



# U.S. Department of Health & Human Services

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**Food and Drug Administration**

## SAVE REQUEST

**USER:** (cwf)  
**FOLDER:** K001960 - 218 pages  
**COMPANY:** POLYMER TECHNOLOGY (POLYTECHG)  
**PRODUCT:** LENS, CONTACT (OTHER MATERIAL) - DAILY (HQD)  
**SUMMARY:** Product: RIGID GAS PERMEABLE CONTACT LENS

**DATE REQUESTED:** Aug 24, 2016

**DATE PRINTED:** Aug 24, 2016

**Note:** Printed



APR 28 2000

**510(k) Premarket Notification**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**FOR**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

**1. SUBMITTER INFORMATION:**

Polymer Technology  
Global Vision Care  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**2. CONTACT PERSON:**

Debra L.B. Ketchum  
Manager, Regulatory Affairs  
Address: 1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450  
Telephone No.: (716) 338-8638  
Fax No.: (716) 338-0702  
E-mail Address: dketchum@bausch.com

**3. DEVICE IDENTIFICATION:**

Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens  
  
Proprietary Name: BOSTON XO (hexafocon A) Contact Lens  
for Orthokeratology  
  
Common Name: Fluoro silicone acrylate rigid gas permeable contact lens  
material

**4. PREDICATE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

**510(k) Premarket Notification**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**5. DESCRIPTION OF THE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206 (green) and 21 CFR Part 74.1602 (violet). The hexafocon A material has an oxygen permeability (Dk) of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN)

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is hexafocon A, is a fluoro silicone acrylate material.

**6. INDICATIONS FOR USE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only. Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

**7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:**

The safety and efficacy of *BOSTON XO (hexafocon A) Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K000795, cleared on May 26, 2000. Also, the use of a rigid gas permeable contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology 510(k) Premarket Notification No. K973697, cleared on April 8, 1998.

**8. SUBSTANTIAL EQUIVALENCE**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 28 2000**

Ms. Debra L.B. Ketchum  
Manager, Regulatory Affairs  
Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

Re: K001960

Trade Name: BOSTON XO (hexafocon A) Contact Lens for Orthokeratology (Daily Wear)

Regulatory Class: II

Product Code: 86 HQD, MUW

Dated: July 26, 2000

Received: July 27, 2000

Dear Ms. Ketchum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device when worn overnight in an orthokeratology fitting and maintenance program have not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation

Page 2 - Ms. Debra L.B. Ketchum

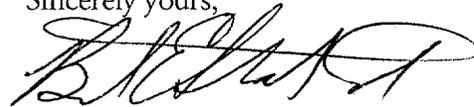
may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Premarket Notification

BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

Polymer Technology  
1400 North Goodman Street  
P.O. Box 450  
Rochester, New York 14603-0450

INDICATIONS FOR USE STATEMENT:

510 (k) number (if known) K001960

Device Name: BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

Indications For Use:

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription use  or Over the Counter Use

  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K001960





## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850**AUG 28 2000**

Ms. Debra L.B. Ketchum  
Manager, Regulatory Affairs  
Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

Re: K001960

Trade Name: BOSTON XO (hexafocon A) Contact Lens for Orthokeratology (Daily Wear)

Regulatory Class: II

Product Code: 86 HQD, MUW

Dated: July 26, 2000

Received: July 27, 2000

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Page 2 - Ms. Debra L.B. Ketchum

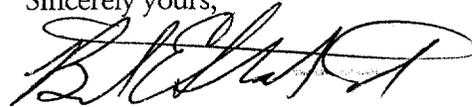
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Sincerely yours,



Bernard E. Statland, M.D., Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Premarket Notification**  
**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

Polymer Technology  
1400 North Goodman Street  
P.O. Box 450  
Rochester, New York 14603-0450

**INDICATIONS FOR USE STATEMENT:**

510 (k) number (if known) K001960

Device Name: BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

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**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription use  or Over the Counter Use

[Signature]  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K001960

[Signature]

SE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Eleanor M. Felton  
Subject: 510(k) Number K001960/S1  
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

A 510(k) summary OR  A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

88 ~~HEB~~ <sup>MUW</sup> Class II

HQD

Review:

(Branch Chief)

*[Signature]*

UEOB

(Branch Code)

8/16/00

(Date)

Final Review Questions?

Contact FDA/CDRH/DOE/DOE/Dial/CDRH/FOIS STATUS @fda.hhs.gov or 301-796-8118

(Division Director)

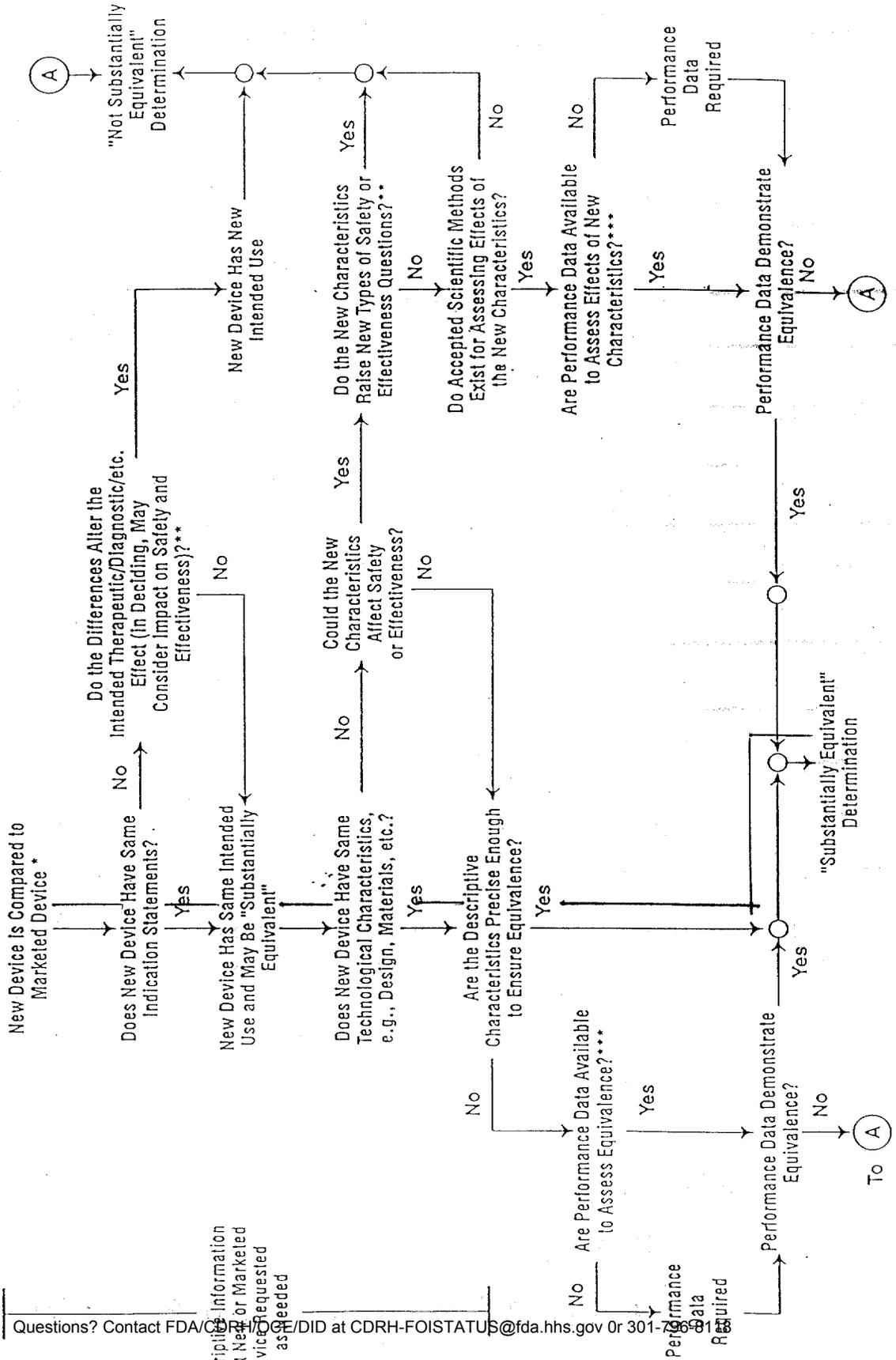
*[Signature]* for DOE

8/16

(Date)

4

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH/DOE/DID at CDRH-FOI@FDA.gov or 301-795-8155

\*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Information is Sometimes Required.  
 \*\*\* Data from 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 001960

Reviewer: Eleanor M. Felton

Division/Branch: DD / VEDB

Device Name: Boston KO (hexaflex) RGP lens for Orthokeratology Daily Wear

Product To Which Compared (510(K) Number If Known): K973697

YES NO

1.	Is Product A Device	✓		If NO = Stop
2.	Is Device Subject To 510(k)?	✓		If NO = Stop
3.	Same Indication Statement?	✓		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NE
5.	Same Technological Characteristics?	✓		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?			If NO = Request Data
11.	Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters on non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.
2. Device Description: The subject device is the similar in design, indications, and labeling as that of the predicate device. The device is not life-supporting or life sustaining; is not implanted (short-term or long-term); does not use software; is not shipped sterile; is to be cleaned, rinsed, disinfected and replaced on the eye; is for prescription use; does not contain drug or biological product as a component; and is not a kit. The lens is a reverse geometry design manufactured from a rigid gas permeable material, hexafocon A. The applicant has provided an engineering drawing of the device and labeling which is similar to the prototype found in the Draft Guidance Document for Orthokeratology Lenses and that of the predicate device

**EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED**

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue: There is no new effect or safety and effectiveness issues regarding the use of this device for the labeled indication for use. The device is quite similar to the predicate device in design and material. The predicate device was tested using a population of human subjects. The application contains written authorization to reference that clinical data.
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**ATTACH ADDITIONAL SUPPORTING INFORMATION**

Date: August 15, 2000  
From: Eleanor M. Felton, HFZ-460 *EF*  
To: Record  
Subject: BOSTON XO (hexafocon A) RGP Lens for Orthokeratology Daily Wear  
K0001960  
Memo of Telephone Conversation

On August 8, 2000 I called Debra Ketchum of Polymer Technology and asked that she provide labeling for the subject device which contains the appropriate statements regarding astigmatism. I told her that I would fax these statements to her to be added to the labeling.

Ms. Ketchum submitted the appropriate labeling in an amendment to the application dated August 9, 2000. This amendment was reviewed and the labeling was determined to be appropriate. It was noted that the summary of safety and effectiveness and Indications statements had not been revised. I called Ms. Ketchum on August 14, 2000 and asked that she make the revisions and fax this information to me. This information containing revisions was received by fax on August 14, 2000. The application is now complete and the subject device is determined to be substantially equivalent to the predicate device.

*Clinical data reported in product labeling is  
based upon the Center OK case cleared K973697*

*JF*

# TELEFAX

# POLYMER TECHNOLOGY

Vision Care Regulatory Affairs  
1400 North Goodman Street  
Rochester, NY 14609

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Tel: 001-716-338-8638  
Fax: 001-716-338-0702

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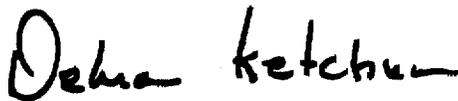
**To:** Eleanor Felton  
**Fax:** 301 480 4201  
**From:** Debra Ketchum  
**Date:** 8/23/00  
**Pages including this cover page:** 1

Dear Eleanor,

**RE: K001960  
BOSTON XO (hexafocon A) Contact Lens for Orthokeratology (Daily Wear)**

Bausch & Lomb agrees to the limitation as stated in the clearance letter to include the warning, "The safety and effectiveness of this device when worn overnight in an orthokeratology fitting and maintenance program have not been established" in the device's labeling.

Sincerely,



Debra Ketchum  
Manager, Regulatory Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

**CDRH**  
**Division of Ophthalmic Devices**

9200 Corporate Boulevard  
Rockville, MD 20850  
FAX NO. 301 480-4201  
or 301 827-4601

Date: 8-24-00 Time: \_\_\_\_\_

To: Debra Ketchum FAX #: 716-338-0702

Organization: Polymer Technology

From: Eleanor Felton

Department: FDA / DID

Subject: Boston XO Lens for orthokeratology (Daily Wear)

No. of Pages: 3  
(Including Cover Sheet)

Comments:

- As Requested
- Response Needed
- For Correction
- FYI
- Signature
- Investigate
- Read and Destroy
- Circulate
- File

Division Director's Office	301 594-2205
Diagnostic and Surgical Devices Branch	301 594-2018
Vitreoretinal and Extraocular Devices Branch	301 594-1744
Intraocular and Corneal Implants Branch	301 594-2053
Mail Code: HFZ 460	

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Please advise if transmission is illegible

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov Or 301-796-8118

10

11

Records processed under FOIA Request #2016-1775 Released by CDRH on 8/31/16

\*\*\*\*\*  
\*\*\* TX REPORT \*\*\*  
\*\*\*\*\*

TRANSMISSION OK

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CONNECTION ID		
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RESULT	OK	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

# CDRH Division of Ophthalmic Devices

9200 Corporate Boulevard  
Rockville, MD 20850  
FAX NO. 301 480-4201  
or 301 827-4601

Date: 8-24-00

Time: \_\_\_\_\_

To: Debra Ketchum

FAX #: 716-338-0702

Organization: Polymer Technology

From: Eleanor Felton

Department: FDA / DOD

Subject: Boston XO Lens for ophthalmology (Daily Wear)

No. of Pages: 3  
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11



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If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.  
Acting Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

*Change of Dr. Stotland*

Enclosure

**TELEFAX****POLYMER TECHNOLOGY**

Vision Care Regulatory Affairs  
1400 North Goodman Street  
Rochester, NY 14609

---

Tel: 001-716-338-8638

Fax: 001-716-338-0702

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**To:** Eleanor Felton

**Fax:** 301 480 4201

**From:** Debra Ketchum

**Date:** 8/14/00

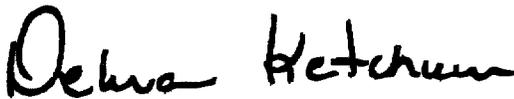
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cover page:**

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Dear Eleanor,

Attached is the revised Summary of Safety and Effectiveness and Indications for Use Statement which you requested during our phone conversation today, August 14, 2000.

Sincerely,



Debra Ketchum  
Manager, Regulatory Affairs

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

---

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**FOR**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

**1. SUBMITTER INFORMATION:**

Polymer Technology  
Global Vision Care  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**2. CONTACT PERSON:**

Debra L.B. Ketchum  
Manager, Regulatory Affairs  
Address: 1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450  
Telephone No.: (716) 338-8638  
Fax No.: (716) 338-0702  
E-mail Address: dketchum@bausch.com

**3. DEVICE IDENTIFICATION:**

Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens

Proprietary Name: BOSTON XO (hexafocon A) Contact Lens  
for Orthokeratology

Common Name: Fluoro silicone acrylate rigid gas permeable contact lens  
material

**4. PREDICATE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

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**5. DESCRIPTION OF THE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206 (green) and 21 CFR Part 74.1602 (violet). The hexafocon A material has an oxygen permeability (Dk) of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN)

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is hexafocon A, is a fluoro silicone acrylate material.

**6. INDICATIONS FOR USE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

**7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:**

The safety and efficacy of *BOSTON XO (hexafocon A) Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K000795, cleared on May 26, 2000. Also, the use of a rigid gas permeable contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology 510(k) Premarket Notification No. K973697, cleared on April 8, 1998.

**8. SUBSTANTIAL EQUIVALENCE**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

Polymer Technology  
1400 North Goodman Street  
P.O. Box 450  
Rochester, New York 14603-0450

**INDICATIONS FOR USE STATEMENT:**

510 (k) number (if known) \_\_\_\_\_

Device Name: BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

**Indications For Use:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, office of Device Evaluation (ODE)

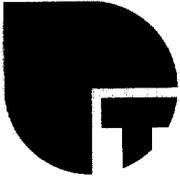
Prescription use \_\_\_\_\_ or Over the Counter Use \_\_\_\_\_

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K001960/AH

**POLYMER TECHNOLOGY**

1400 N. GOODMAN STREET • P.O. BOX 450 • ROCHESTER, NEW YORK 14603-0450



August 9, 2000

Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Center for Devices & Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

RE: 510(k) Premarket Notification  
K001960  
BOSTON XO (hexafocon A) RGP  
Contact Lens for Orthokeratology

Attn: Eleanor Felton, HFZ-460

Dear Ms. Felton:

This is in response for additional information and labeling revisions regarding 510(k), K001960; Boston XO (hexafocon A) RGP Contact Lens for Orthokeratology discussed by telephone on August 8, 2000.

The information marked as confidential and contained in the body of the submission is considered to be confidential within the meaning as set forth in 21 CFR Part 20.

Should you have any questions, please do not hesitate to telephone my office at (716) 338-8638.

Sincerely,

Debra L.B. Ketchum  
Manager, Regulatory Affairs

Enclosures

10 Aug 00 13 51  
FDA/CDRH/OCE/DID

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## **PACKAGE INSERT**

**BOSTON XO (hexafocon A) RIGID GAS  
PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY - 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.

**CAUTION:** Federal Law Prohibits Dispensing Without a Prescription.

### **DESCRIPTION:**

BOSTON XO Rigid Gas Permeable (RGP) contact lenses for daily wear orthokeratology are lathe cut contact lenses with spherical or aspherical]anterior or posterior surfaces in tinted version. The posterior curve is selected so as to property fit an individual eye for orthokeratology and the anterior curve selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

BOSTON XO contact lenses for orthokeratology are made from a fluoro silicone acrylate polymer, hexafocon A, with a water content of less than 1% percent. The tinted lens contains D&C Green #6 for blue, ice blue and green lenses and D&C Violet #2 as color additive for violet lenses. BOSTON XO contact lenses for orthokeratology are to be worn for daily wear only.

### **LENS PARAMETERS AVAILABLE:**

Chord Diameter	Approx 6.5 to 11.5
Center Thickness for Low Minus Lens:	0.10 to 0.30 mm
for Plus Lens:	0.20 to 0.70 mm
Base Curve	6.5 to 11.0 mm
Secondary Curves	0.10 to 2.00 mm
Flatter or steeper than Base Curve	
Peripheral Curves	0.10 to 2.0 mm
Flatter or steeper than Base Curve	
Powers	-10.00 to +3.00 Dioptors

Aspheric Lens Eccentricity -1.5 to 1.5  
(Oblate, Prolate or Tangent Conic)

The physical properties of the lens are:

Refractive Index	1.415
Light Transmittance	92%
Wetting Angle	49°
(Contact Receding Angle)	
Specific Gravity	1.27
Hardness	112
(Rockwell)	
Water Content	<1 %
Oxygen Permeability	140* (100**)
* gas to gas method	
** polarographic method (ISO/Fatt)	

**ACTIONS:**

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular contact lenses are designed to cause little or no effect but BOSTON XO contact lenses for orthokeratology are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the central cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day.

A Myopic Reduction Maintenance Lens or Retainer Lens should be worn each day to maintain the corneal flattening, or the myopia will revert back to the pretreatment level.

**INDICATIONS (USES):**

The BOSTON XO (hexafocon A) RGP Contact Lens for orthokeratology is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

**CONTRAINDICATIONS (REASONS NOT TO USE):**

DO NOT USE YOUR BOSTON XO contact lenses when any of the following conditions exist:

- Acute and subacute inflammations or infection of the anterior segment 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).
- 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, such as mercury or Thimerosal, in a solution which is to be used to care for your contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

**WARNINGS:**

Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential to follow your eye care practitioner's directions and all labeling instructions for proper use of contact lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove your lenses and do not wear them until you have been examined by your eye care practitioner. All contact lens wearers should see their eye care practitioner according to the schedule given to them.

BOSTON XO contact lenses for orthokeratology are to be worn on a daily wear basis only. Do not wear your lenses while sleeping, at the risk of serious adverse reactions.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

## **PRECAUTIONS:**

### **Specific Precautions**

- Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO (hexafocon A) rigid gas permeable lens materials 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 materials. Consequently, when selecting an appropriate lens design and parameter the eye care practitioner should consider all factors that effect lens performance and ocular health. The potential impact of these factors should 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.
- Patients should be instructed to follow the instructions below in order to prevent damage to their eyes or lenses.

### **Solution 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 contact 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 BOSTON XO 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 the lenses are not being worn (stored).

## Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses, as microscopic scratches of 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 information booklet and those prescribed by your eye care practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

## Lens Wearing Precautions

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the patient information booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

### **Lens Case Precautions**

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

### **Topics to Discuss with the Eye care Practitioner**

- Ask your eye care practitioner about wearing your lenses during sporting activities.
- Always contact your eye care practitioner before using any medicine in your eyes.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

### **Who Should Know That the Patient is Wearing Contact Lenses**

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.

**ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO):** Patient's 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 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)

If you notice any of the above: 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 objects

on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it. If the problem continues, you should IMMEDIATELY remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You 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.

**CLINICAL STUDY RESULTS:\***

A total of 138 eyes were enrolled in the clinical study with 110 eyes completing a minimum of 3 months of contact lens wear. Of the completed eyes a total of 106 eyes showed some reduction in myopic refractive error during the 3-month time period that the RGP contact lenses for orthokeratology were worn. The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters.

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

**AVERAGE REDUCTION IN MYOPIA (Diopters)**

INITIAL Myopia	REDUCTION Myopia
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40

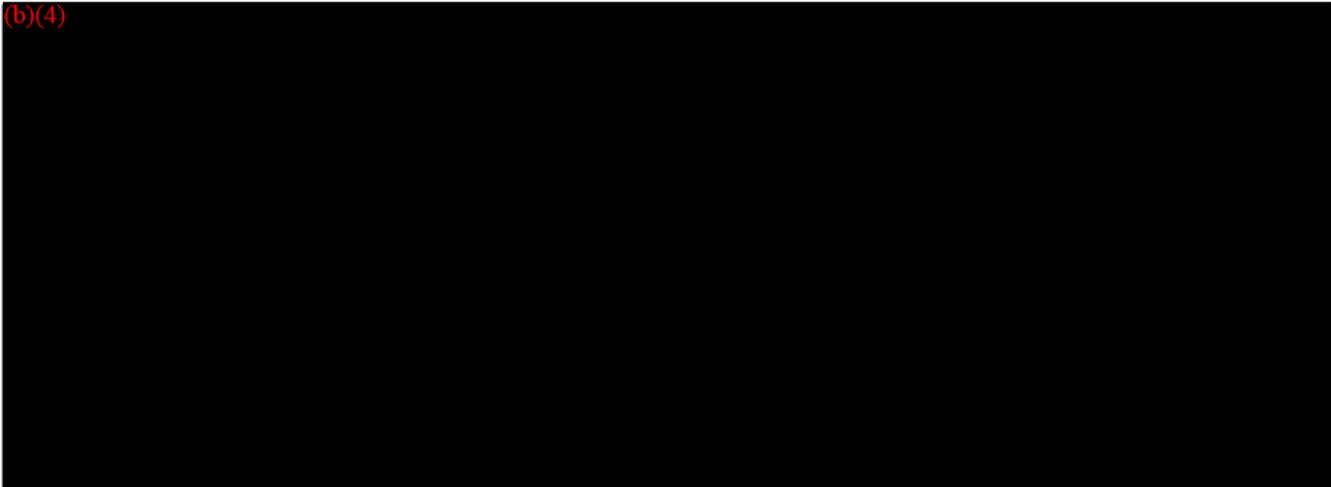
The amount of myopia reduced varied between patients and could not be predicted prior to treatment. There was an insignificant difference between the patients who wore contact lenses prior to the study and those with no previous contact lens experience.

RGP contact lenses for orthokeratology provided a temporary full reduction in some patients with up to 3.00 diopters of myopia. For patients with greater than 3.00 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table.

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL  
TEMPORARY REDUCTION OF MYOPIA

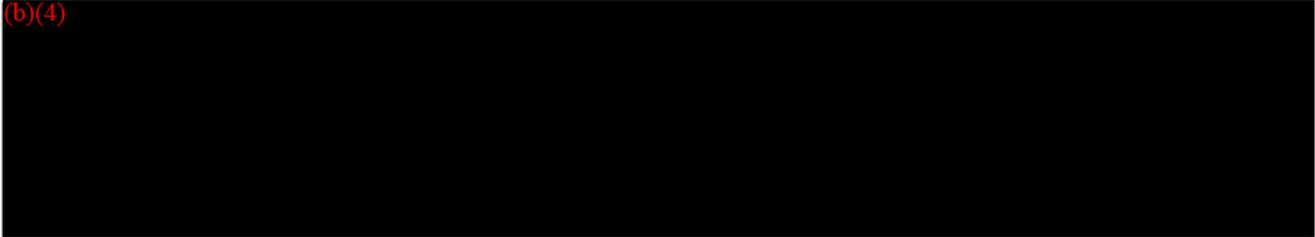
INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO - 2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	72%
-3.25 TO -4.00 D	4%	13%	16%	64%

(b)(4)



EFFECTS ON ASTIGMATISM

(b)(4)



WEARING TIME

The average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours/day
Two weeks	7.8 hours/day
One month	8.0 hours/day
Three months	8.4 hours/day

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three month time period as follows:

Daily Wear Time Worn	Percent of patients
0 to 4 hours	25.5%
4.1 to 8 hours	21.8%
8.1 to 12 hours	23.7%
12.1 to 16 hours	27.2%

\*Data based on CONTEX (siflufocin A) 3-month Clinical Study.

**FITTING:**

Conventional methods of fitting rigid contact lenses for orthokeratology DO NOT APPLY to the BOSTON XO contact lenses for orthokeratology. For a description of fitting techniques, refer to the Fitting Guide for BOSTON XO contact lenses for orthokeratology, copies of which are available from:

Polymer Technology  
 1400 N. Goodman Street  
 P.O. Box 30450  
 Rochester, New York 14603-0450

**WEARING SCHEDULE:**

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

The following schedule depends upon the professional judgment of the eye care practitioner and should be modified according to the response to the initial lenses.

Daily Wear Maximum wearing time:	Wearing Time (Hours)
Day	
1	3
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake

Patients should be advised NOT TO SLEEP while wearing BOSTON XO contact lenses for orthokeratology. Studies have not been conducted to show that the BOSTON XO rigid gas permeable contact lens is safe to wear during sleep. There is a tendency for some patients to overwear the lenses initially. It is important to remind patients to adhere to the maximum wearing schedule above. In order to maintain the orthokeratology effect of myopia reduction lens wear should be continued on a wearing schedule determined by the eye care practitioner. Refer to the Professional Fitting and Information Guide for information on Myopic Reduction Maintenance Lens or Retainer Lens wear.

**LENS CARE DIRECTIONS:**

The lens care products listed below are recommended by Polymer Technology for use with your BOSTON XO orthokeratology contact lenses.

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

BOSTON, BOSTON XO, BOSTON Advance and BOSTON Simplicity are registered trademarks of Polymer Technology.

The directions from the package inserts from these products should be followed. Failure to adhere to these procedures may result in the development of serious ocular complications. 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.

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

BOSTON XO contact lenses for orthokeratology must be both cleaned, rinsed 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 and rinse as directed in the solution labeling. Some solutions may have more than one function, which will be indicated on the label. 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 disinfection solution as recommended by your eye care practitioner.

Tightly close the top of each chamber of the lens storage case.

To disinfect your lenses, leave them in the solution for at least the period of time indicated on the product label. Leave the lenses in the unopened storage case until you are ready to put them in your eye.

#### **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 lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the eye care practitioner.

#### **ENZYME CLEANING:**

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning does not replace routine cleaning and disinfecting. You should carefully follow the instructions in the enzymatic cleaning labeling.

#### **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.

CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL  
EMERGENCY ROOM WITHOUT DELAY.

**HOW SUPPLIED:**

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, dioptic power, diameter, secondary curve, center thickness, color and Lot #.

**REPORTING OF ADVERSE REACTIONS:**

All adverse reactions should be reported immediately to the manufacturer. Telephone 800-333-4730.

8/00

Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**PATIENT INFORMATION BOOKLET (PART 1) FOR POTENTIAL  
USERS:**

BOSTON XO (hexafocon A)  
RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY for  
Daily Wear

**CAUTION:** Federal law prohibits dispensing without a prescription.

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## **GLOSSARY**

Adnexa: Tissues near the eye.

Adverse effects: Undesirable effects.

Aphakia: Eye that does not have a lens structure.

Astigmatism: Eye condition in which one or more surfaces of the cornea or lens has a shape that is not round but more like that of a spoon.

Contact Lens Sticking: Lack of movement of a contact lens on the cornea.

Cornea: The clear, bubble-like structure on the front of the eye, where light first enters the eye.

Corneal abrasion: Loss of cells on the corneal surface due to mechanical trauma.

Corneal edema: Accumulation of fluid in the cornea.

Corneal hypoesthesia: Partial loss of sensitivity to touch in the cornea.

Corneal staining: Bright areas on the cornea where dye collects and which indicates an abrasion or other disturbance of the cornea.

