BIOMEDICS® 55 (ocufilcon D)

BIOMEDICS® 55 Toric (ocufilcon D)

BIOMEDICS® 55 Multifocal (ocufilcon D)

SOFT (HYDROPHILIC) CONTACT LENSES

DAILY WEAR
FOR
PLANNED REPLACEMENT
OR
DAILY DISPOSABLE

PRACTITIONER FITTING GUIDE

July 2009

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LENS FORM AND CHARACTERISTICS

The Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) Soft (Hydrophilic) Contact Lens covers the cornea and extends slightly beyond the limbus, covering a portion of the adjacent sclera. In the hydrated state, the lens tends to conform to the curvatures of the anterior eye.

The lens material (*ocufilcon D*), when hydrated, consists of 45% ocufilcon D and 55% water by weight when immersed in buffered saline. The material has a refractive index of 1.41 and the lens has a visible light transmittance of > 97%. The oxygen permeability of the material at 35°C is 19.6 x 10^{-11} (cm^2/sec) (ml 0_2/ml x mm Hg) determined by the Fatt method.

The hydrophilic properties of the Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) Soft (Hydrophilic) Contact Lens require that it be maintained in a fully hydrated state, in a solution having a tonicity compatible with tears. The lens material is stable, has good mechanical strength, and is elastic in its hydrated state. If the lens dries out, it will become hard and appear somewhat warped, then it is advise to discard the lens.

The Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) Soft (Hydrophilic) Contact Lens is a hemispherical flexible shell, which covers the cornea and may cover the sclera.

LENS PARAMETERS AVAILABLE

Biomedics® 55 ***(ocufilcon D)***

Diameter	14.2 mm
Base Curve	8.6, 8.7, 8.8 & 8.9 mm
Asphere Power	-10.00D to +6.00D in 0.25D increments

Biomedics® 55 ***Toric (ocufilcon D)***

Diameter	14.5 mm
Base Curve	8.70 mm
Sphere Power	-0.00D to -7.00D in 0.25D increments to -6.00 and in 0.50D above -6.00
Cylinder Power	-0.75 and -1.25D
Axis	0° to 180° in 10° increments

Biomedics® 55 ***Multifocal (ocufilcon D)***

Call our Customer Service Department at (800) 341-2020 for current availability

See Price List for Detailed Availability

FITTING CONCEPT

The fitting concept is based on the draping effect of a high water content lens. Various base curves are achieved when the peripheral portion of the Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) (hydrophilic) contact lens flexes to the curvature of the cornea. The water content of the lens combined with thin lens sections permits excellent draping across a broad range of corneal curvatures.

The draping effect of the lens automatically adjusts to the sagittal height for each cornea. The lens parallels the apex of the cornea providing broad apical contact of the central cornea, vaulting or "clearance" of the limbus and light scleral bearing.

PATIENT SELECTION

An examination, including history, refraction, keratometry, biomicroscopy, and other pertinent tests and measurements should be performed. If the patient has the necessary qualifications and no contraindications exist, the patient may be considered for fitting.

ACTIONS

When placed on the human cornea, the hydrated lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

Biomedics® 55 *(ocufilcon D)* SPHERE and ASPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from - 20.00D to +20.00D diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

Biomedics® 55 *(ocufilcon D)* TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from –20.00 to +20.00 diopters and astigmatic corrections from –0.25 to –10.00 diopters.

Biomedics® 55 *(ocufilcon D)* multifocal lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +10.00 diopters and with add powers from +0.25 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 0.75 diopters or less that does not interfere with visual acuity.

The Biomedics® 55 *(ocufilcon D)* Soft (Hydrophilic) Contact Lenses are indicated for single use daily disposable wear or for planned replacement. As prescribed for single use daily disposable wear, patients are instructed to dispose of the lens at each removal. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS

Please refer to the Package Insert (PI01020).

