

BIOMEDICS 55 ASPHERE (ocufilcon D) HYDROPHILIC CONTACT LENSES

PRACTITIONER FITTING GUIDE

IMPORTANT:

This Fitting Guide has been developed to provide practitioners with information covering characteristics of the BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. Please read carefully and keep this information for future use.

INTRODUCTION:

The BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens is for use in the BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens Program, in which practitioners prescribe a Schedule Replacement Program or a Disposable Wear Program.

For Daily Wear:

In the Scheduled Replacement Program, the daily lens wearing time is prescribed by the practitioner. Each time the lens needs to be removed before the replacement time period has elapsed; the lens must be cleaned and disinfected prior to replacing it back on the eye. However, the eye care practitioner is encouraged to determine a lens replacement schedule based upon the response of the patient.

In the Disposable Wear Program, the lens wearing time is prescribed as one use only. Patients are instructed to dispose of the lens at each removal and to use lens care products only on an emergency basis.

The practitioner decides which program is appropriate, recommends a replacement schedule for the patient and provides either the Scheduled Replacement Patient Information Booklet or the Disposable Patient Instruction Booklet.

MATERIAL:

The BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens consists of 45.0% 2-hydroxyethyl methacrylate and methacrylic acid crosslinked with ethyleneglycol dimethacrylate and 55.0% water. The material has a refractive index of 1.41. The contact lens is tinted blue. The BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens contains an ultraviolet absorber and has a visible light transmittance of approximately 90%.

DESIGN:

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.

AVAILABLE LENS PARAMETERS

Powers	+6.00D to -10.00D
Center Thickness	0.025mm to 0.35mm depending on power
Diameter	14.2mm
Base Curve	8.60mm, 8.9 for minus powers 8.80mm for plus powers
Color	Tinted soft blue from edge to edge for visibility purposes.
Oxygen Permeability (Dk)*	19.6×10^{-11} (cm ² /sec)ml O ₂ /ml x mmHg at 35°C

*Method for determination is the Fatt method.

INDICATIONS:

INDICATIONS (USES)

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

The BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens may be prescribed for daily wear or extended wear. The eye-care practitioner may prescribe the BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens 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 chemicals (no heat) or hydrogen peroxide disinfecting systems.

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

PATIENT SELECTION:

Persons who require only vision correction and who would not or could not adhere to a recommended regimen for BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and wearing instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination and to provide a copy of the Patient Information Booklet to patients. Patients selected to wear BIOMEDICS 55 ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part-time), and desired lens usage (reading, recreating or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination. See Contraindications, Warnings and Precaution Sections of the Package Insert for additional information on patient selection.

FITTING PROCEDURE:

- a) Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.
- b) Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
- c) Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH or the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
- d) The lens should cover the patient's cornea fully, provide discernible movement (0.10mm to 0.30mm) after blink, be comfortable for the patient and provide satisfactory visual performance.
- e) Full coverage of the cornea is defined as the lens edge extending beyond the limbus area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
- f) Following a blink the lens should move vertically on the patient's eye about 0.10mm to 0.30mm.
- g) When the lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

FITTING SUMMARY

Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing, and the management of certain adaptive symptoms should be discussed with the patient prior to dispensing. It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight eye redness during the adaptation period.

Although the adaptation period varies for each individual, generally within one week these mild symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their eye care practitioner.

During the first few weeks of extended wear, patients may report a small amount of secretions on their eyelids, hazy vision on awakening and occasional dryness of the eyes during the day. These symptoms are minor and may be alleviated by using a lubricating / rewetting solution.

WEARING SCHEDULE:

The wearing schedule and replacement schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Typically recommended beginning extended wear patients with an initial daily wear schedule recommended by the eye care practitioner, followed by a period of daily wear, and gradual introduction of extended wear one night at a time, unless individual consideration indicate otherwise. Patients should be given a wearing schedule and carefully instructed on the handling and care of their lenses, as discussed in the Package Insert. Also, be sure to complete the Replacement Schedule Records in the Patient Information Booklet. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the WARNINGS Section). Once removed, a lens should remain out of the eye for a period of rest of overnight or longer, as determined by the prescribing eye care practitioner.

FOLLOW UP EXAMINATION:

As with any contact lens, regulatory recall visits are necessary to monitor corneal health and wearer compliance with instructions. (See Package Insert). Be sure to complete the Check-up Visit Schedule in the Patient Information Booklet for your patient when dispensing lenses.

Follow-up examinations are necessary to ascertain the effects of the lenses on the eyes. The following schedule is a suggested guideline:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months
- Every 6 months thereafter

At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief. During extended wear, there are diurnal changes in the appearance of contact lens fit and the eye responses.

The follow-up examination should include the practitioner's usual soft contact lens evaluation procedures:

- Measure visual acuity at distance and near, binocularly and monocularly.
- Assess lens fit (as described in Fitting Procedure) and lens surface quality.
- Following lens removal, conduct a biomicroscopy evaluation of the cornea and conjunctiva.

- Keratometry and a spectacle refraction should be performed at follow-up visits after approximately 1 month of lens wear. Any deviations from the baseline (prefit) measurements should be noted.

If your patients experience any adverse effects or complications with the lens, please be sure to notify CooperVision Inc. toll free at 1-800-341-2020.

A. PRACTITIONER DISINFECTION OF OPEN LENSES

All lenses that have been opened must be discarded.

B. PATIENT LENS CARE

See the accompanying Package Insert and the Patient Information Booklet for information pertaining to lens care and handling.

Lens ordering:

To order the prescription lenses specify power. To order lenses call us toll free at 1-800-341-2020.

It is essential that you review the package insert for a complete discussion of Biomedics 55 Asphere Soft (Hydrophilic) Contact Lenses including the Warnings, Precautions, and Adverse Effects sections of the insert.

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