Corneal ulcer: small area of tissue loss in the cornea.

Disinfection: Destruction of bacteria and viruses but not some spores.

Diopter: Unit of power for glasses or contact lenses.

Enzyming contact lenses: Placing contact lenses in a solution that contains an enzyme that dissolves proteins on the surface of the lens.

Hypoesthesia: Reduced corneal sensitivity to touch.

Iritis: Infection of the iris or colored portion of the eye.

Lacrimal secretion: Tearing.

Myopia: Medical term for nearsightedness.

Myopic Reduction Maintenance Lens: A modification of the orthokeratology contact lens design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening.

Neovascularization: New vessel growth in the cornea.

Orthokeratology: Contact lens fitting procedure that temporarily reduces nearsightedness after contact lenses have been removed.

Refract: Bending of light in order to make it focus.

Refractive anomalies: Eye conditions leading to blurred vision including nearsightedness, farsightedness and astigmatism.

Retainer Lenses: Another name for the Myopic Reduction Maintenance Lens.

Retina: Structure at the back of the eye that receives the light image.

Rewetting contact lenses: Placing a solution in the eye while contact lenses are worn that acts as an artificial tear to wet the lens.

Sticking lens: Lens on the cornea that does not move.

## **INTRODUCTION**

The information in this booklet is to help you decide whether or not to be fitted with the BOSTON XO contact lenses for orthokeratology. Orthokeratology is a contact lens fitting procedure that temporarily reduces nearsightedness (known by the medical name of myopia) after contact lenses have been removed. By temporary it is meant that the contact lenses are worn for a portion of the day and then removed, whereupon the nearsightedness remains reduced for all or part of the remainder of the day. The exact time period over which the myopia remains reduced varies with each patient. Generally, BOSTON XO contact lenses for orthokeratology should be worn for part of each day for the orthokeratology effect to continue.

## **HOW THE EYE FUNCTIONS**

The eye is very much like a camera and must be in good focus to see objects clearly. The focusing power of the eye comes from two eye structures, the cornea and the lens [(Figure 1)]. The cornea is the clear, bubble-like structure on the front of the eye, where light first enters the eye. It provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. In a normal eye light focuses at the retina, at the back of the eye, which acts like the film in a camera. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred, producing myopia [(Figure 2)].

Myopia usually starts in childhood and gets progressively worse through adolescence. It normally stops increasing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

## **HOW BOSTON XO CONTACT LENSES FOR ORTHOKERATOLOGY FUNCTION**

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of nearsightedness by changing the shape (flattening) of the cornea, which is elastic in nature. Contact lenses rest directly on the cornea, separated only by a layer of tears, and can influence the corneal shape. Regular contact lenses are designed to nearly match the shape of the cornea and thereby cause little or no flattening effect but BOSTON XO contact lenses for orthokeratology are designed to purposely not match the shape of the cornea but instead apply slight pressure to the center of the cornea [(Figure 3)], in a design known as reverse geometry. Pressure is produced when the lens is less curved than the cornea, which places more of the lens weight on the center of the cornea. If the cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia [(Figure 4)]. After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day.

Figure 1: Normal Eye

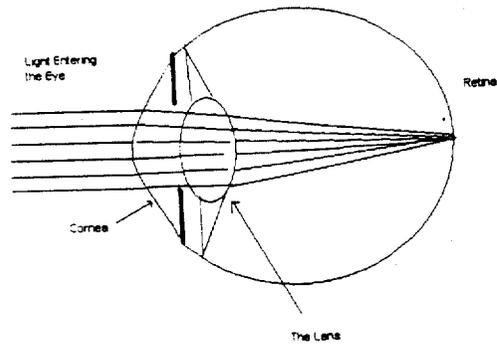


Figure 2: Nearsighted eye

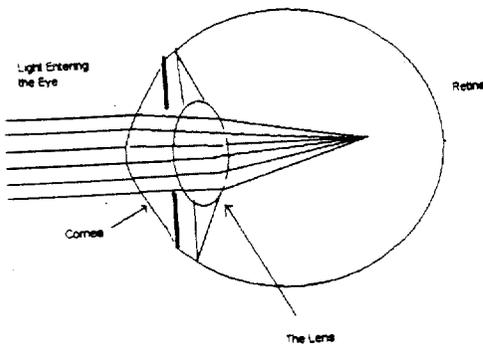


Figure 3: Eye Fitted With BOSTON XO contact lenses for orthokeratology.

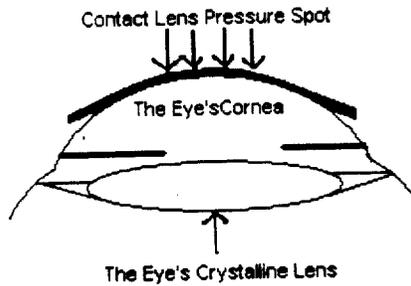
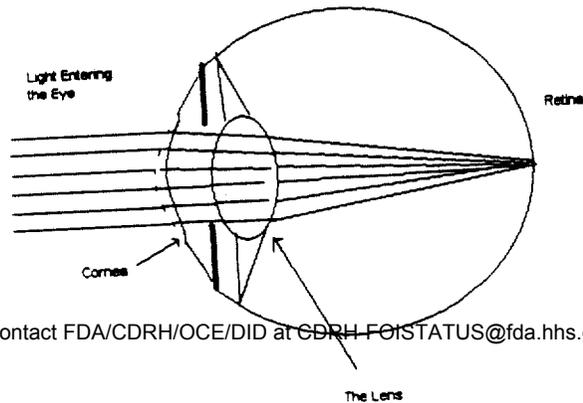


Figure 4: Nearsighted Eye After Orthokeratology



BOSTON XO contact lenses for orthokeratology are indicated for patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still be able to see clearly. This might include such activities as swimming and other sports. BOSTON XO contact lenses for orthokeratology may be indicated in occupations that require exposure to smoke, noxious gases or conditions of low humidity, such as might occur, for example, for flight attendants, in which case their contact lenses can be removed without interference with vision. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

### **ALTERNATIVE WAYS TO CORRECT NEARSIGHTEDNESS**

Nearsightedness (myopia) can be corrected by any method that reduces the focusing power of the eye. The most common methods of reduction are by glasses or regular contact lenses. These represent a means of correcting myopia only during the time that the glasses or regular contact lenses are worn, with no lasting effect on the myopia. Other methods of correcting myopia involve various surgical procedures. These involve techniques to reshape the cornea so that it is flattened in a way that is similar to that produced by BOSTON XO contact lenses for orthokeratology, except that the surgical procedures are permanent.

### **CLINICAL STUDY DATA\***

BOSTON XO contact lenses for orthokeratology may produce a temporary reduction of all or part of your myopia. The amount of reduction will depend on many factors, including the amount of your initial myopia, the elastic characteristics of your eye and the way that your contact lens fits on your eye.

A total of 138 eyes were enrolled in the clinical study with 110 eyes completing a minimum of 3 months of contact lens wear. Of the completed eyes a total of 106 eyes showed some reduction in myopic refractive error during the 3-month time period that the RGP contact lenses for orthokeratology were worn. The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters.

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

AVERAGE REDUCTION IN MYOPIA (Diopters)

INITIAL Myopia	REDUCTION Myopia
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40

The amount of myopia reduced varied between patients and could not be predicted prior to treatment. There was an insignificant difference between the patients who wore contact lenses prior to the study and those with no previous contact lens experience.

RGP contact lenses for orthokeratology provided a temporary full reduction in some patients with up to 3.00 diopters of myopia. For patients with greater than 3.00 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table.

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO - 2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	72%
-3.25 TO -4.00 D	4%	13%	16%	64%

For the 110 eyes that completed this study, the initial visual acuity by best refraction was 20/20 or better for 104 eyes and 20/40 or better for all 110 eyes. At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 99 eyes, 20/40 for 109 eyes and one eye had a visual acuity of 20/70. Nine eyes had a one-line drop in visual acuity for contact lenses compared to best refraction, one eye had a two-line drop and three eyes had a three-line drop. In each case the reduced visual acuity was attributed to residual astigmatism when wearing contact lenses.

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) eyes achieved a visual acuity of 20/20 or better and 78 (71 %) eyes achieved 20/40 or better.

#### AFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 110 eyes (55 patients) which completed the three month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.

#### WEARING TIME

The average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours/day
Two weeks	7.8 hours/day
One month	8.0 hours/day
Three months	8.4 hours/day

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three month time period as follows:

Daily Wear Time Worn	Percent of patients
0 to 4 hours	25.5%
4.1 to 8 hours	21.8%
8.1 to 12 hours	23.7%
12.1 to 16 hours	27.2%

\*Data based on CONTEX (siflufocin A) 3-month Clinical Study.

## **MAINTAINING EFFECTS OF BOSTON XO CONTACT LENSES FOR ORTHOKERATOLOGY -MYOPIC REDUCTION MAINTENANCE LENS OR RETAINER LENS WEAR**

The long-term wear of BOSTON XO contact lenses for orthokeratology does not eliminate the need to continue wearing contact lenses to produce the orthokeratology effect. After the cornea has been flattened by wearing BOSTON XO contact lenses for orthokeratology, new lenses are prescribed that are Myopic Reduction Maintenance Lenses or Retainer Lenses. Retainer Lenses are a modification of the patient's BOSTON XO contact lens for orthokeratology design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The retainer lenses are generally worn for the same schedule as the BOSTON XO contact lenses for orthokeratology and should be worn each day to maintain the orthokeratology effect.

Studies have not been conducted to support the safety of wearing BOSTON XO contact lenses for orthokeratology for overnight or extended wear.

### **RISK ANALYSIS**

There is a small risk involved when any contact lens is worn. It is not expected that BOSTON XO contact lenses for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects which occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of BOSTON XO contact lenses for orthokeratology. Other side effects which sometimes occur in all contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper schedule of care is followed. You should remove your contact lenses if any abnormal signs are present. Never wear your contact lenses while in the presence of noxious substances. Be certain to return for all follow-up visits required by your eye care practitioner.

## **WEARING RESTRICTIONS AND INDICATIONS**

### **INDICATIONS**

The BOSTON XO (hexafocon A) RGP Contact Lens for orthokeratology is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

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

DO NOT USE YOUR BOSTON XO contact lenses for orthokeratology when any of the following conditions exist:

Acute and subacute 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, such as mercury or Thimerosal, in a solution which is to be used to care for your BOSTON XO contact lenses for orthokeratology.  
Any active corneal infection (bacterial, fungal or viral).  
If eyes become red or irritated

### **WARNINGS:**

You should be advised of the following warnings pertaining to contact lens wear:

**Daily wear lenses are NOT indicated for overnight wear, and you should not wear lenses while sleeping.** Clinical studies have shown that the risk of serious adverse reactions such as corneal infection or ulcers is increased when contact lenses are worn overnight.

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 direction 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.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye you should immediately remove your lenses and promptly contact your eye care practitioner.

**PATIENT INSTRUCTIONS (PART 2) AFTER YOUR BOSTON XO  
(hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES FOR  
ORTHOKERATOLOGY HAVE BEEN FITTED**

**CAUTION:** Federal law prohibits dispensing without a prescription.

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    Emergencies

    Wearing and Appointment Schedules

## **PRECAUTIONS:**

### **Specific Precautions**

Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO (hexafocon A) rigid gas permeable lens materials 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 materials.

Consequently, when selecting an appropriate lens design and parameter the eye care practitioner should consider all factors that effect lens performance and ocular health. The potential impact of these factors should 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.

Patients should be instructed to follow the instructions below in order to prevent damage to their eyes or lenses.

### **Solution 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 contact 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 BOSTON XO 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 the lenses are not being worn (stored).

### **Handling Precautions**

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses, as microscopic scratches of 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 this booklet and those prescribed by your eye care practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

### **Lens Wearing Precautions**

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in this booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

### **Lens Case Precautions**

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

### **Topics to Discuss with the Eye care Practitioner**

- Ask your eye care practitioner about wearing your lenses during sporting activities.
- Always contact your eye care practitioner before using any medicine in your eyes.

- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

### **Who Should Know That the Patient is Wearing Contact Lenses**

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.

### **ADVERSE EFFECTS:**

You 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 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 you notice any of the above, 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 objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it. If the problem continues, you should IMMEDIATELY remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You 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.

## **PERSONAL CLEANLINESS FOR LENS HANDLING:**

### **1. Preparing the Lens for Wearing:**

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substance when you handle your lenses. The procedures are:

Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.

Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.

To avoid damaging your lenses, handle them with your fingertips, and be careful to avoid contact with your fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

### **2. Handling the Lenses:**

Develop the habit of always working with the same lens first to avoid mix-ups.

Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks and tears.

### **3. Placing the Lens on the Eye:**

Work over a table, upon which is placed a clean towel.

Do not place lenses on the eye while working over a sink.

For the right eye:

Wet the forefinger of the right hand and place the contact lens on the forefinger of the right hand.

Place the second finger of the left hand on the middle of the upper lid and press upward firmly.

Place the second finger of the right hand on the lower lid and press downward firmly.

Stare into a mirror as though looking through the second finger holding the contact lens. You will later learn to do this without a mirror.

Slowly move the hand to advance the forefinger with the contact lens towards the cornea until the lens touches the cornea and release the lids.

Release the lid and close the eye for a few seconds.

Repeat for the left eye.

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.

**Note:** If after placement of the lens your vision is blurred, check for the following:

The lens is not centered on the eye (see "Centering the Lens", next section in this booklet).

If the lens is centered, remove the lens (see "Removing the Lens" section and check for the following:

- a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- b. The lens is on the wrong eye.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

#### **4. Centering the Lens:**

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow the procedure below.

First locate the lens by pulling away the lids. After the lens is found, gently press on the lid over the lens while looking away from the direction of the lens. Next look back towards the lens.

## 5. **Removing the Lens:**

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. Work over a table with a clean towel. Do not remove lenses over a sink. Place the right index finger of the right hand at the outer corner of the eye. Place the left hand cupped below the eye. Open the eyes wide as if to stare. Continue to keep the eyes open and pull the lids sideways away from nose. Blink quickly and firmly.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING).

**Note:** If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.

### CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE, AND REWETTING/LUBRICATING):

#### 1. **Basic Instructions:**

For continued safe and comfortable wearing of your lenses, it is important that you 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 that may have accumulated during wearing. The ideal time to clean, rinse, and disinfect your lenses is immediately after wearing them. Disinfecting is necessary to destroy harmful germs.

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

When you first receive your lenses, practice how to put the lenses on and removing them while you are in your eye care practitioners 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 eye care practitioner should instruct you about appropriate and adequate procedures and products for your use.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.

Use the recommended system of lens care, which is chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**

Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

To avoid contamination, do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

The lens care products listed below are recommended by Polymer Technology for use with your BOSTON XO orthokeratology contact lenses.

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

BOSTON, BOSTON XO, BOSTON Advance and BOSTON Simplicity are registered trademarks of Polymer Technology.

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. **Clean**  
Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of cleaning solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for about 20 seconds. Do not clean the lens by rubbing it between the thumb and index fingers, as this may cause lens warpage.
- b. **Rinse**  
Rinse the lens thoroughly with clean tap water to remove the cleaning solution, mucus, and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- c. **Disinfect**  
After cleaning and rinsing the lenses disinfect them by using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.
- d. **Storage**  
To store lenses, disinfect and leave them in the closed case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the storage solution package insert or your eye care practitioner for information on storage of your lenses.

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 to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.

Note: BOSTON XO contact lenses for orthokeratology cannot be heat (thermally) disinfected.

- e. **Care of Your Lens Case**  
Contact lens cases can be a source of bacteria growth. After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

f. **Lubricating/Rewetting**

Your eye care practitioner will recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to rewet (lubricate) your lenses while you are wearing them to make them more comfortable.

**2. LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:**

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does not replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

**3. CARE FOR A STICKING (NONMOVING) LENS:**

If the lens sticks (stops moving) or cannot be removed, you should apply 5 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eye care practitioner.

**4. EMERGENCIES:**

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

**5. WEARING AND APPOINTMENT SCHEDULES:**

Prescribed Wearing Schedule

Daily Wear

Maximum wearing time:

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8 and after	

Your appointments are on:

Month	Year	Time	Date
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

**PATIENT/EYECARE PRACTITIONER INFORMATION:**

Name  
Address  
Phone Number  
Emergency Phone Number

MANUFACTURER  
Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

8/00

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**PROFESSIONAL FITTING AND INFORMATION GUIDE FOR BOSTON XO  
(hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES FOR  
ORTHOKERATOLOGY**

**CAUTION:** Federal Law Prohibits Dispensing Without a Prescription.

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- Package Insert

**DESCRIPTION:**

BOSTON XO (hexafocon A) Rigid Gas Permeable (RGP) contact lenses for daily wear orthokeratology are lathe cut contact lenses with spherical or aspherical anterior or posterior surfaces in tinted version. The posterior curve is selected so as to properly fit an individual eye for orthokeratology and the anterior curve selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

BOSTON XO contact lenses for orthokeratology are made from a fluoro silicone acrylate polymer, hexafocon A, with a water content of less than 1%. The tinted lens contains D&C Green #6 for blue, ice blue and green lenses and D&C Violet #2 as color additive for violet lenses. BOSTON XO contact lenses for orthokeratology are to be worn for daily wear only.

**LENS PARAMETERS AVAILABLE:**

Chord Diameter	Approx 6.5 to 11.5
Center Thickness for Low Minus Lens:	0.10 to 0.30 mm
for Plus Lens:	0.20 to 0.70 mm
Base Curve	6.5 to 11.0 mm
Secondary Curves	0.10 to 2.00 mm
Flatter or steeper than Base Curve	
Peripheral Curves	0.10 to 2.0 mm
Flatter or steeper than Base Curve	
Powers	-10.00 to +3.00 Dioptors
Aspheric Lens Eccentricity	-1.5 to 1.5
(Oblate, Prolate or Tangent Conic)	

The physical properties of the lens are:

Refractive Index	1.415
Light Transmittance	92%
Wetting Angle	49°
(Contact Receding Angle)	
Specific Gravity	1.27
Hardness	112
(Rockwell)	
Water Content	<1 %
Oxygen Permeability	140* (100**)
* gas to gas method	
** polarographic method (ISO/Fatt)	

**ACTIONS:**

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular contact lenses are designed to cause little or no effect but BOSTON XO contact lenses for orthokeratology are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day. A myopic reduction maintenance lens or retainer lens must be worn each day to maintain the corneal flattening, or the myopia will revert back to the pre-treatment level.

**INDICATIONS (USES):**

The BOSTON XO (hexafocon A) RGP Contact Lens for orthokeratology is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

**CONTRAINDICATIONS (REASONS NOT TO USE) WARNINGS AND ADVERSE REACTIONS:**

DO NOT USE BOSTON XO contact lenses for orthokeratology when any of the following conditions exist:

Acute and subacute inflammations or infection of the anterior segment 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).

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, such as mercury or Thimerosal, in a solution which is to be used to care for contact lenses.

Any active corneal infection (bacterial, fungal or viral).

If eyes become red or irritated.

**Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.**

**PRECAUTIONS:**

Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO contact lens for orthokeratology materials are safe and effective for their intended use. However, 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 were 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 reduction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

**SELECTION OF PATIENTS:**

Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses described above. BOSTON XO contact lenses for orthokeratology are indicated for myopic patients who desire to have time periods during the day, in which they do not need to wear their contact lenses, but still be able to see clearly. This might include such activities as swimming and other sports. BOSTON XO contact lenses for orthokeratology may be useful in occupations that require exposure to smoke, noxious gases or conditions of low humidity, such as would be the case for flight attendants, if their lenses can be worn before exposure to the noxious substance and removed during its presence. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

BOSTON XO contact lenses for orthokeratology are primarily intended for patients who are within the following parameters.

Refractive error:       -1.00 to -3.00 diopters  
Keratometry:           39 to 48 diopters  
Visual Acuity:         20/30 to 20/400

**FITTING PROCEDURE:**

BOSTON XO contact lenses for orthokeratology are designed to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted.

**BOSTON XO Lens Description**

The BOSTON XO contact lens for orthokeratology has a design known as reverse geometry. This means that the secondary curve on the posterior surface has a radius of curvature that is steeper (shorter radius) than the base curve (central curve). The secondary curve is surrounded by a flatter peripheral curve near the edge. In this way the geometry of the secondary curve is in the opposite relationship to the base curve, as occurs with standard rigid gas permeable contact lenses.

The function of the steep secondary curve in the BOSTON XO contact lens for orthokeratology is to allow the base curve to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design, that is fitted flat on the cornea, there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and decenter on the cornea. With the BOSTON XO contact lens for orthokeratology there is support for the lens at both the

central cornea and also in the area of the secondary curve. This will tend to reduce lens rocking and aid in centering.

The secondary and alignment curve relationships are altered to achieve an optimal lens design for each patient's individual cornea.

### **Predicting Lens Results**

Various methods have been proposed for predicting the amount of corneal flattening that may be achieved for a given patient by orthokeratology. There is some evidence that patients with corneas of higher eccentricities are more likely to undergo greater amounts of corneal flattening than do patients with more spherical corneas. Corneal eccentricity can be measured by video keratography or by comparing central and peripheral keratometry readings. Other studies have not supported these conclusions, however, and further research is needed. It is not possible at this time to predict which patients will achieve the greatest corneal flattening with BOSTON XO contact lenses for orthokeratology.

BOSTON XO contact lenses for orthokeratology may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fitted. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

### **Clinical Study Results:\***

A total of 138 eyes were enrolled in the clinical study with 110 eyes completing a minimum of 3 months of contact lens wear. Of the completed eyes a total of 106 eyes showed some reduction in myopic refractive error during the 3-month time period that the RGP contact lenses for orthokeratology were worn. The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters.

35 eyes (32%) had a reduction of between 0.25 and 1.00 D,  
35 eyes (32%) between 1.25 and 2.00 D,  
25 eyes (23%) between 2.25 and 3.00 D,  
10 eyes (9%) between 3.25 and 4.00 D and,  
1 eye (1 %) reduced by 4.25 D

Other clinical refractive outcomes:

- 1 eyes had no change and 3 eyes increased in minus power by 0.25D.
- The reduction in myopia was greater for eyes with a higher initial refractive error.
- 0 eyes over -3.50D were able to achieve a full reduction in myopia.
- For eyes with an initial myopia of greater than 3.75D the average final exam reduction in myopia was 2.75D.
- The limit in initial myopia that could be reduced to emmetropia in was -3.50D.

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

AVERAGE REDUCTION IN MYOPIA (Diopters)

INITIAL Myopia	REDUCTION Myopia
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40

The average reduction was 1.69 diopters with a range from 0.25 to 4.25 diopters. The amount of myopia reduced varied between patients and could not be predicted prior to treatment. There was an insignificant difference between the patients who wore contact lenses prior to the study and those with no previous contact lens experience.

RGP contact lenses for orthokeratology provided a temporary full reduction in some patients with up to 3.00 diopters of myopia. For patients with greater than 3.00 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction is shown in the following table:

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO - 2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	72%
-3.25 TO -4.00 D	4%	13%	16%	64%

For the 110 eyes that completed this study, the initial visual acuity by best refraction was 20/20 or better for 104 eyes and 20/40 or better for all 110 eyes. At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 99 eyes, 20/40 for 109 eyes and one eye had a visual acuity of 20/70. Nine eyes had a one-line drop in visual acuity for contact lenses compared to best refraction, one eye had a two-line drop and three eyes had a three-line drop. In each case the reduced visual acuity was attributed to residual astigmatism when wearing contact lenses.

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) eyes achieved a visual acuity of 20/20 or better and 78 (71 %) eyes achieved 20/40 or better. ✓

*Effects on*  
ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 110 eyes (55 patients) which completed the three month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.

The following changes were noted:

Decrease

- From 0.12 to 1.00D was observed for 36 eyes (32%)
- From 1.12 to 1.50D for 3 eyes (3%)
- No eyes decreased more than 1.50D.

Increase

- From 0.12 to 1.00D was observed for 45 eyes (41%)
- From 1.12 to 2.00D for 15 eyes (14%)
- From 2.12 to 3.00D for 1 eye (1%)
- From 3.12 to 3.50D for 1 eye (1%)
- No eyes increased more than 3.50D

## WEARING TIME

The average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours
Two weeks	7.8 hours
One month	8.0 hours
Three months	8.4 hours

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three month time period as follows:

Daily Wear Time Worn	Percent of patients
0 to 4 hours	25.0%
4.1 to 8 hours	23.7%
8.1 to 12 hours	21.8%
12.1 to 16 hours	27.2%

\*Data based on CONTEX (siflufocin A) 3-month Clinical Study.

## **MYOPIC REDUCTION MAINTENANCE LENS OR RETAINER LENS WEAR**

Studies have shown that the long-term wear of BOSTON XO contact lenses for orthokeratology does not eliminate the need to continue wearing contact lenses in order to maintain the orthokeratology effect. After the cornea has been flattened by wearing BOSTON XO contact lenses for orthokeratology, the patient will need to continue wearing Myopic Reduction Maintenance Lenses or Retainer lenses for a portion of each day. A Retainer lens may be either the last BOSTON XO contact lens for orthokeratology design or a modification of this design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The last pair of lenses in the fitting program is usually used as the first Retainer Lens. If it is found that this lens has a secondary curve that is too tight for the lens to be worn on a long-term basis, a new Retainer Lens is prescribed which has the same base curve but a flatter secondary curve, usually by one or two diopters. The retainer lenses are generally worn for the same daily schedule as the BOSTON XO contact lenses for orthokeratology and must be worn each day to maintain the orthokeratology effect.

One of the most common and effective schedules is to wear the retainer lens for several hours in the morning and a few hours before bedtime. Higher lens powers may require additional wearing time.

It is important to make certain that the retainer lenses center well on the cornea, as the same lens will be worn for a prolonged period. Check the patient's lenses every 3 to 4 months.

### **RISK ANALYSIS**

There is a small risk involved when any contact lens is worn. It is not expected that the BOSTON XO contact lens for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects that occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that the same side effects will also occur in some wearers of BOSTON XO contact lenses for orthokeratology. Other side effects that sometimes occur in all contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper patient control is exercised. Patients should be instructed to remove the contact lenses if any abnormal signs are present. Patients should be instructed never to wear their contact lenses while in

the presence of noxious substances. Patients should be instructed in the importance and necessity of returning for all follow-up visits required by the eye care practitioner.

Studies have not been conducted to support the safety and effectiveness of wearing BOSTON XO contact lenses for orthokeratology for overnight wear.

### **FITTING OF BOSTON XO CONTACT LENSES:**

BOSTON XO contact lenses for orthokeratology may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

1. Prefitting Examination:
  - A. complete refraction and visual health examination should be performed.
  - B. pre-fitting patient history and examination are necessary to:
    - determine whether a patient is a suitable candidate for BOSTON XO contact lenses for orthokeratology.(consider patient hygiene and mental and physical state).
    - collect and record baseline clinical information to which post-fitting examination results can be compared.
2. Initial Lens Power Selection:

Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.
3. Initial Lens Diameter Selection:

Usually, lens diameters between 9.8 mm to 11.5 mm are chosen to maximize centering to the cornea and to minimize lens movement. Lens diameters outside of this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

#### Determining Starting Lens Diameter:

If K is	41.00 and flatter use 10.6 mm diameter
	41.25 to 45.25 use 10.0 mm diameter
	45.50 and steeper use 9.8 mm diameter

Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.)

4. Initial Lens Base Curve Selection:

The base curve of the first lens fitted is generally as flat as the number of diopters as the refractive error plus .75 diopters flatter than the flattest keratometric finding but may vary according to the following table, which takes into account the corneal astigmatism. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

Corneal Astigmatism	9.5	10.0	10.5
0 to .75	2.25 flatter	2.50 flatter	2.75 flatter
1.00 to 1.50	2.00 flatter	2.25 flatter	2.50 flatter
< 1.50	2.00 flatter	2.00 flatter	2.25 flatter

As shown in the above table, the base curve determination is a function of corneal cylinder and lens diameter. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgement of the lens movement and riding position as well as the fluorescein pattern analysis.

5. Initial Lens Evaluation

Movement:

Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm.) and then upward with the lid motion (average 1 mm.) as with a regular RGP contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm).

Positioning:

The lens should position centrally or slightly superiorly to minimize both lens movement and lid sensation. The lens should not ride more than 2 mm below center nor 3 mm above center

Characteristics of a Tight (too steep) Lens:

A lens that is too tight will show reduced movement upon blinking. The lens will be centered or decentered inferiorly and exhibit little or no movement. Bubbles may be detected behind the lens.

Characteristics of a Loose (too flat) Lens:

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

## **TRIAL LENSES:**

### Trial Lens Fitting

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the table given for base curve selection. Trial lenses are essential in fitting patients whose corneal topography has been distorted by previous contact lens wear.

### Dispensable Inventory Set

A dispensable inventory set consists of a series of lenses for any given target power of 10.0 to 10.6 diameter to cover K range of 40.50 to 46.00 in half diopter increments. The power of all lenses is +0.75. Standard sets are available covering -1.50 to -6.00 target powers.

