



Alden Optical – NOVAKONE (sphere) Catalog No. **AONKS**
(hioxifilcon D – 54%)

Alden Optical - NOVAKONE TORIC Catalog No. **AONKT**
(hioxifilcon D – 54%)

Package Insert Version NK 2016.1
Alden Soft (hydrophilic) Contact Lens for Daily Wear

CAUTION

Federal (USA) 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 patients prescribed lens.

DESCRIPTION

NOVAKONE lenses for daily wear are manufactured from hioxifilcon D material.

NOVAKONE SPHERICAL lenses are manufactured with a spherical front surface for the correction of visual acuity in persons requiring keratoconus management who are myopic or hyperopic. NOVAKONE SPHERICAL lenses are available clear or with a blue visibility-handling tint, [phthalocyaninato (2-)] copper.

NOVAKONE TORIC lenses have a toric anterior or posterior surface generated for the purpose of correcting vision in persons requiring keratoconus management and who possess astigmatism. NOVAKONE TORIC lenses are designed with dynamic stabilization or thin zones for orientation. NOVAKONE TORIC lenses are available clear or with a blue visibility-handling tint, [phthalocyaninato (2-)] copper.

NOVAKONE lenses are flexible hemispherical shells of the following dimensions:

ALDEN SOFT CONTACT LENSES are flexible hemispherical shells of the following dimensions:

- Chord Diameter: 10.0 mm to 16.0mm
- Center Thickness: 0.35 mm standard
- Central Base Curve: 5.4 mm to 8.6 mm
- Fitting Curve 8.3 mm to 8.9 mm
- Spherical Powers (toric lenses): -30.00 D. to +30.00 D.
- Spherical Powers (spherical lenses) -30.00 D. to +30.00 D.
- Cylinder Powers, (toric lenses) -0.50 D. to -10.00 D.
- Axis (Toric lenses) 1 to 180

The NOVAKONE (hioxifilcon D) lens is manufactured from a non-ionic lens material made from a homo-polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA). The NOVAKONE Lens (hioxifilcon D) consists of 46% hioxifilcon D and 54% water by weight when immersed in buffered normal saline.

PHYSICAL PROPERTIES

	NOVAKONE (hioxifilcon D)
Refractive Index	1.510 (dry) / 1.408 (hydrated)
Light Transmittance	> 95%
Water Content	54%
Specific Gravity	1.300 (dry) / 1.136 (hydrated)
Oxygen Permeability	21

ACTIONS

When placed on the cornea, the NOVAKONE (hioxifilcon D) lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS

The NOVAKONE SPHERICAL lens is indicated for daily wear for persons requiring keratoconus management for the correction of refractive ametropia (myopia, hyperopia) in aphakic and not aphakic persons with otherwise non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

The NOVAKONE TORIC lens is indicated for daily wear for persons requiring keratoconus management for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with otherwise non-diseased eyes and who possess refractive astigmatism not exceeding 10 Diopters.

The lenses are available for either conventional wear or planned replacement modalities.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE ALDEN SOFT CONTACT LENSES when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality (other than keratoconus) that affects the cornea, conjunctiva, or eyelids, except where prosthetic lens is required.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (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, which is to be used to care for ALDEN SOFT CONTACT LENSES.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- Patient is 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 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; 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.

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:

Clinical studies have demonstrated that contact lenses manufactured from hioxifilcon B, hioxifilcon D, hioxifilcon A, polymacon and methafilcon 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.

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 eyecare 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 should be carefully monitored by the prescribing eye care practitioner.

Aphakic patients should not be fitted with NOVEKONE LENSES 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.

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 use in both heat and 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 unpreserved 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) 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 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 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 microscopic 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 NOVAKONE LENSES and those prescribed 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.
- 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 lenses.
- 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 could occur:

- Eyes stinging, burning, itching (irritation), or other eye pain.
- Comfort is less than when lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) of 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, look closely at the lens. If the lens is in any way damaged, DO NOT PUT THE LENS BACK ON THE EYE. Place the lens in the storage 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 lens, then reinsert it. After reinsertion, if the problem continues, the patient should IMMEDIATELY REMOVE THE LENS 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 THE LENS 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 apply to NOVEKONE SOFT CONTACT LENSES. For a detailed description of the fitting techniques, refer to the NOVAKONE CONTACT LENSES Professional Fitting and Information Guide, copies of which are available from:

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

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 NOVAKONE LENSES 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 NOVAKONE SOFT CONTACT LENS IS SAFE TO WEAR DURING SLEEP. WEARING THE LENSES WHILE SLEEPING INCREASES THE RISK OF INFECTION AND PERMANENT DAMAGE TO VISION.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

Certain atmospheric or environmental conditions can cause eye irritation, consult your eye care practitioner regarding the use of contact lenses when these conditions exist.

LENS CARE DIRECTIONS

Eye care practitioners should review lens care directions with the patient, including both basic 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, rinse and dry hands before handling contact lenses. Always use FRESH, STERILE, UNEXPIRED lens care solutions. 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 LENS CARE SYSTEMS UNLESS INDICATED ON SOLUTION LABELING. Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth. Lenses 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 lenses. Eye care practitioners may recommend a lubricating/rewetting solution, which can be used to wet (lubricate) lenses 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 the 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 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 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 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 ENZYMIC 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 LENS. 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, dioptic 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

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