
PACKAGE INSERT

The BOSTON® Lens II
(itafocon A)
The BOSTON® Lens IV
(itafocon B)
Contact Lenses

Silicone Acrylate
Rigid Gas Permeable
Contact Lenses
For
Daily Wear

IMPORTANT:
Please read carefully and keep this
information for future use

**THE BOSTON
LENS II**

**THE BOSTON
LENS IV**

DESCRIPTION

The BOSTON Lens II and The BOSTON Lens IV are daily wear lenses approved in clear, blue, or dark blue. The tinted lenses contain the color additive D & C Green No. 6. The BOSTON Lens II is also available as a green tinted lens and contains the color additives D & C Green No. 6 and D & C Yellow No. 10.

These lenses are wettable, non-hydrophilic contact lenses that are not surface-treated and are composed of methyl-methacrylate-dimethylitaconate-sioxanyl copolymer.

The BOSTON Lens II & IV can be manufactured in a range of base curves (5.0 - 9.0 mm) and chord diameters (7.0 - 1.5 mm) to permit custom fitting of the cornea. They can be manufactured in powers of -20.00 to +20.00 diopters. They may have a center thickness of 0.07 mm to 0.65 mm depending on power and chord diameter.

THE BOSTON LENS II

PHYSICAL PROPERTIES

Hardness (Rockwell R)	118-121
Specific Gravity	1.13
Refraction Index	1.471
Light Transmittance (Above 500 NM)	>90%
Water content	<1%
Oxygen Permeability*	14.6 x 10 ⁻¹¹ ml O ₂ cm ² /ml mm Hg (35° C)**
Wetting Angle** (after soaking in BOSTON™ Conditioning Solution)	20°

THE BOSTON LENS IV

PHYSICAL PROPERTIES

Hardness (Rockwell R)	116-119
Specific Gravity	1.10
Refraction Index	1.468
Light Transmittance (Above 500 NM)	>90%
Water content	<1%
Oxygen Permeability*	26.3 x 10 ⁻¹¹ ml O ₂ cm ² /ml mm Hg (35° C)**
Wetting Angle** (after soaking in BOSTON™ Conditioning Solution)	17°

* The method of Irving Fatt, Ph. D.

** The method of Maurice Postor, O.D.

*** Oxygen Permeability is measured at 28.7 x 10⁻¹¹ mlO₂ @ 35° C as reported by Kenyon, Polse and O'Neal "Ocular Response to Extended Wear of Hard Gas Permeable Lenses," The CLAO Journal, April 1985, Volume 11, Number 2.

ACTIONS

When placed on the human cornea, the lens acts as a refracting medium to focus light rays on the retina to improve visual acuity.

INDICATIONS

These lenses are indicated for daily wear. These lenses are intended for correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic, or have keratoconus and may exhibit up to 4.00D of corneal astigmatism that does not interfere with visual acuity.

CONTRAINDICATIONS

Do not use these lenses when any of the following conditions are present:

1. Acute or subacute inflammation of the anterior segment of the eye.
2. Any eye disease in which wearing the lens adversely affects the eye.
3. Insufficiency of lacrimal secretion (dry eyes).
4. Corneal hypoesthesia (reduced corneal sensitivity) — except that which is temporarily produced by previous PMMA or soft lens wear.
5. Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
6. Any active corneal infection, including bacterial, fungal or viral infection.
7. Allergy to any ingredient in a solution which may be used to care for these lenses.

LENS CARE REGIMEN

BOSTON Solutions are the recommended lens care solutions for these contact lenses. These are BOSTON™ Cleaner, BOSTON™ Conditioning Solution and BOSTON™ Reconditioning Drops.

- Always use FRESH cleaning and conditioning solutions.
- Do not use heat (thermal) lens care systems.
- Never expose these lenses to excessive heat.
- Do not use saliva.

Always keep the lenses completely immersed in conditioning solution when the lenses are not being worn.

If your lens feels dry on the eye or becomes uncomfortable, instill one to three drops of a reconditioning solution, such as BOSTON Reconditioning Drops, while the lenses are on the eye, as needed or as directed by your eye care practitioner. The alternative recommendation is to remove the lenses and condition with a few drops of conditioning solution. The lens must move freely on the eye for the continued health of the eye. If dryness or discomfort continues, immediately consult your eye care practitioner.

WARNINGS

SERIOUS DAMAGE TO THE EYE AND LOSS OF VISION MAY RESULT FROM PROBLEMS WITH CONTACT LENSES AND LENS CARE SOLUTIONS. IMMEDIATELY REMOVE THE LENSES AND CONSULT YOUR PRACTITIONER TO IDENTIFY THE CAUSE OF ANY UNEXPLAINED EYE DISCOMFORT, WATERING, VISION CHANGE, OR REDNESS OF THE EYE AND TO BEGIN ANY NECESSARY TREATMENT.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your lenses and lens care products. 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.

WARNING: The BOSTON Lens II and The BOSTON Lens IV are **NOT** intended for extended wear.

PRECAUTIONS

Clinical studies have demonstrated that contact lenses manufactured from both lens materials, The BOSTON Lens II (itafocon A) and The BOSTON Lens IV (itafocon B), 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 the material.

Consequently, when selecting an appropriate lens design and parameter, the eye care practitioner must consider all factors that affect lens performance and ocular health. The potential impact of these factors must be weighed against the patient's needs; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored.