**CAUTION:** Non-sterile lenses, clean and condition lenses prior to use.

Eye care practitioners should educate contact lens technicians concerning proper care of trial lenses. Each contact lens is shipped non-sterile in a case with no solution (dry). Therefore in order to insure disinfection, clean and condition lenses prior to use. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected, following the manufacturer's instruction.

### Trial Lens Procedure

Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

1. **Centering**  
Lens should center as well or better than a regular RGP lens. The lens should be fitted according to the interpalpebral fitting philosophy. Lenses fitted according to the "lid attachment" philosophy, in which the lens purposely rides in a high position should be avoided.

2. Movement

Lens movement should be equivalent to or slightly less than a regular RGP lens, fitted-according to the interpalpebral philosophy.

Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with definite central touch, approximately 3 to 4 mm. diameter with a surrounding area of pooling. In the periphery there should be another area of touch and near the edge a thin band of pooling.

The area of pooling near the transition between the base curve and secondary curve serves as a reservoir for tears and as a potential space for corneal shifting during the flattening process of orthokeratology. The cornea molds by flattening the central cornea, which reduces the space near the transition reservoir. Hence, the size of the transition reservoir, as observed from the fluorescein pattern, is a good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

The fluorescein pattern provides the best method for monitoring the fit of the contact lens over time. As the cornea flattens, the area of pooling at the transition becomes less and less. When this occurs the lens begins to tighten and at some point barely moves on the cornea. The lack of pooling at the transition area indicates that the lens should be changed for another that has a flatter base curve.

When the cornea has flattened enough for the desired reduction of the patient's myopia (even though the fluorescein pattern indicates that further flattening is possible) it is time to switch to a retainer lens. A retainer lens is a contact lens that is designed to maintain the current level of corneal flattening without additional flattening. It is usually made with the same reverse geometry design as the last lens used for corneal flattening but with less steepness for the secondary curve.

### Limits of Flattening

In some cases the corneal flattening stops before a full reduction of the refractive error has been accomplished. Additional flattening may be possible by using a lens with a steeper secondary curve. If no further corneal flattening occurs, it is an indication that the patient should be fitted with a retainer lens.

### **FOLLOW UP CARE:**

- a. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more

- comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which occur that are related to contact lens wear.
  - c. With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement. These are indications that the lens can be exchanged for another of flatter base curve. Usually, a lens with a 0.50 diopters flatter base curve should be the next choice, with variations from this up to the judgment of the eye care practitioner.

A lens with excessive movement should be replaced with another that is 0.2 to 0.5 mm larger in diameter.

If the cornea shows no flattening, assess the lens position, fluorescein pattern and Corneal Topography, if available. Call your Authorized Boston Manufacturer or contact Polymer Technology for assistance.

- d. After the lens removal, conduct a thorough biomicroscopy examination to detect the following:
  1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- e. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

Solutions to various lens wearing problems are given in the following table  
Ortho-K Problem Solving

Fitting too flat may de-center the lens, cause vision problems and increase corneal astigmatism. The most important points to remember are:

1. CENTERING
2. 1-2 mm MOVEMENT
3. MODERATE APICAL TOUCH
4. PATIENT COMFORT

Problem	Possible Cause	Solution
Tight lens or no movement	BC too steep Diameter too large	Flatten BC Reduce diameter
Loose lens	BC too flat Diameter too small	Steeepen BC Increase diameter
High-riding lens	BC too flat Diameter too small High myopia or high amount of corneal astigmatism	Steeepen BC Increase diameter Use looser fits because of extra weight
Low-riding lens	CK & TK may be similar	Use trial lenses to determine better centration
Flare, Glare or Ghosts	BC too flat Poor centration OZD too small	Steeepen BC Increase size Use larger OZD
Instability of Ortho-k changes	Quick, large corneal changes induces quicker & larger regression Rigidity of the cornea	Smaller BC changes Good centration at all times Longer retainer wear Increase center thickness
Fogging and scratchy lens	Dirty lens Improper care & handling of lenses Improper blinking Oily eye make-up removers	See "lens care"
Increase in corneal astigmatism	Lens de-centered Spherical lens being used	Improve centration Smaller BC changes
Poor VA with lenses	De-centered lens; displacement of corneal & visual axis	Improve centration Check over-refraction
Poor VA w/out lenses	Displacement of corneal & visual axis irregular corneal astigmatism	Steeepen BC increase diameter; improve centration

### **RECOMMENDED INITIAL WEARING SCHEDULE:**

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

The following schedule depends upon the professional judgment of the eye care practitioner and should be modified according to the response to the initial lenses.

## Daily Wear

Maximum wearing time:

Day	Wearing Time (Hours)
1	3
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake

## Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

The retainer lens schedule must be customized for each patient. The retainer lens wearing time begins with the same wearing time required for the last fitted BOSTON XO contact lenses for orthokeratology. There is considerable variability, however, as many patients require several hours more or less than the averages.

After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the first retainer lenses, the retainer lens wearing time can be reduced daily by intervals of one hour. This may continue for as long as the patient can see clearly for the remainder of the day following lens removal. When it is found that the patient experiences a visual decrement following lens removal, the previous wearing time is then followed on a constant basis.

### **HANDLING OF LENSES:**

Standard procedures for rigid gas permeable lenses may be used.

**Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.**

### **PATIENT LENS CARE DIRECTIONS:**

Please see package insert and patient information booklet.

### **VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS:**

Standard charts may be used.

**REPORTING OF ADVERSE REACTIONS:**

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

Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450  
800-333-4730

**HOW SUPPLIED:**

Each lens is supplied non-sterile in an individual flat pack case containing one or two lenses. The container is marked with the base curve, distance power, diameter, center thickness, color and lot number.

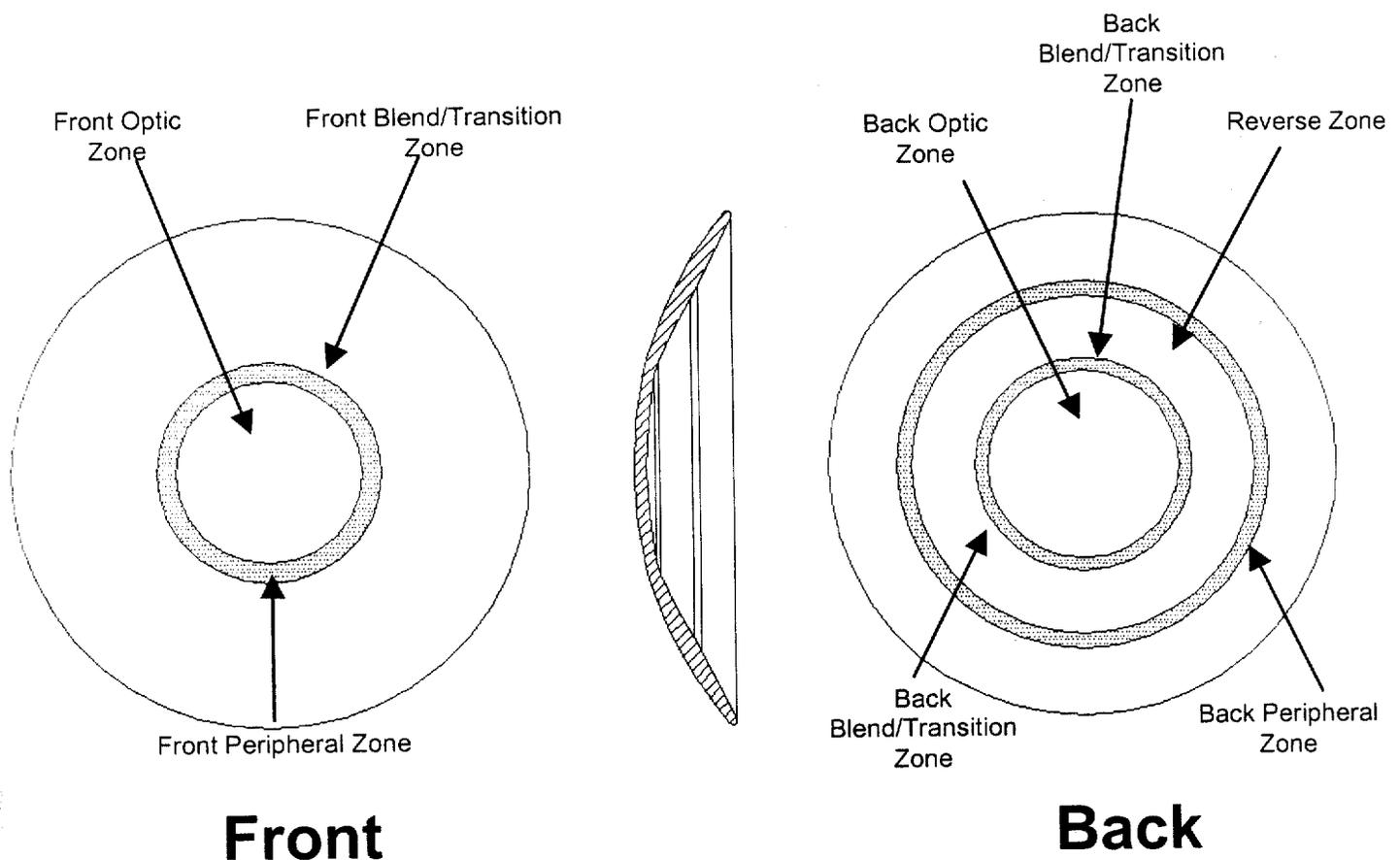
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**BOSTON® XO RGP LENS DESCRIPTION FOR ORTHOKERATOLOGY:**

The BOSTON® XO contact lenses for orthokeratology are commonly referred to as reverse geometry orthokeratology lenses. This means that the reverse zone (secondary zone) on the posterior surface contains curves that are steeper (shorter radius) than those curves in the central optic zone. The function of this reverse zone is to allow the curves in the central zone to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design, that is fitted flat on the cornea, there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and de-center on the cornea. With the BOSTON® XO contact lens there is support for the lens at both the central cornea and in the peripheral zone surrounding the reverse zone. The curves in the peripheral zone are steeper than the central zone but flatter than the reverse zone. This relationship between zones will tend to reduce lens rocking, balance out the pressures and aid in centering.

The front surface design consists of a central optic zone and a peripheral zone.

Each zone on the back and front can be comprised of a multitude of spherical and/or aspherical curves to achieve the desired flattening or steepening in geometry required of individual patients. Additionally, blend/transition zones can be added between the primary zones on the lens to optimize the fit for an individual patient.



Records processed under FOIA Request #2016-1775 Released by CDRH on 8/31/16

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\*\*\* TX REPORT \*\*\*  
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

### CDRH Division of Ophthalmic Devices

9200 Corporate Boulevard  
Rockville, MD 20850  
FAX NO. 301 480-4201  
or 301 827-4601

Date: 8-8-00

Time: \_\_\_\_\_

To: Debra Ketchum

FAX #: 716-338-0702

Organization: Pdymor Technology

From: Eleanor Felton

Department: FDA

Subject: Labeling

No. of Pages: 5  
(Including Cover Sheet)

Comments:

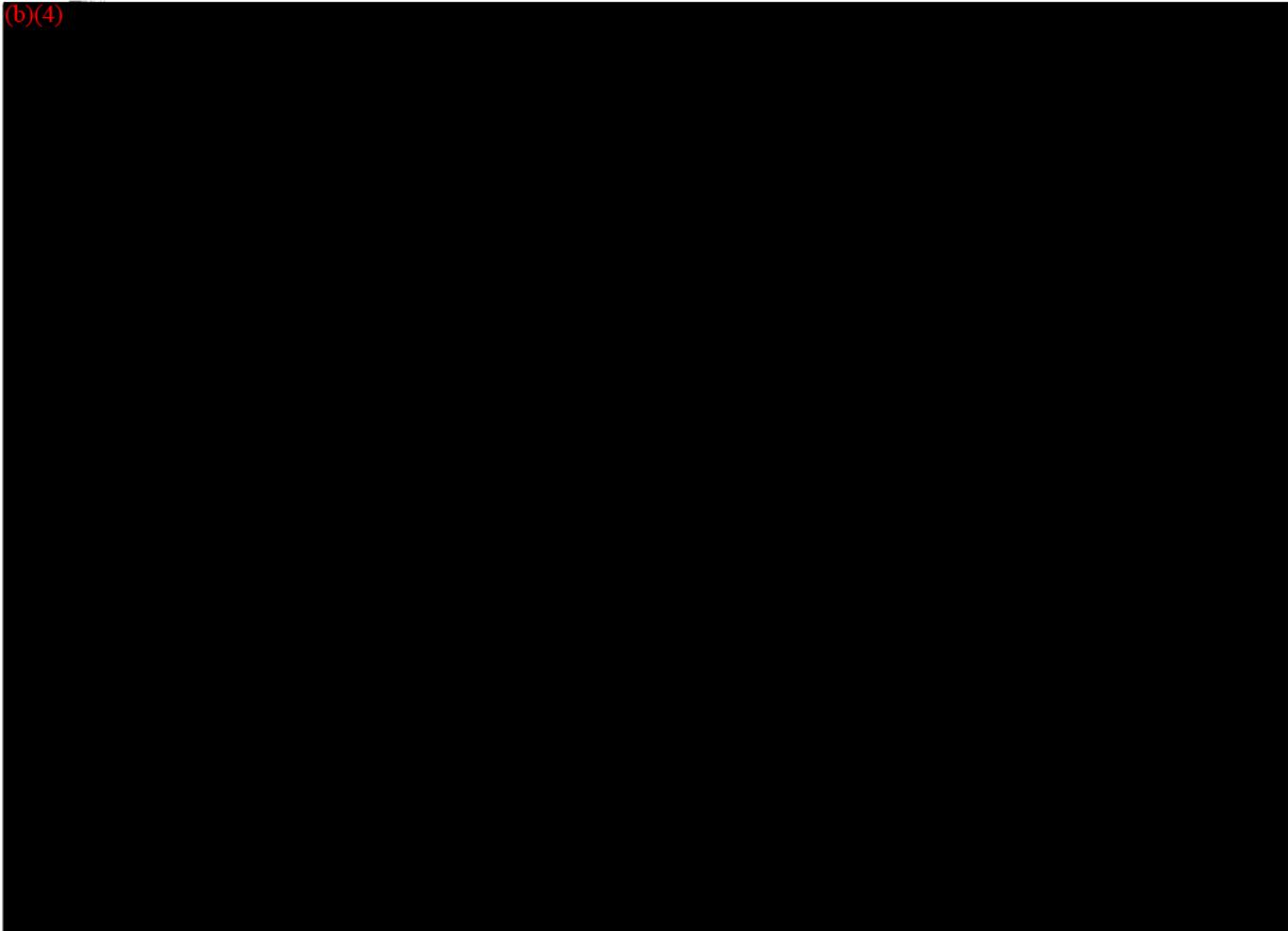
- As Requested       FYI       Read and Destroy
- Response Needed       Signature       Circulate
- For Correction       Investigate       File

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov Or 301-796-8118

73

PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

(b)(4)



EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the (b) eyes (55 patients) which completed the three month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.

WEARING TIME

The average wearing time required for patients who wore CONTEX OK™ (orthokeratology) contact lenses for various time periods was as follows:

One week	7.7 hours
Two weeks	7.8 hours
One month	8.0 hours
Three months	8.4 hours

pg. 12

pg. 24

**PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY  
REDUCTION OF MYOPIA**

INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D. UNDER FULL REDUCTION	FINAL V.A. 20/20 or better	FINAL V.A. 20/40 or better
≤1.00 D	52%	84%	78%	100%
-1.25 to -2.00 D.	36%	55%	74%	96%
-2.25 to -3.00 D.	18%	35%	48%	72%
-3.25 to -4.00 D.	4%	13%	16%	64%

For the patients (110 eyes) that completed the study, the initial visual acuity by best refraction was 20/20 or better for 104 eyes and 20/40 or better for all eyes (110). At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 99 eyes, 20/40 for 109 eyes and one eye had a visual acuity of 20/70. Nine eyes had a one-line drop in visual acuity for contact lenses compared to best refraction, one eye had a two-line drop and three eyes had a three-line drop. In each case the reduced visual acuity was attributed to residual astigmatism when wearing contact lenses.

The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 43 (39%) eyes achieved a visual acuity of 20/20 or better and 78 (71%) eyes achieved 20/40 or better.

#### EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 110 eyes (55 patients) which completed the three month clinical, 8% showed no change in corneal astigmatism, 32% showed a decrease less than one diopter, while 41% showed an increase less than one diopter and 16% showed an increase greater than one diopter.

is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment.

<u>Corneal Astig.</u>	<u>9.5</u>	<u>10.0</u>	<u>10.5</u>
0 to .75	2.25 flatter	2.50 flatter	2.75 flatter
1.00 to 1.50	2.00 flatter	2.25 flatter	2.50 flatter
> 1.50	2.00 flatter	2.00 flatter	2.25 flatter

As shown in the above table, the base curve determination is a function of corneal cylinder and lens diameter. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment of the lens movement and riding position as well as the fluorescein pattern analysis.

### 5. Initial Lens Evaluation

#### Movement:

Blink induced lens movement should show downward lens movement with the lid motion (average 3 mm.) and then upward with the lid motion (average 3 mm.) as with a regular RGP contact lens. During the interblink period the lens should have little or no motion (average less than one millimeter).

#### Positioning:

The lens should position centrally or slightly superiorly to minimize both lens movement and lid sensation. The lens should not ride more than 2 mm. below center nor 3 mm. above center.

#### Characteristics of a Tight (too steep) Lens

A lens that is too tight will show reduced movement upon blinking. The lens will be centered or decentered inferiorly and exhibit little or no movement. Bubbles may be detected behind the lens.

#### Characteristics of a Loose (too flat) Lens

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

The following changes were noted:

**Decrease**

- from 0.12 to 1.00D was observed for 36 eyes (32%)
- from 1.12 to 1.50D for 3 eyes (3%)
- No eyes decreased more than 1.50 D.

**Increase**

- from 0.12 to 1.00D was observed for 45 eyes (41%)
- from 1.12 to 2.00D for 15 eyes (14%)
- from 2.12 to 3.00D for 1 eye (1%)
- from 3.12 to 3.50D for 1 eye (1%)
- No eyes increased more than 3.50D

**WEARING TIME**

The average wearing time required for patients who wore CONTEX OK™ (orthokeratology) contact lenses for various time periods was as follows:

One week	7.7 hours
Two weeks	7.8 hours
One month	8.0 hours
Three months	8.4 hours

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three-month time period as follows:

Time Worn	Percent of patients		
0 to 4 hours	25.5%	4.1 to 8 hours	21.8%
8.1 to 12 hours	23.7%	12.1 to 16 hours	27.2%

**RETAINER LENS WEAR**

Studies have shown that the long-term wear of CONTEX OK™ (orthokeratology) contact lenses does not eliminate the need to continue wearing contact lenses in order to maintain the orthokeratology effect. After the cornea has been flattened by wearing CONTEX OK™ (orthokeratology) contact lenses, the patient will need to continue wearing Retainer lenses for a portion of each day. A Retainer lens may be either the last CONTEX OK™ (orthokeratology) contact lens design or a modification of this design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The last pair of lenses in the fitting program is usually used as the first Retainer Lens. If it is found that this lens has

## Ortho-K Problem Solving \_\_\_\_\_

Fitting too flat may de-center the lens, cause vision problems and increase corneal astigmatism. The most important points to remember are:

1. CENTERING
2. 1-2 mm MOVEMENT
3. MODERATE APICAL TOUCH
4. PATIENT COMFORT

Problem	Possible Cause	Solution
Tight lens or no movement	BC too steep diameter too large	flatten BC reduce diameter
Loose lens	BC too flat diameter too small	steepen BC increase diameter
High-riding lens	BC too flat diameter too small high myope high amount of corneal astigmatism	steepen BC increase diameter use OK-5/P (OK-5/P fits looser because of extra weight)
Low-riding lens	CK & TK may be similar	use OK trial lenses to determine better centration
Flare, Glare or Ghosts	BC too flat poor centration OZD too small	steepen BC increase size use OK-6 (larger OZD)
Instability of Ortho-k changes	quick, large corneal changes induces quicker & larger regression rigidity of the cornea	smaller BC changes good centration at all times longer retainer wear increase center thickness
Fogging and scratchy lens	dirty lens improper care & handling of lenses improper blinking oily eye make-up removers	see "Lens Care"
increase in corneal astigmatism	lens de-centered spherical lens being used? starting corneal cyl >3 D	improve centration use OK design lenses smaller BC changes
Poor VA with lenses	de-centered lens; displacement of corneal & visual axis	improve centration check over-refraction
Poor VA w/out lenses	displacement of corneal & visual axis irregular corneal astigmatism	steepen BC; increase diameter; improve centration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

July 27, 2000

POLYMER TECHNOLOGY  
GLOBAL VISION CARE  
1400 N GOODMAN STREET  
ROCHESTER, NY 14692  
ATTN: DEBRA L.B. KETCHUM

510(k) Number: K001960  
Product: RIGID GAS  
PERMEABLE  
CONTACT LENS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

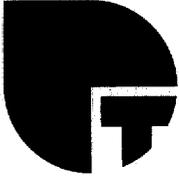
Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K001960/51

**POLYMER TECHNOLOGY**

1400 N. GOODMAN STREET • P.O. BOX 450 • ROCHESTER, NEW YORK 14603-0450



July 26, 2000

Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Center for Devices & Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

RE: 510(k) Premarket Notification  
K001960  
BOSTON XO (hexafocon A) RGP  
Contact Lens for Orthokeratology

SK-29

RECEIVED  
27 JUN 00 13 56  
FDA/CDRH/ODE/DMS

Attn: Eleanor Felton, HFZ-460

Dear Ms. Felton:

This is in response to questions raised regarding 510(k), K001960; Boston XO (hexafocon A) RGP Contact Lens for Orthokeratology received by facsimile on July 12, 2000.

**Question #1:**

The applicant stated that the color additives conform to 21 CFR 74.3206. The applicant has not identified the name(s) of the color additives used. 21 CFR 74.3206 is the listing number for D&C Green No. 6. The proposed labeling for the subject device mentions D&C Green No. 6 and D&C Violet #2. The applicant should name the color additives in the Summary of Safety and Effectiveness and ALL appropriate listings.

**Response #1:**

The color additives, D&C Green No. 6 and D&C Violet #2 and appropriate CFR references have been named in the Summary of Safety and Effectiveness. A revised Summary of Safety and Effectiveness can be found in Appendix A.

**Question #2:**

The applicant has provided only a fitting guide as proposed labeling for this device. The applicant should provide the appropriate fitting guide, provide the two patient information booklets, the package insert, and the shipping label. This labeling should also include data to show the expected amount of myopic reduction to be expected with this lens. A copy of the orthokeratology prototype is available on the website.

**Response #2:**

The proposed fitting guide, patient information booklets (2), package insert and shipping label have been submitted in accordance with the Guidance for



Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses Guidance Document issued April 10, 2000. As required in the guidance document, clinical data to show the expected amount of myopic reduction has been included. The clinical data provided was extracted from the Summary of Safety and Effectiveness in 510(k) K973697 cleared on April 8, 1998. A letter of authorization from the 510(k) holder can be found in Appendix B. The revised labeling can be found in Appendix C.

**Question #3:**

The applicant has included inappropriate labeling for the CONTEX-OK lenses in this document. The comparative labeling is for overnight wear of lenses not currently approved for commercial distribution.

**Response #3:**

Labeling for CONTEX-OK Daily Wear Orthokeratology program has not been provided. The inappropriate labeling for the CONTEX-OK lenses should be disregarded.

**Question #4:**

The document contains a letter (page 48) that does not relate to the subject device. Why is it here?

**Response #4:**

The above letter (page 48) was inadvertently submitted. This letter should be removed.

**Question #5:**

The Indications for Use in the Indication for Use Statement should be the same as that in the proposed labeling.

**Response #5:**

The Indications for Use in the revised proposed labeling, Appendix B, has been corrected to be consistent with the Indications for Use Statement.

The information marked as confidential and contained in the body of the submission is considered to be confidential within the meaning as set forth in 21 CFR Part 20.

Should you have any questions, please do not hesitate to telephone my office at (716) 338-8638.

Sincerely,

Debra L.B. Ketchum  
Manager, Regulatory Affairs

Enclosures

## CONTENTS

Revised Summary of Safety and Effectiveness	Appendix A, pages 1-2
Letter of Authorization	Appendix B, page 3
Revised Labeling	
Shipping Container Label	Appendix C, pages 4
Package Insert	Appendix C, pages 5 - 16
Patient Information Booklet (Part 1) for Potential Users	Appendix C, pages 17 - 27
Patient Information Booklet (Part 2) After Your Boston XO RGP Contact Lenses for Orthokeratology Have Been Fitted	Appendix C, pages 28 - 38
Profession Fitting and Information Guide for Boston XO RGP Contact Lenses for Orthokeratology	Appendix C, pages 39 - 55

RECEIVED  
21 JUN 00 13 56  
FDA/CDRH/OCE/DMD

**510(k) Premarket Notification**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**FOR**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

**1. SUBMITTER INFORMATION:**

Polymer Technology  
Global Vision Care  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**2. CONTACT PERSON:**

	Debra L.B. Ketchum
	Manager, Regulatory Affairs
Address:	1400 North Goodman Street
	P.O. Box 30450
	Rochester, New York 14603-0450
Telephone No.:	(716) 338-8638
Fax No.:	(716) 338-0702
E-mail Address:	dketchum@bausch.com

**3. DEVICE IDENTIFICATION:**

Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens

Proprietary Name: BOSTON XO (hexafocon A) Contact Lens  
for Orthokeratology

Common Name: Fluoro silicone acrylate rigid gas permeable contact lens  
material

**4. PREDICATE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

**510(k) Premarket Notification**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**5. DESCRIPTION OF THE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206 (green) and 21 CFR Part 74.1602 (violet). The hexafocon A material has an oxygen permeability (Dk) of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN)

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is hexafocon A, is a fluoro silicone acrylate material.

**6. INDICATIONS FOR USE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens must be disinfected using a chemical disinfection system only.

**7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:**

The safety and efficacy of *BOSTON XO (hexafocon A) Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K000795, cleared on May 26, 2000. Also, the use of a rigid gas permeable contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology 510(k) Premarket Notification No. K973697, cleared on April 8, 1998.

**8. SUBSTANTIAL EQUIVALENCE**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

July 25, 2000

Polymer Technology  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**RE: CONTEX (silflucocon A) Rigid Gas Permeable (orthokeratology)  
Contact Lens  
510(k) K973697**

To Whom It May Concern:

We are herewith authorizing Polymer Technology to refer to the above referenced 510(k) Premarket Approval Notification in support of the following applicant's submission:

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology  
510(k) Premarket Notification - K001960**

Sincerely,

  
Nick Stoyan  
President  
Contex, Inc.

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## SHIPPING CONTAINER LABEL

BOSTON XO (hexafocon A) RIGID GAS PERMEABLE CONTACT LENS FOR  
ORTHOKERATOLOGY - Daily Wear

CONTENTS: One/Two contact lens(es)

CAUTION: Non-sterile. Clean and condition lenses prior to use.

Base Curve:	6.50 to 11.00 mm
Diameter:	Approx. 6.5 to 11.5 mm
Power:	-10.00 to +3.00 Diopters
Secondary Curve:	0.10 to 2.00 mm Flatter or Steeper than Base Curve
Color:	Blue, Ice Blue, Green and Violet
Center Thickness:	For Low Minus Lens: 0.10 to 0.30 mm For Plus Lens: 0.20 to 0.70 mm

Lot Number:

CAUTION: Federal law prohibits dispensing without a prescription.

Polymer Technology  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

## **PACKAGE INSERT**

**BOSTON XO (hexafocon A) RIGID GAS  
PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY - 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.

**CAUTION:** Federal Law Prohibits Dispensing Without a Prescription.

### **DESCRIPTION:**

BOSTON XO Rigid Gas Permeable (RGP) contact lenses for daily wear orthokeratology are lathe cut contact lenses with spherical or aspherical]anterior or posterior surfaces in tinted version. The posterior curve is selected so as to property fit an individual eye for orthokeratology and the anterior curve selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

BOSTON XO contact lenses for orthokeratology are made from a fluoro silicone acrylate polymer, hexafocon A, with a water content of less than 1% percent. The tinted lens contains D&C Green #6 for blue, ice blue and green lenses and D&C Violet #2 as color additive for violet lenses. BOSTON XO contact lenses for orthokeratology are to be worn for daily wear only.

