60% XC ASPHERIC
60% MULTIFOCAL EP
(*omafilcon A*)

SOFT (HYDROPHILIC) CONTACT LENSES
FOR DAILY WEAR

PROFESSIONAL FITTING AND INFORMATION GUIDE

PROFESSIONAL FITTING AND INFORMATION GUIDE

60% XC ASPHERIC
60% MULTIFOCAL EP
(omafilcon A)
Soft (Hydrophilic) Contact Lenses

CAUTION: **Federal (USA) Law Restricts this Device toSale by or on the order of a Licensed Eyecare Practitioner**

TABLE OF CONTENTS

INTRODUCTION:

60% XC Aspheric and 60% Multifocal EP (*omafilcon A*) Soft (Hydrophilic) Contact Lenses are made of a polymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimeth-acrylate. The lens material has a permanently fixed tint using color additive VAT Blue 6.

PRODUCT DESCRIPTION:

The physical properties of the cast mold lenses are:

Refractive Index at 25° C	1.40
Light Transmittance	> 90%
Water Content	60% ± 2%
Oxygen Permeability*	
Polargraphic Fatt Method	21×10^{-11}
Modified Fatt Method Guard Ring Edge Corrected	25×10^{-11}

*(cm^2/sec) (ml O_2/ml x mm Hg) at 35°C as measured by 201T Permeometer connected to a polarographic cell.

LENS PARAMETERS:

60% XC Aspheric

DESCRIPTION: 60% XC Aspheric (*omafilcon A*) Soft (hydrophilic) Contact Lenses are a hemispherical shell available in the following dimensions:

Chord Diameter:	14.2 mm
Base Curve:	8.50 mm
Powers:	+0.50 to +6.00D and plano to -10.00D*
	* 0.50 D steps above -6.00D
	otherwise all power steps are in 0.25D increments
Center thickness:	0.075 mm to 0.246 mm (dependent on power)

60% Multifocal EP

DESCRIPTION: 60% Multifocal EP (*omafilcon A*) Soft (hydrophilic) Contact Lenses are a hemispherical shell available in the following dimensions:

Chord Diameter:	14.4 mm
Base Curve:	8.70 mm
Powers:	+4.00 to -6.00 D in 0.25 D steps
Add Powers:	+1.00
Center thickness:	0.15 mm to 0.35 mm (dependent on power)

ACTIONS:

In its hydrated state, the soft contact lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

INDICATIONS (USES):

Aspheric: 60% XC Aspheric (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.

Multifocal: 60% Multifocal EP (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in non-aphakic persons with non-diseased eyes. The lens may be worn by persons who have astigmatism of 2.00D or less that does not interfere with visual acuity.

60% XC Aspheric and 60% Multifocal EP (*omafilcon A*) Soft (hydrophilic) Contact lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients. The lens is to be cleaned, rinsed and disinfected each time it is removed from the patients eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE this contact lens when any of the following conditions exist:

- Previously diagnosed primary Sjogren's Syndrome Tear Deficiency, Autoimmune connective tissue disease which may involve secondary Sjogren's syndrome. Such conditions include rheumatoid arthritis, polyarthritis, Wegener's granulomatosis, systemic lupus erythematosus, systemic sclerosis, primary bilary cirrhosis, and mixed connective tissue disease
- Acute and subacute inflammation between the lens, iris, and cornea, i.e., the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Any active corneal infection: purulent (pus) bacterial, fungal, or viral infection
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses
- Allergy to any ingredient, such as thimerosal or mercury, in a solution which must be used to care for the lens
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- If eyes become red or irritated

WARNINGS:

Patients were not studied who exceed the conditions characterized by any of the following diagnostic parameters:

- Rose Bengal staining >12 on a scale of 18
- Fluorescein staining >12 on a scale of 15
- Meibomian gland dysfunction >3 on a scale of 0-4

Patients should be advised of the following warnings pertaining to contact lens wear:

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight. Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eyecare practitioner.

PRECAUTIONS:

Special Precautions for Eyecare Practitioners:

Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including on-eye lens dehydration, oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner, since individual patient response may vary.

Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.

- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses easily or should have someone else available to remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Eyecare practitioners should carefully advise patients that different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the 60% XC Aspheric and 60% Multifocal EP Contact Lens and those prescribed by the eyecare practitioner.
- Always use FRESH unexpired lens care solutions.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- Do not use saliva or anything other than the recommended solutions to wet your lenses.
- For patients on a frequent replacement program, to prevent your lenses from becoming dry (dehydrated), always keep them completely immersed in the recommended storage solution when the lenses are not being worn. Discard a lens that has become dried out.
- If the lens sticks (stops moving) on the eye, follow the directions on Care for a Sticking Lens. The lens must move freely on the eye for continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Never use tweezers or other tools to remove the lens from the lens container. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always handle lenses carefully and avoid dropping them.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- Always inform the doctor (health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform employer of being a contact lenses wearer. Some jobs may require use of eye protection equipment or may require that patient not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure health. Patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS:

The patient should be informed that the following problems may occur:

- Eyes sting, burn, or itch (irritation) or other eye pain
- Comfort is less than when lens was first placed on-eye
- Feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to IMMEDIATELY REMOVE LENSES.

- If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, DO NOT put the lens back on-eye. Place the lens in the lens case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse and disinfect the lenses; then reinsert them. **If the problem continues, DO NOT put the lens back on your eye; immediately consult an eye care practitioner.**

WHEN ANY OF THE ABOVE SYMPTOMS OCCUR, A SERIOUS CONDITION SUCH AS INFECTION, ABRASION, CORNEAL ULCER, NEOVASCULARIZATION, UVEITIS, OR IRITIS MAY BE PRESENT. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

CLINICAL TEST RESULTS:

Dry Eye patients have been categorized in the Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes, published in the CLAO Journal, October 1995, Vol. 21, No. 4.

The Safety and Effectiveness of the *omafilcon A* Soft Contact Lens in defined Dry Eye patients was demonstrated by the results of a clinical trial which are summarized here. The study patients dry eye condition is defined as arising from Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only). Lenses were not tested in subjects having severe cases of Dry Eye syndrome. All subjects were existing contact lens wearers, who met the Dry Eye diagnostic inclusion criteria - please refer to Table 1 Results of Eye Diagnostic Data, for summary of limits of diagnostic parameters studied.

Table 1 Results of Eye Diagnostic Data
Data table reporting upper limit of dry eye severity for those patients entered into study, also reports the number of eyes meeting each of the four diagnostic parameters as well as the distribution of score within each parameter.

	Eyes meeting Shirmer Requirement	Eyes meeting Rose Bengal Requirement	Eyes meeting Fluorescein Requirement	Eyes meeting Meibomian Gland Requirement
Number of eyes	29	80	37	87
Mean	3.17	4.84	4.24	2.39
Std. Deviation	1.69	1.91	1.94	0.49
Min.	0	3	3	2
Max.	5	12	12	3

This clinical study was a 3-month, 76 subject, randomized, comparative, crossover study consisting of two parts or Phases. Each part lasted 6-weeks. Soft contact lenses of the type worn by subjects immediately prior to study enrollment were used as Control lenses. In the first part of the study, subjects were assigned to wear either *omafilcon A* contact lenses or a fresh pair of their existing (Control) lenses on a daily wear basis in both eyes. At the 6 week interval, subjects crossed over to wearing the other lens in both eyes.

The study premise was that the issuance of new lenses, either Control or *omafilcon A*, would result in better performance data relative to the Pre-study condition. The material characteristics of the *omafilcon A* lens should allow a greater degree of improvement for the subgroup who wore the *omafilcon A* lens in Phase 1 than that observed in the Control subgroup (who wore new lenses of the type worn prior to study enrollment). In Phase 2, if the Phase 1 lens was the Control lens, the *omafilcon A* lens was expected to maintain or further improve the clinical performance. If the Phase 1 lens was *omafilcon A*, some erosion from the performance demonstrated by the use of *omafilcon A* lenses in this subgroup, would be observed by switching to the Control lens in Phase 2.

In Phase 1, the baseline against which the performance of the lens (Control or Test) was measured is the pre-study entry data. In Phase 2, the baseline against which the lens was measured is the data at the crossover point in the study.