Biomedics® 55 (*ocufilcon D*) FITTING PROCEDURE

- 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.
- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
- 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 of the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
- The lens should cover the patient's cornea fully, provide discernible movement (0.10mm to 1.00mm) after blink, be comfortable for the patient and provide satisfactory visual performance.
- 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.
- Following a blink the lens should move vertically on the patient's eye about 0.10mm to 1.00mm.
- When 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.

Biomedics® 55 (*ocufilcon D*) TORIC FITTING PROCEDURE

1. Determine Patient's Power Requirements:
   a. Convert the patient's spectacle Rx to minus cylinder form.
   b. The sphere and cylinder power of the contact lens prescription is the same as the spectacle Rx when the power is less than 4.00 D in both meridians. When the power is greater than or equal to 4.00 D, vertex the prescription to the spectacle plane.

      (See EXAMPLE) to determine the most appropriate axis.

EXAMPLE: History of nasal rotation on eye being fit

OD Spectacle Rx: -5.00 –2.00 x 180

-7.00
180 — -5.00
90

OD Contact Lens Rx: -4.75 –1.75 x 180

-6.50
180 — -4.75
90

Clinical experience has shown that the initial spherical and cylindrical power may vary by +/- 0.25 diopters and the axis of the initial lens may vary by 5 degrees on cylinders up to 2.00 diopters and 3 degrees for cylinders over 2.00 diopters without diminishing visual acuity of the patient.

If you wish, call CooperVision's Consultation Department with the patient's spectacle Rx and central K readings and they will make the proper compensations for your Biomedics® 55 Rx.

2. Equilibration:
   Allow a minimum of 15 minutes for the trial lenses to equilibrate after insertion, before evaluation of fit and vision.

3. Check Lens Fit:
   A properly centered lens will provide complete corneal coverage at all times. Decentration which leaves 0.50mm or less of the lens extending onto the sclera in any position will likely result in decreased or fluctuating vision. The diameter of the lens should be such that the lens extends past the limbus 1.0-2.0mm on both the nasal and temporal sides of the cornea.

   Movement of the lens with blinking is important to maintain optimum corneal physiology. The lens should move 0.50-1.5mm when the patient blinks and lag 0.50-1.5mm in upward gaze. While some patients may be able to maintain adequate corneal health with less movement, tight lenses should be avoided. If the lens is exhibiting minimal movement, apply a slight amount of digital pressure against the lower lid. The lens should move freely and easily, and return to the centered position when released. A tight lens will resist movement.

4. To Determine the Optimum Power and Axis for the Final Lens:
   a. Measure the amount of lens rotation, if any. Be sure the eye for which lens rotation is being evaluated is sighting straight ahead (i.e., down the optic axis of the slit lamp), as parallax resulting from misalignment can yield inaccurate measurements.
   b. If acuity is less than desired, do a complete over-refraction to include sphere, cylinder and axis and call CooperVision's Consultation Department with the following information:
      i. Contact lens parameters
      ii. Over-refraction (sphere, cylinder and axis) and visual acuity
      iii. Lens specifications (base curve, sphere, cylinder, axis)
      iv. Any lens rotation

5. When 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 lens 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/re-wetting solution.

PATIENT MANAGEMENT AND FOLLOW-UP CARE

1. Dispensing Visit

The lenses are delivered sterile, immersed in buffered saline solution, and supplied in a blister pack. Insertion and removal is done in the conventional manner used for soft hydrophilic contact lenses.

Evaluate patient's lenses on the eyes for physical fit as described in the preceding discussion. Instruct the patient on the technique for soft lens insertion and removal, as well as all aspects of lens care, including cleaning, disinfection, storage, and handling. Dispense to the patient written instructions on lens care and a copy of the Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) soft (hydrophilic) Contact Lens Patient Instruction Booklet. Review these instructions carefully with your patient.

2. Recommended Wearing Schedule

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 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.