### **LENS PARAMETERS AVAILABLE:**

Chord Diameter	Approx 6.5 to 11.5
Center Thickness for Low Minus Lens:	0.10 to 0.30 mm
for Plus Lens:	0.20 to 0.70 mm
Base Curve	6.5 to 11.0 mm
Secondary Curves	0.10 to 2.00 mm
Flatter or steeper than Base Curve	
Peripheral Curves	0.10 to 2.0 mm
Flatter or steeper than Base Curve	
Powers	-10.00 to +3.00 Dioptors

Aspheric Lens Eccentricity  
(Oblate, Prolate or Tangent Conic)

*Value?*

The physical properties of the lens are:

Refractive Index	1.415
Light Transmittance	92%
Wetting Angle	49°
(Contact Receding Angle)	
Specific Gravity	1.27
Hardness	112
(Rockwell)	
Water Content	<1 %
Oxygen Permeability	140* (100**)
* gas to gas method	
** polarographic method (ISO/Fatt)	

**ACTIONS:**

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular contact lenses are designed to cause little or no effect but BOSTON XO contact lenses for orthokeratology are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the central cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day.

A Myopic Reduction Maintenance Lens or Retainer Lens should be worn each day to maintain the corneal flattening, or the myopia will revert back to the pretreatment level.

**INDICATIONS (USES):**

The BOSTON XO (hexafocon A) RGP Contact Lens for orthokeratology is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

*Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wear schedule.*

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**CONTRAINDICATIONS (REASONS NOT TO USE):**

DO NOT USE YOUR BOSTON XO contact lenses when any of the following conditions exist:

- Acute and subacute inflammations or infection of the anterior segment 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).
- 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, such as mercury or Thimerosal, in a solution which is to be used to care for your contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

**WARNINGS:**

Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential to follow your eye care practitioner's directions and all labeling instructions for proper use of contact lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove your lenses and do not wear them until you have been examined by your eye care practitioner. All contact lens wearers should see their eye care practitioner according to the schedule given to them.

BOSTON XO contact lenses for orthokeratology are to be worn on a daily wear basis only. Do not wear your lenses while sleeping, at the risk of serious adverse reactions.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

## **PRECAUTIONS:**

### **Specific Precautions**

- Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO (hexafocon A) rigid gas permeable lens materials 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 materials. Consequently, when selecting an appropriate lens design and parameter the eye care practitioner should consider all factors that effect lens performance and ocular health. The potential impact of these factors should 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.
- Patients should be instructed to follow the instructions below in order to prevent damage to their eyes or lenses.

### **Solution 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 contact 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 BOSTON XO 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).

*sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.*

## **Handling Precautions**

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses, as microscopic scratches of 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 information booklet and those prescribed by your eye care practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

## **Lens Wearing Precautions**

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the patient information booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

### **Lens Case Precautions**

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

### **Topics to Discuss with the Eye care Practitioner**

- ✓ Ask your eye care practitioner about wearing your lenses during sporting activities.
- Always contact your eye care practitioner before using any medicine in your eyes.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

### **Who Should Know That the Patient is Wearing Contact Lenses**

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.

**ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO):** Patient's 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 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)
- If you notice any of the above: **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 objects on it, or the problem stops and the lens appears undamaged, you should

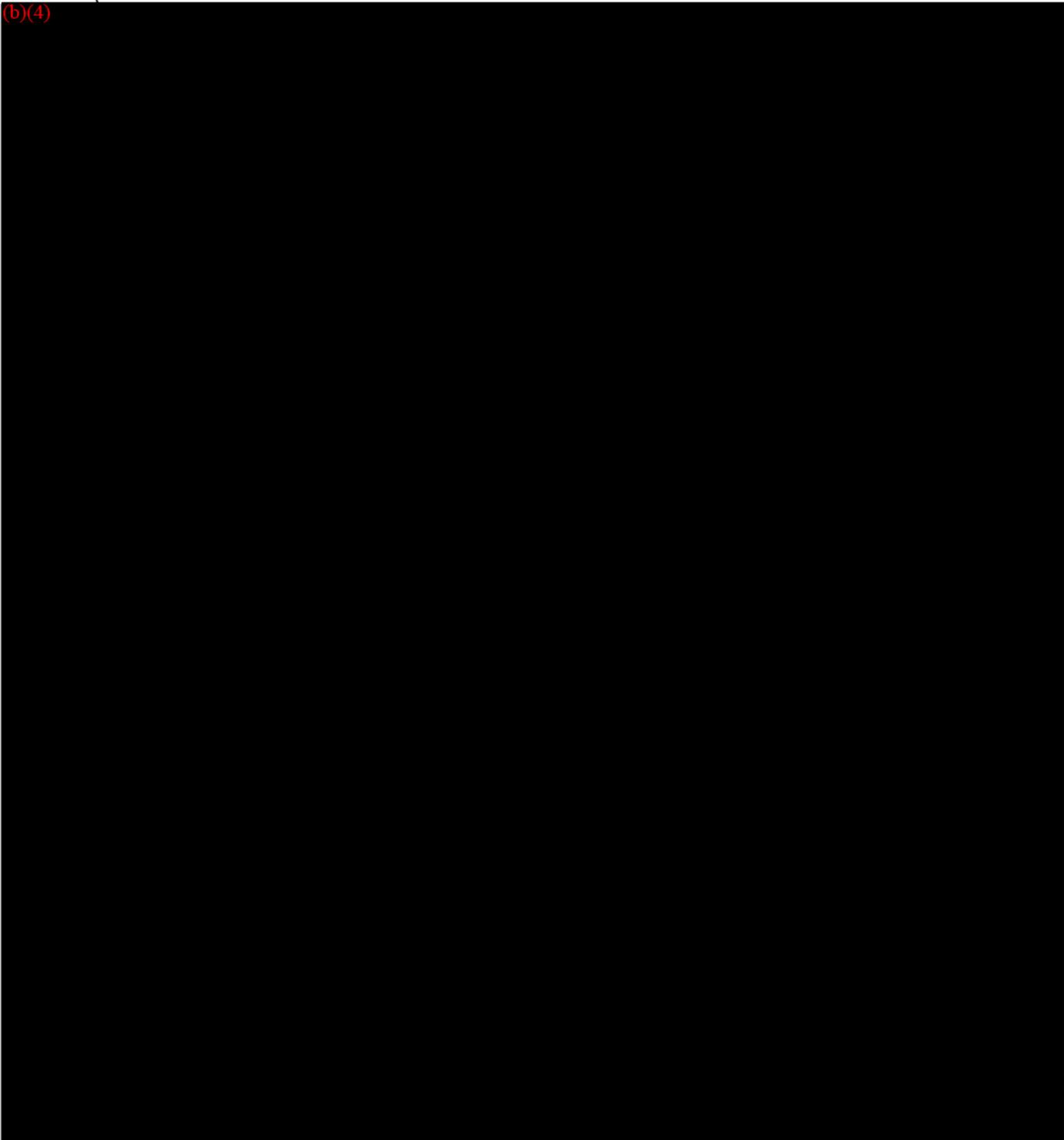
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thoroughly clean, rinse and disinfect the lens; then reinsert it. If the problem continues, you should IMMEDIATELY remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You 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.

CLINICAL STUDY RESULTS:

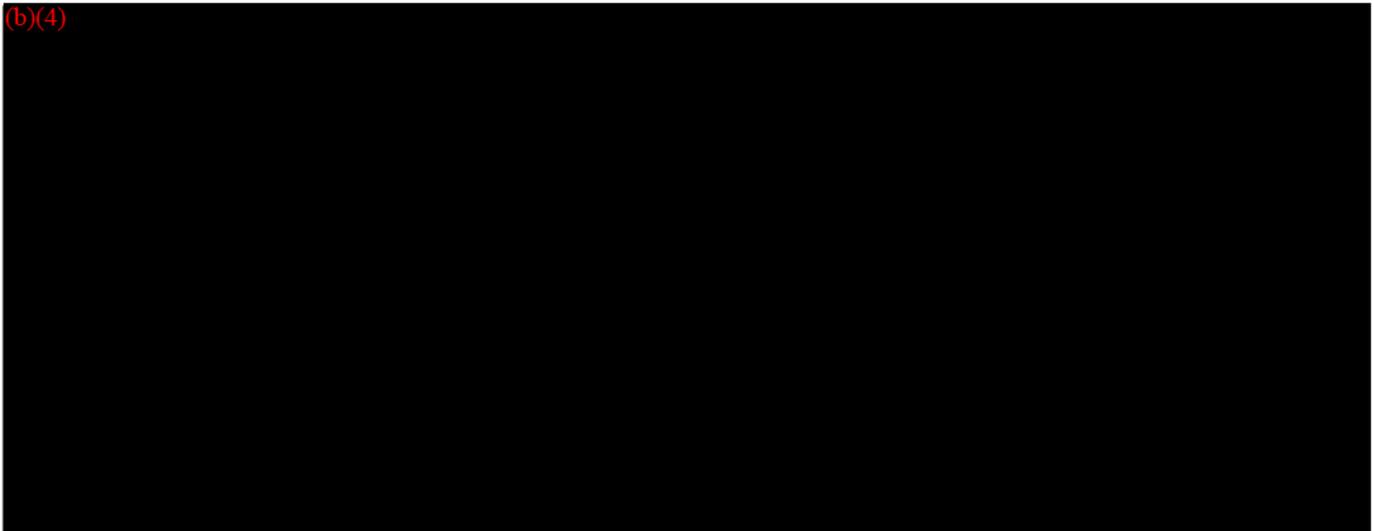
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**PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL  
TEMPORARY REDUCTION OF MYOPIA**

INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO - 2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	72%
-3.25 TO -4.00 D	4%	13%	16%	64%

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**WEARING TIME**

The average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours/day
Two weeks	7.8 hours/day
One month	8.0 hours/day
Three months	8.4 hours/day

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three month time period as follows:

Daily Wear Time Worn	Percent of patients
0 to 4 hours	25.5%
4.1 to 8 hours	21.8%

8.1 to 12 hours 23.7%  
12.1 to 16 hours 27.2%

\*Data based on CONTEX (siflufocon A) 3-month Clinical Study (submitted in 510(k) #K973697, cleared on April 8, 1998.) ?

**FITTING:**

Conventional methods of fitting rigid contact lenses for orthokeratology DO NOT APPLY to the BOSTON XO contact lenses for orthokeratology. For a description of fitting techniques, refer to the Fitting Guide for BOSTON XO contact lenses for orthokeratology, copies of which are available from:

Polymer Technology  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**WEARING SCHEDULE:**

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to follow the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

The following schedule depends upon the professional judgment of the eye care practitioner and should be modified according to the response to the initial lenses.

Daily Wear

Maximum wearing time:

Day	Wearing Time (Hours)
1	3
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake

25

Patients should be advised NOT TO SLEEP while wearing BOSTON XO contact lenses for orthokeratology. Studies have not been conducted to show that the BOSTON XO rigid gas permeable contact lens is safe to wear during sleep. There is a tendency for some patients to overwear the lenses initially. It is important to remind patients to adhere to the maximum wearing schedule above. In order to maintain the orthokeratology effect of myopia reduction lens wear should be continued on a wearing schedule determined by the eye care practitioner. Refer to the Professional Fitting and Information Guide for information on Myopic Reduction Maintenance Lens or Retainer Lens wear.

**LENS CARE DIRECTIONS:**

Patient should be advised to follow the directions contained in the package insert for the Adjunct Solutions. The Adjunct Solutions which were used with BOSTON XO contact lenses for orthokeratology are as follows:

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

BOSTON, BOSTON XO, BOSTON Advance and BOSTON Simplicity are registered trademarks of Polymer Technology.

The directions from the package inserts from these products should be followed. Failure to adhere to these procedures may result in the development of serious ocular complications. 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.

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

BOSTON XO contact lenses for orthokeratology must be both cleaned, rinsed 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 <sup>the same lens</sup> 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 disinfection solution as recommended by your eye care practitioner.

Tightly close the top of each chamber of the lens storage case.

To disinfect your lenses, leave them in the solution for at least the period of time indicated on the product label. Leave the lenses in the unopened storage case until you are ready to put them in your eye.

#### **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 lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the eye care practitioner.

#### **ENZYME CLEANING:**

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning does not replace routine cleaning and disinfecting. You should carefully follow the instructions in the enzymatic cleaning labeling.

#### **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.

CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

#### **HOW SUPPLIED:**

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, dioptic power, diameter, secondary curve, center thickness, color and Lot #.

**REPORTING OF ADVERSE REACTIONS:**

All adverse reactions should be reported immediately to the manufacturer. Telephone 800-333-4730.

7/00

Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**PATIENT INFORMATION BOOKLET (PART 1) FOR POTENTIAL  
USERS:**

BOSTON XO (hexafocon A)  
RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY for  
Daily Wear

**CAUTION:** Federal law prohibits dispensing without a prescription.

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Maintaining Effects of BOSTON XO Contact Lens for Orthokeratology Myopic  
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## **GLOSSARY**

**Adnexa:** Tissues near the eye.

**Adverse effects:** Undesirable effects.

**Aphakia:** Eye that does not have a lens structure.

**Astigmatism:** Eye condition in which one or more surfaces of the cornea or lens has a shape that is not round but more like that of a spoon.

**Contact Lens Sticking:** Lack of movement of a contact lens on the cornea.

**Cornea:** The clear, bubble-like structure on the front of the eye, where light first enters the eye.

**Corneal abrasion:** Loss of cells on the corneal surface due to mechanical trauma.

**Corneal edema:** Accumulation of fluid in the cornea.

**Corneal hypoesthesia:** Partial loss of sensitivity to touch in the cornea.

**Corneal staining:** Bright areas on the cornea where dye collects and which indicates an abrasion or other disturbance of the cornea.

**Corneal ulcer:** small area of tissue loss in the cornea.

**Disinfection:** Destruction of bacteria and viruses but not some spores.

**Diopter:** Unit of power for glasses or contact lenses.

**Enzyming contact lenses:** Placing contact lenses in a solution that contains an enzyme that dissolves proteins on the surface of the lens.

**Hypoesthesia:** Reduced corneal sensitivity to touch.

**Iritis:** Infection of the iris or colored portion of the eye.

**Lacrimal secretion:** Tearing.

**Myopia:** Medical term for nearsightedness.

**Myopic Reduction Maintenance Lens:** A modification of the orthokeratology contact lens design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening.

**Neovascularization:** New vessel growth in the cornea.

**Orthokeratology:** Contact lens fitting procedure that temporarily reduces nearsightedness after contact lenses have been removed.

**Refract:** Bending of light in order to make it focus.

**Refractive anomalies:** Eye conditions leading to blurred vision including nearsightedness, farsightedness and astigmatism.

**Retainer Lenses:** Another name for the Myopic Reduction Maintenance Lens.

**Retina:** Structure at the back of the eye that receives the light image.

**Rewetting contact lenses:** Placing a solution in the eye while contact lenses are worn that acts as an artificial tear to wet the lens.

**Sticking lens:** Lens on the cornea that does not move.

## **INTRODUCTION**

The information in this booklet is to help you decide whether or not to be fitted with the BOSTON XO contact lenses for orthokeratology. Orthokeratology is a contact lens fitting procedure that temporarily reduces nearsightedness (known by the medical name of myopia) after contact lenses have been removed. By temporary it is meant that the contact lenses are worn for a portion of the day and then removed, whereupon the nearsightedness remains reduced for all or part of the remainder of the day. The exact time period over which the myopia remains reduced varies with each patient. Generally, BOSTON XO contact lenses for orthokeratology should be worn for part of each day for the orthokeratology effect to continue.

## **HOW THE EYE FUNCTIONS**

The eye is very much like a camera and must be in good focus to see objects clearly. The focusing power of the eye comes from two eye structures, the cornea and the lens [(Figure 1)]. The cornea is the clear, bubble-like structure on the front of the eye, where light first enters the eye. It provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. In a normal eye light focuses at the retina, at the back of the eye, which acts like the film in a camera. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred, producing myopia [(Figure 2)].

Myopia usually starts in childhood and gets progressively worse through adolescence. It normally stops increasing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

## **HOW BOSTON XO CONTACT LENSES FOR ORTHOKERATOLOGY FUNCTION**

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of nearsightedness by changing the shape (flattening) of the cornea, which is elastic in nature. Contact lenses rest directly on the cornea, separated only by a layer of tears, and can influence the corneal shape. Regular contact lenses are designed to nearly match the shape of the cornea and thereby cause little or no flattening effect but BOSTON XO contact lenses for orthokeratology are designed to purposely not match the shape of the cornea but instead apply slight pressure to the center of the cornea [(Figure 3)], in a design known as reverse geometry. Pressure is produced when the lens is less curved than the cornea, which places more of the lens weight on the center of the cornea. If the cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia [(Figure 4)]. After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day.

Figure 1: Normal Eye

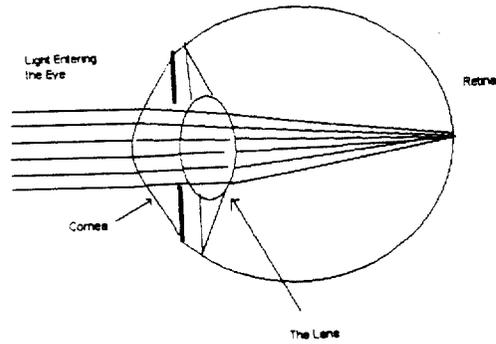


Figure 2: Nearsighted eye

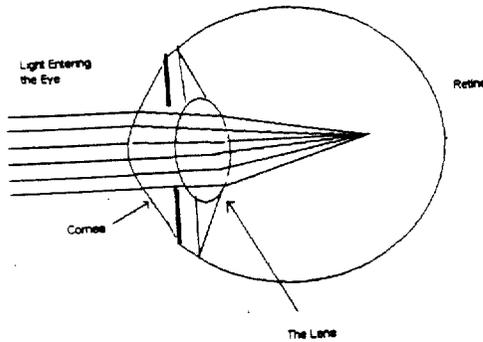


Figure 3: Eye Fitted With BOSTON XO contact lenses for orthokeratology.

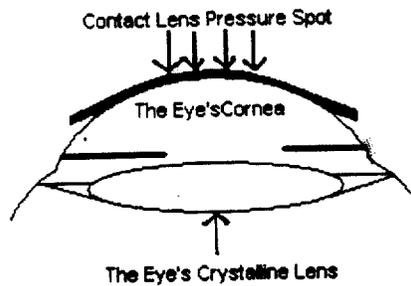
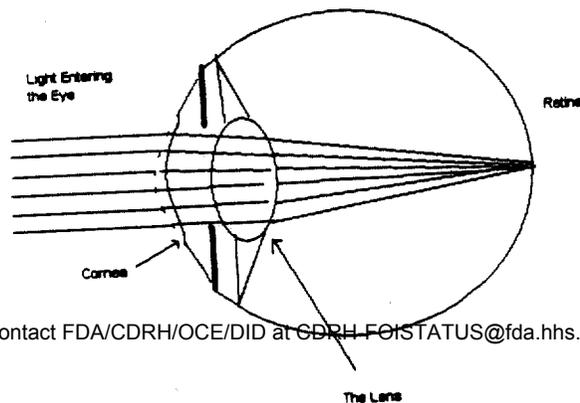


Figure 4: Nearsighted Eye After Orthokeratology



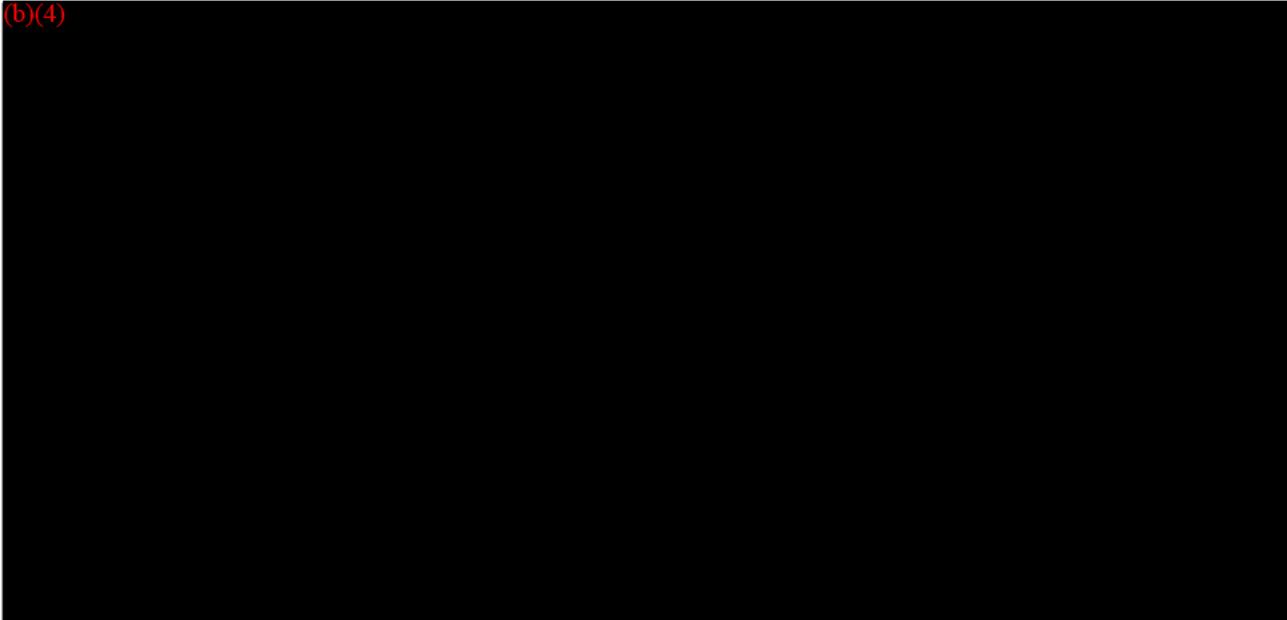
BOSTON XO contact lenses for orthokeratology are indicated for patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still be able to see clearly. This might include such activities as swimming and other sports. BOSTON XO contact lenses for orthokeratology may be indicated in occupations that require exposure to smoke, noxious gases or conditions of low humidity, such as might occur, for example, for flight attendants, in which case their contact lenses can be removed without interference with vision. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

### **ALTERNATIVE WAYS TO CORRECT NEARSIGHTEDNESS**

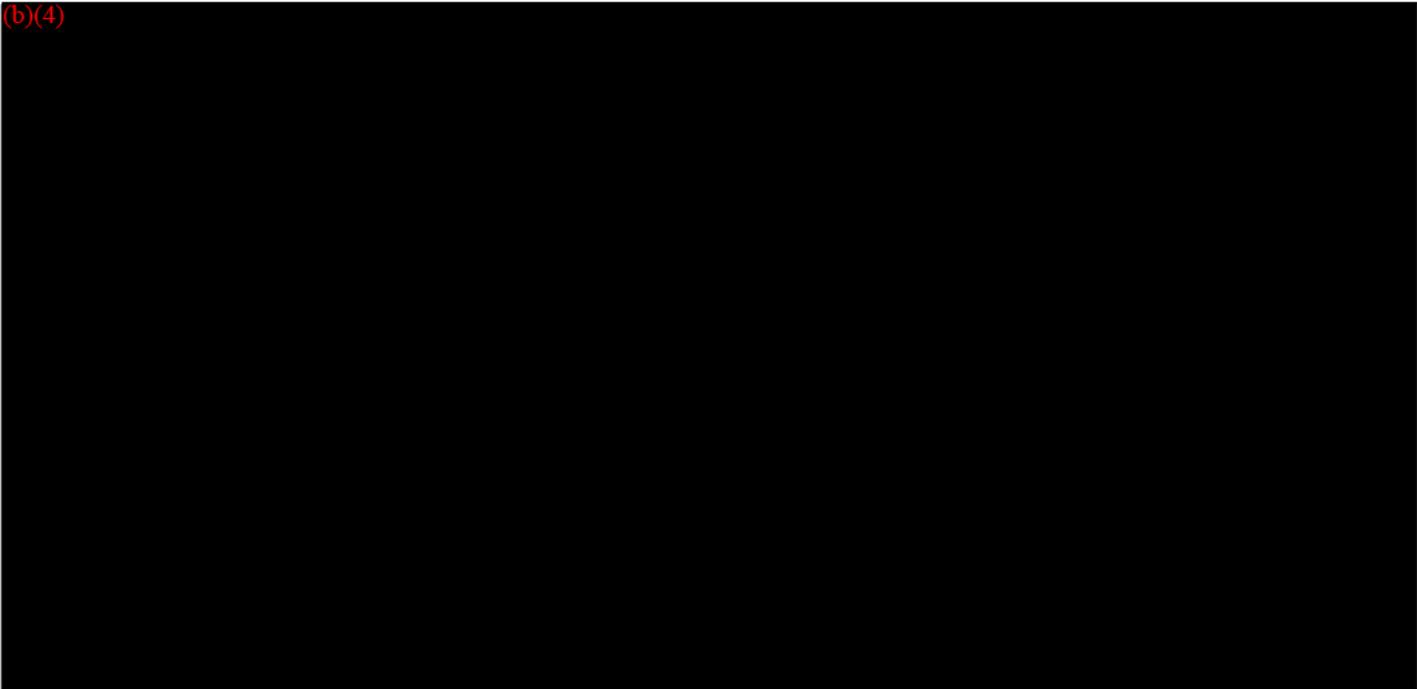
Nearsightedness (myopia) can be corrected by any method that reduces the focusing power of the eye. The most common methods of reduction are by glasses or regular contact lenses. These represent a means of correcting myopia only during the time that the glasses or regular contact lenses are worn, with no lasting effect on the myopia. Other methods of correcting myopia involve various surgical procedures. These involve techniques to reshape the cornea so that it is flattened in a way that is similar to that produced by BOSTON XO contact lenses for orthokeratology, except that the surgical procedures are permanent.

### **CLINICAL STUDY DATA**

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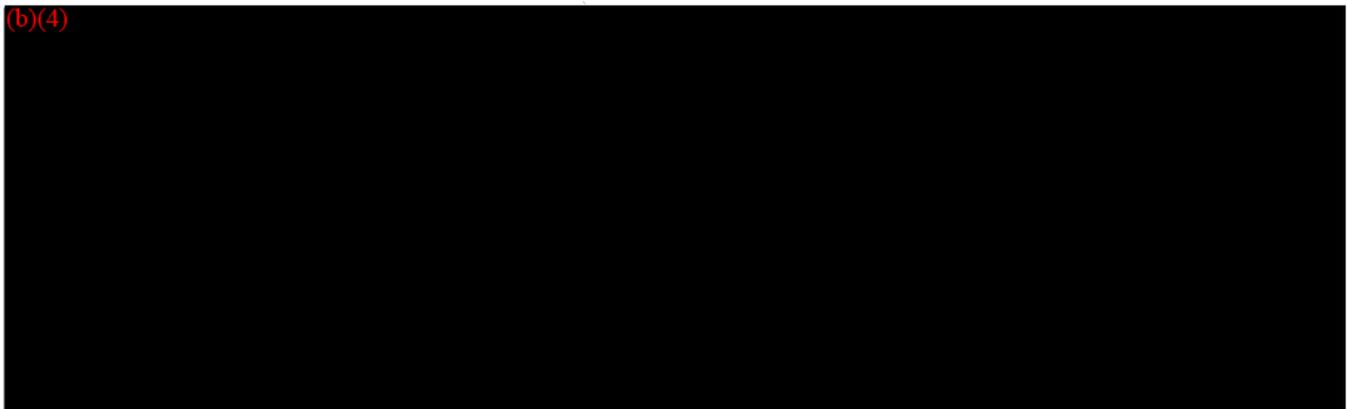


AVERAGE REDUCTION IN MYOPIA (Diopters)



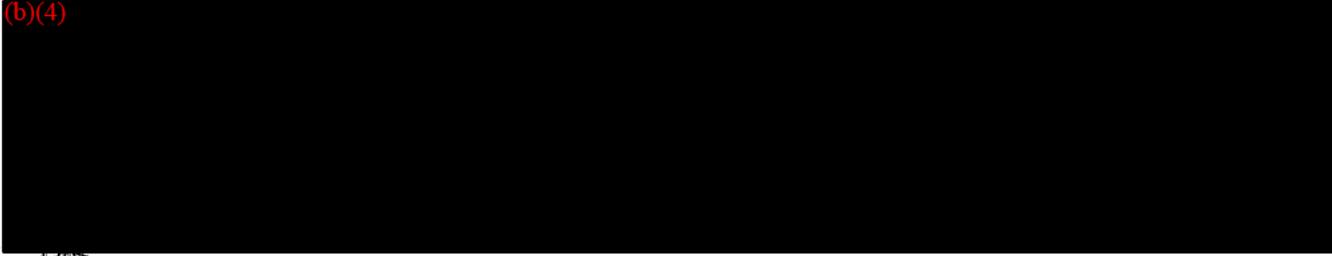
PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO - 2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	72%
-3.25 TO -4.00 D	4%	13%	16%	64%



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WEARING TIME

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## **MAINTAINING EFFECTS OF BOSTON XO CONTACT LENSES FOR ORTHOKERATOLOGY -MYOPIC REDUCTION MAINTENANCE LENS OR RETAINER LENS WEAR**

The long-term wear of BOSTON XO contact lenses for orthokeratology does not eliminate the need to continue wearing contact lenses to produce the orthokeratology effect. After the cornea has been flattened by wearing BOSTON XO contact lenses for orthokeratology, new lenses are prescribed that are Myopic Reduction Maintenance Lenses or Retainer Lenses. Retainer Lenses are a modification of the patient's BOSTON XO contact lens for orthokeratology design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The retainer lenses are generally worn for the same schedule as the BOSTON XO contact lenses for orthokeratology and should be worn each day to maintain the orthokeratology effect.