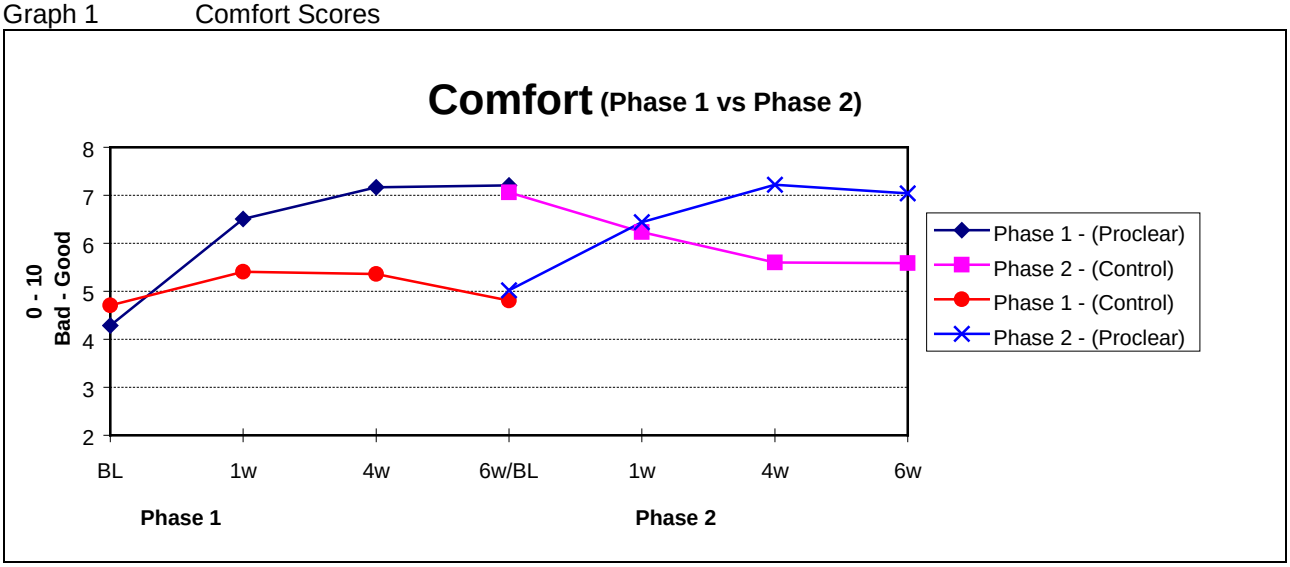
Conclusion

The differences noted between the experience of *omafilcon A* contact lens wear and Control lens wear, by study Phase, supports the premise that on entry to the clinical trial, an improvement over baseline measures is gained as a function of a change to fresh lenses. It also supports the premise that the change is greater for the *omafilcon A* lens wearing subjects in Phase 1. On crossover, the premise was that the improved subjective clinical performance achieved through *omafilcon A* lens wear in Phase 1 might be diminished or lost by use of Control lenses in Phase 2. Conversely, the improved subjective clinical performance, gained from use of fresh Control lenses in Phase 1, were expected to be manifest in the early interval(s), but possibly erode thereafter. On crossover to *omafilcon A* use in Phase 2, any subjective clinical performance in Phase 1 was projected to be sustained or further increased. The clinical data confirmed this later premise as well.

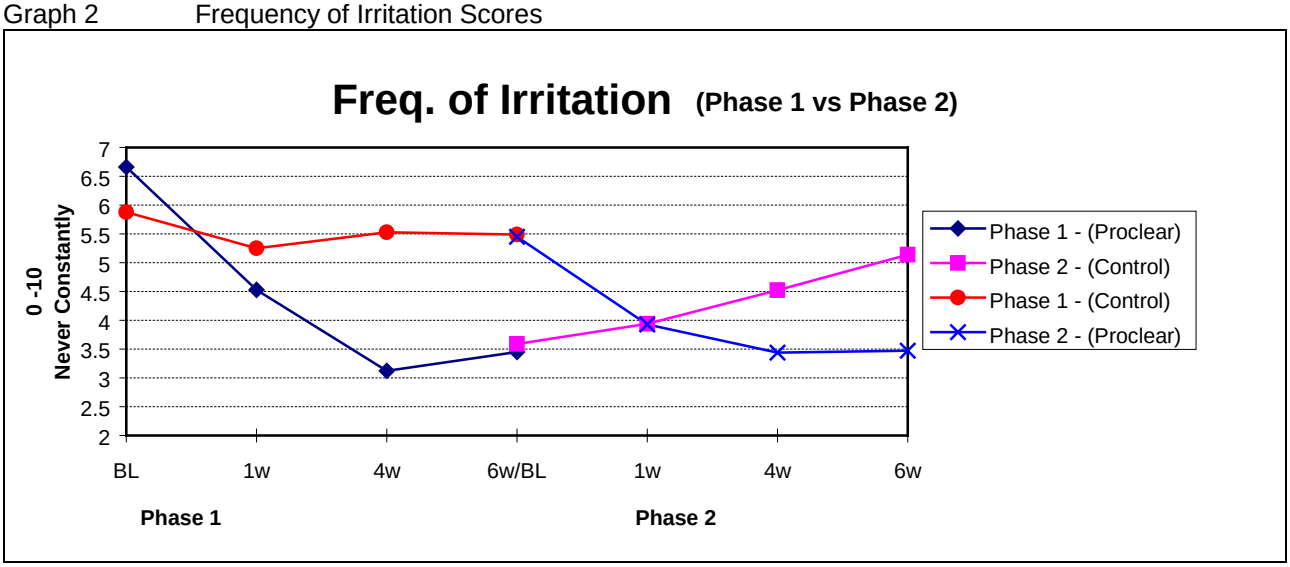
The clinical study subjects were required to provide their Self-evaluation of symptoms, problems and complaints on a Visual Analogue Scale (VAS) at each post-fit interval. These data have been analyzed and graphed. Please see Graphs 1 to 4 for graphs of mean scores for the *omafilcon A* and control populations, as a function of study Phase.

