# PACKAGE

Boston® EQUALENS® II (oprifocon A)

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

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

Please read carefully and keep this information for future use. This package insert is intended for the eve care practitioner but should be made available to patients upon request. The eve 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® II Rigid Gas Permeable Contact Lens material, oprifocon A, for daily wear or extended wear is composed of methyl-methacrylatefluoroitaconate-siloxanyl copolymer with an ultraviolet absorber (Uvinul D-49). The lenses are available in clear (untinted) blue or green. The tinted lenses contain the following color additives

Color Additive D&C Green No. 6 D&C Green No. 6 D&C Yellow No. 18

The Boston EQUALENS Contact Lens is a hemi spherical shell of the following dimensions: Spherical Lens Design

Diameter Base Curve Range	-20.000 to +20.000 (daily wear) -20.00D TO +12.00D (extended wear) in 0.25D increments 7.0 mm to 11.5 mm 5.00 mm to 9.00 mm in 0.01 mm increments	{ x **Pc
Aspherica	99	
manufacture of these le (oprifocon A) mate	designs are patented; enses in Boston EQUALENS II rials are authorized to d labs only)	% TRANSMISSION
Power Range	-20.00D to +20.00D (daily wear) -20.00D TO +12.00D (extended wear)	Ж.

	in 0.01 mm increments	
Toric Lens Designs (Daily Wear)		
Power Range	-20.00D to +20.00D in 0.25D increments	
Diameter Base Curve Range	7.0 mm to 11.5 mm 6.80 mm to 9.50 mm in 0.05 mm increments	
Toricity	Up to 9.00 Diopters	
Bifocal/Multifocal Lens Designs (Daily Wear)		
(0 C tt d t t t d		

Base Curve Range 6.00 mm to 9.20 mm

(Some of these designs are patented: nanufacture of these lenses in Boston EQUALENS II (oprifocon A) materials are authorized to

	rais are datironized to	
licensed labs only)		Long term exposure to UV radiation is one of the
wer Range meter se Curve Range	-20.00D to +12.00D in 0.25D increments 8.5 mm to 11.5 mm 6.30 mm to 9.50 mm in 0.01 mm increments	risk factors associated with cataracts. Exposure is based on a number of factors such as environmer tal conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdox
gment Position	-2.00 mm to +1.00 mm in 0.1 mm increments	actitivies). UV-absorbing contact lenses help pro-
d Powers	+1.00D to +3.75D in 0.25D increments	vide protection against harmful UV radiation. However, clinical studies have not been done to
sm Ballast	0.5 to 3.5 prism diopters in 0.5D increments	demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or
Scleral Lens Designs (Daily Wear)		other eye disorders. Consult your eye care prati-

(Each clear tinted lens is designed to rest on the external sclera and vault the cornea and imbus thereby enclosing a compartment filled vith sterile, buffered non-preseved saline solu tion, which provides an aqueous environment for and virtually neutralizes the optics of the

-25.00D to +35.00D			
in 0.25D increments			
16 mm to 26 mm			
± 0.25 mm			
2.50 mm to 6.00 mm			
± 0.1 mm			

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.

# FOUALENS II GP Material are-

1.423

Surface Character Hydrophobic Wetting Angle Water Content <1%

Oxygen Permeability 127\* (85\*\*) \* Polymer Technology, Gas to Gas Method x 10<sup>-11</sup> (cm<sup>2</sup>/sec) (mL O<sub>2</sub> x mmHg) ) @ 35° C)

- in 0.25D increment 7.0 mm to 11.5 mm

in 0.01 mm increments	BOSTON EQUALENS II - 0.07 mm thick Boston
esigns (Daily Wear)	EQUALENS II (Clear) Contact Lens/Material.
-20.00D to +20.00D in 0.25D increments 7.0 mm to 11.5 mm 6.80 mm to 9.50 mm in 0.05 mm increments	CORNEA - Human cornea from a 24-year-old pi as described in Lerman, S., <u>Radiant Energy and</u> <u>Eye</u> , MacMillan, New York, 1980, p. 58. <u>CRYSTALLINE LENS</u> - Human crystalline lens fr
	a 25-year-old person as described in Wayler M

CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5.

other eye disorders. Consult your eye care pratitioner for more information. UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UVabsorbing goggles or sunglasses. Persons should

The physical/optical properties of Boston

Specific Gravity Refractive Index Light Absorption (640 nm) 10.0 Blue Light Absorption (640 nm) 4.8 Green (Absorbance Units/Inch)

Polarographic Method (ISO/Fatt)

**EQUALENS II** 

continue to use their protective UV-absorbing

The Boston EQUALENS II Contact Lens when placed

on the human cornea, acts as a refracting medium

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.

to focus light rays on the retina to improve visual

eyewear as directed.