Studies have not been conducted to support the safety of wearing BOSTON XO contact lenses for orthokeratology for overnight or extended wear.

### **RISK ANALYSIS**

There is a small risk involved when any contact lens is worn. It is not expected that BOSTON XO contact lenses for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

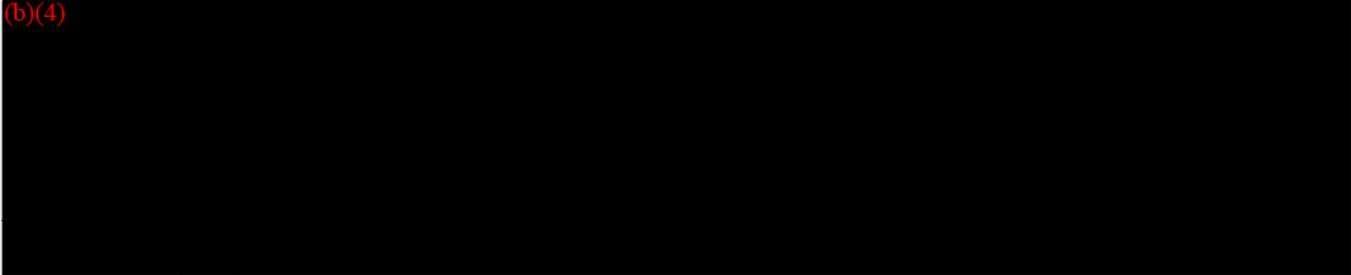
The two most common side effects which occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of BOSTON XO contact lenses for orthokeratology. Other side effects which sometimes occur in all contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper schedule of care is followed. You should remove your contact lenses if any abnormal signs are present. Never wear your contact lenses while in the presence of noxious substances. Be certain to return for all follow-up visits required by your eye care practitioner.

## WEARING RESTRICTIONS AND INDICATIONS

### INDICATIONS

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### CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE YOUR BOSTON XO contact lenses for orthokeratology when any of the following conditions exist:

- Acute and subacute 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, such as mercury or Thimerosal, in a solution which is to be used to care for your BOSTON XO contact lenses for orthokeratology.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated

### WARNINGS:

You should be advised of the following warnings pertaining to contact lens wear:

**Daily wear lenses are NOT indicated for overnight wear, and you should not wear lenses while sleeping.** Clinical studies have shown that the risk of serious adverse reactions such as corneal infection or ulcers is increased when contact lenses are worn overnight.

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 direction 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.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye you should immediately remove your lenses and promptly contact your eye care practitioner.

## **PATIENT INSTRUCTIONS (PART 2) AFTER YOUR BOSTON XO (hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY HAVE BEEN FITTED**

**CAUTION:** Federal law prohibits dispensing without a prescription.

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    Handling The Lenses

    Placing The Lens On The Eye

    Centering The Lens

    Removing The Lens

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    Lens Deposits And Use Of Enzymatic Cleaning Procedures

    Care For A Sticking (Nonmoving) Lens

    Emergencies

    Wearing and Appointment Schedules

## **PRECAUTIONS:**

### **Specific Precautions**

Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO (hexafocon A) rigid gas permeable lens materials 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 materials. Consequently, when selecting an appropriate lens design and parameter the eye care practitioner should consider all factors that effect lens performance and ocular health. The potential impact of these factors should 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.

Patients should be instructed to follow the instructions below in order to prevent damage to their eyes or lenses.

### **Solution 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 contact 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 BOSTON XO 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).

• *sterile unexpired solutions* ✓

### **Handling Precautions**

- ✓ Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- ✓ Be certain that your fingers or hands are free of foreign material before touching your contact lenses, as microscopic scratches of 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 this booklet and those prescribed by your eye care practitioner.
- ✓ Always handle your lenses carefully and avoid dropping them.
- ✓ Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- ✓ Do not touch the lens with your fingernails.
- ✓ To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

### **Lens Wearing Precautions**

- ✓ If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in this booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- ✓ Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- ✓ Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- ✓ If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

### **Lens Case Precautions**

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

### **Topics to Discuss with the Eye care Practitioner**

- ✓ Ask your eye care practitioner about wearing your lenses during sporting activities.
- ✓ Always contact your eye care practitioner before using any medicine in your eyes.

- ✓ As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

### **Who Should Know That the Patient is Wearing Contact Lenses**

- ✓ Inform your doctor (health care practitioner) about being a contact lens wearer.
- ✓ Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.

### **ADVERSE EFFECTS:**

You 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 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 you notice any of the above, 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 objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it. If the problem continues, you should IMMEDIATELY remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You 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.

**PERSONAL CLEANLINESS FOR LENS HANDLING:**

**1. Preparing the Lens for Wearing:**

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substance when you handle your lenses. The procedures are:

Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.

Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.

To avoid damaging your lenses, handle them with your fingertips, and be careful to avoid contact with your fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

**2. Handling the Lenses:**

Develop the habit of always working with the same lens first to avoid mix-ups.

Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks and tears.

**3. Placing the Lens on the Eye:**

Work over a table, upon which is placed a clean towel.

Do not place lenses on the eye while working over a sink.

For the right eye:

Wet the forefinger of the right hand and place the contact lens on the forefinger of the right hand.

Place the second finger of the left hand on the middle of the upper lid and press upward firmly.

Place the second finger of the right hand on the lower lid and press downward firmly.

Stare into a mirror as though looking through the second finger holding the contact lens. You will later learn to do this without a mirror.

Slowly move the hand to advance the forefinger with the contact lens towards the cornea until the lens touches the cornea and release the lids.

Release the lid and close the eye for a few seconds.

Repeat for the left eye.

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.

**Note:** If after placement of the lens your vision is blurred, check for the following:

The lens is not centered on the eye (see "Centering the Lens", next section in this booklet).

If the lens is centered, remove the lens (see "Removing the Lens" section and check for the following:

- a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
- b. The lens is on the wrong eye.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

#### **4. Centering the Lens:**

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow the procedure below.

First locate the lens by pulling away the lids. After the lens is found, gently press on the lid over the lens while looking away from the direction of the lens. Next look back towards the lens.

## 5. **Removing the Lens:**

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. Work over a table with a clean towel. Do not remove lenses over a sink. Place the right index finger of the right hand at the outer corner of the eye. Place the left hand cupped below the eye. Open the eyes wide as if to stare. Continue to keep the eyes open and pull the lids sideways away from nose. Blink quickly and firmly.
- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading **CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING)**.

**Note:** If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.

### CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE, AND REWETTING/LUBRICATING):

#### 1. **Basic Instructions:**

For continued safe and comfortable wearing of your lenses, it is important that you 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 that may have accumulated during wearing. The ideal time to clean, rinse, and disinfect your lenses is immediately after wearing them. Disinfecting is necessary to destroy harmful germs.

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

When you first receive your lenses, practice how to put the lenses on and removing them while you are in your eye care practitioners 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 eye care practitioner should instruct you about appropriate and adequate procedures and products for your use.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.

Use the recommended system of lens care, which is chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**

Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

To avoid contamination, do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

The lens care products listed below are recommended by Polymer Technology for use with your BOSTON XO orthokeratology contact lenses.

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

BOSTON, BOSTON XO, BOSTON Advance and BOSTON Simplicity are registered trademarks of Polymer Technology.

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. **Clean**  
Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of cleaning solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for about 20 seconds. Do not clean the lens by rubbing it between the thumb and index fingers, as this may cause lens warpage.
- b. **Rinse**  
Rinse the lens thoroughly with clean tap water to remove the cleaning solution, mucus, and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- c. **Disinfect**  
After cleaning and rinsing the lenses disinfect them by using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.
- d. **Storage**  
To store lenses, disinfect and leave them in the closed case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the storage solution package insert or your eye care practitioner for information on storage of your lenses.

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 to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.

Note: BOSTON XO contact lenses for orthokeratology cannot be heat (thermally) disinfected.

- e. **Care of Your Lens Case**  
Contact lens cases can be a source of bacteria growth. After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

- f. **Lubricating/Rewetting**  
Your eye care practitioner will recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to rewet (lubricate) your lenses while you are wearing them to make them more comfortable.

**2. LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:**

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does not replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

**3. CARE FOR A STICKING (NONMOVING) LENS:**

If the lens sticks (stops moving) or cannot be removed, you should apply 5 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eye care practitioner.

**4. EMERGENCIES:**

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

**5. WEARING AND APPOINTMENT SCHEDULES:**

**Prescribed Wearing Schedule**

**Daily Wear**

Maximum wearing time:

Day	Wearing Time (Hours)
1	3
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake

**PATIENT/EYECARE PRACTITIONER INFORMATION:**

Name

Address

Phone Number

Emergency Phone Number

**MANUFACTURER**

Polymer Technology

1400 North Goodman Street

P.O. Box 30450

Rochester, New York 14603-0450

**PROFESSIONAL FITTING AND INFORMATION GUIDE FOR BOSTON XO  
(hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES FOR  
ORTHOKERATOLOGY**

**CAUTION:** Federal Law Prohibits Dispensing Without a Prescription.

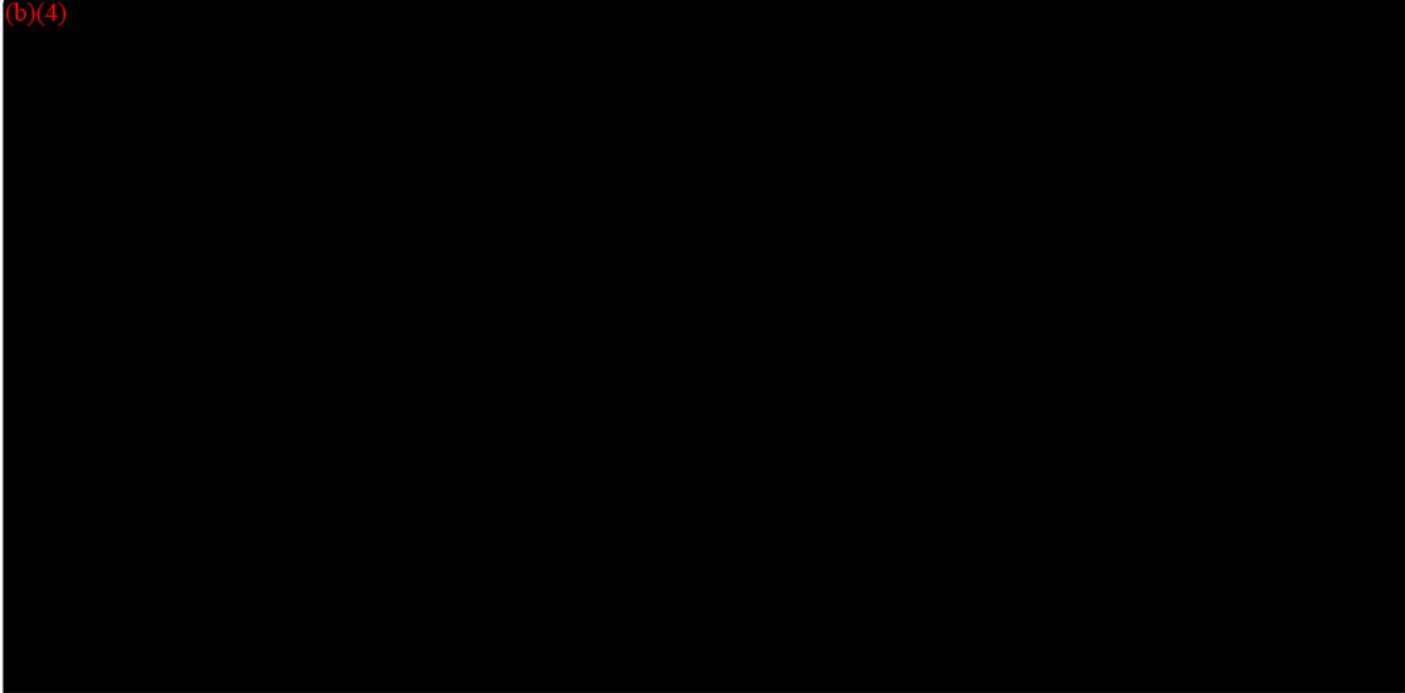
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**INTRODUCTION:**

BOSTON XO contact lenses for orthokeratology are made from a fluoro silicone acrylate

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**LENS PARAMETERS AVAILABLE:**

Chord Diameter	Approx 6.5 to 11.5
Center Thickness for Low Minus Lens:	0.10 to 0.30 mm
for Plus Lens:	0.20 to 0.70 mm
Base Curve	6.5 to 11.0 mm
Secondary Curves	0.10 to 2.00 mm
Flatter or steeper than Base Curve	
Peripheral Curves	0.10 to 2.0 mm
Flatter or steeper than Base Curve	
Powers	-10.00 to +3.00 Dioptors
Aspheric Lens Eccentricity (Oblate, Prolate or Tangent Conic)	Values ✓

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The physical properties of the lens are:

Refractive Index	1.415
Light Transmittance	92%
Wetting Angle	49°
(Contact Receding Angle)	
Specific Gravity	1.27
Hardness	112
(Rockwell)	
Water Content	<1 %
Oxygen Permeability	140* (100**)

\* gas to gas method

\*\* polarographic method (ISO/Fatt)

**ACTIONS:**

BOSTON XO contact lenses for orthokeratology produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. Contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular contact lenses are designed to cause little or no effect but BOSTON XO contact lenses for orthokeratology are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea. If the cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day. A myopic reduction maintenance lens or retainer lens must be worn each day to maintain the corneal flattening, or the myopia will revert back to the pre-treatment level.

**INDICATIONS (USES):**

The BOSTON XO (hexafocon A) RGP Contact Lens for orthokeratology is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

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**CONTRAINDICATIONS (REASONS NOT TO USE) WARNINGS AND ADVERSE REACTIONS:**

DO NOT USE BOSTON XO contact lenses for orthokeratology when any of the following conditions exist:

Acute and subacute inflammations or infection of the anterior segment 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).

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, such as mercury or Thimerosal, in a solution which is to be used to care for contact lenses.

Any active corneal infection (bacterial, fungal or viral).

If eyes become red or irritated.

**Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.**

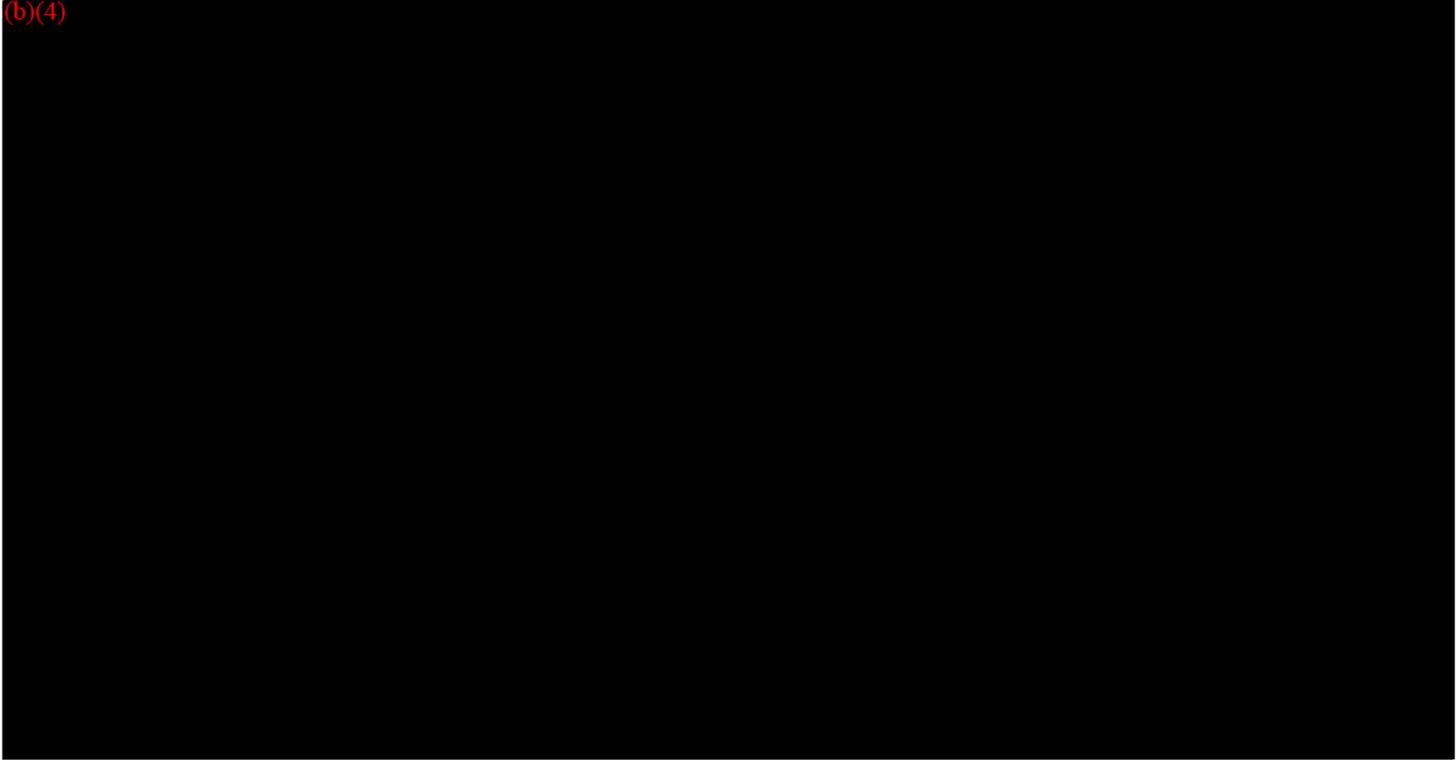
**PRECAUTIONS:**

Clinical studies have demonstrated that contact lenses manufactured from the BOSTON XO contact lens for orthokeratology materials are safe and effective for their intended use. However, 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 were 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 reduction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

**SELECTION OF PATIENTS:**

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**FITTING PROCEDURE:**

BOSTON XO contact lenses for orthokeratology are designed to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted.

**BOSTON XO Lens Description**

The BOSTON XO contact lens for orthokeratology has a design known as reverse geometry. This means that the secondary curve on the posterior surface has a radius of curvature that is steeper (shorter radius) than the base curve (central curve). The secondary curve is surrounded by a flatter peripheral curve near the edge. In this way the geometry of the secondary curve is in the opposite relationship to the base curve, as occurs with standard rigid gas permeable contact lenses.

The function of the steep secondary curve in the BOSTON XO contact lens for orthokeratology is to allow the base curve to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design, that is fitted flat on the cornea, there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and decenter on the cornea. With the BOSTON XO contact lens for orthokeratology there is support for the lens at both the

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central cornea and also in the area of the secondary curve. This will tend to reduce lens rocking and aid in centering.

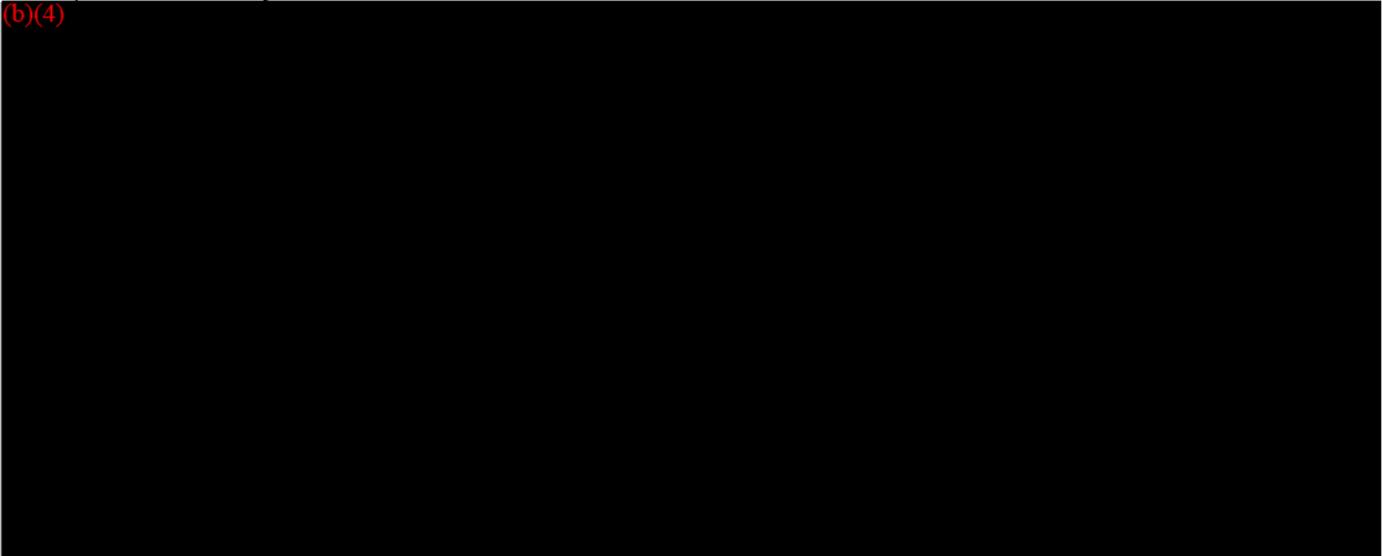
The secondary and alignment curve relationships are altered to achieve an optimal lens design for each patient's individual cornea.

### **Predicting Lens Results**

Various methods have been proposed for predicting the amount of corneal flattening that may be achieved for a given patient by orthokeratology. There is some evidence that patients with corneas of higher eccentricities are more likely to undergo greater amounts of corneal flattening than do patients with more spherical corneas. Corneal eccentricity can be measured by video keratography or by comparing central and peripheral keratometry readings. Other studies have not supported these conclusions, however, and further research is needed. It is not possible at this time to predict which patients will achieve the greatest corneal flattening with BOSTON XO contact lenses for orthokeratology.

BOSTON XO contact lenses for orthokeratology may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fitted. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

### **Clinical Study Results:**



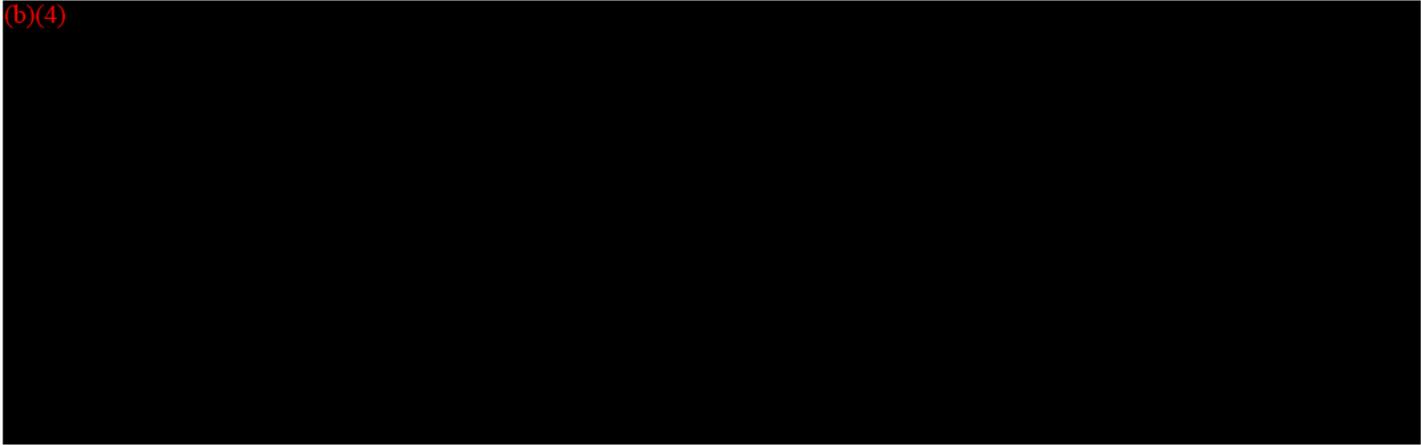
Other clinical refractive outcomes:

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- - 
  - 
  - 
  -

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

AVERAGE REDUCTION IN MYOPIA (Diopters)

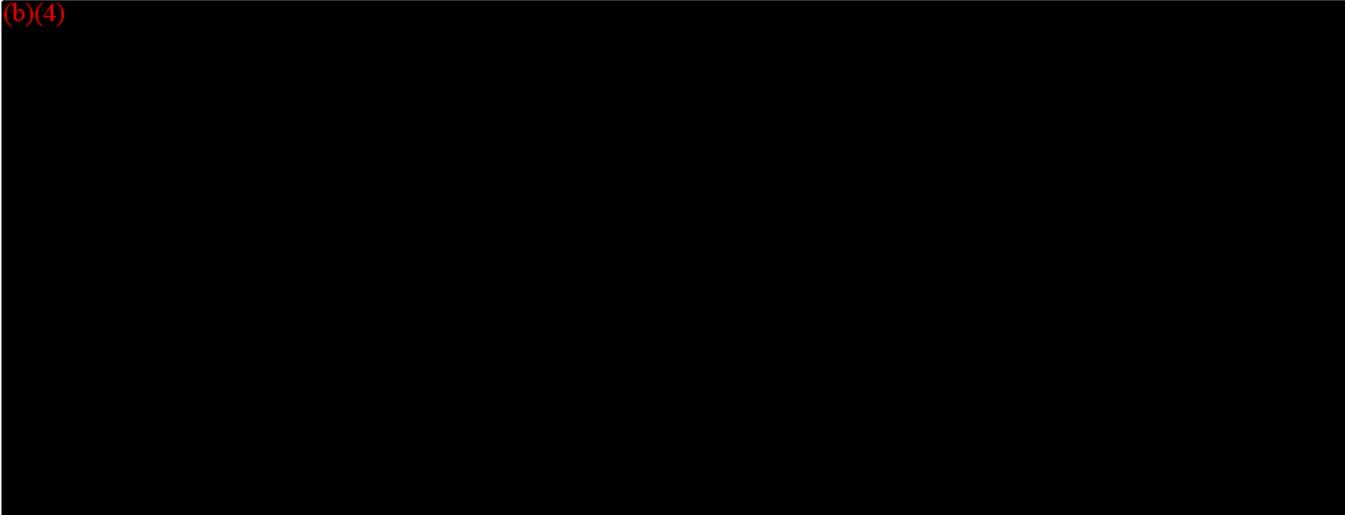
INITIAL Myopia	REDUCTION Myopia
-1.00	0.80
-2.00	1.50
-3.00	2.00
-4.00	2.40



PERCENT OF EYES THAT ACHIEVED FULL OR PARTIAL TEMPORARY REDUCTION OF MYOPIA

INITIAL MYOPIA	FULL TEMPORARY REDUCTION	UP TO 0.50 D UNDER FULL REDUCTION	FINAL V.A. 20/20 OR BETTER	FINAL V.A. 20/40 OR BETTER
<1.00 D	52%	84%	78%	100%
-1.25 TO - 2.00 D	36%	55%	74%	96%
-2.25 TO -3.00 D	18%	35%	48%	72%
-3.25 TO -4.00 D	4%	13%	16%	64%

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WEARING TIME

*Effects on Astigmatism*

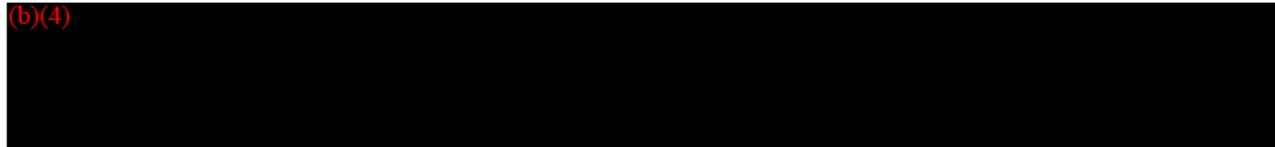
The average wearing time required for patients who wore RGP contact lenses for orthokeratology for various time periods was as follows:

One week	7.7 hours
Two weeks	7.8 hours
One month	8.0 hours
Three months	8.4 hours

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three month time period as follows:

Daily Wear Time Worn	Percent of patients
0 to 4 hours	25.0%
4.1 to 8 hours	23.7%
8.1 to 12 hours	21.8%
12.1 to 16 hours	27.2%

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## **MYOPIC REDUCTION MAINTENANCE LENS OR RETAINER LENS WEAR**

Studies have shown that the long-term wear of BOSTON XO contact lenses for orthokeratology does not eliminate the need to continue wearing contact lenses in order to maintain the orthokeratology effect. After the cornea has been flattened by wearing BOSTON XO contact lenses for orthokeratology, the patient will need to continue wearing Myopic Reduction Maintenance Lenses or Retainer lenses for a portion of each day. A Retainer lens may be either the last BOSTON XO contact lens for orthokeratology design or a modification of this design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The last pair of lenses in the fitting program is usually used as the first Retainer Lens. If it is found that this lens has a secondary curve that is too tight for the lens to be worn on a long-term basis, a new Retainer Lens is prescribed which has the same base curve but a flatter secondary curve, usually by one or two diopters. The retainer lenses are generally worn for the same daily schedule as the BOSTON XO contact lenses for orthokeratology and must be worn each day to maintain the orthokeratology effect.

