WARNINGS
PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS
DO NOT USE AT SERIOUS INJURY TO THE EYE. Inform the employer that patients follow their 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 FROM IMPROPER AND/or INADEQUATE USE OF LENS CARE PRODUCTS.  SHOULD YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

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 at the risk of various 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:
Clinical studies have demonstrated that contact lenses manufactured from hioxifilcon D, hioxifilcon D, hiolcon A, polymacon and methafilcon A are safe for use by all intended users. However, the clinical studies have not included all design configurations or lens parameters that are presently available in this lens material.

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 materials were not evaluated in significant numbers. 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, 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 must be carefully monitored by the eye care practitioner.

Aphakic patients should not be fitted with NOVAKONE lenses until the determination is made that the eye has healed completely.

Patients who have had keratotomy (RK) may be prone to new vascular ingrowth into the cornea. More frequent follow-up care may be required and the patient should be informed that the examination is conducted at an early stage. Patients should be discontinued from lenses wear if new vascular growth starts to appear around the incision.

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 colored. Whenever fluorescein dye is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for use in eye. Wait at least one hour before reinserting lenses. 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 properly handle the lenses. If no one else is available who can remove the lenses for the patient, the patient should be instructed to keep the lens OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION of the problem and prompt treatment to avoid eye damage.

FITTING
Conventional methods of fitting contact lenses apply to NOVAKONE SOFT CONTACT LENSES. For further information, refer to the NOVAKONE CONTACT LENSES Professional Fitting and Information Guide, copies of which are available from:

Alden Optical
6 Lancaster Parkway
Lancaster, PA 15606 (724) 937-5181

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

Certain atmospheric or environmental conditions can cause eye irritation, contact lens parameters, and lens care information and specific instructions on the lens care regimen recommended for the patient:

Basic Instructions:
Care of contact lenses takes very little time and involves THREE essential steps – CLEANING, RINSING AND DISINFECTION. Each step in itself is important, and one step is not to be replaced by the other. Always wash and rinse dry and hands before handling contact lenses. Always use FRESH, STERIL, UNEXPED contact lens solutions for disinfection. Use the recommended lens care system. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. DO NOT ALTERNATE OR MIX SOLUTIONS. The solution must be labeled with "ON SOLUTION LABELING." Do not use saliva or anything other than the recommended solutions for lubricating or wetting contact lenses. Always keep the lenses completely immersed in the recommended storage solutions, even when not being worn (stored). Protected periods of drying will damage the lenses. Follow the lens care directions for care of a dried out (dehydrated) lens if the lens surface does become dried out.

If the lens sticks (stopping on move) 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 non-movement 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 wash hands before the lenses touch the eye. Refrigerated solutions are less likely to damage lenses than cold-ice.

Do not touch contact lenses with the fingers or hands if the hands are not free of any lotion or creams, as microorganisms on the hands may cause, disturbing distorted vision and/or injury to the eye.

Carefully handle the insertion, removal, cleaning, disinfection, storing and wearing instructions in the Patient instructions for NOVAKONE LENSES and follow the instructions described by the eye care practitioner.

Never wear lenses beyond the period recommended by the eye care practitioner.

Contact lenses should never be shared between users.

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.

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Wear the lenses only as instructed by the eye care practitioner

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Instruct the dryer (health care) practitioner about being a contact lens wearer.

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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 lenses with fingernails.

Contact eye care practitioners before using any medicine or medications in the eyes.

Always contact the eye care practitioner before using any medicine or medications in the eyes.

Any allergic reaction or extreme sensitivity to any lens care products used or contact lenses.

Any contact lenses while pregnant or lactating.

Any active corneal infection (bacterial, fungal, or viral).

Any known or suspected hypersensitivity to lens materials.

Any patient is unable to follow lens care regimen or unable to obtain assistance to do so.

At least one contact lens should be fitted per eye. Eye care practitioners should carefully instruct patients about the following:

In the event of an allergic reaction, contact the eye care practitioner immediately.

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 wash hands before the lenses touch the eye. Refrigerated solutions are less likely to damage lenses than cold-ice.

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At least one contact lens should be fitted per eye. Eye care practitioners should carefully instruct patients about the following:

In the event of an allergic reaction, contact the eye care practitioner immediately.
Chemical (NOT HEAT) Lens Disinfection:
1. Wash and rinse your hands thoroughly BEFORE HANDLING LENSES.
2. After removal of lenses, CLEAN the lenses 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. Fill contact lens carrying case with the recommended disinfection and storage solution and place lenses in the proper cells and soak as recommended in solution labeling.

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 manufacture; 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 manufacture or your eye care practitioner.

Lens Care Regimen:
Patients must adhere to the lens care regimen recommended by their eye care practitioner for the lens care of NOVAKONE LENSES. Failure to follow this procedure may result in development of serious ocular infections

Care for a Dried out (dehydrated) Lens:
If for some reason, your lenses dry out completely, it is important to minimize handling, 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 non-movement of the lens continues after 15 minutes, the patient should IMMEDIATELY consult the eye care practitioner.

Storage:
The NOVAKONE LENSES must be stored only in the recommended solutions. If left exposed to the air, the lenses will dehydrate. If lens dehydrates, reference above section on caring for dried out (dehydrated) dry lens.

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 NOVAKONE LENSES. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

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 buffered sterile normal saline solution USP. The glass vial is marked with the base curve, diameter, dioptric power, color, manufacturing lot number, and expiration date of the lens.

REPORTING OF ADVERSE REACTIONS:
All serious adverse experiences and adverse reactions observed in patients wearing NOVAKONE LENSES or experienced with the lenses should be reported to:

Alden Optical
6 Lancaster Parkway
Lancaster, NY 14086 USA
(716) 937-9181

January 2016