ACTIONS

200 300 400 500 600 700 800 The lens may be disinfected using a chemical disin-WAVELENGTH nm fection system only.

DO NOT USE the Boston EQUALENS II Contact Lens CORNEA - Human cornea from a 24-year-old person when any of the following conditions exist:

INDICATIONS (USES)

fection as recommended by the eye care practi-

tioner. The lens is indicated for extended wear for

the correction of refractive ametropia (myopia and

hyperopia) in not-aphakic persons with non-dis-

eased eyes in powers from -20.00D to +12.00D.

The lens is indicated for daily wear for the correc-

tion of refractive ametropia (myopia, hyperopia,

astigmatism and presbyopia) in aphakic and not-

The Boston Scieral (oprifocon A) RGP Contact Lens

cantly reduced vision due to the presence of a dis-

1. precludes satisfactory spectacle lens correction

demonstrates significantly improved rigid con-

3. is incapable of wearing traditional corneal lenses

because of the inability to achieve adequate

lens centration/stability and/or tolerance to

Furthermore, eves suffering from certain ocular

surface disorders may benefit from the physical

CONTRAINDICATIONS (REASONS NOT TO USE)

Acute or subacute inflammation or infection of

Corneal hypoesthesia (reduced corneal sensitivity),

protection and the saline bath provided by a scleral

for Daily Wear is indicated for eyes having signifi-

aphakic persons with non-diseased eyes.

torted corneal surface that:

tact lens corrected vision

physical contact with a lens.

as described in Lerman, S., Radiant Energy and the ve. 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,

## the cornea, conjunctiva, or evelids Severe insufficiency of lacrimal secretion (dry eyes)

the anterior chamber of the eye

Long term exposure to UV radiation is one of the if nonaphakic risk factors associated with cataracts. Exposure is based on a number of factors such as environmen- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses tal conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor Allergic reactions of ocular surfaces or adnexa actitivies). UV-absorbing contact lenses help pro-

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 II Contact Lenses.

Any active corneal infection (bacterial, fungal,

or viral) Red or irritated eyes

# WARNINGS

in significant numbers. Consequently, when selecting an appropriate lens design and parame Patients should be advised of the following warnings pertaining to contact lens wear: ters, the eye care practitioner should consider all characteristics of the lens that can affect lens

 Problems with contact lenses and lens care prodperformance and ocular health, including oxygen ucts could result in serious injury to the eye. It is essential that patients follow their eye care practhickness, and optic zone diameter. titioner'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 weighed against the patient's need for refractive loss of vision.

 Daily wear lenses are not indicated for overnight wear, and daily wear patients should be instructed Boston EQUALENS II (oprifocon A) RGP Contact Lens not to wear lenses while sleeping. Clinical studies is indicated for daily wear or extended wear from 1 have shown that the risk of serious adverse reacto 7 days between removals for cleaning and disintions is increased when these lenses are worn

- presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual • If a patient experiences eye discomfort, excessive requirements vary with the individual and should tearing, vision changes, or redness of the eye, the be considered when selecting the most appropripatient should be instructed to immediately ate type of lens for each patient. remove lenses and promptly contact his or her Aphakic patients should not be fitted with Boston eve 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
- Clinical studies indicate that the majority of patients who wish to wear Boston EQUALENS II Contact Lenses for extended wear do so with favorable results. However, suitability as an extended wear patient should be discussed with
- · 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.

### Any eye disease, injury, or abnormality that affects PRECAUTIONS

Blue

Green

for contact lens users.

the eve care practitioner.

overnight.