One of the most common and effective schedules is to wear the retainer lens for several hours in the morning and a few hours before bedtime. Higher lens powers may require additional wearing time.

It is important to make certain that the retainer lenses center well on the cornea, as the same lens will be worn for a prolonged period. Check the patient's lenses every 3 to 4 months.

### **RISK ANALYSIS**

There is a small risk involved when any contact lens is worn. It is not expected that the BOSTON XO contact lens for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects that occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that the same side effects will also occur in some wearers of BOSTON XO contact lenses for orthokeratology. Other side effects that sometimes occur in all contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper patient control is exercised. Patients should be instructed to remove the contact lenses if any abnormal signs are present. Patients should be instructed never to wear their contact lenses while in

the presence of noxious substances. Patients should be instructed in the importance and necessity of returning for all follow-up visits required by the eye care practitioner.

Studies have not been conducted to support the safety and effectiveness of wearing BOSTON XO contact lenses for orthokeratology for overnight wear.

### **FITTING OF BOSTON XO CONTACT LENSES:**

BOSTON XO contact lenses for orthokeratology may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

1. Prefitting Examination:
  - A. complete refraction and visual health examination should be performed.
  - B. pre-fitting patient history and examination are necessary to:
    - determine whether a patient is a suitable candidate for BOSTON XO contact lenses for orthokeratology.(consider patient hygiene and mental and physical state).
    - collect and record baseline clinical information to which post-fitting examination results can be compared.
2. Initial Lens Power Selection:

Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.
3. Initial Lens Diameter Selection:

Usually, lens diameters between 9.8 mm to 11.5 mm are chosen to maximize centering to the cornea and to minimize lens movement. Lens diameters outside of this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

#### **Determining Starting Lens Diameter:**

If K is	41.00 and flatter use 10.6 mm diameter
	41.25 to 45.25 use 10.0 mm diameter
	45.50 and steeper use 9.8 mm diameter

Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.)

4. Initial Lens Base Curve Selection:

The base curve of the first lens fitted is generally as flat as the number of diopters as the refractive error plus .75 diopters flatter than the flattest keratometric finding but may vary according to the following table, which takes into account the corneal astigmatism. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

5. Initial Lens Evaluation

Movement:

Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm.) and then upward with the lid motion (average 1 mm.) as with a regular RGP contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm).

Positioning:

The lens should position centrally or slightly superiorly to minimize both lens movement and lid sensation. The lens should not ride more than 2 mm below center nor 3 mm above center

Characteristics of a Tight (too steep) Lens:

A lens that is too tight will show reduced movement upon blinking. The lens will be centered or decentered inferiorly and exhibit little or no movement. Bubbles may be detected behind the lens.

Characteristics of a Loose (too flat) Lens:

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

**TRIAL LENSES:**

Trial Lens Fitting

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the table given for base curve selection. Trial lenses are essential in fitting patients whose corneal topography has been distorted by previous contact lens wear.

## Dispensable Inventory Set

A dispensable inventory set consists of a series of lenses for any given target power of 10.0 to 10.6 diameter to cover K range of 40.50 to 46.00 in half diopter increments. The power of all lenses is +0.75. Standard sets are available covering -1.50 to -6.00 target powers.

**CAUTION:** Non-sterile lenses, clean and condition lenses prior to use.

Eye care practitioners should educate contact lens technicians concerning proper care of trial lenses. Each contact lens is shipped non-sterile in a case with no solution (dry). Therefore in order to insure disinfection, clean and condition lenses prior to use. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected, following the manufacturer's instruction.

## Trial Lens Procedure

Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

1. **Centering**  
Lens should center as well or better than a regular RGP lens. The lens should be fitted according to the interpalpebral fitting philosophy. Lenses fitted according to the "lid attachment" philosophy, in which the lens purposely rides in a high position should be avoided.
2. **Movement**  
Lens movement should be equivalent to or slightly less than a regular RGP lens, fitted-according to the interpalpebral philosophy.

Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with definite central touch, approximately 3 to 4 mm. diameter with a surrounding area of pooling. In the periphery there should be another area of touch and near the edge a thin band of pooling.

The area of pooling near the transition between the base curve and secondary curve serves as a reservoir for tears and as a potential space for corneal shifting during the flattening process of orthokeratology. The cornea molds by flattening the central cornea, which reduces the space near the transition reservoir. Hence, the size of the transition reservoir, as observed from the fluorescein pattern, is a

good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

The fluorescein pattern provides the best method for monitoring the fit of the contact lens over time. As the cornea flattens, the area of pooling at the transition becomes less and less. When this occurs the lens begins to tighten and at some point barely moves on the cornea. The lack of pooling at the transition area indicates that the lens should be changed for another that has a flatter base curve.

When the cornea has flattened enough for the desired reduction of the patient's myopia (even though the fluorescein pattern indicates that further flattening is possible) it is time to switch to a retainer lens. A retainer lens is a contact lens that is designed to maintain the current level of corneal flattening without additional flattening. It is usually made with the same reverse geometry design as the last lens used for corneal flattening but with less steepness for the secondary curve.

### Limits of Flattening

In some cases the corneal flattening stops before a full reduction of the refractive error has been accomplished. Additional flattening may be possible by using a lens with a steeper secondary curve. If no further corneal flattening occurs, it is an indication that the patient should be fitted with a retainer lens.

### **FOLLOW UP CARE:**

- a. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which occur that are related to contact lens wear.
- c. With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement. These are indications that the lens can be exchanged for another of flatter base curve. Usually, a lens with a 0.50 diopters flatter base curve should be the next choice, with variations from this up to the judgment of the eye care practitioner.

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A lens with excessive movement should be replaced with another that is .2 to .5 mm larger in diameter.

If the cornea shows no flattening, access the lens position, fluorescein pattern and Corneal Topography, if available. Call your Authorized Boston Manufacturer or contact Polymer Technology for assistance.

- d. After the lens removal, conduct a thorough biomicroscopy examination to detect the following:
  - 1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- e. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

Solutions to various lens wearing problems are given in the following table  
Ortho-K Problem Solving

Fitting too flat may de-center the lens, cause vision problems and increase corneal astigmatism. The most important points to remember are:

- 1. CENTERING
- 2. 1-2 mm MOVEMENT
- 3. MODERATE APICAL TOUCH
- 4. PATIENT COMFORT

Problem	(b)(4)
Tight lens or no movement	
Loose lens	
High-riding lens	
Low-riding lens	
Flare, Glare or Ghosts	
Instability of Ortho-k changes	
Fogging and scratchy lens	
Increase in corneal astigmatism	
Poor VA with lenses	
Poor VA w/out lenses	

**RECOMMENDED INITIAL WEARING SCHEDULE:**

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

The following schedule depends upon the professional judgment of the eye care practitioner and should be modified according to the response to the initial lenses.

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**Daily Wear**

Maximum wearing time:

Day	Wearing Time (Hours)
1	3
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake

**Myopic Reduction Maintenance Lens (Retainer Lens) Schedule**

The retainer lens schedule must be customized for each patient. The retainer lens wearing time begins with the same wearing time required for the last fitted BOSTON XO contact lenses for orthokeratology. There is considerable variability, however, as many patients require several hours more or less than the averages.

After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the first retainer lenses, the retainer lens wearing time can be reduced daily by intervals of one hour. This may continue for as long as the patient can see clearly for the remainder of the day following lens removal. When it is found that the patient experiences a visual decrement following lens removal, the previous wearing time is then followed on a constant basis.

**HANDLING OF LENSES:**

Standard procedures for rigid gas permeable lenses may be used.

**Caution: BOSTON XO contact lenses for orthokeratology are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.**

**PATIENT LENS CARE DIRECTIONS:**

Please see package insert and patient information booklet.

**VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS:**

Standard charts may be used.

**REPORTING OF ADVERSE REACTIONS:**

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

Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450  
800-333-4730

**HOW SUPPLIED:**

Each lens is supplied non-sterile in an individual flat pack case containing one or two lenses. The container is marked with the base curve, distance power, diameter, center thickness, color and lot number.

*Painted (mo/yr)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

July 18, 2000

POLYMER TECHNOLOGY  
GLOBAL VISION CARE  
1400 N GOODMAN STREET  
ROCHESTER, NY 14692  
ATTN: DEBRA L.B. KETCHUM

510(k) Number: K001960  
Product: RIGID GAS  
PERMEABLE  
CONTACT LENS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) E. M. Felber

Subject: 510(k) Number 15001960

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept). *Telephone Hold*
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?  YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed (required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

80 HQD Class IV

Review: [Signature]  
(Branch Chief)

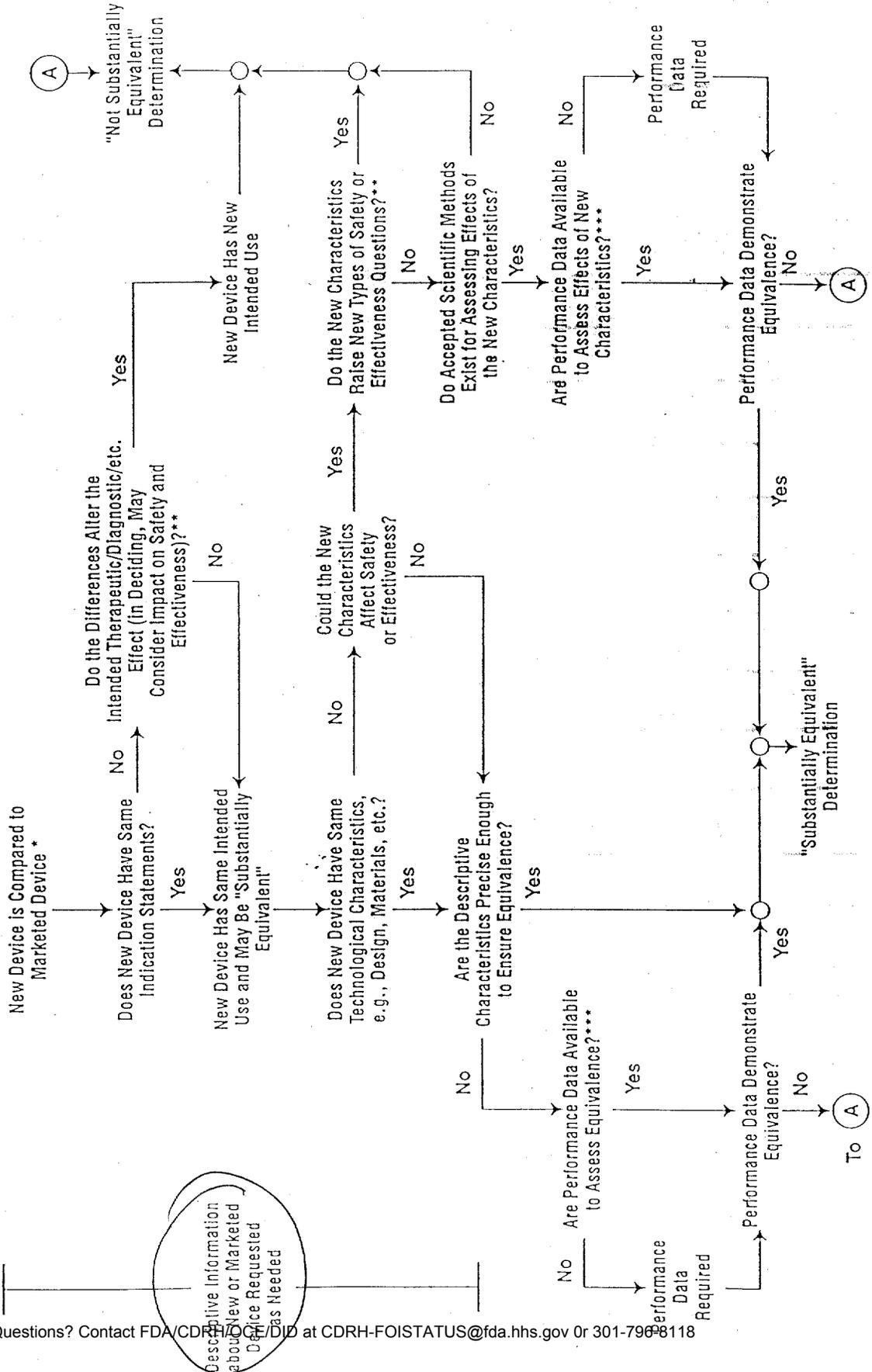
V803  
(Branch Code)

7/17/16  
(Date)

Final Review: [Signature] for DOES  
(Division Director)

(Date)

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov Or 301-796-8118

Descriptive Information about New or Marketed Device Requested (as Needed)

\* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices is Unclear.

\*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Technical Information is Sometimes Required.

\*\*\* Data May be Required in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Date: July 10, 2000  
From: Eleanor M. Felton, HFZ-460  
To: Record  
Subject: K001960  
BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for  
Orthokeratology (Daily Wear)  
Polymer Technology

Polymer Technology has submitted a premarket notification (510(K) application for the above referenced device. The applicant has submitted an incomplete and inaccurate application. The following was noted:

1. The applicant stated that the color additives conform to 21 CFR 74.3206. The applicant has not identified the name(s) of the color additives used. 21 CFR 74.3206 is the listing number for D&C Green No. 6. The proposed labeling for the subject device mentions D&C Green No. 6 and D&C Violet #2. The applicant should name the color additives in the Summary of Safety and Effectiveness and ALL appropriate listings.
2. The applicant has provided only a fitting guide as proposed labeling for this device. The applicant should provide the appropriate fitting guide, provide the two patient information booklets, the package insert, and the shipping label. This labeling should also include data to show the expected amount of myopic reduction to be expected with this lens. A copy of the orthokeratology prototype is available on the website.
3. The applicant has included inappropriate labeling for the CONTEX-OK lenses in this document. The comparative labeling is for overnight wear of lenses not currently approved for commercial distribution.
4. The document contains a letter (page 48) that does not relate to the subject device. Why is it here?
5. The Indications for Use in the Indication for Use Statement should be the same as that in the proposed labeling.

On July 12, 2000 I called Debra Ketchum and discussed the above issues with her. I also faxed a copy of the list to her. I informed Ms. Ketchum that the application will be placed on telephone hold until a response is received.

This application should be placed on Telephone Hold.

Records processed under FOIA Request #2016-1775 Released by CDRH on 8/31/16

\*\*\*\*\*  
\*\*\* TX REPORT \*\*\*  
\*\*\*\*\*

TRANSMISSION OK

TX/RX NO 0997  
CONNECTION TEL 917163380702  
SUBADDRESS  
CONNECTION ID  
ST. TIME 07/12 11:55  
USAGE T 01'49  
PGS. SENT 2  
RESULT OK



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

### CDRH Division of Ophthalmic Devices

9200 Corporate Boulevard  
Rockville, MD 20850  
FAX NO. 301 480-4201  
or 301 827-4601

Date: 7-12-00 Time: \_\_\_\_\_

To: Debra Ketchum FAX #: 716-338-0702

Organization: \_\_\_\_\_

From: Eleanor Felton

Department: FDA

Subject: Boston XO Lens for Orthokeratology

No. of Pages: 2  
(Including Cover Sheet)

Comments:

As Requested       FYI       Read and Destroy

Response Needed       Signature       Circulate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov Or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

# CDRH Division of Ophthalmic Devices

9200 Corporate Boulevard  
Rockville, MD 20850  
FAX NO. 301 480-4201  
or 301 827-4601

Date: 7-12-00

Time: \_\_\_\_\_

To: Debra Ketchum

FAX #: 716-338-0702

Organization: \_\_\_\_\_

From: Eleanor Felton

Department: FDA

Subject: Boston XO Lens for Orthokeratology

No. of Pages: 2  
(Including Cover Sheet)

Comments:

- As Requested
- FYI
- Read and Destroy
- Response Needed
- Signature
- Circulate
- For Correction
- Investigate
- File

Division Director's Office	301 594-2205
Diagnostic and Surgical Devices Branch	301 594-2018
Vitreoretinal and Extraocular Devices Branch	301 594-1744
Intraocular and Corneal Implants Branch	301 594-2053
Mail Code: HFZ 460	

**THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.** If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

1. The applicant stated that the color additives conform to 21 CFR 74.3206. The applicant has not identified the name(s) of the color additives used. 21 CFR 74.3206 is the listing number for D&C Green No. 6. The proposed labeling for the subject device mentions D&C Green No. 6 and D&C Violet #2. The applicant should name the color additives in the Summary of Safety and Effectiveness and ALL appropriate listings.
2. The applicant has provided only a fitting guide as proposed labeling for this device.. The applicant should provide the appropriate fitting guide, provide the two patient information booklets, the package insert, and the shipping label. This labeling should also include data to show the expected amount of myopic reduction to be expected with this lens. A copy of the orthokeratology prototype is available on the website.
3. The applicant has included inappropriate labeling for the CONTEX-OK lenses in this document. The comparative labeling is for overnight wear of lenses not currently approved for commercial distribution.
4. The document contains a letter (page 48) that does not relate to the subject device. Why is it here?
5. The Indications for Use in the Indication for Use Statement should be the same as that in the proposed labeling.

## Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name:						K 00196 d						
Submitter (Company):												
Items which should be included (circle missing & needed information)						S P E C I A L		A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING
						YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:										✓		
a) "Special 510(k): Device Modification"						GO TO # 2,3						
b) "Abbreviated 510(k)"								GO TO # 2,4,5				
c) Traditional 510(k)										GO TO #2, 5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS											✓ IF ITEM IS NEEDED	
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class												
b) OR a statement that the device is not yet classified						FDA may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA						
d) compliance with Section 514 - performance standards						NA						
e) address of manufacturer												
f) Truthful and Accurate Statement												
g) Indications for Use enclosure												
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)												
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)												
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals												
k) Proposed Labeling:												
i) package labeling (user info)												✓
ii) statement of intended use												
iii) advertisements or promotional materials												
i) MRI compatibility (if claimed)												
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:												
i) Labeling												✓
ii) intended use												✓
iii) physical characteristics												
iv) anatomical sites of use												
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR												* If no - STOP not a special

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<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
c) <b>STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
	<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE DRIVE</b>						
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

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inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 7/6/07

Reviewer: [Signature]  
 Concurrence by Review Branch: [Signature]

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	✓	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Public Health Service

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

June 27, 2000

POLYMER TECHNOLOGY  
GLOBAL VISION CARE  
1400 N GOODMAN STREET  
ROCHESTER, NY 14692  
ATTN: DEBRA L.B. KETCHUM

510(k) Number: K001960  
Received: 27-JUN-2000  
Product: RIGID GAS PERMEABLE  
CONTACT LENS

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

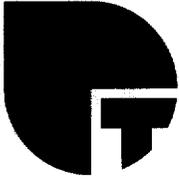
Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff  
Office of Device Evaluation

15001960

**POLYMER TECHNOLOGY**

1400 N. GOODMAN STREET • P.O. BOX 450 • ROCHESTER, NEW YORK 14603-0450



June 26, 2000

Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Center for Devices & Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

RE: 510(k) Premarket Notification  
BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

Dear Sir or Madam:

Pursuant to 21 CFR Part 807, we are submitting the subject premarket notification for your review prior to market introduction.

The information marked as confidential and contained in the body of the submission is considered to be confidential within the meaning as set forth in 21 CFR Part 20.

*Note: For the convenience of the Reviewer, an additional copy of the Indications Statement Form, and the 510(k) Summary were placed at the front of the attached submission.*

Should you have any questions, please do not hesitate to telephone me at (716) 338-8638 or Douglas Fortunato at (716) 338-5477.

Sincerely,

Debra Ketchum  
Manager, Regulatory Affairs

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21 JUN 00 11 56  
FDA/CDRH/OCE/DHO

JK  
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OP  
H  
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# Center for Devices and Radiological Health Premarket Submission Cover Sheet

Date of Submission:

FDA Document Number:

## Section A Type of Submission

- |   |   |  |   |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k)        | <input type="checkbox"/> IDE            | <input type="checkbox"/> PMA           | <input type="checkbox"/> PMA Supplement - Regular     |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment  | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special     |
|   | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> Report        | <input type="checkbox"/> PMA Supplement - 30 day      |
|   | <input type="checkbox"/> IDE Report     |  | <input type="checkbox"/> PMA Supplement - Panel Track |

## Section B1 Reason for Submission - 510(k)s Only

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> New device                                 | <input checked="" type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials or manufacturing process |
| <input type="checkbox"/> Other reason (specify):<br>Modified Device |  |   |

## Section B2 Reason for Submission - PMAs Only

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> New device                         | <input type="checkbox"/> Change in design, component or specification:  | <input type="checkbox"/> Location change:    |
| <input type="checkbox"/> Withdrawal                         | <input type="checkbox"/> Software                                       | <input type="checkbox"/> Manufacturer        |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive                                 | <input type="checkbox"/> Sterilizer          |
| <input type="checkbox"/> Licensing agreement                | <input type="checkbox"/> Other (specify below)                          | <input type="checkbox"/> Packager            |
| <input type="checkbox"/> Labeling change:                   | <input type="checkbox"/> Process change:                                | <input type="checkbox"/> Report submission:  |
| <input type="checkbox"/> Indications                        | <input type="checkbox"/> Manufacturer                                   | <input type="checkbox"/> Annual or periodic  |
| <input type="checkbox"/> Instructions                       | <input type="checkbox"/> Sterilizer                                     | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics        | <input type="checkbox"/> Packager                                       | <input type="checkbox"/> Adverse reaction    |
| <input type="checkbox"/> Shelf life                         |   | <input type="checkbox"/> Device defect       |
| <input type="checkbox"/> Trade name                         | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment           |
| <input type="checkbox"/> Other (specify below)              | <input type="checkbox"/> Request for applicant hold                     |  |
| <input type="checkbox"/> Change in ownership                | <input type="checkbox"/> Request for removal of applicant hold          |  |
| <input type="checkbox"/> Change in correspondent            | <input type="checkbox"/> Request for extension                          |  |
| <input type="checkbox"/> Other reason (specify):            | <input type="checkbox"/> Request to move or add manufacturing site      |  |

## Section B3 Reason for Submission - IDEs Only

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> New device                    | <input type="checkbox"/> Change in:                | <input type="checkbox"/> Response to FDA letter concerning:          |
| <input type="checkbox"/> Addition of institution       | <input type="checkbox"/> Correspondent             | <input type="checkbox"/> Conditional approval                        |
| <input type="checkbox"/> Expansion/extension of study  | <input type="checkbox"/> Design                    | <input type="checkbox"/> Deemed approved                             |
| <input type="checkbox"/> IRB certification             | <input type="checkbox"/> Informed consent          | <input type="checkbox"/> Deficient final report                      |
| <input type="checkbox"/> Request hearing               | <input type="checkbox"/> Manufacturer              | <input type="checkbox"/> Deficient progress report                   |
| <input type="checkbox"/> Request waiver                | <input type="checkbox"/> Manufacturing             | <input type="checkbox"/> Disapproval                                 |
| <input type="checkbox"/> Termination of study          | <input type="checkbox"/> Protocol - feasibility    | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Withdrawal of application     | <input type="checkbox"/> Protocol - other          | <input type="checkbox"/> Request meeting                             |
| <input type="checkbox"/> Unanticipated adverse effect  | <input type="checkbox"/> Sponsor                   | <input type="checkbox"/> IOL submissions only:                       |
| <input type="checkbox"/> Emergency use:                | <input type="checkbox"/> Report submission:        | <input type="checkbox"/> Change in IOL style:                        |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator      | <input type="checkbox"/> Request for protocol waiver                 |
| <input type="checkbox"/> Additional information        | <input type="checkbox"/> Annual progress           |  |
| <input type="checkbox"/> Other Reason (specify):       | <input type="checkbox"/> Site waiver limit reached |  |
|  | <input type="checkbox"/> Final                     |  |

RECEIVED  
 27 JUN 00 11 56  
 FDA/CDRH/OCE/DMD

151

FDA Document Number:

**Section C Product Classification**

Product code: 86 HQD	C.F. R. Section 21 CFR 886.5916	Device Class
Classification Panel: Ophthalmic Devices		<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified

**Section D Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and data.  <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1 86 HQD	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K973697	1 CONTEX OK	1 CONTEX Inc.
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

**Section E Product Information - Applicable to All Applications**

Common or usual name or classification name:

Trade or proprietary or model name	Model number
1 Rigid Gas Permeable Contact Lens	1 Not Applicable
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K000795	2 K973697	3	4	5	6
7	8	9	10	11	12

Data included in submission:  Laboratory Testing       Animal trials       Human trials

Indications (from labeling):  
  
**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology is indicated for daily wear in an orthokeratology fitting program for temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lenses must be disinfected using a chemical disinfection system only.**

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		<b>FDA Document Number:</b>	
<b>Section F Manufacturing / Packaging / Sterilization Sites</b>			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		<b>FDA establishment registration number:</b> 1281950	
		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager/Relabeler	
<b>Company / Institution name:</b> POLYMER TECHNOLOGY			
<b>Division name (if applicable):</b> n/a		<b>Phone number (include area code):</b> (716) 338-8638	
<b>Street address:</b> 100 Research Drive		<b>FAX number (include area code):</b> (716) 338-0702	
<b>City:</b> Wilmington	<b>State / Province:</b> MA	<b>Country:</b> United States	<b>ZIP / Postal Code:</b> 01887
<b>Contact name:</b> Debra L.B. Ketchum			
<b>Contact title:</b> Manager, Regulatory Affairs			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		<b>FDA establishment registration number:</b>	
		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager/Relabeler	
<b>Company / Institution name:</b>			
<b>Division name (if applicable):</b>		<b>Phone number (include area code):</b>	
<b>Street address:</b>		<b>FAX number (include area code):</b>	
<b>City:</b>	<b>State / Province:</b>	<b>Country:</b>	<b>ZIP / Postal Code:</b>
<b>Contact name:</b>			
<b>Contact title:</b>			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		<b>FDA establishment registration number:</b>	
		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager/Relabeler	
<b>Company / Institution name:</b>			
<b>Division name (if applicable):</b>		<b>Phone number (include area code):</b>	
<b>Street address:</b>		<b>FAX number (include area code):</b>	
<b>Contact name:</b>			
<b>Contact title:</b>			

FDA Document Number:

**Section G Applicant or Sponsor**

Company / Institution name: POLYMER TECHNOLOGY		FDA establishment registration number: 1313525	
Division name (if applicable): Global Vision Care		Phone number (include area code): (716) 338-8638	
Street address: 1400 N. Goodman Street		FAX number (include area code): (716) 338-0702	
City: Rochester	State / Province: New York	Country: United States	ZIP / Postal Code: 14692-0450
Signature: <i>Debra L.B. Ketchum</i>			
Name: Debra L.B. Ketchum			
Title: Manager, Regulatory Affairs			

**Section H Submission correspondent (if different from above)**

Company / Institution name:			
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

## 510(k) Elements List

Reference: Instructions for Premarket Submission Cover Sheet - March 14, 1995

	Authority (21 CFR)	Page Number
510(k) Elements		
Device trade or proprietary name	807.87	4
Device common or usual name or classification	807.87	4
Establishment registration number (only applies if establishment is registered)	807.87	3
Class in which the device has been put under section 513 of the act and, if known, the appropriate panel; or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.		4
Action taken by the party required to register to comply with the requirements of the act under Section 514 for special controls.	807.87	4
Proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and the directions for its use. (Blue Book Memo #G91-1).	807.87	5
510(k) summary or a 510(k) statement.	807.87(h)	49 - 50
For class III only, a class III certification and class III summary.	807.87(l)	n/a
Photographs of the device.	807.87	n/a
Engineering drawings of the device.	807.87	n/a
Identification of the marketed device(s) to which equivalence is claimed during labeling and description of the device. Affiliated 510(k) numbers and product codes are voluntary in cover sheet.	807.87	6
Statement of similarities and/or differences with marketed devices.	807.87	6
Data to show consequences and effects of a modified device.	807.87	7
Submitter's name and address.	807.87	3
Contact person, telephone number and fax number	807.87	3
Representative/Consultant if applicable	807.87	n/a
Table of Contents	807.87	vi - viii
Name and address of manufacturing/packaging/sterilization facilities. Registration number of each facility when one exists.	807.87	14
Comparison table of the new device to the marketed device(s)	807.87	6
Action taken to comply with voluntary standards.	807.87	4
Performance data (bench, animal, clinical)	807.87	7
Sterilization information (Blue Book Memo #K90-1)	807.87	n/a
Software information (Blue Book Memo #K91-1)	807.87	n/a
Hardware information	807.87	n/a
Information requested in specific guidance documents (if applicable for this device)	807.87	*
Kit Certification Statement (for kit submission only)	807.87	n/a
Truthful and Accurate Statement	807.87	1

\*Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997.