Follow the instructions below to prevent damage to your eyes or to your lenses.

Before you leave your practitioner's office, be able to remove your lenses.

WEARING RESTRICTIONS

- Always wash and rinse hands thoroughly and dry with a lint-free towel before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams or deodorants come in contact with your lenses and if the lenses are contaminated by infectious or non-infectious debris.
- Avoid using aerosol products such as hair spray while wearing your lenses. If hair sprays are used, keep your eyes closed until the spray has settled, otherwise the lenses may be damaged.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Do not swim with your lenses in place.
- Never use tweezers or other tools to remove your lens from the lens container.
- Always inform your doctor (general health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure continued health. CHECK WITH YOUR EYE CARE PRACTITIONER.

These lenses are less resistant to chipping or breakage during patient handling than traditional hard lenses. Patients should always handle the lenses gently and avoid dropping them on hard surfaces.

MEDICATION AND EYE DROPS

The safety of this lens when used with medications has not been established. If these lenses become dry or uncomfortable during wear, one to three drops of a reconditioning solution, such as BOSTON Reconditioning Drops, may be instilled while the lenses are on the eye, as needed or as directed by your eye care practitioner. The lens may also be removed, rinsed and conditioned with a few drops of conditioning solution.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

The following problems may occur:

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

If you notice any of these adverse effects, IMMEDIATELY REMOVE YOUR LENSES.

- 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 your eye. Place the lens in the storage case and contact your 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, thoroughly clean, rinse and condition the lenses, then reinsert them.
- If the problem continues, DO NOT put the lens back on your eye but IMMEDIATELY consult your eye care practitioner.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting rigid contact lenses apply to these lenses. Copies of these fitting instructions are available from your contact lens laboratory, or:

Polymer Technology Corporation
100 Research Drive
Wilmington, MA 01887

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION

WEARING SCHEDULE: THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to overwear lenses initially. It is important to adhere to the initial wearing schedule.

DAILY WEAR — (DURING WAKING HOURS)

The suggested wearing schedule for these lenses is*

DAY	WEARING TIME
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	All Waking Hours

WARNING: The BOSTON Lens II and The BOSTON Lens IV are **NOT** intended for extended wear.

*If the lenses continue to be well tolerated.

CLEANING, STORAGE AND CONDITIONING

These lenses **MUST BE BOTH CLEANED AND CONDITIONED. ONE PROCEDURE DOES NOT REPLACE THE OTHER.** Cleaning is necessary to remove mucus and other deposits from the lens surface. Conditioning is necessary for lens comfort and to prevent the growth of harmful germs.

Laboratory studies have shown that using the complete BOSTON care regimen is an effective disinfecting procedure to prevent the growth of harmful germs. In addition, BOSTON Conditioning Solution enhances the wettability of the lens polymer. BOSTON Reconditioning Drops relieve minor irritation, discomfort and blurring which may occur during lens wear.

If your lens feels dry on the eye or becomes uncomfortable, instill one to three drops of a reconditioning solution, such as BOSTON Reconditioning Drops, while the lenses are on the eye, as needed or as directed by your eye care practitioner. The alternative recommendation is to remove the lenses and condition with a few drops of conditioning solution.

- Always clean and rinse the same lens first to avoid mix-ups.
- Disinfect your lenses by thoroughly cleaning them, rinsing them in tap water to remove the cleaning solution and soaking for four hours (or overnight) in conditioning solution.
- Condition your lenses using fresh conditioning solution.
- After you clean and thoroughly rinse each contact lens, place the lens into its correct storage chamber and fill the chamber with conditioning solution so as to completely cover the lens.
- Tightly close the top of each chamber of the lens storage case.
- **DO NOT HEAT THE CONDITIONING SOLUTION AND LENSES.**
- Leave the lenses in the unopened storage case until you are ready to put them in your eyes.

LENS CARE DIRECTIONS

Always wash and rinse your hands before handling your contact lenses.

Follow these basic instructions for general lens care to clean, rinse and condition your lenses:

- Never use heat (thermal) care systems.
- Carefully read your Patient Care Guide for lens care details.
- Your lenses must be **BOTH** cleaned and conditioned each time you remove them. Cleaning is necessary to remove mucus and film from the lens surface. Conditioning is necessary for lens comfort and to prevent the growth of harmful germs.
- The following solutions are recommended to care for your lenses:
 - BOSTON Cleaner
 - BOSTON Conditioning Solution
 - BOSTON Reconditioning Drops

DO NOT USE THESE SOLUTIONS WITH HEAT. Such use can damage your lens. These contact lenses cannot be heat (thermally) disinfected.
- After removing the lens from soaking in the lens storage case, rinse briefly in fresh conditioning solution if desired, and insert.
- After you remove your lenses from the lens storage case, empty and rinse your lens storage case and allow it to dry. When you next use the case, refill it with fresh conditioning solution.

HOW SUPPLIED

Each lens is supplied in a plastic lens storage case. The case is labeled with the base curve, dioptic power, diameter and center thickness of the lens, lens material, lot number and expiration date.

The BOSTON™ Starter Kit is a package containing the solutions required for lens cleaning, disinfection, wetting and storage. It contains the following:

1. Instructions for The BOSTON™ Care System
2. Lens Storage Case
3. BOSTON Cleaner
4. BOSTON Conditioning Solution
5. BOSTON Reconditioning Drops