Practitioner Note: Boston FOLIALENS II Contact Lenses are not sterile when shipped from the Authorized Boston Manufacturer. 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 this lens in conditions of low illumination for

Center Thickness

> 0.55 mm

> 0.65 mm

the following colors and center thicknesses:

Special Precautions for Eye Care Practitioners:

• Due to the small number of patients enrolled in

clinical investigation of lenses, all refractive pow-

ers, design configurations, or lens parameters

available in the lens material are not evaluated

permeability, wettability, central and peripheral

correction; therefore, the continuing ocular

- Do not use saliva or anything other than the recommended solutions for lubricating or wet ting 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

health of the patient and lens performance on

EQUALENS II Contact Lenses until the determina-

tion is made that the eve has healed completely.

Before leaving the eye care practitioner's office

can remove the lenses for him or her.

becomes red or irritated.

safety precautions:

solutions.

to insertion.

the patient should be able to promptly remove

Eye care practitioners should instruct the patient

• The presence of the ultraviolet (UV) light absorber

fluorescein patterns adequately. (Refer to the

Fitting Guide for detailed instructions.)

Different solutions often cannot be used

Eye care practitioners should carefully instruct

patients about the following care regimen and

together, and not all solutions are safe for use

- Do not heat the wetting/soaking solution

- Always use fresh unexpired lens care

for the use of contact lens solutions.

the Boston EQUALENS II Contact Lenses.

with all lenses. Use only recommended solutions

and/or lenses. Keep them away from extreme

- Always follow directions in the package inserts

- Use only a chemical (not heat) lens care system.

Use of a heat (thermal) care system can warp

in the Boston EQUALENS II Contact Lens material

may require equipment enhancement to visualize

to remove the lenses immediately if the eve

lenses or should have someone else available who

the eye should be carefully monitored by the

· Patients who wear contact lenses to correct

prescribing eve care practitioner.

 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 eve for the continued health of the eve. If nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eve 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.

Never wear lenses beyond the period recom-

- . Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materi als, as microscopic scratches on the lenses may occur, causing distorted vision and/or injury to
- Carefully follow the handling, insertion, removal. cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Boston EQUALENS II Contact Lens and those prescribed by the eye care practitioner.
- mended by the eye care practitioner. If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep
- eves 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 con-
- tact 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

- . Comfort is less than when lens was first placed on
- Feeling of something in the eye such as a foreign body, scratched area
- Excessive watering (tearing) of the eyes · Unusual eve 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 eve care practitioner. If the lens has dirt, an evelash, 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 II (oprifocon A) Contact Lenses. For a detailed description of the fitting techniques, refer to the Boston EQUALENS II Professional Fitting and Information Guide, copies of which are available from:

Practitioner Marketing Representative Polymer Technology, a Bausch & Lomb company 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.

 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.

# DAILY WEAR (DURING WAKING HOURS)

The suggested daily wear schedule for Boston EQUALENS II Contact Lens is: DAY WEARING TIME (Hours)\*

The Boston EQUALENS II Contact Lenses are indi-

cated for daily wear or extended wear. The maxi-

mum suggested wearing time for these lenses is:

## 4 to 8 hours 6 to 10 hours 8 to 14 hours 10 to 15 hours 12 to All Waking Hours

\*if the lenses continue to be well-tolerated

EXTENDED WEAR (OVERNIGHT) The suggested wearing schedule for Boston

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

The maximum suggested wearing time for Boston EQUALENS II Contact Lenses extended wear is 1. week (7 days). Lenses should be removed for cleaning and disinfecting for 8-10 hours (overnight) at

## LENS CARE DIRECTIONS

Eve care practitioners should review with the patient

## General Lens Care (First Clean and Rinse, Then Disinfect Lenses) **Basic Instructions:**

contact lenses

Use the recommended system of lens care,

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- fected 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.

LENS CARE TABLE

Lens Care System

Chemical (Not Heat)

Boston ADVANCE® Cleaner or

Boston ADVANCE® Comfort

or Boston® Conditioning

Solution

Disinfect, Rinse Boston SIMPLICITY® Mult

Lubricate/Rewet Boston® Rewetting Drops

• Note: Some solutions may have more than one

Read the label on the solution bottle, and follow

. Clean one lens first (always the same lens first

to avoid mix-ups), rinse the lens thoroughly

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 sys-

and/or the eve care practitioner. Follow the

instructions provided in the disinfecting solu-

tem recommended by the manufacturer

ing disinfection, the patient should be

instructed to consult the package insert or the

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.

eye care practitioner for information on storage Rochester, NY 14609

as directed by your eye care practitioner to

function, which will be indicated on the label.