**510(k) Premarket Notification**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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Polymer Technology  
1400 North Goodman Street  
P.O. Box 450  
Rochester, New York 14603-0450

**INDICATIONS FOR USE STATEMENT:**

510 (k) number (if known) \_\_\_\_\_

Device Name: BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

Indications For Use:

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens must be disinfected using a chemical disinfection system only.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription use \_\_\_\_\_ or Over the Counter Use \_\_\_\_\_

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**FOR**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

**1. SUBMITTER INFORMATION:**

Polymer Technology  
Global Vision Care  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**2. CONTACT PERSON:**

Debra L.B. Ketchum  
Manager, Regulatory Affairs  
Address: 1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450  
Telephone No.: (716) 338-8638  
Fax No.: (716) 338-0702  
E-mail Address: dketchum@bausch.com

**3. DEVICE IDENTIFICATION:**

Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens

Proprietary Name: BOSTON XO (hexafocon A) Contact Lens  
for Orthokeratology

Common Name: Fluoro silicone acrylate rigid gas permeable contact lens  
material

**4. PREDICATE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

510(k) Premarket Notification  
**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**5. DESCRIPTION OF THE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206. The hexafocon A material has an oxygen permeability (Dk) of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN)

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is hexafocon A, is a fluoro silicone acrylate material.

**6. INDICATIONS FOR USE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens must be disinfected using a chemical disinfection system only.

**7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:**

The safety and efficacy of *BOSTON XO (hexafocon A) Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K000795, cleared on May 26, 2000. Also, the use of a rigid gas permeable contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology 510(k) Premarket Notification No. K973697, cleared on April 8, 1998.

**8. SUBSTANTIAL EQUIVALENCE**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

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**510(K) Premarket Notification  
BOSTON XO (hexafocon A) Contact Lens  
for Orthokeratology**

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**510(k) Premarket Notification**  
**BOSTON XO (hexafocon A) Contact Lens for Orthokeratology**

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**510(k) Premarket Notification**

**BOSTON XO (hexafocon A) RGP Contact Lenses for Orthokeratology**

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**Premarket Notification**

**Truthful and Accurate Statement**

I certify that in my capacity as Regulatory Affairs Manager for Polymer Technology, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

*Debra L.B. Ketchum*

Debra L.B. Ketchum  
Regulatory Affairs Manager  
Polymer Technology  
P.O. Box 450  
1400 N. Goodman Street  
Rochester, New York 14692-0450

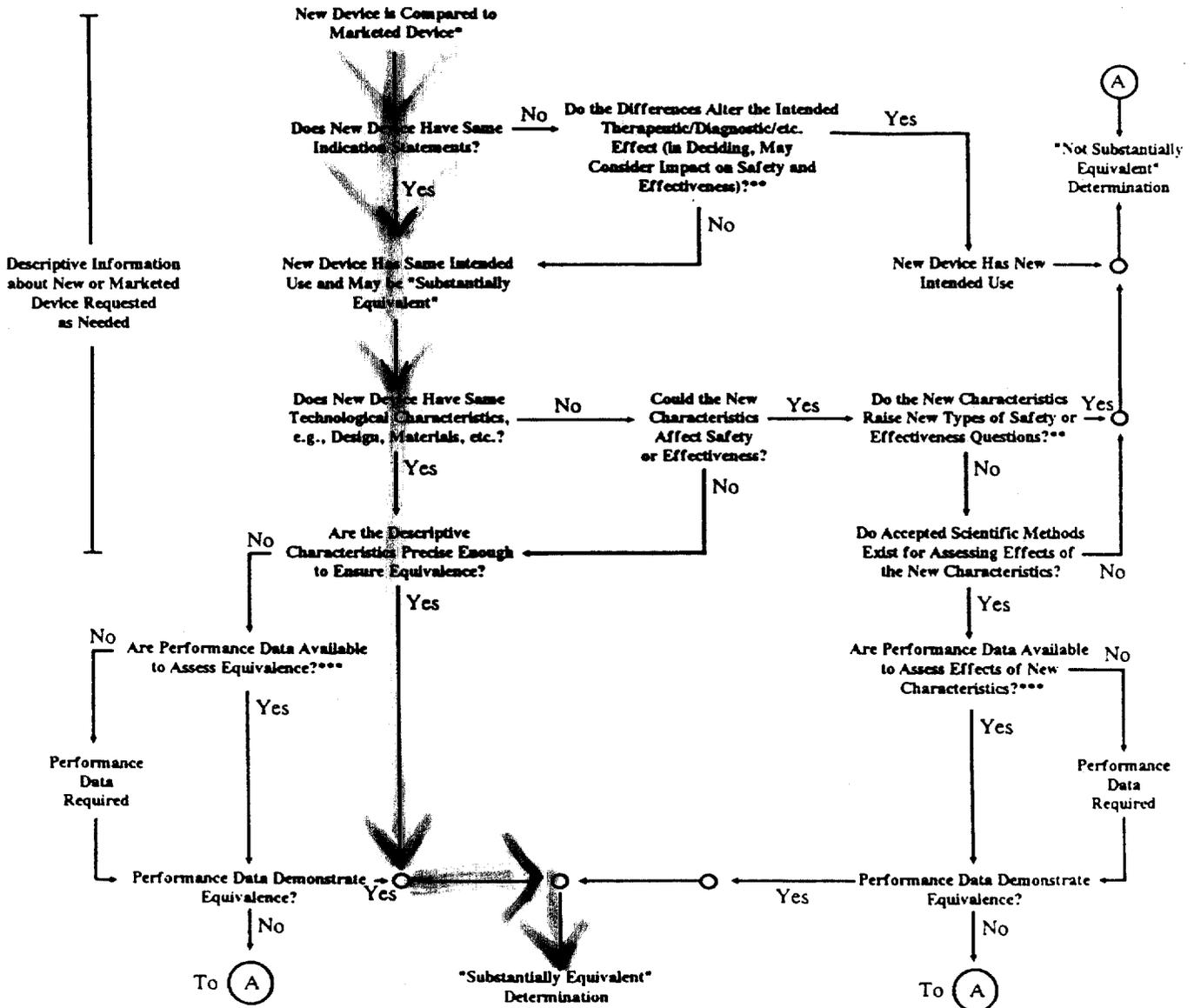
*6-26-00*

Date

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[Premarket Notification (510(k)) Number]

### A3 - 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



- \* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" devices is unclear.
- \*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- \*\*\* Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.



**510(K) PREMARKET NOTIFICATION**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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5. **REASON FOR 510(K) SUBMISSION:** Additional indication
6. **DEVICE IDENTIFICATION:**  
Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens  
Proprietary Name: BOSTON XO (hexafocon A) RGP Contact Lens Material  
for Orthokeratology  
Common Name: Fluoro silicone acrylate rigid gas permeable contact lens  
material

7. **CLASSIFICATION NAME AND REFERENCE:**

21 CFR 886.5916

Class II Ophthalmic Device

Daily wear contact lenses were reclassified from Class III to Class II medical devices under 59 FR 94 - 10397, March 4, 1994.

**Class:** These devices are Group III, Hydrophobic Material.

**Device Panel and Product Code:**

Ophthalmic: 86 HQD

8. **PERFORMANCE STANDARDS:**

No performance standards for this device have been promulgated under Section 514, Federal Food, Drug and Cosmetic Act.

Polymer Technology followed the CDRH guidelines Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994 and Testing Guidelines for Class III Contact Lenses, April 1988

9. **INDICATIONS FOR USE:**

The *BOSTON XO (hexafocon A) RGP Contact Lenses for Orthokeratology* are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens must be disinfected using a chemical disinfection system only.

The Statement of Indications for Use can be found in Appendix 1.

10. **DESCRIPTION OF THE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206. The hexafocon A material has an oxygen permeability (Dk) of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN).

**510(K) PREMARKET NOTIFICATION**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

---

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is hexafocon A, is a fluoro silicone acrylate material.

**11. PROPOSED LABELING AND PACKAGING**

Proposed draft labeling can be found in Appendix 2. This includes professional fitting and information guide for *Boston XO (hexafocon A) RGP Contact Lenses for Orthokeratology*.

A copy of the Contex OK Contact Lens for Orthokeratology Fitting and Information Guide is also included in Appendix 2.

Advertising for the *BOSTON XO (hexafocon A) RGP Contact Lenses for Orthokeratology* has not been developed at this time.

**12. MANUFACTURING INFORMATION:**

12.1 The manufacturing process, packaging materials, and methods for *Boston XO (hexafocon A) RGP Contact Lenses for Orthokeratology* is identical to the process used for the currently marketed product, as described in the Boston XO (hexafocon A) Contact Lens Material 510(k) K000795.

**13. SHELF LIFE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a hydrophobic contact lens material with <1% water content. This material will be shipped dry. Based on the Premarket Notification Guidance Document for Daily Wear Contact Lenses, May 12, 1994, shelf-life studies are not required for clearance of this material.”

**14. STERILIZATION**

*BOSTON XO (hexafocon A) RGP Contact Lenses for Orthokeratology* are shipped dry and labeled non-sterile, so therefore they are not required to be sterilized. Additionally, the proposed labeling includes the statement “Practitioner Note: The *BOSTON XO (hexafocon A) RGP Contact Lenses for Orthokeratology* are not sterile when shipped from the authorized manufacturer. Prior to dispensing, clean and disinfect the lenses.

Contact lens finishing laboratories that are authorized to manufacture the *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* are required to be in compliance with bioburden testing requirements. Guidance for this testing can be found in the Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994. Contact lens finishing laboratories must demonstrate an average bioburden level of <100 CFR/lens.

**510(K) PREMARKET NOTIFICATION**  
**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

**15. MARKETED SUBSTANTIALLY EQUIVALENT DEVICES**

**15.1 Introduction:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

**15.2 Basis of Equivalence:**

**Substantial Equivalency Comparison Summary**  
**Similarities**

Feature	BOSTON XO	CONTEX OK
Indications for use	Same	Same
Contact Lens Material Type (Hydrophobic)	Same	Same
Water content	<1.0%	<1.0%
Lens Design	Same	Same

**Differences**

USAN polymer	hexafocon A	siflufocon A
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**Physicochemical Properties Comparison Summary**

Physicochemical Properties	BOSTON XO	CONTEX OK
Refractive Index	1.415 ± 0.002	1.443 ± 0.003
Light Absorbance	4.6 ± 0.02	10.2 ± 0.06
Water content	<1.0%	<1.0%
Specific Gravity	1.26 ± 0.01	1.22 ± 0.02
Wetting Angle (Captive Air Bubble)	49°	52° ± 3°
Dry Hardness (Rockwell)	110 – 115	117 - 120
Oxygen Permeability	100	18

**510(K) PREMARKET NOTIFICATION**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**16. SAFETY AND EFFICACY INFORMATION**

The safety and efficacy of *BOSTON XO (hexafocon A) RGP Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K000795, cleared on May 26, 2000. Also, the use of a contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the CONTEX OK (siflufocon A) Contact Lens for Orthokeratology 510(k) Premarket Notification No. K973697, cleared on April 8, 1998.

**17. SUMMARY OF SAFETY AND EFFECTIVENESS**

A Summary of Safety and Effectiveness is contained in Appendix III.

**18. REQUEST FOR CONFIDENTIALITY**

Information marked as confidential and contained in the body of the submission is considered confidential by Polymer Technology within the meaning as set forth in 21 CFR Part 20.

**510(K) PREMARKET NOTIFICATION**  
**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

---

**Appendix 1**

**Statement of Indication For Use**

**510(k) Premarket Notification**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

Polymer Technology  
1400 North Goodman Street  
P.O. Box 450  
Rochester, New York 14603-0450

**INDICATIONS FOR USE STATEMENT:**

510 (k) number (if known) \_\_\_\_\_

Device Name: BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

Indications For Use:

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens must be disinfected using a chemical disinfection system only.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription use \_\_\_\_\_ or Over the Counter Use \_\_\_\_\_

**510(K) PREMARKET NOTIFICATION**

**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

---

**Appendix 2**

**Proposed Packaging and Labeling**

**Polymer Technology  
1400 N. Goodman Street  
PO Box 450  
Rochester, NY 14603-0450**

***BOSTON<sup>®</sup> XO  
RGP CONTACT LENSES  
FOR ORTHOKERATOLOGY***

**PROFESSIONAL FITTING  
&  
INFORMATION GUIDE**

# PROFESSIONAL FITTING AND INFORMATION GUIDE FOR BOSTON® XO RGP CONTACT LENSES FOR ORTHOKERATOLOGY

**CAUTION: Federal law prohibits dispensing without a prescription.**

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**INTRODUCTION:**

BOSTON® XO RGP Contact Lenses for Orthokeratology are made from a fluoro silicone acrylate polymer with water content of less than one percent.

**PRODUCT DESCRIPTION:**

The BOSTON® XO contact lenses are rigid gas permeable contact lenses in an orthokeratology design. The lens material, hexafocon A, is a fluoro silicone acrylate polymer, which contains D & C Green #6 as a color additive for blue & ice blue contact lenses and which contains D & C Violet #2 as a color additive for violet contact lenses. The BOSTON® XO RGP Contact Lenses for Orthokeratology have the following dimensions:

**LENS PARAMETERS AVAILABLE:**

Chord Diameter.....	Approx. 6.5 to 13.0 mm
Base Curve .....	6.50 to 11.00 mm
Secondary Zone Curves.....	0.10 to 2.0 mm Flatter or Steeper than Base Curve
Peripheral Zone Curves.....	0.10 to 2.0 mm Flatter or Steeper than Base Curve
Powers .....	-10.00 to +3.00 Diopters
Center Thickness	
For Low Minus Lens:.....	0.10 to 0.30 mm
For Plus Lens:.....	0.20 to 0.70 mm

**THE PHYSICAL PROPERTIES OF THE LENS ARE:**

Refractive Index .....	1.415
Light Absorbance (640nm).....	8.5 Blue
Light Absorbance (640nm).....	5.3 Ice Blue
Light Absorbance (585nm).....	5.3 Violet
(absorbance units/inch)	
Light Transmittance .....	92%
Average %T (400-800nm)	
Wetting Angle.....	49°
Specific Gravity .....	1.27
Water Content.....	<1%
Oxygen Permeability .....	140* (100**)
*gas to gas method	
**polarographic method (ISO/Fatt)	

**ACTIONS:**

BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. The contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular contact lenses are designed to cause little or no effect, but BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology are designed to purposely flatten the cornea by applying slight pressure to the central area. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day. A retainer lens must be worn each day to maintain the corneal flattening, or the myopia will revert back to the pre-treatment level.

**INDICATIONS (USES):**

The BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for daily wear in an orthokeratology-fitting program for the temporary reduction of myopia of up to 3.00 diopters. The lens must be disinfected using a chemical disinfecting system only.

**Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.**

**CONTRAINDICATIONS (REASONS NOT TO USE) AND ADVERSE REACTIONS:**

**DO NOT USE BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology when any of the following conditions exist:**

- Acute and subacute inflammations or infection of the anterior segment 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).
- 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 that is to be used to care for contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

**Caution: BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology are not sterile when shipped from the Authorized BOSTON Manufacturers. Prior to dispensing, clean and disinfect the lenses.**

**PRECAUTIONS:**

Clinical studies have demonstrated that rigid gas permeable contact lenses are safe and effective for their intended use. However, due to the small number of patients enrolled in clinical investigation of lenses, all lens parameters available in the lens material were 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 reduction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

**SELECTION OF PATIENTS:**

Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with BOSTON® XO RGP Contact Lenses and who do not have any of the contraindications described in the package insert for the BOSTON® XO material. BOSTON® XO RGP Contact Lenses for Orthokeratology are indicated for myopic patients who desire to have time periods during the day, in which they do not need to wear their contact lenses, but still be able to see clearly. This might include such activities as swimming and other water sports. BOSTON® XO RGP Contact Lenses for Orthokeratology may be useful in occupations that require exposure to smoke, noxious gases or conditions of low humidity, such as would be the case for flight attendants, if their lenses can be worn before exposure to the noxious substance and removed during its presence. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

BOSTON® XO RGP Contact Lenses for Orthokeratology are indicated for patients who are within the following parameters:

- Refractive error ..... -1.00 to -3.00 diopters
- Keratometry ..... 39.00 to 48.00 diopters
- Visual Acuity ..... 20/30 to 20/800

**FITTING PROCEDURE:**

BOSTON® XO RGP Contact Lenses for Orthokeratology are designed to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted.

**BOSTON® XO RGP CONTACT LENSES FOR ORTHOKERATOLOGY**  
**DESCRIPTION:**

The BOSTON® XO RGP Contact Lenses for Orthokeratology are commonly referred to as Ortho K lenses. This means that the reverse zone (secondary zone) on the posterior surface contains curves that are steeper (shorter radius) than those curves in the central optic zone. The function of this reverse zone is to allow the curves in the central zone to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design, that is fitted flat on the cornea, there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and de-center on the cornea. With the BOSTON® XO RGP Contact Lenses for Orthokeratology, there is support for the lens at both the central cornea and in the peripheral zone surrounding the reverse zone. The curves in the peripheral zone are steeper than the central zone but flatter than the reverse zone. This relationship between zones will tend to reduce lens rocking, balance out the pressures and aid in centering.

The front surface design consists of a central optic zone and a peripheral zone.

Each zone on the back and front can be comprised of a multitude of spherical and/or aspherical curves to achieve the desired flattening or steepening in geometry required of individual patients. Additionally, blend/transition zones can be added between the primary zones on the lens to optimize the fit for an individual patient.

**Orthokeratology for Presbyopes:**

For patients over 35 years old you must be careful because as they reach forty they may lose near vision. If we reduce them to Plano power, then they will have even more difficulty reading.

**PREDICTING RESULTS:**

Various methods have been proposed for predicting the amount of corneal flattening that may occur for a given patient by orthokeratology. There is some evidence that patients with corneas of higher eccentricities are more likely to undergo greater amounts of corneal flattening than do patients with more spherical corneas. Corneal eccentricity can be measured by Corneal Topography or by comparing central and peripheral (temporal) keratometry readings.

BOSTON® XO Contact Lenses for Orthokeratology may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way the contact lenses are fit. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

**WEARING TIME:**

The average wearing time required for patients who wear BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology for various time periods are as follows:

One week .....	7.7 hours/day
Two weeks.....	7.8 hours/day
One month.....	8.0 hours/day
Three months .....	8.4 hours/day

**RETAINER LENS WEAR:**

Studies have shown that the long-term wear of orthokeratology RGP contact lenses does not eliminate the need to continue wearing RGP contact lenses in order to maintain the orthokeratology effect. After the cornea has been flattened by wearing BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology, the patient will usually need to continue wearing retainer RGP lenses each day. A retainer lens may be either the last BOSTON<sup>®</sup> XO RGP contact lens design or a modification of this design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The last pair of lenses in the fitting program is usually used as the first Retainer Lens. If it is found that this lens has an alignment curve that is too tight for the lens to be worn on a long-term basis, a new retainer lens is prescribed which has the same base curve and secondary curve but a flatter alignment curve, usually by a half or one diopter.

**Note: Patients with a higher refractive error may require additional wearing time.**

It is important to make certain that the retainer lenses center well on the cornea, as the same lens will be worn for a prolonged period. Check the patient's lenses routinely.

## **RISK ANALYSIS:**

There is a small risk involved when any contact lens is worn. It is not expected that the BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects, which occur in rigid contact lens wearers, are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology. Other side effects, which sometimes occur in all contact lens wearers, are pain, redness, tearing, irritation, discharge, and abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper patient control is exercised. Patients should be instructed to remove the contact lenses if any abnormal signs are present. Patients should be instructed never to wear their contact lenses while in the presence of noxious substances.

**Patients should be instructed in the importance and necessity of returning for all follow-up visits required by the eye care practitioner.**

## **FITTING OF BOSTON<sup>®</sup> XO RGP CONTACT LENSES FOR ORTHOKERATOLOGY:**

BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

### **1. Pre-fitting Examination:**

A complete refraction and visual health examination should be performed. A pre-fitting patient history and examination are necessary to:

- a. Determine whether a patient is a suitable candidate for BOSTON<sup>®</sup> XO RGP Contact Lenses for Orthokeratology (consider patient hygiene and mental and physical state).
- b. Collect and record baseline clinical information to which post-fitting examination results can be compared.

### **2. Initial Power Selection:**

Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.

**3. Initial Diameter Selection:**

Usually, lens diameters between 9.8 mm and 11.5 mm are chosen to maximize centering on the cornea to minimize lens movement. Lens diameters outside of this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgement.

**Determining Starting Lens Diameter:**

If K is	Use
41.00 and flatter .....	10.6 mm diameter
41.25 to 45.25 .....	10.0 mm diameter
45.50 and steeper .....	9.8 mm diameter

Lens diameter is primarily a function of the number of diopters flatter than the flattest K that the lens is fit, but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.).

**4. Initial Base Curve Selection:**

The base curve of the first lens is generally fitted as flat as the number of diopters as the refractive error plus .75 diopters flatter than the flattest keratometric finding but may vary according to the following table, which takes into account the corneal astigmatism. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

**5. Fitting Curve:**

Otherwise called the secondary curve or the Tear Reservoir, this zone dictates the amount of change to the cornea. It can be from 1-15 diopters steeper than base curve.

**6. Alignment Curve:**

Otherwise called the mid-peripheral curve this zone works as a balance point for the lens to rest on the periphery of the cornea. If the alignment curve is too tight, flatten the curve by a half or one diopter. If it is too loose, steepen the curve by a half or one diopter.

## **7. Initial Lens Evaluation:**

### **Movement:**

Blink induced lens movement should show minimal lens movement with the lid motion (average 1 mm) and then upward with the lid motion (average 1 mm). During the interblink period the lens should have little or no motion (average less than 1 mm).

### **Positioning:**

The lens should position centrally or slightly superiorly to minimize both lens movement and lid sensation. The lens should not ride more than 2 mm below center nor 3 mm above corneal center.

### **Characteristics of a Tight (too steep) Lens:**

A lens that is too tight will show reduced movement upon blinking. The lens will be centered or de-centered inferiorly or superiorly and exhibit little or no movement. Bubbles may be detected behind the lens.

### **Characteristics of a Loose (too flat) Lens:**

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

## **TRIAL LENSES:**

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Trial lenses are essential in fitting patients whose corneal topography has been distorted by previous contact lens wear.

### **Dispensable Inventory Set:**

A dispensable inventory set consists of a series of lenses for any given target power, of 10.0 or 10.6 diameters to cover a K range of 40.50 to 46.00 in half diopter increments. The power of all lenses is +0.75.

### **CAUTION: Non sterile lenses, clean and condition lenses prior to use.**

Eye care practitioners should educate contact lens technicians concerning proper care of trial lenses. Each contact lens is shipped non-sterile in a case with no solution (dry). Therefore, in order to insure disinfecting, clean and condition lenses prior to use. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens.

Prior to reusing or before dispensing to a patient, lenses should be surface cleaned and disinfected, following the manufacturer's instruction.

### **Trial Lens Procedure:**

Select a trial lens based on the flat K and target power, then place the lens upon the eye. Evaluate the lens using white light for the following:

#### **1. Centering:**

It is important that lens should center as well or better than a regular RGP lens. Fitting techniques, in which the lens purposely rides in a high position, should be avoided.

#### **2. Movement:**

Lens movement should be slightly less than a regular RGP lens.

**Evaluate the Fluorescein Pattern:**

The fluorescein pattern should show a lens with definite central touch, approximately 3 to 4 mm in diameter with a surrounding area of pooling. In the periphery there should be another area of touch and near the edge a thin band of pooling. This pattern looks somewhat like a "Bulls-Eye".

The area of pooling near the transition between the base curve and secondary curve serves as a reservoir for tears and as a potential space for corneal shifting during the flattening process of orthokeratology. The cornea molds by flattening the central cornea, which reduces the space near the transition reservoir. Hence, the size of the transition reservoir, as observed from the fluorescein pattern, is a good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

The fluorescein pattern combined with Corneal Topography provides the best method for monitoring the fit of the contact lens over time. As the cornea flattens, the area of pooling at the transition becomes less and less. When this occurs, the lens begins to tighten and at some point barely moves on the cornea. The lack of pooling at the transition area indicates that the lens should be changed for another that has a flatter base curve. When the cornea has flattened enough for the desired reduction of the patient's myopia (even though the fluorescein pattern indicates that further flattening is possible) it is time to switch to a retainer lens. A retainer lens is a contact lens that is designed to maintain the current level of corneal flattening without additional flattening. It is usually made with the same orthokeratology design as the last lens used for corneal flattening but with less steepness for the alignment curve.

**Limits of Flattening:**

In some cases the corneal flattening stops before a full reduction of the refractive error has been accomplished. Additional flattening may be possible by using a lens with different design parameters. If no further corneal flattening occurs, it is an indication that the patient should be fitted with a retainer lens.

## **FOLLOW UP CARE:**

1. Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.
2. Prior to a follow-up examination, the contact lenses should be worn overnight and the patient should be asked to identify any problems, which occur that are related to contact lens wear.
3. With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement. These are indications that the lens can be exchanged for another of flatter alignment curve. Usually, a lens with a 0.50 diopters flatter alignment curve should be the next choice, with variations up to the judgment of the eye care practitioner. A lens with excessive movement should be replaced with another that has a half to one diopter steeper alignment curve as well as .2 mm to .5 mm larger in diameter. If the cornea shows no flattening, assess the lens position, fluorescein pattern and Corneal Topography if available. Call your Authorized BOSTON Manufacturer or contact Polymer Technology for assistance.
4. After the lens removal, conduct a thorough biomicroscopy examination to detect the following:
  - a. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
  - b. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

**RECOMMENDED INITIAL WEARING SCHEDULE:**

Although many eye care practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wear time to the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

**Daily Wear:**

**Note: The following daily wear schedule depends upon the professional judgment of the eye care practitioner and should be modified according to the response to the initial lenses.**

**Maximum wearing time:**

Day	Wearing Time (Hours)
1 .....	3
2 .....	6
3 .....	7
4 .....	8
5 .....	9
6 .....	10
7 .....	15
8 And After .....	All Hours Awake

**Daily Wear Retainer Lens Schedule:**

The retainer lens schedule must be customized for each patient. The retainer lens wearing time begins with the same wearing time required for the last fitted BOSTON® XO RGP Contact Lenses for Orthokeratology. There is considerable variability, as many patients require several hours more or less than the averages. After a period of several weeks or months, the retainer lens wearing time can be reduced daily by intervals of one hour.

This may continue for as long as the patient can see clearly for the remainder of the day following lens removal. When it is found that the patient experiences a visual decrement following lens removal, the previous wearing time is then followed on a daily basis.

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**HANDLING OF LENSES:**

Standard procedures for rigid gas permeable lenses may be used.

**Caution: BOSTON® XO RGP Contact Lenses for Orthokeratology are not sterile when shipped from the Authorized BOSTON Manufacturers. Prior to dispensing, clean and disinfect the lenses.**

**PATIENT LENS CARE DIRECTIONS:**

Please see the BOSTON® XO Package Insert.

**VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS:**

Standard charts may be used.

**REPORTING OF ADVERSE REACTIONS:**

All serious adverse experiences and adverse reactions observed in-patients wearing the lenses should be reported to:

Polymer Technology  
1400 N. Goodman Street  
PO Box 450  
Rochester, NY 14603-0450  
Phone 1-800-333-4730

**HOW SUPPLIED:**

Each lens is supplied non-sterile in an individual flat pack case containing one or two lenses. The container is marked with the base curve, distance power, diameter, center thickness, color, and lot number.

**TECHNICAL ASSISTANCE:**

For further technical assistance please contact your Authorized BOSTON® Manufacturer or Polymer Technology.

# CONTEX<sup>INC.</sup>

*Inventors of Reverse Geometry OK<sup>®</sup> Lenses*

## **OK<sup>®</sup> B, D, & BB SERIES<sup>™</sup>**

### **PROFESSIONAL FITTING & INFORMATION GUIDE**

***CONTEX OK<sup>®</sup> CONTACT LENSES FOR ORTHOKERATOLOGY***



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# PROFESSIONAL FITTING AND INFORMATION GUIDE FOR CONTEX OK<sup>®</sup>-B, D & BB SERIES<sup>™</sup> RIGID GAS PERMEABLE CONTACT LENSES FOR ORTHOKERATOLOGY

**CAUTION: Federal law prohibits dispensing without a prescription.**

**WARNING: Contains a fluorinated compound, which harms public health and environment by destroying ozone in the upper atmosphere. A notice similar to the above warning has been placed in the patient information of this product, pursuant to EPA regulation.**

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**INTRODUCTION:**

CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are made from a fluoro silicone acrylate polymer with a water content of less than one percent.