Further basis for modification in indication for use to permit inclusion of Defined Dry Eye subjects was studied by measurement of contact lens Resistance to On-eye Dehydration. The data indicated that the Relative Dehydration for the *omafilcon A* lenses in Dry Eyes was consistently low as compared to that reported for the population of Control lenses in Dry Eyes p=0.0001. The Matched Pair analysis confirms that the hydration retention characteristic of the *omafilcon A* material in the *omafilcon A* lens is significantly more resistant to on-eye dehydration than the Control lenses. Please see Table 2 for Water Content Results by Lens Material Type.

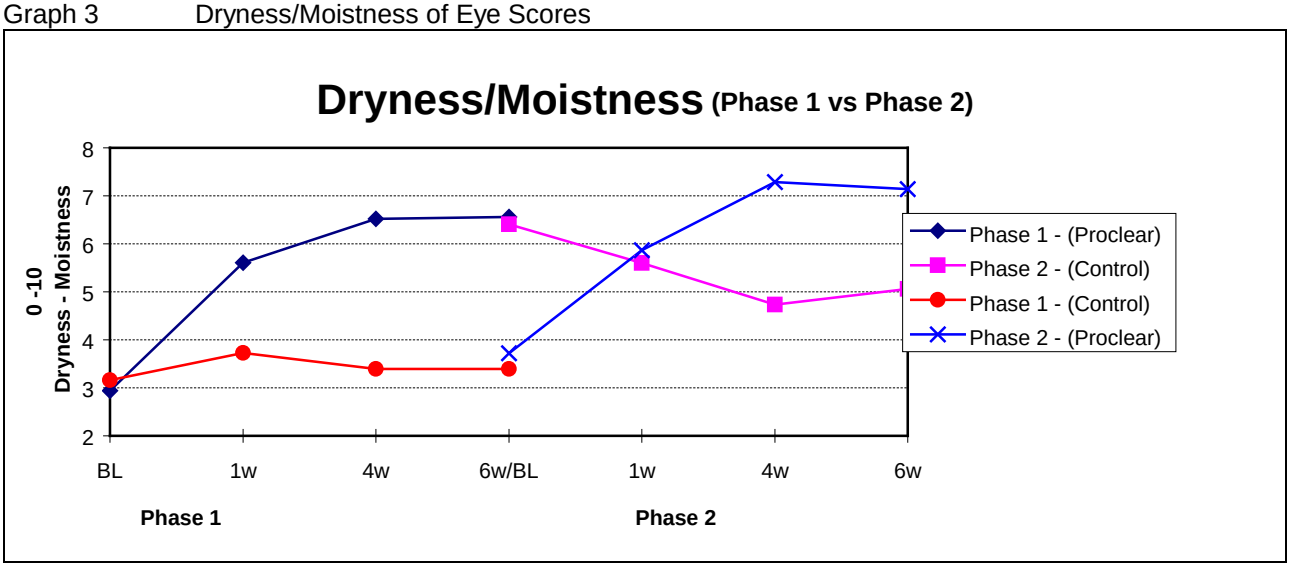
Graph 1 Comfort Scores



Graph 2 Frequency of Irritation Scores



Graph 3 Dryness/Moistness of Eye Scores



Graph 4 Frequency that Eyes Feel Dry Scores

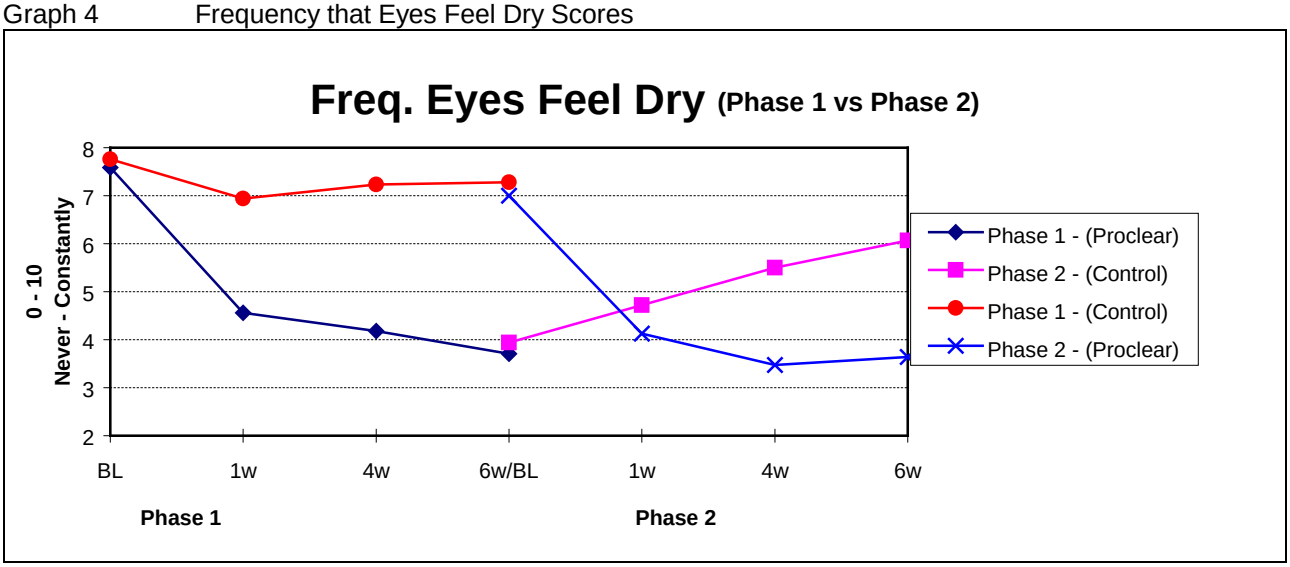


Table 2 Water Content Results by Lens Material Type

		Group1		Group 2		Group 4	
Material		omafilcon A	Control	omafilcon A	Control	omafilcon A	Control
Number of Eyes		28	23	8	6	42	44
Baseline Water Content (%)	Mean	61.0	40.9	60.0	68.4	61.2	57.1
	SD	1.07	6.45	1.07	7.36	0.94	6.73
Water Content 6 Weeks (%)	Mean	60.0	40.1	60.1	65.5	60.2	53.1
	SD	1.56	7.15	1.48	5.86	1.63	6.65
Absolute difference of Water Content at 6 Weeks (%)	Mean	1.36	1.80	1.63	2.92	1.49**	3.99
	SD	1.54	1.61	1.22	1.69	1.58	3.81
Relative Dehydration at 6 Weeks (%)	Mean	2.21**	4.65	2.65	4.09	2.41**	6.78
	SD	2.46	4.15	1.98	1.69	2.54	6.34

The lenses in the study ranged in power from -9.00 to + 6.00 D, encompassing center thicknesses of 0.07 mm to 0.31 mm. Not every quarter diopter power was represented in the study, therefore individual patient on-eye dehydration response may vary.

N.B. No measurements were completed for lenses from Group 3 due to insufficient lenses for statistical analysis.
Asterisks indicate significant differences: * $p \leq 0.05$, ** $p \leq 0.001$

Control Lenses used in above Groups are:

Group 1 - Low water content (<50%), Nonionic

Group 2 - High water content (≥50%), Nonionic

Group 4 - High water content (≥50%), Ionic

SELECTION OF PATIENTS:

Patients selected to wear 60% XC Aspheric and 60% Multifocal EP (*omafilcon A*) (hydrophilic) Soft Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The 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.

Patients who experience mild discomfort and related dry eye symptoms during lens wear arising from Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only) may wear these lenses with improved comfort compared to other soft (hydrophilic) contact lenses. For details on assessment of patients who experience mild discomfort or symptoms related to eye dryness during lens wear associated with Evaporative Tear Deficiency or Aqueous Tear Deficiency please see section in this guide titled Dry Eye Diagnostic Assessments.