Boston® ONE STEP

Liquid Enzymatic Cleaner

and Cushion) Action Solution

Formula Conditioning Solution

The lens care products listed below are recommended by Polymer Technology for use with the Boston EQUALENS II Contact Lens. Eye care practitioners may recommend alternate products that

are appropriate for the patient's use with his or her lens(es).

6 and after All Waking Hours

Lenses should be removed daily for cleaning and Boston® Cleaner disinfecting for 4 hours (or overnight) before Boston ADVANCE® Comfort Formula Conditioning Solution or Boston® Conditioning

Purpose

Enzymatic

instructions.

tion packaging.

of lenses.

EQUALENS II Contact Lens for extended wear is to during all waking hours. Then; Multi-Action Boston SIMPLUS™ Multi-Actio (Clean, Condition, Solution or

# DAY WEARING TIME (Hours)\*

15-21 24 hours a day \*if the lenses continue to be well-tolerated.

the end of 1 week of extended wear, or more frequently depending on the overall patient tolerance.

lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

Always wash, rinse, and dry hands before handling

- Always use fresh unexpired lens care solutions.
- 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.
- Lenses should be cleaned, rinsed, and disin-

Replace lens case at regular intervals as recom mended by the lens case manufacturer or your

 Eye care practitioners may recommend a lubr cating/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 II Contact Lenses.
- Boston EQUALENS II 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

## 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 solu tions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMED ATELY WITH TAP WATER, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTAC THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL

## HOW SUPPLIED

Each lens is supplied (nonsterile) 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 patient

EMERGENCY ROOM WITHOUT DELAY.

wearing Boston EQUALENS II Contact Lenses or • To store lenses, disinfect and leave them in the adverse experiences with the lenses should be closed/unopened case until ready to wear. If reported to: lenses are not to be used immediately follow-Consumer Affairs Polymer Technology, a Bausch & Lomb company

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1-800-333-4730

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1400 North Goodman Street Rochester, NY 14609

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 The potential impact of these factors on the patient's ocular health should be carefully

# PATIENT

Boston® EQUALENS® II

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

Spherical, Aspherical, Toric Bifocal/Multifocal & Scleral Rigid Gas Permeable Nyopia, Hyperopia, Astigmatism & Presbyopia in Aphakic and Not-Aphakic Persons

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

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Introduction

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Removing the Lens Caring for Your Lenses

(Cleaning, Rinsing, Disinfecting, Storage and Rewetting/Lubricating)

Basic Instructions Care for a Sticking (Nonmoving) Lens

Emergencies Instructions for Monovision Wearer Prescribed Wearing Schedule

## CONTRAINDICATIONS (REASONS NOT TO USE)

when any of the following conditions exist: · Acute or subacute inflammation or infection of

- the anterior chamber of the eye

- Any systemic disease that may affect the eye or
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing
- Allergy to any ingredient in a solution which is to be used to care for the Boston EQUALENS II

are manufactured from a rigid gas permeable plas- Problems with contact lenses and lens care prodtic material. They are intended for daily wear or extended wear use. It is essential that you follow the recommended handling, cleaning and storage procedures. Failure to do so may eventually impair the performance of your lenses. You should always carry a spare pair of lenses with you.

## WEARING RESTRICTIONS AND INDICATIONS

Boston® EQUALENS® II (oprifocon A) Contact Lenses

Boston EQUALENS II (oprifocon A) RGP Contact Lens s indicated for daily wear or extended wear from 1 7 days between removals for cleaning and disinection as recommended by the eye care practitioner. The lens is indicated for extended wear for the correction of refractive ametropia (myopia and hyperopia) in not-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 not-aphakic persons with non-diseased eyes.

The Boston Scleral (oprifocon A) RGP Contact Lens for Daily Wear is indicated for eyes having significantly reduced vision due to the presence of a distorted corneal surface that:

- demonstrates significantly improved rigid con tact lens corrected vision 3. is incapable of wearing traditional corneal lenses
- because of the inability to achieve adequate lens centration/stability and/or tolerance to physical contact with a lens. Furthermore, eyes suffering from certain ocular sur-

face disorders may benefit from the physical protection and the saline bath provided by a scleral The lens may be disinfected using a chemical disin-

fection system only. Lens Case Cleaning and Maintenance The Boston EQUALENS II Contact Lenses described in this booklet should be removed from your eves

for routine cleaning and disinfecting as prescribed by your eye care practitioner. IF YOU ARE ON A DAILY WEAR SCHEDULE, DO NOT WEAR YOUR Bostor EQUALENS II CONTACT LENSES WHILE SLEEPING.