3. Follow-Up Care

Follow-up care includes routine periodic progress examinations, management of specific problems, if any, and review of proper lens care and handling. Barring complications, the recommended schedule of follow-up examinations should be:

Daily Wear

a. One week post-dispensing.
b. One month after dispensing.
c. Three months after dispensing.
d. Every six months thereafter.

4. Procedures and Instrumentation for Follow-Up Visits (with lenses on, preferably for at least six hours)

a. Record patient's symptoms, if any.
b. Check visual acuity and refract over lens.
c. Check for residual astigmatism with the aid of a refractor or loose trial lenses (do not use autorefractor).
d. Biomicroscopy:
   i. Examine the conjunctiva and lids.
   ii. Check for lens edge impingement of the sclera, indentation, or vessel blanching, using low to medium magnification.
   iii. Check integrity of lens edges.
   iv. Check for surface deposits, deep scratches or edge nicks.

5. Procedures for Follow-Up Visits (with lenses removed):

a. Perform a biomicroscopic examination of the cornea and limbus, both with and without the use of fluorescein; check for edema, injection, vascularization, corneal staining, or any indication of iritis.
b. Measure corneal curvatures with keratometer and compare to original values and mire quality. Any deviations from baseline (pre-fit) should be noted.
c. Check for spectacle blur shortly after lenses are removed. Record all measurable values and any remarkable findings.

If any of the above observations are judged to be abnormal, professional judgment is to be used in alleviating the problem and restoring the eye to optimal conditions. If the criteria for a well-fitted lens are not reached during any follow-up examinations, the patient's fitting procedure should be repeated. The patient should be refitted, with necessary follow-up examinations also repeated.

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitted Lens

A well-fit Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) Soft (Hydrophilic) Contact Lens best satisfies the following criteria:

- Full corneal coverage.
- Good centration (concentric about the visible iris).
- Satisfactory lens sag (in up gaze 0.10 to 1.00mm is ideal) with the blink.
- The lens moves freely when manipulated with digital pressure against the lower lid.
- Satisfactory comfort response by the patient.
- Satisfactory vision response by the patient.

2. Characteristics of a Tight (Steep) Lens

A tight Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) Soft (hydrophilic) Contact Lens would display some or all of the following characteristics:

- Good centration.
- Little or no up gaze sag.
- The lens resists movement when manipulated with digital pressure against the lower lid.
- Good comfort
- Vision may be blurred and clear immediately following blink.
- Bubble(s) under the lens.
- Conjunctival indentation and/or blanching of limbal vessels at the lens edge.
- Limbal-conjunctival hyperemia.

3. Characteristics of a Loose (Flat) Lens

A loose Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) Soft (hydrophilic) Contact Lens would display some or all of the following characteristics:

- Decentration (usually temporally and/or superiorly).
- Excessive up gaze sag.
- Reduced comfort response-usually lower lid sensation.
- Lens edge standoff.
- Unstable vision.

CARE OF LENSES

Please refer to the “Lens Care Directions” section of the Package Insert.

PATIENT CARE OF LENSES

Please refer to the Package Insert and the Scheduled Replacement Patient Information Booklets for information pertaining to Cleaning/Disinfecting, Lens Care, and Handling Instructions.

HOW SUPPLIED

Each lens is supplied sterile in a blister containing buffered saline solution. The blisters are packed in boxes. The following information is provided: the base curve, diameter, dioptric power, manufacturing lot number of the lens and the expiration date of the product.

REPORTING ADVERSE REACTIONS

All serious adverse experiences and adverse reactions in patients wearing the Biomedics® 55 (*ocufilcon D*), Biomedics® 55 Toric (*ocufilcon D*), or Biomedics® 55 Multifocal (*ocufilcon D*) Soft (Hydrophilic) Contact Lens or experienced with the lenses should be reported to:

CooperVision, Inc.
711 North Road
Scottsville, NY 94080
USA
800-341-2020