DRY EYE DIAGNOSTIC ASSESSMENTS:

Patients were studied who exhibited conditions characterized by any of the following diagnostic parameters:

- Schirmer test without anesthesia at five minutes range of ≥ 0 to ≤ 5 mm
- Rose Bengal staining range of ≥ 3 to ≤ 12 on a scale of 18
- Fluorescein staining ≥ 3 to ≤ 12 on a scale of 15
- Meibomian gland dysfunction ≥ 2 to ≤ 3 on a scale of 0-4

Below are instructions for performing diagnostic assessments for each of the four parameters tested.

- **Schirmer Test Instructions**

The Schirmer test is done without anesthesia, under ambient light conditions, using Whatman #41 paper. Room temperature and humidity should be relatively consistent from test to test. The time of administration of the last drop and the time of testing are recorded.

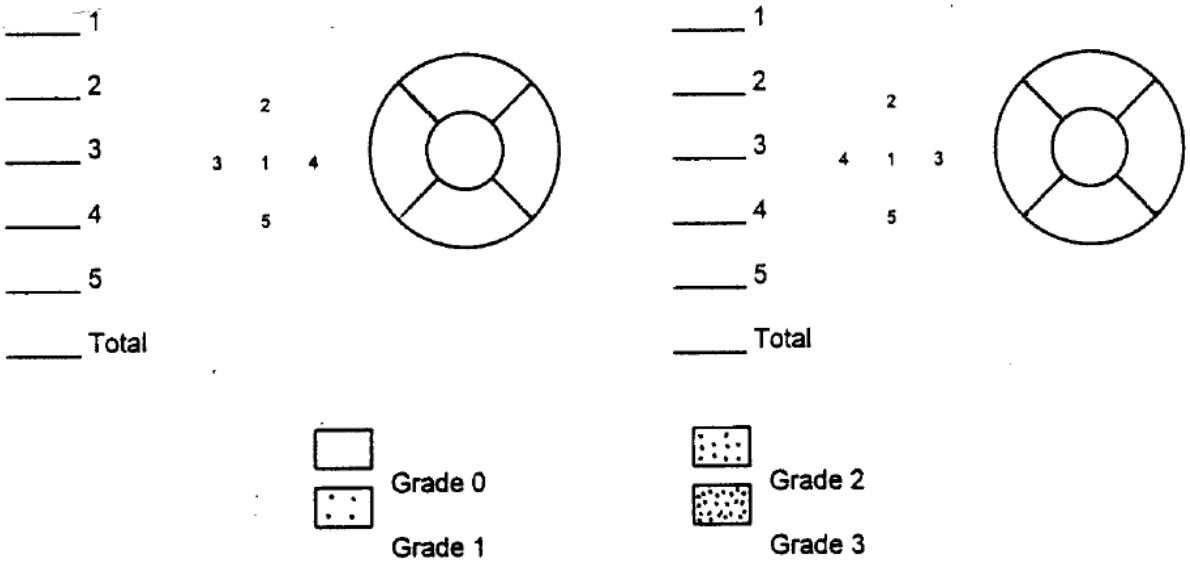
Ask the subject to look forward and upwards and blink normally while a strip is placed in the right eye followed by placement in the left eye. Place the strip at the junction of the middle and lateral one-third of the lower eyelid, taking care to avoid contamination of strip with skin oils.

Remove strips after 5 minutes and measure and record the amount of wetting of the strip in millimeters.

- **Fluorescein Staining Instructions**

Either fluorescein strips or solutions (1 - 2%) may be used. If strips are used, they should be wet with a standardized drop-volume of non-prserved saline solution.

The cornea is examined 3 minutes after the last instillation of fluorescein by light passed through a cobalt blue filter and examined through a biomicroscope containing a Wratten #12 barrier filter. Results are recorded on a corneal diagram as shown below. Punctate staining is recorded using the abovementioned standardized grading system of 0 - 3 for each of the five areas shown on the diagram. A summation of the points assigned to each area is made for each eye.