- Severe insufficiency of lacrimal secretion
- Corneal hypoesthesia (reduced corneal sensitivity), if nonaphakic
- be exaggerated by wearing contact lenses
- contact lenses or using contact lens solutions
- Contact Lens material
- Any active corneal infection (bacterial, fungal. or viral)
- Red or irritated eyes

ucts could result in serious injury to the eye. It is essential to follow your eye care practitioner's directions and all labeling instructions for prope use of lenses and lens care products, including the lens case. Eve problems, including corneal ulcers, can develop rapidly and lead to loss of

 If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, imme diately remove lenses and promptly contact

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.

for contact lens users.

PRECAUTIONS

solutions.

ting lenses.

- 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, the lenses. It is best to put on lenses before smoking increases the risk of ulcerative keratitis putting on makeup. Water-based cosmetics are
- natients who wish to wear Boston FOLIALENS I Contact Lenses for extended wear do so with favorable results. However, your suitability as an extended wear patient should be discussed with your contact lens practitioner.
- cleaning, disinfecting, storing and wearing inpractitioner as directed. If your lenses are for extended wear, your eye care practitioner may Contact Lens and those prescribed by the eye care prescribe more frequent visits. practitioner. Studies have shown that contact lens wearers . Never wear lenses beyond the period recom-

pensing, clean and disinfect the lens(es) accord-

ing to the appropriate lens care regimen.

for the use of contact lens solutions.

the labeling directions.

- Use only a chemical (not heat) lens care system.

Use of a heat (thermal) care system can warp

should be discarded after the time specified in

recommended solutions for lubricating or wet-

- Always keep the lenses completely immersed in

the recommended storage solution when the

lenses are not being worn (stored). If dry stor-

age is desired to store the lenses for a longer

period of time, they must first be cleaned,

rinsed with water and carefully dried by blot-

ting with a soft lint-free tissue prior to being

the Boston EQUALENS II Contact Lenses.

- Sterile unpreserved solutions, when used,

- Do not use saliva or anything other than the

DO NOT USE the Boston EQUALENS II Contact Lens Practitioner Note: Boston EQUALENS II Contact Lenses are not sterile when shipped from the

- Any eve disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- (dry eyes)

- Daily wear lenses are not indicated for overnight

placed in a clean, dry lens storage case. Ideally, these lenses should be rehydrated overnight. If the lens sticks (stops moving) on the eye, follow

- The risk of ulcerative keratitis has been shown to the recommended directions on Care for a Sticking Lens. The lens should move freely on the eve for the continued health of the eve. If nonmovement of the lens continues, immediately consult your 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
- Clinical studies indicate that the majority of . 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 · Carefully follow the handling, insertion, removal
- All contact lens wearers must see their eye care
- who are smokers have a higher incidence of adverse reactions than nonsmokers.

eves closed until the spray has settled. · Always handle lenses gently and avoid dropping them on hard surfaces. Authorized Boston Manufacturer, Prior to dis-Avoid all harmful or irritating vapors and fumes

while wearing lenses.

lenses during water activities and other sports. You should carefully adhere to the following care . Inform your doctor (health care practitioner) that regimen and safety precautions:

- you wear contact lenses. Before leaving the eye care practitioner's office, you should be able to promptly remove lenses or Never use tweezers or other tools to remove should have someone else available who can lenses from the lens case unless specifically indiremove the lenses for you. cated for that use. Pour the lens into the hand.
- You should remove your lens immediately if your Do not touch the lens with fingernails. eye becomes red or irritated.
- Always contact your eye care practitioner before Different solutions often cannot be used using any medicine in the eyes. together, and not all solutions are safe for use Always inform your employer that you wear con-
- with all lenses. Use only recommended solutions. tact lenses. Some jobs may require use of eye Do not heat the wetting/soaking solution and protection equipment or may require that you lenses. Keep them away from extreme heat. not wear contact lenses.
- Always use **fresh unexpired** lens care · As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Follow your eye care practitioner's instruc-- Always follow directions in the package insert tion as to a recommended follow-up schedule.

