
PACKAGE INSERT

**Boston® EQUALENS®
(itafluorofocon A)**

*Extended Wear
Spherical & Aspherical
Rigid Gas Permeable
Contact Lenses for
Myopia & Hyperopia
in Not-Aphakic Persons*

*Daily Wear
Spherical, Aspherical, Toric &
Bifocal/Multifocal
Rigid Gas Permeable
Contact Lenses for
Myopia, Hyperopia, Astigmatism
& Presbyopia in Aphakic and
Not-Aphakic Persons*

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.*

CAUTION:

*Federal (USA) Law restricts this
device to sale by or on the order
of a licensed practitioner.*

DESCRIPTION

The Boston® EQUALENS® Rigid Gas Permeable Contact Lens material, itafluorofocon A, for daily wear or extended wear is composed of methyl-methacrylate-fluoroitaconate-siloxanyl copolymer with an ultraviolet absorber (Uvinul D-49). The lenses are available in clear (untinted), blue, or electric blue. The tinted lenses contain the color additive D & C Green No. 6.

The Boston EQUALENS Contact Lens is a hemispherical shell of the following dimensions:

Spherical Lens Design	
Power Range	-20.00D to +20.00D (daily wear) -20.00D TO +12.00D (extended wear) in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	5.00 mm to 9.00 mm in 0.01 mm increments
Aspherical Lens Designs	
<i>(Some of these designs are patented; manufacture of these lenses in Boston EQUALENS (itafluorofocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +20.00D (daily wear) -20.00D TO +12.00D (extended wear) in 0.25D increments in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.00 mm to 9.20 mm in 0.01 mm increments
Toric Lens Designs (Daily Wear)	
Power Range	-20.00D to +20.00D in 0.25D increments
Diameter	7.0 mm to 11.5 mm
Base Curve Range	6.80 mm to 9.50 mm in 0.05 mm increments
Toricity	Up to 9.00 Diopters
Bifocal/Multifocal Lens Designs (Daily Wear)	
<i>(Some of these designs are patented; manufacture of these lenses in Boston EQUALENS (itafluorofocon A) materials are authorized to licensed labs only)</i>	
Power Range	-20.00D to +12.00D in 0.25D increments
Diameter	8.5 mm to 11.5 mm
Base Curve Range	6.30 mm to 9.50 mm in 0.01 mm increments
Segment Heights	-2.00 mm to +1.00 mm in 0.5 mm increments
Add Powers	+1.00D to +3.75D in 0.5D increments
Prism Ballast	0.5 to 3.5 prism diopters in 0.5D increments

The lenses described above can have a center thickness of 0.07 to 0.65 mm that will vary with lens design, power and diameter.

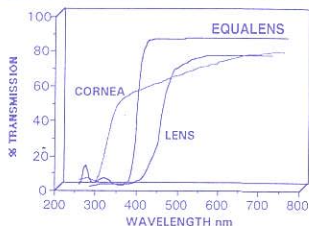
The physical/optical properties of the lens are:

Specific Gravity	1.19
Refractive Index	1.439
Light Absorbance (640 nm)	10.0 Blue
Light Absorbance (640 nm)	23.6 Electric Blue
*Absorbance (units/inch):	
Surface Character	Hydrophobic
Wetting Angle	30°
Water Content	<1%
Oxygen Permeability	64* (47**)

* Polymer Technology, Gas to Gas Method

1 x 10⁻¹¹ (cm³/sec) (mL C. x mmHg) / @ 35° C)

**Polarographic Method (ISO/Fatt)



EQUALENS - 0.07 mm thick Boston EQUALENS (Clear) Contact Lens/Material.

CORNEA - Human cornea from a 24-year-old person as described in Lerman, S., *Radiant Energy and the Eye*, Macmillan, New York, 1980, p. 58.

CRYSTALLINE LENS - Human crystalline lens from a 25-year-old person as described in Waxler, M., Hitchins, V.M., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

NOTE

Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

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

The Boston EQUALENS Contact Lens when placed on the human cornea, acts as a refracting medium to focus light rays on the retina to improve visual acuity. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

Boston EQUALENS (itafluorofocon A) RGP Contact Lenses are indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lens is indicated for extended wear for the correction of refractive ametropia (myopia and hyperopia) in non-aphakic persons with non-diseased eyes in powers from -20.00D to +12.00D.

The lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non-aphakic persons with non-diseased eyes.

The lens may be disinfected using a chemical disinfection system only.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Boston EQUALENS Contact Lens when any of the following conditions exist:

- Acute or subacute 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 lacrimal secretion (dry eyes)
- Corneal hyposthesia (reduced corneal sensitivity), if nonaphakic
- 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 using contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Boston EQUALENS Contact Lens material.
- 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 daily wear 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.
- 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.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.
- Clinical studies indicate that the majority of patients who wish to wear Boston EQUALENS Contact Lenses for extended wear do so with favorable results. However, suitability as an extended wear patient should be discussed with the eye care practitioner.
- All contact lens wearers must see their eye care practitioner as directed. If the lenses are for extended wear, the eye care practitioner may prescribe more frequent visits.