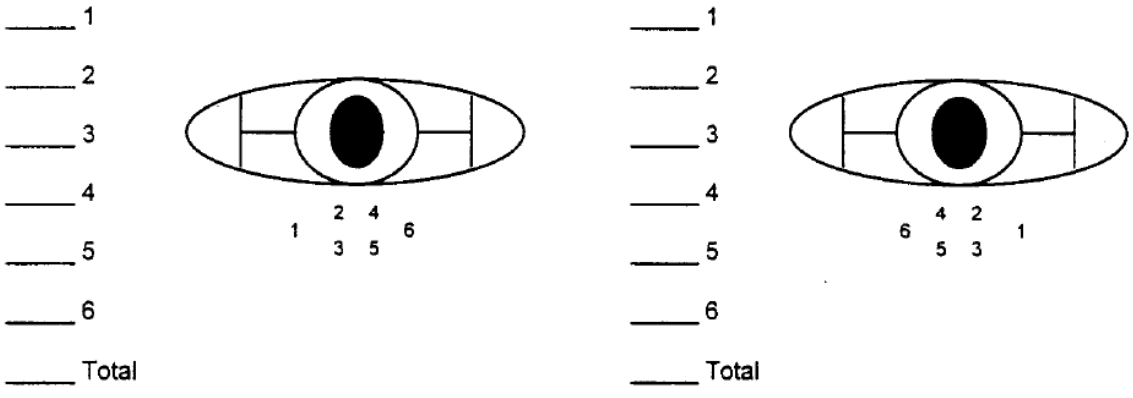


- **Rose Bengal Staining Instructions**

Suggested technique uses 2 - 5 ml of 1% rose bengal applied to the bulbar conjunctiva. After 15 seconds, the conjunctiva is examined by light passed through a green filter. Because the dye may be uncomfortable for the patient, a drop of topical anesthetic may be instilled in the dye placed on the eye.

Alternatively, rose bengal strips (Smith & Nephew) may be used by first applying unpreserved saline to the impregnated strip, then touching the strip to the inferior palpebral conjunctiva.

Results are recorded for the three areas of the temporal and nasal conjunctiva of each eye and a grade of 0 - 3 (as noted in the previous section on Fluorescein Staining) is assigned to each area of the diagram. A summation of the points assigned to each area is made for each eye.



- **Meibomian Gland Secretion Assessment Instructions**

Using the broad beam of the slit lamp, the inferior lid margin is examined in the following manner:

1. Asking the subject to look up, the edge of the nail of the examiner's finger is placed approximately 2 mm below the lashes and the lid margin is pressed. Approximately 4 - 5 glands are pressed at each time and are observed for the amount and quality of meibomian excreta. This procedure is repeated until the entire lid margin has been covered.

2. Evidence of erythema and any abnormalities are noted.

3. A similar examination is conducted of the upper lid, asking the subject to look down and slightly everting the upper lid with the fingernail.

4. An overall assessment is made and graded using the semi-quantitative scale as noted below.

Meibomian Gland Secretion Grading Scale

Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Normal	Turbid secretion, plugging of ≤ 25%	Turbid secretion, plugging of 26% -50%	Turbid secretion, plugging of > 50%	Toothpaste secretion with plugging of most glands

Note: The presence of lid margin erythema increases grade score by 1/2 grade

---

FITTING PROCEDURE OUTLINE:

1. Pre-fitting examination
2. Initial lens power selection
3. Initial lens base curve/ diameter selection
4. Initial lens evaluation
5. Follow-up care

FITTING PROCEDURE:

1. Pre-Fitting Examination
   A pre-fitting patient history and examination are necessary to:

   - determine whether a patient is a suitable candidate for daily wear contact lenses (consider patient hygiene and mental and physical state),

   - make ocular measurements for initial contact lens parameter selection,

   - collect and record baseline clinical information to which post-fitting examination results can be compared.

   A pre-fitting examination should include measurement of the patient's sphero-cylinder refraction, a detailed slit lamp examination, an assessment

of the patient's tear film, and measurement of corneal curvature (keratometry). If the patient has the necessary qualifications and no contraindications exist, the patient may be accepted for fitting.

2. Initial Lens Power Selection

Select a diagnostic lens as close as possible in power to the patient's own best vision sphere refraction. Calculate the required lens power by spherical over-refraction, correcting for back vertex distance where appropriate.

3. Initial Lens Base Curve and Diameter Selection

It is recommended that a lens of the STANDARD design is used as a diagnostic fitting lens; i.e. 8.5/14.2 for 60% XC Aspheric and 8.7/14.4 for 60% Multifocal EP.

4. Initial Lens Evaluation

Diagnostic lens fit should be evaluated after a settling period of 10-20 minutes using the lens assessment criteria (see Clinical Assessment section).

5. Follow-up Care

a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 (four) continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

c. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d. After the lens removal, conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.

2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.