# ADVERSE FEFECTS

The following problems may occur:

 Eves stinging, burning, itching (irritation), or other . Comfort is less than when lens was first placed on

less likely to damage lenses than oil-based products

structions that follow for the Boston EQUALENS II

If aerosol products such as hair spray are used

while wearing lenses, exercise caution and keep

Ask your eve care practitioner about wearing

mended by your eye care practitioner.

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

Sensitivity to light (photophobia)

Reduced sharpness of vision (poor visual acuity)

Blurred vision, rainbows, or halos around objects

- · Place the lens on the top of the index finger of your dominant hand. Place the middle finger.
- hold down the lower lid.

if desired.

- Use the forefinger or middle finger of your other hand to lift the upper lid and then place the lens on the eye. It is not necessary to press the lens against the eye.
- If the discomfort or problem stops, then look Gently release the lids and blink. The lens will closely at the lens. If the lens is in any way damcenter automatically. Always verify its proper aged, do not put the lens back on the eye. Place position by checking your vision immediately the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an evelash Use the same technique or reverse the hand or other foreign body on it, or the problem stops when inserting the other lens. and the lens appears undamaged, you should
  - There are other methods of lens placement. If the above method is difficult for you, your eye care practitioner will provide you with an alternate method

If the lens is centered, remove the lens (see

"Removing the Lens" section) and check for

disinfect, and place on the eve again.

niques are not performed properly. To center a

Close your evelids and gently massage the lens

lens follow one of the procedures below.

that you have the following items available:

2) Two Bottle Care System

Roston ADVANCE® Cleaner or

One Bottle Care System

Always remove the same lens first.

removal:

b. There are two suggested methods of lens

Boston SIMPLUS<sup>™</sup> Multi-Action Solution

Removes Protein, Cleans, Disinfects.

into place through the closed lids.

When any of the above problems occur, a serious Note: If after placement of the lens, your vision condition such as infection, corneal ulcer, neovasis blurred, check for the following: cularization, or iritis may be present. You should The lens is not centered on the eve (see keep the lens off the eve and seek immediate "Centering the Lens," next in this booklet).

### PERSONAL CLEANLINESS FOR LENS HANDLING the following: 1. Preparing the Lens for Wearing a. Cosmetics or oils on the lens. Clean, rinse,

- It is essential that you learn and use good b. The lens is on the wrong eve. hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most If you find that your vision is still blurred after important aspect of proper contact lens care. In checking the above possibilities, remove both particular, your hands should be clean and free lenses and consult your eye care practitioner. of any foreign substances when you handle your lenses. The procedures are:
- Very rarely, a lens that is on the cornea will be Always wash your hands thoroughly with a mild displaced onto the white part of the eye during soap, rinse completely, and dry with a lint-free lens wear. This can also occur during placement towel before touching your lenses. and removal of the lenses if the correct tech-
- lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing. Handle the lenses with your fingertips, and be

Avoid the use of soaps containing cold cream.

 Gently push the off-centered lens onto the careful to avoid contact with fingernails. It is helpful to keep your fingernails short and cornea while the eve is open using finger pres sure on the upper or lower lid next to the edge of the lens.

Start off correctly by getting into the habit of 5. Removing the Lens always using proper hygienic procedures so that they become automatic. Before removing your lenses, it is recommended

## 2. Handling the Lenses

Dry eyes

If you notice any of the above:

• Immediately remove lenses.

thoroughly clean, rinse, and disinfect the lenses;

then reinsert them. After reinsertion, if the prob-

lem continues, immediately remove the lenses

and consult your eye care practitioner.

professional identification of the problem and

prompt treatment to avoid serious eye damage.

- A lens storage case. Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and Boston® Cleaner, AND examine it to be sure that it is moist, clean, Boston ADVANCE® Comfort Formula clear, and free of any nicks or cracks. Conditioning Solution or Boston® 3. Placing the Lens on the Eye Conditioning Solution.

