

## PACKAGE INSERT

### CARDINAL APEX® CONTACT LENSES

#### Rigid Contact Lenses for Daily Wear

##### 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 patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens. Cardinal Apex® Lenses should be fitted only by a contact lens fitter trained in the fitting of conventional (non-reverse geometry) contact lenses.

##### Non-sterile. Clean and condition lenses prior to use.

##### DESCRIPTION

Cardinal Apex® Contact Lenses are wettable, rigid contact lenses that are made from medical grade polymers. Apex® Contact Lenses are available in a variety of colours.

##### Available Lens Design Parameters

Power Range: -30.00D to +50.00D in 0.25D increments  
Diameter: 6.0mm to 16.5mm  
Base Curve: Range 4.00mm to 16.00mm in 0.01mm increments  
Toricity Up to 10.00 Diopters  
Prism Ballast 0.5 to 4.0 prism diopters in 0.25D increments  
Maximum Axial Edge Lift: 0.85mm  
Maximum Eccentricity of 1.25 e  
Add Powers +1.00D to +4.00D in 0.25D increments  
Segment widths: 1.6mm to 4.0mm in 0.1 mm increments

Some Materials May contain UV absorbers

##### WARNING

UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

##### ACTIONS

Cardinal Apex® Contact Lenses, when placed on the cornea, act as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

##### INDICATIONS (USES)

Cardinal Apex® Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, presbyopia and keratoconus) in aphakic and not aphakic persons with non-diseased eyes. These contact lenses may be disinfected using a chemical disinfecting system only.

##### CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Cardinal Apex® Contact Lenses when any of the following conditions exist:

- Acute and sub-acute inflammations 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 tears (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic.
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient in a solution which is to be used to care for your Cardinal Apex® Lenses.
- Any active corneal infection (bacterial, fungal or viral).
- Red or irritated eyes

##### WARNINGS

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 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**.
- Daily wear lenses are not indicated for overnight wear, and should not be worn 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 eye care practitioner.

##### PRECAUTIONS

**Practitioner Note:** Apex® Contact Lenses are not sterile when shipped from Cardinal Contact Lens Inc. Prior to dispensing, clean and disinfect the lens(es) according to the appropriate lens care regimen.

Patients may experience a reduction in visibility while wearing these lenses in conditions of low illumination for the following colour and center thickness:

| Colour        | Center Thickness |
|---------------|------------------|
| Blue          | >0.65mm          |
| Ice Blue      | >0.65mm          |
| Electric Blue | >0.35mm          |
| Violet        | >0.65mm          |
| Green         | >0.55mm          |
| Brown         | >0.20mm          |
| Gray          | >0.30mm          |

##### Special Precautions for Eye Care Practitioners:

- 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 should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear 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.
- Aphakic patients should not be fitted with the Cardinal Apex® Contact Lenses until the determination is made that the eye has healed completely.
- Before leaving the eye care practitioner's office, the patient should be able to properly 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 lenses immediately if the eye becomes red or irritated.
- The presence of an ultraviolet (UV) light absorber in the Cardinal Apex® Contact Lenses may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)

##### 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 with the lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Cardinal Apex® contact lenses.
- 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 solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when not being worn (stored).
- If the lens sticks (stops moving) on the eye, follow the recommended directions on "Care for a 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-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the *Patient Lens Care Instructions for Cardinal Apex® Contact Lenses* and in 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 gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eye care practitioner about wearing lenses during water activities and other sports.
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. To remove the lens from the lens case, pour the solution containing the lens into the palm of your hand.

- Do not touch the lens with fingernails.
- Always contact your eye care practitioner before using any medicine in the eyes.

- Always inform your employer that you wear contact lenses. 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 EFFECTS

Patients should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye, such as a foreign body or 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 these conditions, the patient should be instructed to IMMEDIATELY REMOVE THE LENSES.

The patient should be advised to follow these instructions:

- If the discomfort or problem stops, then 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 objects on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it.

If the problem continues, **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, and 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 including corneal scarring, opacification, blindness or loss of eye.

##### FITTING

Conventional methods of fitting contact lenses apply to Cardinal Apex® Contact Lenses. For a detailed description of the fitting techniques, refer to the Cardinal Apex® Professional Fitting and Information Guide, copies of which are available from:

Cardinal Contact Lens Inc.  
7-38 Cowansview Rd.  
Cambridge, ON, Canada. N1R 7N3. Phone:1-800-263-3973

##### WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner.

Patients tend to overwear 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.

Cardinal Apex Contact Lenses are indicated for daily wear. The suggested wearing time for these lenses is:

| DAY       | WEARING TIME (Hours)*  |
|-----------|------------------------|
| 1         | 4 to 8 Hours           |
| 2         | 6 to 10 Hours          |
| 3         | 8 to 14 Hours          |
| 4         | 10 to 15 Hours         |
| 5         | 12 to All Waking Hours |
| 6 & after | All Waking Hours       |

\*if the lenses continue to be well-tolerated.

##### WARNING: Cardinal Apex® Contact Lenses are NOT intended for overnight (extended) wear.

##### 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.

##### Cardinal Apex® Contact Lenses cannot be heat (thermally) disinfected.

The lens care products listed below are recommended for use with the Cardinal Apex® Contact Lenses. Eye care practitioners may recommend alternate products that are appropriate for the patient's use with his or her lens(es).

| LENS CARE TABLE   |  |
|-------------------|--|
| Product Purpose   | Lens Care System <i>Chemical (Not Heat)</i>  |
| Clean             | Boston Advance® Cleaner or Boston® Cleaner   |
| Disinfect         | Boston Advance® Comfort Formula Conditioning Solution or Boston® Conditioning Solution |
| Store             | Boston Advance® Comfort Formula Conditioning Solution or Boston Conditioning Solution  |
| Multi-Action      | Boston SIMPLUS™ Multi-Action Solution  |
| Lubricate/Rewet   | Boston® Rewetting Drops  |
| Enzymatic Cleaner | Boston® One Step Enzymatic Liquid Enzymatic Cleaner                                    |

The directions found in the package inserts from these products should be followed. Failure to adhere to these Procedures may result in the development of serious ocular complications (**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. . A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. **Do not mix or alternate the disinfection and storage systems unless so indicated on the product label, or if advised by the eye care practitioner.**

Inform the patient of the following lens care suggestions:

- Always wash, rinse and dry your hands before handling lenses
- Never use tweezers or other tools to remove your lenses from the lens container. Pour the lens from the case into your hand.
- Cardinal Apex® Contact Lenses must be both cleaned and disinfected each time you remove them.
- One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface.
- Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups.
- Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfecting solution as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in it's chamber.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect lenses, leave them in the solution for at least the period indicated on the product label.
- Leave the lenses in the closed storage case until ready to put them in eye. 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.

##### LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the case manufacturer (DO NOT USE TAP WATER), and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the eye care practitioner.

##### ENZYMATIC CLEANING

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning does not replace routine cleaning and disinfecting. The patient should carefully follow the instructions in the enzymatic cleaning labeling.

##### CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving/cannot be removed), the patient should be instructed to apply one to three drops of a 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 5 minutes, the patient should immediately consult the eye care practitioner.

##### EMERGENCIES

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 then remove lenses promptly. The patient should **CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

##### HOW SUPPLIED

Each lens is supplied non-sterile in a plastic case. The invoice is marked with the base curve, power in diopters, diameter, center thickness, colour, plus other pertinent parameters and Lot number. Additional parameters of add power, segment width, prism ballast and truncation may be included for bifocal/multifocal lenses.

##### REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported immediately to the manufacturer.

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