3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. if the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN OFFICE CARE OF TRIAL LENSES:

Eyecare practitioner should educate contact lens technicians concerning proper care of trial lenses.

Each contact lens is shipped sterile in a blister package with sterile buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister should not be opened until immediately prior to use.

Prior to reusing in diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

Lens Cleaning (for frequent replacement schedules)

1. Cleaning the lens surface with cleaning solution must be done prior to storage by placing three drops of cleaner on each side of the lens and rubbing between thumb and index finger for 20 seconds, or in the palm of the hand.
2. Rinsing of both lens surfaces after cleaning must be done using a steady stream of rinsing solution for 10 seconds. To avoid contamination of the solution, do not contact the tip of the dropper bottle to any surface. The cap should always be closed to avoid contamination or evaporation when not in use.
3. Disinfection by soaking the lens in disinfection solution for at least four hours must be done each day the lens is worn (daily wear) and after each time the lens has been removed from the cornea. Fresh soaking solution must be used for each soaking. Before reinsertion of the lens, rinse thoroughly with rinsing solution, observing all the above precautions to prevent contamination of the solutions.

Chemical (Not Heat) Disinfection

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened lens case until ready to put on the eyes.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

RECOMMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

Daily Wear
Maximum wearing time:

Days	1	2	3	4
Hours**	4	6	8	All waking hours

**While patients who experience discomfort and related dry eye symptoms during lens wear arising from Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only) may wear these lenses with improved comfort compared to other soft (hydrophilic) contact lenses, their wearing time may be less than it would if they did not have dry eye symptoms.

Studies have not been conducted to show that these soft contact lenses are safe to wear during sleep.

CLINICAL ASSESSMENT

1. Criteria of a Well-Fitting Lens

A well-fitting lens will provide:
- Good standard of comfort
- Full corneal coverage in all directions of gaze
- Satisfactory movement following blink (approximately 0.2-0.5mm)
- Free movement and smooth recovery when digitally moved via the lower lid (the Push-up Test)

2. Criteria of a Tight (Steep) Lens

A tight lens may show some or all of the following:
- Good comfort
- Poor movement following a blink
- Resistance to movement and slow recovery on Push-up Test
- Conjunctival indention and compression of the conjunctival vessels

3. Criteria of a Loose (Flat) Lens

A loose lens may show some or all of the following:
- Poor comfort
- Excessive movement on blinking
- Easy movement on Push-up Test
- Lifting of the lens edge (edge stand-off)

MONOVISION FITTING GUIDELINES:

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 0.75 diopter) in one eye may not be a good candidate for monovision with the 60% XC Aspheric or 60% Multifocal EP Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

(1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near

tasks is usually in one direction correct the eye on that side for near:

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left with a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

For spectacle add powers up to +1.75D use the low add lens and for spectacle powers of +2.00D and above use the high add lens.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. the longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions:

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.

- Having a third contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. this is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.

- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.

- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.

- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

***** The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

***** All patients should be supplied with a copy of the 60% XC Aspheric or 60% Multifocal EP Patient Instruction manual.

HANDLING OF 60% XC ASPHERIC AND 60% MULTIFOCAL EP CONTACT LENSES:

The handling characteristics of the 60% XC Aspheric and 60% Multifocal EP lens is similar to other soft contact lenses of similar water content. Patients should, therefore, receive the standard instructions for insertion and removal of a lens of this water content.

PATIENT LENS CARE DIRECTIONS:

(for frequent replacement daily wear)

The lens may be disinfected using either peroxide or chemical disinfection system. See Package Insert for more details.

CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide)

o Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened lens case until ready to put on the eyes.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

See the appropriate package insert for instructions on the care of a dried out (dehydrated) lens.

CARE FOR A STICKING LENS

If the lens sticks (cannot be removed), the patient should be instructed to apply several 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 5 minutes, the patient should immediately consult eye care practitioner.

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: *FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.*

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing 60% XC Aspheric or 60% Multifocal EP Contact Lenses or experienced with the lenses should be reported to:

711 North Road
Scottsville, NY 14546
800-341-2020

www.coopervision.com

HOW SUPPLIED:

Each lens is sterilized and supplied in a blister package containing buffered saline solution. The blister package is marked with the base curve, dioptric power, diameter, manufacturing lot number of the lens and expiration date.

PACKAGE INSERT:

For the 60% XC Aspheric Package Insert, please reference PI01017.

For the 60% Multifocal EP Package Insert, please reference PI01021.