## After thoroughly washing and rinsing your

- hands, and after proper cleaning and conditioning of the lens, follow these steps to insert the
- Remove the lens from its storage compart-Conditions & Cushions) or Boston SIMPLICITY® Multi-Action Solution (Clean, Condition, Disinfect, Rinse & Cushion) Rinse the lens with fresh conditioning solution. A clean towel.
- Inspect the lens to be sure that it is clean, uniformly wet and free of debris.
- Rub several drops of conditioning solution over the lens surfaces.
- of the same hand close to the lower lash and 1) Place a towel under your eye to catch the

- 2) Place the tip of the forefinger of one hand on the middle of the upper lid margin and the forefinger of the other hand on the middle of the lower lid margin.
- together. The lens should be wedged out of your eye onto your hand or towel. 4) The lens may come out but remain on your
- white part of your eye. If the latter occurs, recenter the lens onto your cornea before repeating the removal procedure

towel and lean over until you are looking down at the surface.

- Do not use saliva or anything other than the of your upper and lower lids, stretch the skin outward and slightly upward. (Do not allow your lid to slide over the lens.)
- pressure of your eyelids and the lens will non out onto the clean surface of the towel, or you may catch the lens in the palm of your hand.
- procedure.
- described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECT ING, STORAGE AND REWETTING/LUBRICATING). Note: If these methods of removing your lenses
- CARING FOR YOUR LENSES (CLEANING, RINSING,

# DISINFECTING, STORAGE AND REWETTING/LUBRICATING)

your lenses, it is important that you first clean and rinse, then disinfect your lenses after each removal, using the care regimen recommended by your eye care practitioner. Cleaning and rinsing are necessary to remove mucus, secretions. films, or deposits which may have accumulated during wear. The ideal time to clean your lenses. is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

Wash, rinse, and dry your hands thoroughly.

EQUALENS II Contact Lens.

always practice your lens care routine: dling contact lenses

- 3) Press the lid margin inward and then Use the recommended system of lens care (chemical not heat) and carefully follow instruc-
- evelid or hand or be decentered onto the

## BLINK METHOD Seat yourself at a table covered with a clean

Place your index finger at the outer junction

- recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth. The lens care products listed below are recom 2) Blink briskly. The lens will be pinched by the mended by Polymer Technology for use with
- your Boston EQUALENS II Contact Lens. Your eve care practitioner may recommend alteruse with your Boston EQUALENS II Contact Lens.
- c. Remove the other lens by following the same
- d. Follow the required lens care procedures

are difficult for you, your eye care practitioner will provide you with an alternate method.

# 1. Basic Instructions For continued safe and comfortable wearing of

You should adhere to the recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses and do not have someone avail able to place and remove them for you, you should not attempt to wear contact lenses. When you first get your lenses, be sure you can

place the lenses on your eyes and remove them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your evecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the Boston

Always wash rinse and dry hands before han

For safe contact lens wear, you should know and

tions on solution labeling. Different solutions

often cannot 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.

Always remove, clean, rinse and disinfect your

lenses according to the schedule prescribed

by your eye care practitioner. The use of an

stitute for disinfection.

enzyme or any cleaning solution does not sub-

nate products that are appropriate for you to

LENS CARE TABLE

Lens Care System

Boston® Cleaner

Chemical (Not Heat)

Boston ADVANCE® Cleaner or

Boston ADVANCE® Comfort

or Boston® Conditioning

Boston ADVANCE® Comfort

or Boston® Conditioning

Solution

Multi-Action Boston SIMPLUS™ Multi

Disinfect, Rinse Boston SIMPLICITY® Multi-

Lubricate/Rewet Boston® Rewetting Drops

Boston® ONE STEP

to remove the cleaning solution, mucus, and

tions provided in the cleaning solution labeling.

Put that lens into the correct chamber of the

lens storage case. Then repeat the procedure

After cleaning, disinfect lenses using the above

recommended system by your eye care practi

tioner and/or the lens manufacturer. Follow

the instructions provided in the disinfection

film from the lens surface. Follow the instruc-

Liquid Enzymatic Cleaner

lean, Condition, Action Solution or

and Cushion) Action Solution

low instructions.

for the second lens

solution labeling.