PRECAUTIONS

Practitioner Note: Boston EQUALENS Contact Lenses are not sterile when shipped from the Authorized Boston Manufacturer. Prior to dispensing, clean and disinfect (the lenses) according to the appropriate lens care regimen.

- Patients may experience a reduction in visibility while wearing this lens in conditions of low illumination for the following colors and center thicknesses:

Color	Center Thickness
Blue	> 0.65 mm
Electric Blue	> 0.35 mm

Special Precautions for Eye Care Practitioners:

- 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 are 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 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 Boston EQUALENS 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 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.
- The presence of the ultraviolet (UV) light absorber in the Boston EQUALENS Contact Lens material 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 often cannot be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Do not heat the wetting/soaking solution and/or lenses. Keep them away from extreme heat.
 - Always use **fresh unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can warp the Boston EQUALENS Contact Lenses.
 - 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 the lenses are not being worn (stored). If dry storage is desired to store the lenses for a longer period of time, they must first be cleaned, rinsed with water and carefully dried by blotting with a soft lint-free tissue prior to being placed in a clean, dry lens storage case. Ideally, these lenses should be cleaned and disinfected prior to insertion.
- 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 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-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 Instructions for the Boston EQUALENS 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 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) that you wear contact lenses.
- Never use tweezers or other tools to remove lenses from the lens case unless specifically indicated for that use. Pour the lens into the 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

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 the eye
- Feeling of something in the eye such as a foreign body, scratched area
- Excessive watering (tearing) of the eyes

- Always remove, clean, rinse, and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of a cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Polymer Technology for use with the Boston EQUALENS Contact Lens. 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 (Chemical (Not Heat))
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 (Clean, Condition, Disinfect, Rinse, and Cushion)	Boston SIMPLICITY [®] Multi-Action Solution
Lubricate/Rewet	Boston [®] Rewetting Drops
Weekly Enzymatic Cleaner	Boston [®] ONE STEP Liquid Enzymatic Cleaner

- **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.
 - Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly as directed by your eye care practitioner to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the 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. Follow the instructions provided in the disinfecting solution packaging.
 - To store lenses, 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.
 - After removing the lenses from the lens case, empty and rinse the lens storage case with solutions as recommended by the lens case manufacturer or the eye care practitioner; 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.

- 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.
- Eye care practitioners may recommend a weekly enzymatic cleaner which can be used to effectively remove protein deposits from Boston EQUALENS Contact Lenses.
- Boston EQUALENS Contact Lenses **cannot** be heat (thermally) disinfected.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer or the eye care practitioner, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.

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

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, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied (monsterile) in a plastic lens storage case. The case is labeled with the base curve, diopter power, diameter, center thickness, color, UV-absorber and lot number.

REPORTING OF ADVERSE REACTIONS

All serious adverse reactions observed in patients wearing Boston EQUALENS Contact Lenses or adverse experiences with the lenses should be reported to:

Consumer Affairs
Polymer Technology (USA) Corporation
1400 North Goodman Street
Rochester, NY 14609
1-800-333-4730

- 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 the above, he or she should be instructed to:

- **Immediately remove 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 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 lenses; then reinsert them. After reinsertion, 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, 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 Boston EQUALENS (litafluorofocon A) Contact Lenses. For a detailed description of the fitting techniques, refer to the Boston EQUALENS Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative
Polymer Technology (USA) Corporation
1400 North Goodman Street
Rochester, NY 14609
1-800-225-1241

Professional Fitting Guides are also available through your Authorized Boston Manufacturer.

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.

The Boston EQUALENS Contact Lenses are indicated for daily wear or extended wear. The maximum suggested wearing time for these lenses is:

DAILY WEAR (DURING WAKING HOURS)

The suggested daily wear schedule for Boston EQUALENS Contact 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 and after	All Waking Hours

*if the lenses continue to be well-tolerated.

Lenses should be removed daily for cleaning and disinfecting for 4 hours (or overnight) before wearing.

EXTENDED WEAR (OVERNIGHT)

The suggested wearing schedule for Boston EQUALENS Contact Lenses for extended wear is to initially adapt to daily wear during the first week of wear as described above. During the second week, the patient should comfortably wear the lenses during all waking hours. Then:

DAY	WEARING TIME (Hours)*
15-21	24 hours a day

*if the lenses continue to be well-tolerated.

The maximum suggested wearing time for Boston EQUALENS Contact Lenses extended wear is 1 week (7 days). Lenses should be removed for cleaning and disinfecting for 8-10 hours (overnight) at the end of 1 week of extended wear, or more frequently depending on the overall patient tolerance.

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:

General Lens Care (First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

- Always use **fresh unexpired** lens care solutions.
- Use the recommended system of lens care, chemical (not heat) and carefully follow instructions on solution labeling. Different solutions often cannot be used together, and not all solution are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling or if advised by the eye care practitioner.**
- 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.