

Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery (hioxiflcon A), (hioxiflcon B), (acoflcon A), (acoflcon B), (methafilcon A) & (helflcon A) Soft Contact Lens for Daily Wear

CAUTION:
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

IMPORTANT

Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to the patient upon request. The eye care practitioner should provide the patient with the wearer's guide that pertains to the patient's prescribed lens.

DESCRIPTION

The **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery (hioxiflcon A), (hioxiflcon B), (alcoflcon A), (acoflcon B), (methafilcon A) & (helflcon A) Soft Contact Lens for Daily Wear** are fabricated from one of the above materials which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The non-ionic lens material, **hioxiflcon A**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (GMA) with N-vinyl-2-pyrrolidone (NVP). It consists of 41% hioxiflcon A and 59% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in a blue visibility-handling tint, phthalocyanato (2) – (copper).

The physical properties of the **hioxiflcon A** lens are:

Refractive Index	1.404 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	59%
Specific Gravity	1.18 (hydrated)
Oxygen Permeability	18 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fat method).

The non-ionic lens material, **hioxiflcon B**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (GMA) with N-vinyl-2-pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and cross-linked with Diethyl Malate (DAM). It consists of 52% hioxiflcon B and 48% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in a blue visibility-handling tint, phthalocyanato (2) – (copper).

The physical properties of the **hioxiflcon B** lens are:

Refractive Index	1.404 (hydrated)
Light Transmission (tinted)	greater than 95%
Water Content	48%
Specific Gravity	1.136 (hydrated)
Oxygen Permeability	15 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fat method).

The non-ionic lens material, **acoflcon A**, is a terpolymer based on high purity Glycerol Methacrylate, 2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2-pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and cross-linked with Diethyl Malate (DAM). It consists of 42% acoflcon A and 58% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in a blue visibility-handling tint, Color additive 'Reactive Blue 4'.

The physical properties of the **acoflcon A** lens are:

Refractive Index	1.40 (hydrated)
Light Transmission (tinted)	greater than 93%
Water Content	58%
Specific Gravity	1.103 (hydrated)
Oxygen Permeability	25.50 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fat method).

The non-ionic lens material, **acoflcon B**, is a terpolymer based on high purity Glycerol Methacrylate, 2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2-pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and cross-linked with Diethyl Malate (DAM). It consists of 51% acoflcon B and 49% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4'.

The physical properties of the **acoflcon B** lens are:

Refractive Index	1.42 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	49%
Specific Gravity	1.142 (hydrated)
Oxygen Permeability	15.8 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fat method).

The non-ionic lens material, **methafilcon A**, is a co-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and Methacrylic Acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in normal buffered saline solution.

The physical properties of the **methafilcon A** lens are:

Refractive Index	1.415 (hydrated)
Light Transmission (clear)	greater than 95%
Water Content	55%
Specific Gravity	1.099 (hydrated)
Oxygen Permeability	18.8 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fat method).

The non-ionic lens material, **helflcon A**, is a random co-polymer of 2-hydroxyethyl methacrylates and N-vinyl pyrrolidone cross-linked with ethylene glycol dimethacrylate (EGDMA). The co-polymer consists of 55% helflcon A and 45% water by weight when immersed in normal buffered saline solution. Lenses are available in clear and with a blue visibility handling tint, phthalocyanine blue.

The physical properties of the **helflcon A** lens are:

Refractive Index	1.43 (hydrated)
Light Transmission (clear)	greater than 95%
Light Transmission (tinted)	greater than 95%
Water Content	45%
Specific Gravity	1.117 (hydrated)
Oxygen Permeability	16 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fat method).

The **Flexlens, and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** is a flexible transparent hemispherical shell of the following dimensions:

- * Chord Diameter: 10.0 mm to 16.0 mm
- * Center Thickness: varies with power
- * Base Curve: 6.0 mm to 10.8 mm
- * Cylinder Power: -0.50D to -10.00D
- * Axis: in 1 degree increments
- * Spherical Power: -30.00 to +30.00 Diopters

The **Flexlens Multifocal Soft Contact Lens for Daily Wear** is a flexible transparent hemispherical shell of the following dimensions:

- * Chord Diameter: 10.0 mm to 16.0 mm
- * Center Thickness: varies with power
- * Base Curve: 7.5 mm to 9.5 mm
- * Spherical Powers: -20.00 to +20.00 Diopters
- * Cylinder Power: -0.50D to -10.00D
- * Axis: in 1 degree increments
- * Add Power: +1.00 diopters to +3.50 diopters (.50D increments)
- * Pupil Zone: 3.0 mm to 7.0 mm (.5 mm increments)

NOTE

Flexlens Multifocal Soft Contact Lens for Daily Wear is available only in hioxiflcon A and hioxiflcon B material.

ACTIONS

In the hydrated state, the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear**, when placed on the cornea, act as a refracting medium to focus light rays on the retina.