Formula Conditioning Solution

Formula Conditioning Solution

- Always use fresh unexpired lens care solutions.
  - Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan
    - mendation on how to store your lenses. Boston EQUALENS II Contact Lenses cannot be heat (thermally) disinfected. After removing your lenses from the lens case,

• To store lenses, disinfect and leave them in the tion takes place. The longer these symptoms per-

solution(s) recommended by the lens case manufacturer or the eye care practitioner then allow the lens case to air dry. When the If you require very sharp near vision during procase is used again, refill it with fresh storage. solution. Lens cases should be replaced at reqular intervals as recommended by the lens case manufacturer or the eye care practitioner.

closed/unopened case until ready to wear. If

lenses are not to be used immediately follow-

to begin wearing them again after a few weeks,

ask your eve care practitioner for a recom-

empty and rinse the lens storage case with

Your eve care practitioner may recommend a

weekly enzymatic cleaner which can be used

to effectively remove protein deposits from

continues after 5 minutes, you should immedi-

Package Insert or your eye care practitioner

for information on storage of your lenses.

ing disinfection, you should consult the

lubricating/rewetting solution for your use. spectacles to wear over the monovision correction Lubricating/Rewetting solutions can be used to to provide the clearest vision for critical tasks. You wet (lubricate) your lenses while you are wearing them to make them more comfortable. · Your eye care practitioner may recommend a

### your Boston EQUALENS II Rigid Gas Permeable Contact Lenses. 2. Care for a Sticking (Nonmoving) Lens

If the lens sticks (stops moving/cannot be removed), you should be instructed to apply one patient after carefully considering and to three drops of a recommended lubricating or discussing your needs. rewetting solution directly to your eye and wait WEARING AND APPOINTMENT SCHEDULES until the lens begins to move freely on the eye before removing it. If nonmovement of the lens DAILY WEAR (DURING WAKING HOURS)

## ately consult your eyecare practitioner. 3. 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 after each use. Lens cases should be replaced at regular intervals as recom-6 and after All Waking Hours mended by the lens case manufacturer or the eve care practitioner

## 4. Emergencies If chemicals of any kind (household products

 Note: Some solutions may have more than one gardening solutions, laboratory chemicals, etc.) function, which will be indicated on the label. are splashed into your eyes, you should: FLUSH Read the label on the solution bottle, and fol-YOUR EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE YOUR LENSES PROMPTLY. IF POSSIBLE. AND IMMEDIATELY CONTACT YOUR EYE CARE . Clean one lens first (always the same lens first PRACTITIONER OR VISIT A HOSPITAL EMERGENCY to avoid mix-ups) and rinse the lens thoroughly ROOM WITHOUT DELAY. as recommended by your eye care practitione

## INSTRUCTIONS FOR THE MONOVISION WEARER • You should be aware that, as with any type of lens correction, there are advantages and compro-

mises to monovision contact lens therapy. The benefit of clear near vision in straight-ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptasist, the poorer is your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It recommended that you first wear these contact lenses in familiar situations which are not visually demanding. For example, it would be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers' license requirements with monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illu mination, such as driving at night. If this happens you may want to discuss with your eye care practi tioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- longed close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required. Some monovision patients require supplemental
- should discuss this with your eye care practitioner. It is important that you follow your eye care. practitioner's suggestions for adaptation to monovision contact lens therapy. You should
- The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the

discuss any concerns that you may have during

and after the adaptation period.

Prescribed Wearing Schedule WEARING TIME (Hours)\* 4 to 8 Hours 6 to 10 Hours 8 to 14 Hours 10 to 15 Hours 12 to All Waking Hours

The prescribed wearing schedule for Boston EQUALENS II Contact Lens for extended wear is to

### 15-21 24 hours a day

The maximum suggested wearing time for Boston

Your appointments are on-PATIENT/EYE CARE PRACTITIONER INFORMATION: Eye Care Practitioner Information Practitioner Name: \_\_\_

Practitioner Address:\_ Practitioner Phone Number: \_\_

\*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)

initially adapt to daily wear during the first week of wear as described above. During the second week. you should comfortably wear the lenses during all waking hours. Then;

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

WEARING TIME (Hours)

EQUALENS II Contact Lens/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 fre quently if recommended by your eye care practitione Practice Name Recommended Lens Care Regimen:\_ Cleaning Solution: Conditioning Solution:

Minimum number of hours lenses to be worn at time of appointment:

APPOINTMENT SCHEDULE

**IMPORTANT:** In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PRACTITIONER IMMEDIATELY

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1-800-333-4730

Rewetting Solution:

Weekly Enzymatic Cleaner:

Print date: 1/04