

**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 remedied, 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.

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