**SPECIAL PRACTITIONER
WARNING**

INSTRUCT YOUR PATIENTS:

DO NOT WEAR THE FLEXLENS Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear **WHILE NAPPING OR SLEEPING**. WEARING THE FLEXLENS, FLEXLENS MULTIFOCAL AND FLEXLENS POST REFRACTIVE SURGERY SOFT CONTACT LENS FOR DAILY WEAR **WHILE NAPPING OR SLEEPING** COULD RESULT IN SERIOUS INJURY TO THE EYE.

INDICATIONS

The **Flexlens (hioxiflcon A), (hioxiflcon B), (acoflcon A), (acoflcon B) Soft Contact Lens for Daily Wear (lathe-cut)** are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia. Examples include, but are not limited to: adult and pediatric aphakia, and irregular astigmatism created by keratoconus, trauma, or post keratoplasty.

The **Flexlens (hioxiflcon A), (hioxiflcon B), (acoflcon A), (acoflcon B) Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear (lathe-cut)** are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia following corneal refractive surgery.

Flexlens Multifocal Soft Contact Lenses (hioxiflcon A and hioxiflcon B) for Daily Wear (lathe-cut) are indicated for daily wear use for the correction of refractive ametropia (myopia, hyperopia and/or presbyopia) in non-aphakic persons.

The lens may be disinfected with a chemical (not heat) disinfection system.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** when any of the following conditions are present:

- * Acute and sub acute inflammation or infection of the anterior chamber of the eye.
- * Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- * Severe insufficiency of lacrinal secretion (dry eyes).
- * Corneal hypoessthesia (reduced corneal sensitivity), if not-aphakic.
- * Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- * Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- * Allergy to any ingredient, such as mercury or thimerosal, in a solution that is to be used to care for the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** lens.
- * Any active corneal infection (bacterial, fungi, or viral)
- * If eyes become red or irritated.
- * Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

* PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. IT IS ESSENTIAL THAT PATIENTS FOLLOW THEIR EYE CARE PRACTITIONER'S DIRECTION AND ALL LABELING INSTRUCTIONS FOR PROPER USE OF LENSES AND LENS CARE PRODUCTS, INCLUDING THE LENS CARE, EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

- * All contact lens wearers must see their eye care practitioner as directed.
- * 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.

PRECAUTIONS

Special Precautions for eye care practitioner:

Please read carefully and keep this information for future use

IMPORTANT

PACKAGE INSERT



FLEXLENS, FLEXLENS MULTIFOCAL & FLEXLENS POST REFRACTIVE SURGERY CONTACT LENSES

* 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 were 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 oxygen permeability, wet ability, central and peripheral thickness, and optic zone diameter.

* The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive correction. Therefore, the prescribing eyecare practitioner should carefully monitor the continuing ocular health of the patient and lens performance on the eye.

* Aphakic patients should not be fitted with the Flexlens Soft Contact Lens for Daily Wear until the determination is made that the eye has healed completely.

* Patients who have had radial keratotomy (RK) may be more prone to new vessel growth along incision lines. More frequent follow-up care may be required to ensure that any neovascularization is detected at an early stage. Patients should be discontinued from lens wear if new vessel growth starts to approach the pupillary zone.

* Clinical studies have demonstrated that contact lenses manufactured from (thioxiflicon A), (thioxiflicon B), (acoflicon A), (methafilcon A) & (hethylcon A) are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material.

* Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wet ability, 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 eye care practitioner.

* Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

* 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. Wait at least one hour before replacing the lens. Too early replacement may allow the lenses to absorb residual Fluorescein irreversibly.

* Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

* Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- * Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile. 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 chemical disinfection. Always use **FRESH, STERILE, UNEXPIRED** lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Sterile unopened solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses. Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage the lenses. Follow the lens care directions for care for a dried out (dehydrated) dry lens if the lens surface does become dried out.
- * If the lens sticks (stops moving) on the eye, follow the recommended directions on care for sticking lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to **IMMEDIATELY** consult his or her eye care practitioner.
- * Always wash and rinse 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.
- * Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- * Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** contact lens and those prescribed by the eye care practitioner.
- * Never wear lenses beyond the period recommended by the eye care practitioner.
- * If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- * Always handle lenses carefully and avoid dropping them.
- * Avoid all harmful or irritating vapors and fumes while wearing lenses.
- * Ask the eye care practitioner about wearing lenses during sporting activities.
- * Inform the doctor (health care practitioner) about being a contact lens wearer.
- * Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.
- * Pour the lens into the hand.
- * Do not touch the lens with fingernails.
- * Always contact the eye care practitioner before using any medicine or medications in the eyes.
- * Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lens.
- * As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The 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 stinging, burning, itching (irritation), or other eye pain.
- * Comfort is less than when lens was first placed on eye.
- * Feeling that something is in the eye such as a foreign body or scratched area.
- * Excessive watering (tearing) or the eye.
- * Unusual eye secretions.
- * Redness of the eye.
- * 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 discomfort or problems stops, then look closely at the lens. If the lens is in any damage, **DO NOT PUT THE LENS BACK ON THE EYE.** Place the lens in the storage case and contact the eye 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. After reinsertion, if the problem continues, the patient should **IMMEDIATELY REMOVE THE LENSES AND CONSULT THE EYE CARE PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **KEEP LENSES OFF THE**

EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lenses do apply to **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** contact lenses. For a detailed description of the fitting techniques, refer to **Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** contact lens fitting Guide, copies of which are available from:

X-Cel Contacts / Flexlens Products
 2775 Premier Pkwy., Suite 600
 Duluth, GA 30097
 800-241-9312

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to over wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

The **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** are indicated for daily wear. The maximum suggested wearing time for these lenses is:

DAY	HOURS
1	6
2	8
3	10
4	12
5	14
6	All Waking hours *

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear IS SAFE TO WEAR DURING SLEEP.

* WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

LENS CARE DIRECTIONS

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

* **Basic Instructions:**

Care of contact lens takes very little time and involves THREE essential steps – **CLEANING, RINSING AND DISINFECTING**. Each step in itself is important, and one step is not to be replaced by the other.
 Always wash, rinse and dry hands before handling contact lens.
 Always use **FRESH, STERILE UNEXPIRED** lens care solutions.
 Use the recommended chemical (not heat) lens care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lens.

DO NOT ALTER/DATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lens. Do not put lens in the mouth. Lens should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lens. Eyecare practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lens while they are being worn to make them more comfortable.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

* **Lens cleaning, disinfection, and storage:**

Clean one lens first (always the same lens first to avoid mix-ups), **rinse** the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning, **disinfect** lenses using the system recommended by the manufacturer and/or the eye care practitioner. To store lens, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on storage of lenses.

* **Chemical (NOT HEAD) Lens Disinfection:**

1. Wash and rinse your hands thoroughly **BEFORE HANDLING LENS.**
2. After removal of lens, **CLEAN** the lens by applying three drops of cleaner to each surface. Then rub the lens between your fingers for 20 seconds.
3. **AFTER CLEANING**, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. The lens should then be placed in a lens case and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the solution bottle.

Note: **DO NOT HEAT THE DISINFECTION SOLUTION AND LENSES.**

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.

* **Lens Case Cleaning and Maintenance:**

Contact lens cases can be a source of bacteria growth. After removing the lenses from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

* **Lens Care Regimen:**

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear**. Failure to follow this procedure may result in development of serious ocular infections.

* **Care for a Dried Out (dehydrated) Dry Lens:**

If for some reason, your lenses dry out completely a minimum of handling is important, as they are very brittle in the dehydrated state. Carefully place them in rinsing or storage solution for a minimum of thirty minutes during which time they will become soft and flexible. Then follow the cleaning, rinsing, and disinfecting procedures - including soaking the lens in storage and disinfection solution for four hours before wearing again.

* **Care for a sticking (nonmoving) lens:**

If the lens sticks (cannot be removed), the patient should be instructed to apply 3 to 4 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 nonmovement of the lens continues after 15 minutes, the patient should **IMMEDIATELY** consult the eye care practitioner.

* **Storage:**

The **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** must be stored only in the recommended solutions. If exposed to the air, the lenses will dehydrate. If lens dehydrates, reference above section on caring for dried out (dehydrated) dry lens.

* **Lenses prescribed for frequent replacement:**

The **Flexlens and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** may be prescribed in a frequent replacement program and should be thrown away after the recommended wearing period prescribed by the eyecare practitioner.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

RECOMMENDED LENS CARE PRODUCTS

The eyecare practitioner should recommend a care system that is appropriate for the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. The table below shows solutions that are recommended for use with the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear**.

Daily Cleaner:	<ul style="list-style-type: none"> • Alcon Opti-Free Daily Cleaner
Rinsing Solution:	<ul style="list-style-type: none"> • Alcon Saline for Sensitive Eyes.
Disinfecting Solution:	<ul style="list-style-type: none"> • Alcon Opti-Free (Rinsing, Disinfecting and Storage Solution) • Alcon Opti-One (Multi-Purpose Solution)
Lubricant/Rewetting Drops:	<ul style="list-style-type: none"> • Alcon Opti-Free Rewetting Drops
Enzymatic Cleaner:	<ul style="list-style-type: none"> • Alcon Optizyme Enzymatic Cleaner

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.

HOW SUPPLIED:

Each lens is supplied sterile in a glass vial containing sterile buffered saline solution USP. The glass vial is marked with the base curve, diameter, dioptric power, cylinder power and axis, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **Flexlens, Flexlens Multifocal and Flexlens Post Refractive Surgery Soft Contact Lens for Daily Wear** or experienced with the lenses should be reported to:

X-Cel Contacts / Flexlens Products
 2775 Premier Pkwy., Suite 600
 Duluth, GA 30097
 800-241-9312

PRINT DATE
 January 2007



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