**PRODUCT DESCRIPTION:**

The CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are rigid gas permeable contact lenses in a double reverse geometry design. The lens material, siflufocon A, is a fluoro silicone acrylate polymer, which contains D & C Green #6 as a color additive. The CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses have the following dimensions:

**LENS PARAMETERS AVAILABLE:**

Chord Diameter .....	Approx. 6.5 to 13.0 mm	Center Thickness
For Low Minus Lens: .....	0.10 to 0.30 mm	
For Plus Lens: .....	0.20 to 0.70 mm	
Base Curve .....	6.50 to 11.00 mm	
Fitting Curves .....	0.10 to 2.0 mm	Flatter or Steeper than Base Curve
Alignment Curves .....	0.10 to 2.0 mm	Flatter or Steeper than Base Curve
Peripheral Curves .....	0.10 to 2.0 mm	Flatter or Steeper than Base Curve
Powers .....	-10.00 to +5.00	Diopters

**THE PHYSICAL PROPERTIES OF THE LENS ARE:**

Refractive Index .....	1.43	(Nd at 25 degrees)
Light Transmittance .....	> 92.5%	(370-760 nm)
Wetting Angle .....	24.0	
(Contact Receding Angle)		
Specific Gravity .....	1.25	
Hardness .....	82	
Water Content .....	<1%	
Oxygen Permeability .....	81 x 10 <sup>-11</sup>	DK at 35 degrees C
(cm <sup>2</sup> /sec)(ml O <sub>2</sub> x Hg)		Revised Method of Irving Fatt

**ACTIONS:**

CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses produce a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and compensate for myopia. The contact lenses rest directly on the corneal tear layer and can influence the corneal shape. Regular contact lenses are designed to cause little or no effect, but CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are designed to purposely flatten the cornea by applying slight pressure to the central area. After the contact lens is removed, the cornea retains its altered shape for part or all of the remainder of the day. A retainer lens must be worn each night to maintain the corneal flattening, or the myopia will revert back to the pre-treatment level.

**INDICATIONS (USES):**

The CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for overnight wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 6.00 diopters. The lens may be disinfected using a chemical disinfecting system only.

**Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.**

**CONTRAINDICATIONS (REASONS NOT TO USE) AND ADVERSE REACTIONS:**

**DO NOT USE CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses when any of the following conditions exist:**

- Acute and subacute inflammations or infection of the anterior segment 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).
- 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, such as mercury or Thimerosal, in a solution which is to be used to care for contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

**Caution: CONTEX OK<sup>®</sup> (orthokeratology) contact lenses are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.**

**PRECAUTIONS:**

Clinical studies have demonstrated that contact lenses manufactured from the CONTEX OK<sup>®</sup> lens materials are safe and effective for their intended use. However, 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 were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive reduction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

**SELECTION OF PATIENTS:**

Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses and who do not have any of the contraindications described in the package insert.

CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are indicated for myopic patients who desire to have time periods during the day, in which they do not need to wear their contact lenses, but still be able to see clearly. This might include such activities as swimming and other water sports. CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses may be useful in occupations that require exposure to smoke, noxious gases or conditions of low humidity, such as would be the case for flight attendants, if their lenses can be worn before exposure to the noxious substance and removed during its presence. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are indicated for patients who are within the following parameters:

Refractive error.....	-1.00 to -6.00 diopters
Keratometry.....	39.00 to 48.00 diopters
Visual Acuity.....	20/30 to 20/800

**FITTING PROCEDURE:**

CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are designed to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted.

**CONTEX OK<sup>®</sup>-B, D & BB SERIES<sup>™</sup> LENS DESCRIPTIONS:**

The CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses are commonly referred to as double reverse geometry, third generation orthokeratology lenses. This means that the secondary curve on the posterior surface has a radius of curvature that is steeper (shorter radius) than the base curve (central curve). The secondary curve is surrounded by a mid-peripheral alignment zone with a radius of curvature that is steeper than the base curve but flatter than the secondary curve. The mid-peripheral alignment curve is surrounded by a flatter true aspheric peripheral curve out to the edge. In this way the geometry of the secondary & alignment curve is in the opposite relationship to the base curve, when compared to standard rigid gas permeable contact lenses.

The function of the steep secondary curve is to allow the base curve to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design, that is fitted flat on the cornea, there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and de-center on the cornea. With the CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lens there is support for the lens at both the central cornea and in the area of the alignment or mid-peripheral curve. This will tend to reduce lens rocking, balance out the pressures and aid in centering.

The secondary and alignment curve relationships are altered to achieve an optimal lens design for each patient's individual cornea.

**OK-B & D SERIES DESCRIPTIONS:**

The OK-B & D Series lenses are both four zone designs. The first, the optic zone is typically 6.0 mm in diameter. The second zone, the reverse zone is a narrow but steep reverse curve that is anywhere from 3 to 17 diopters steeper than the base curve. The reverse zone creates a narrow but brilliant pooling (staining or clearance) ring that allows the flatter fitting lens to match the shape of the patient's cornea. The third zone, the alignment (B, D or mid-peripheral zone) zone is also fit steeper than base curve. However, it is generally fit between 0 and five diopters steeper than base curve. The alignment zone aligns the mid-peripheral cornea thereby forcing the lens to center. This zone also contains the compressed corneal tissue within the first two zones. This zone is about .9 mm wide on the OK-B Series and 1.0 mm wide on the OK-D series. The only difference between the OK-B and D is that the D Series has a wider alignment curve and fits somewhat tighter for better centering and faster results. However, the OK-B Series provides a thicker tear layer and therefore can offer a healthier post-wear cornea, but the results may not be as fast.

### **OK-BB SERIES DESCRIPTION:**

The OK-BB Series is a five zone design that was designed for higher myopes who require daily wear. The minimum diameter of 10.2 mm is due to the wider second zone. This wider reverse zone allows the lens to be fit flatter than the standard OK-B & D without having to steepen the reverse curve any more. The wider second zone also tends to decrease the amount of lock-up that is seen when these compression designs are used for daily wear. The third zone, the alignment zone works the same as with the OK-B & D Series, but is much narrower due to the presence of the fourth zone. The fourth zone works as a second alignment zone. It is typically one diopter flatter than the third zone. This helps to promote much needed tear exchange for daily wear patients. It also helps to avoid binding in the mid-peripheral area.

All three of these designs, including the OK-"+" Series utilize a True Aspheric Ski-Spline peripheral curve to further promote tear exchange. As with all RGP lenses, they must center for best results.

### **OK-B+ & D+ SERIES DESCRIPTIONS:**

We would like to introduce the OK-B+, D+ & BB+ Series. We have made modifications to the existing design configuration that reduces more myopia, speeds-up results and still maintains a healthy cornea with an adequate tear layer underneath the lens. Though our OK-B, D & BB Series lenses provide adequate results on most patients, we constantly work to make the lenses better.

The OK-B+ & D+ designs utilize a steeper secondary curve for faster results. To keep the same fit when switching from a OK-B to a B+, the alignment or "B" curve must be a bit flatter. However, it may be best to tighten the lens a bit to obtain maximum myopia reduction. To tighten the fit we suggest using the OK-"+" Series, but with the alignment curve equal to the flat central K reading. We have done testing here in our laboratory and so far results are excellent.

#### **Same fit:**

(OK-B) 6010 B 4.5 = (OK-B+) 6011 B+ 4

These two designs will fit identical, yet the 6011 B+ 4 will provide faster results.

**Tighter fit:** (OK-B) 6010 B 4.5 = (OK-B+) 6011 B+ 4.5 (FULL ALIGNMENT)

The 6011 B+4.5 will fit 10 microns tighter and should provide faster results.

The doctor may notice a slightly deeper tear layer in the reverse or fitting curve. They should not be alarmed if there are bubbles in the reverse curve upon dispensing because they should disappear after one or two nights of wear. This deeper tear layer causes greater, quicker myopia reduction. If the bubbles do not go away after two nights of wear, then the alignment curve needs to be either flatter or steeper.

**WHAT DESIGN & DIAMETER, FOR WHAT PATIENT?:****Plano to -2.87 diopters:**

For patients up to -2.87 diopters we recommend the OK-D or D+ Series in a 10.0 mm diameter. These work best because the slightly wider third (alignment) curve forces the lenses to center better.

**-3.00 to -6.00 Diopters:**

For patients -3.00 to -6.00 diopters we recommend the OK-B or B+ Series in a 10.6 mm diameter. If there is still centering problems then try the OK-D+ Series in a 10.6 mm diameter.

**Over -6.00 Diopters:**

The OK-BB is an excellent choice for high myopia patients who want to attempt a nighttime wear program. Because the reverse curve is wider, we can fit flatter because we don't have to use such a steep curve in the reverse zone to attain the same tear volume. The OK-BB Series also works well as a daily wear lens because the alignment zone is broken into two zones, with the second one being flatter than the first. This helps to promote tear exchange and avoid lock-up.

**Orthokeratology for Presbyopes:**

For patients over 35 years old you must be careful because as they reach forty they may lose near vision. If we reduce them to Plano power, then they will have even more difficulty reading. Other than this there are no other concerns unless they have been a long time RGP patient. Sometimes the cornea gets harder after extended RGP wear, so these patients may not mold quickly.

These are suggestions for starting cases. If you are troubleshooting problem cases then other suggestions may be made.

**PREDICTING RESULTS:**

Various methods have been proposed for predicting the amount of corneal flattening that may occur for a given patient by orthokeratology. There is some evidence that patients with corneas of higher eccentricities are more likely to undergo greater amounts of corneal flattening than do patients with more spherical corneas. Corneal eccentricity can be measured by Corneal Topography or by comparing central and peripheral (temporal) keratometry readings.

CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way the contact lenses are fit. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

**WEARING TIME:**

The average wearing time required for patients who wear CONTEX OK<sup>®</sup>-B, D & BB Series contact lenses for various time periods are as follows:

One week .....	7.7 hours
Two weeks .....	7.8 hours
One month .....	8.0 hours
Three months .....	8.4 hours

There was considerable variability, however, as many patients required several hours more or less than the averages as shown for the three-month time period.

Time Worn	Percent of Patients
0 to 4 hours .....	25.5%
4.1 to 8 hours .....	21.8%
8.1 to 12 hours .....	23.7%
12.1 to 16 hours .....	27.2%

**RETAINER LENS WEAR:**

Studies have shown that the long-term wear of CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses does not eliminate the need to continue wearing contact lenses in order to maintain the orthokeratology effect. After the cornea has been flattened by wearing CONTEX OK<sup>®</sup> lenses, the patient will usually need to continue wearing retainer lenses each night. A retainer lens may be either the last CONTEX OK<sup>®</sup> contact lens design or a modification of this design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. The last pair of lenses in the fitting program is usually used as the first Retainer Lens. If it is found that this lens has an alignment curve that is too tight for the lens to be worn on a long-term basis, a new retainer lens is prescribed which has the same base curve and secondary curve but a flatter alignment curve, usually by a half or one diopter. The retainer lenses are generally worn for the same overnight schedule as the CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses and must be worn each night to maintain the orthokeratology effect.

**Note: Patients with a higher refractive error may require additional wearing time.**

It is important to make certain that the retainer lenses center well on the cornea, as the same lens will be worn for a prolonged period. Check the patient's lenses every 3 to 4 months.

**RISK ANALYSIS:**

There is a small risk involved when any contact lens is worn. It is not expected that the CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects, which occur in rigid contact lens wearers, are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses. Other side effects, which sometimes occur in all contact lens wearers, are pain, redness, tearing, irritation, discharge, and abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper patient control is exercised. Patients should be instructed to remove the contact lenses if any abnormal signs are present. Patients should be instructed never to wear their contact lenses while in the presence of noxious substances.

**Patients should be instructed in the importance and necessity of returning for all follow-up visits required by the eyecare practitioner.**

**FITTING OF CONTEX OK<sup>®</sup> CONTACT LENSES:**

CONTEX OK<sup>®</sup> (orthokeratology) contact lenses may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

**1. Pre-fitting Examination:**

A complete refraction and visual health examination should be performed. A pre-fitting patient history and examination are necessary to:

- a. Determine whether a patient is a suitable candidate for CONTEX OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses (consider patient hygiene and mental and physical state).
- b. Collect and record baseline clinical information to which post-fitting examination results can be compared.

**2. Initial Power Selection:**

Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.

**3. Initial Diameter Selection:**

Usually, lens diameters between 9.8 mm and 11.5 mm are chosen to maximize centering on the cornea to minimize lens movement. Lens diameters outside of this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgement.

**Determining Starting Lens Diameter:**

If K is	Use
41.00 and flatter .....	10.6 mm diameter
41.25 to 45.25 .....	10.0 mm diameter
45.50 and steeper .....	9.8 mm diameter

Lens diameter is primarily a function of the number of diopters flatter than flat CK that the lens is fit, but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.).

**4. Initial Base Curve Selection:**

The base curve of the first lens is generally fitted as flat as the number of diopters as the refractive error plus .75 diopters flatter than the flattest keratometric finding but may vary according to the following table, which takes into account the corneal astigmatism. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment.

**5. Fitting Curve:**

Otherwise called the secondary curve or the Tear Reservoir, this zone dictates the amount of change to the cornea. It can be from 1-15 diopters steeper than base curve.

**6. Alignment Curve:**

Otherwise called the mid-peripheral curve this zone works as a balance point for the lens to rest on the periphery of the cornea. If the alignment curve is too tight, flatten the curve by a half or one diopter. If it is too loose, steepen the curve by a half or one diopter.

**Note: Items 1 to 6 apply to the OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses.**

**Please see the sample calculated OK<sup>®</sup>-B, D & BB Series<sup>™</sup> contact lenses in the following tables:**

OK <sup>®</sup> -B Series™ Fitting Examples						
Spec. Rx	Flat K	E-Value	B Design	Base Curve	Power	Diameter
-2.00	43.00	.0 - .35	606.5 B3.25	8.39 (40.25 D)	+.75	9.8 - 10.6
		.36 - .65	606.5 B2.75			
		.66 - up	606.5 B2.25			
-3.00	43.00	.0 - .35	608.5 B4.25	8.60 (39.25 D)	+.75	9.8 - 10.6
		.36 - .65	608.5 B3.75			
		.66 - up	608.5 B3.25			
-4.00	43.00	.0 - .35	6010.5 B5.25	8.82 (38.25 D)	+1.00	9.8 - 10.6
		.36 - .65	6010.5 B4.75			
		.66 - up	6010.5 B4.25			

OK <sup>®</sup> -D Series™ Fitting Examples						
Spec. Rx	Flat K	E-Value	D Design	Base Curve	Power	Diameter
-2.00	43.00	.0 - .35	606.5 D3.25	8.39 (40.25 D)	+.75	9.8 - 10.6
		.36 - .65	606.5 D2.75			
		.66 - up	606.5 D2.25			
-3.00	43.00	.0 - .35	608.5 D4.25	8.60 (39.25 D)	+.75	9.8 - 10.6
		.36 - .65	608.5 D3.75			
		.66 - up	608.5 D3.25			
-4.00	43.00	.0 - .35	6010.5 D5.25	8.82 (38.25 D)	+1.00	9.8 - 10.6
		.36 - .65	6010.5 D4.75			
		.66 - up	6010.5 D4.25			

OK <sup>®</sup> -BB Series™ Fitting Examples						
Spec. Rx	Flat K	E-Value	BB Design	Base Curve	Power	Diameter
-2.00	43.00	.0 - .35	605.5 B2.75 B1.75	8.39 (40.25 D)	+.75	10.6
		.36 - .65	605.5 B2.25 B1.25			
		.66 - up	605.5 B1.75 B.75			
-3.00	43.00	.0 - .35	607.5 B2.75 B1.75	8.60 (39.25 D)	+.75	10.6
		.36 - .65	607.5 B3.25 B2.25			
		.66 - up	607.5 B2.75 B1.75			
-4.00	43.00	.0 - .35	609.5 B3.75 B2.75	8.82 (38.25 D)	+1.00	10.6
		.36 - .65	609.5 B4.25 B3.25			
		.66 - up	609.5 B3.75 B2.75			

<b>OK<sup>®</sup>-B+ Series<sup>™</sup> Fitting Examples</b>						
Spec. Rx	Flat K	E-Value	B+ Design	Base Curve	Power	Diameter
-2.00	43.00	.0 - .35	607.5 B3.25	8.39 (40.25 D)	+.75	9.8 - 10.6
		.36 - .65	607.5 B2.75			
		.66 - up	607.5 B2.25			
-3.00	43.00	.0 - .35	609.5 B4.25	8.60 (39.25 D)	+.75	9.8 - 10.6
		.36 - .65	609.5 B3.75			
		.66 - up	609.5 B3.25			
-4.00	43.00	.0 - .35	6011.5 B5.25	8.82 (38.25 D)	+1.00	9.8 - 10.6
		.36 - .65	6011.5 B4.75			
		.66 - up	6011.5 B4.25			

<b>OK<sup>®</sup>-D+ Series<sup>™</sup> Fitting Examples</b>						
Spec. Rx	Flat K	E-Value	D+ Design	Base Curve	Power	Diameter
-2.00	43.00	.0 - .35	607.5 D3.25	8.39 (40.25 D)	+.75	9.8 - 10.6
		.36 - .65	607.5 D2.75			
		.66 - up	607.5 D2.25			
-3.00	43.00	.0 - .35	609.5 D4.25	8.60 (39.25 D)	+.75	9.8 - 10.6
		.36 - .65	609.5 D3.75			
		.66 - up	609.5 D3.25			
-4.00	43.00	.0 - .35	6011.5 D5.25	8.82 (38.25 D)	+1.00	9.8 - 10.6
		.36 - .65	6011.5 D4.75			
		.66 - up	6011.5 D4.25			

<b>OK<sup>®</sup>-BB+ Series<sup>™</sup> Fitting Examples</b>						
Spec. Rx	Flat K	E-Value	BB+ Design	Base Curve	Power	Diameter
-2.00	43.00	.0 - .35	606.5 B2.75 B1.75	8.39 (40.25 D)	+.75	10.6
		.36 - .65	606.5 B2.25 B1.25			
		.66 - up	606.5 B1.75 B.75			
-3.00	43.00	.0 - .35	608.5 B3.75 B2.75	8.60 (39.25 D)	+.75	10.6
		.36 - .65	608.5 B3.25 B2.25			
		.66 - up	608.5 B2.75 B1.75			
-4.00	43.00	.0 - .35	6010.5 B4.75 3.75	8.82 (38.25 D)	+1.00	10.6
		.36 - .65	6010.5 B4.25 3.25			
		.66 - up	6010.5 B3.75 2.75			

The previous tables and parameters are only general recommendations and the specifications for an individual patient will depend on the eyecare practitioner's professional judgment of the lens movement and riding position as well as the fluorescein pattern analysis.

## **7. Initial Lens Evaluation:**

### **Movement:**

Blink induced lens movement should show minimal lens movement with the lid motion (average 1 mm) and then upward with the lid motion (average 1 mm). During the interblink period the lens should have little or no motion (average less than 1 mm).

### **Positioning:**

The lens should position centrally or slightly superiorly to minimize both lens movement and lid sensation. The lens should not ride more than 2 mm below center nor 3 mm above center.

### **Characteristics of a Tight (too steep) Lens:**

A lens that is too tight will show reduced movement upon blinking. The lens will be centered or de-centered inferiorly or superiorly and exhibit little or no movement. Bubbles may be detected behind the lens.

### **Characteristics of a Loose (too flat) Lens:**

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

## **TRIAL LENSES:**

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the table given for base curve selection. Trial lenses are essential in fitting patients whose corneal topography has been distorted by previous contact lens wear.

### **Dispensable Inventory Set:**

A dispensable inventory set consists of 12 lenses for any given target power, of 10.0 or 10.6 diameters to cover a K range of 40.50 to 46.00 in half diopter increments. The power of all lenses is +0.75. Standard 60 and 120 lens sets are available that cover -1.50 to -6.00 target powers.

**CAUTION: Non sterile lenses, clean and condition lenses prior to use.**

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses. Each contact lens is shipped non-sterile in a case with no solution (dry). Therefore in order to insure disinfecting, clean and condition lenses prior to use. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens.

Prior to reusing or before dispensing to a patient, lenses should be surface cleaned and disinfected, following the manufacturer's instruction.

**Trial Lens Procedure:**

Select a trial lens based on the flat K and target power, then place the lens upon the eye. Evaluate the lens using white light for the following:

**1. Centering:**

Lens should center as well or better than a regular RGP lens. The lens should be fitted according to the interpalpebral fitting philosophy. Lenses fitted according to the "lid attachment" philosophy, in which the lens purposely rides in a high position, should be avoided.

**2. Movement:**

Lens movement should be slightly less than a regular RGP lens, fitted according to the interpalpebral philosophy.

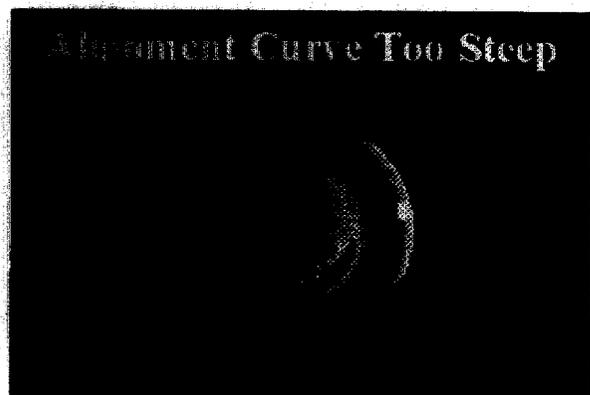
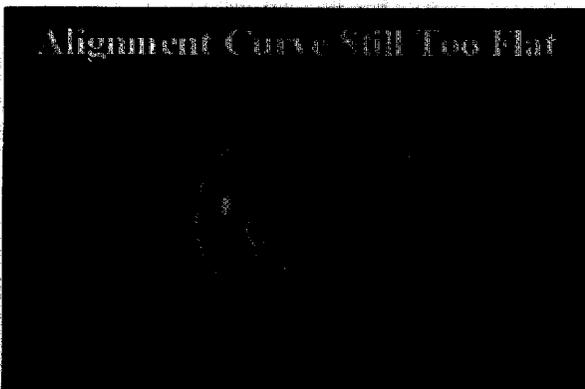
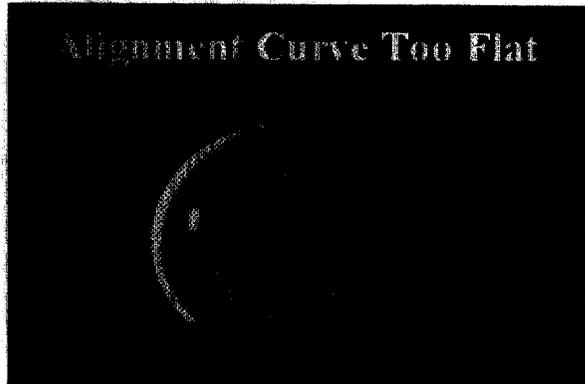
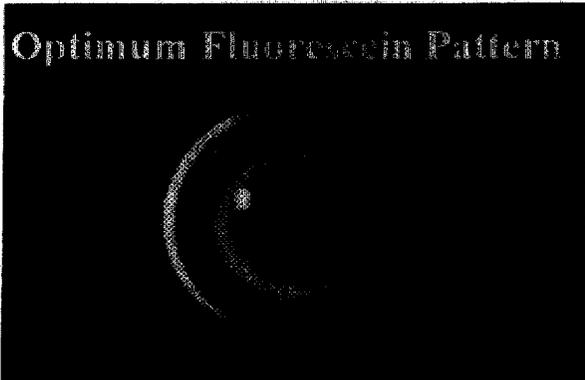
**Evaluate the Fluorescein Pattern:**

The fluorescein pattern should show a lens with definite central touch, approximately 3 to 4 mm in diameter with a surrounding area of pooling. In the periphery there should be another area of touch and near the edge a thin band of pooling. This pattern looks somewhat like a "Bulls-Eye".

The area of pooling near the transition between the base curve and secondary curve serves as a reservoir for tears and as a potential space for corneal shifting during the flattening process of orthokeratology. The cornea molds by flattening the central cornea, which reduces the space near the transition reservoir. Hence, the size of the transition reservoir, as observed from the fluorescein pattern, is a good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

## OK-B, D & BB Series Fluorescein Evaluation

- ### Desired Fluorescein Pattern
- 2.2 mm Central Bearing
  - 8.0 mm Narrow But Brilliant Secondary Ring
  - 1.0 mm Wide Bearing In Alignment Zone
  - Adequate Edgelift
  - Lens Must Be Centered!
  - 1.2 mm Movement On The Blink



The above information is to only be used for ordering and prescribing Contex lenses for your patients. Any other use of this information is prohibited. Contex lenses are protected by Patents and are only available through Contex, Inc. Sherman

The fluorescein pattern combined with Corneal Topography provide the best method for monitoring the fit of the contact lens over time. As the cornea flattens, the area of pooling at the transition becomes less and less. When this occurs, the lens begins to tighten and at some point barely moves on the cornea. The lack of pooling at the transition area indicates that the lens should be changed for another that has a flatter base curve. When the cornea has flattened enough for the desired reduction of the patient's myopia (even though the fluorescein pattern indicates that further flattening is possible) it is time to switch to a retainer lens. A retainer lens is a contact lens that is designed to maintain the current level of corneal flattening without additional flattening. It is usually made with the same reverse geometry design as the last lens used for corneal flattening but with less steepness for the alignment curve.

**Limits of Flattening:**

In some cases the corneal flattening stops before a full reduction of the refractive error has been accomplished. Additional flattening may be possible by using a lens with a steeper more aggressive secondary curve. If no further corneal flattening occurs, it is an indication that the patient should be fitted with a retainer lens.

**FOLLOW UP CARE:**

1. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.
2. Prior to a follow-up examination, the contact lenses should be worn overnight and the patient should be asked to identify any problems which occur that are related to contact lens wear.
3. With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement. These are indications that the lens can be exchanged for another of flatter alignment curve. Usually, a lens with a 0.50 diopters flatter alignment curve should be the next choice, with variations up to the judgment of the eyecare practitioner. A lens with excessive movement should be replaced with another that has a half to one diopter steeper alignment curve as well as .2 mm to .5 mm larger in diameter. If the cornea shows no flattening, assess the lens position, fluorescein pattern and Corneal Topography if available. Refer to the Troubleshooting Chart,

call your authorized distributor or contact Contex for assistance.

4. After the lens removal, conduct a thorough biomicroscopy examination to detect the following:
  - a. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
  - b. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

**Solutions to various lens wearing problems are given in the following table:**

## OK<sup>®</sup>-B, D & BB SERIES™ TROUBLESHOOTING CHART

This chart assumes the maximum base curve has been fit  
and that lid interaction is minimal.

PROBLEM	FIX
<b>Alignment Curve Bearing Too Heavy:</b>	<b>Flatten the Alignment Curve:</b> Example, if B4, lower to B3. This will decrease the sagittal depth by .020 microns.
<b>Alignment Curve Bearing Too Light or Not 360 degrees:</b>	<b>Steepen the Alignment Curve:</b> If B2, raise to B3. This will increase the sagittal depth by .020 microns
<b>Lens De-Centered Superior:</b> Lift lid to see if lens centers without lids. If lid attached, increase or decrease diameter to eliminate lid interaction. If lens stays up, determine if it is tight or loose. It may be either.	<b>If Tight:</b> Flatten the Alignment Curve. If B2, make B1.5 or B1. <b>If Loose:</b> Steepen the Alignment Curve. If B2, make B2.5 or B3. These changes will increase or decrease the sagittal depth by .010 or .020 microns.
<b>Lens De-Centered Inferior:</b> Determine if lens is tight or loose by nudging the lens to center with lid or finger and access fluorescein pattern. Typically nighttime wear low riding lenses are loose.	<b>If Tight:</b> Flatten the Alignment Curve. If bubbles occur in the Secondary Zone and the lens is too tight and has been tried, flatten the Secondary Curve. If tight with acceptable fluorescein in Secondary, flatten Alignment Curve. <b>If Loose:</b> Steepen Alignment Curve. If pooling in secondary not brilliant, steepen (fitting) Secondary and Alignment Curves.
<b>Lens De-Centered Temporal:</b> Typically caused by a loose lens.	<b>Try a Larger Diameter:</b> Steepen the Alignment Curve. If B2, raise to B3. This increases the sagittal depth by .020 microns.
<b>Lens De-Centered Nasal:</b> Determine if lens is de-centering loose or tight.	<b>Try a larger diameter:</b> If tight, flatten Alignment Curve by half or one diopter. If Loose, steepen Alignment Curve by half or one diopter.
<b>Central bearing heavy with no mid-peripheral bearing:</b>	<b>Double check calculated lens design:</b> Steepen Alignment Curve by at least a diopter (.020 microns). Example: B3 to B4
<b>Central bearing light with heavy mid-peripheral bearing.</b>	<b>Flatten Alignment Curve:</b> At least a half diopter (.010 microns). Example: B4 to B3.5
<b>Well centered lens with good fluorescein evaluation but no improvement:</b>	<b>Flatten Base Curve, Secondary (fitting) Curve and/or Alignment Curve:</b> A half diopter (.010 microns).
<b>Induced With-The-Rule Astigmatism:</b> Typically caused by a lid attached fit or sloppy loose high riding lens.	<b>Steepen Secondary (fitting) Curve and/or B (Alignment) Curve:</b> Create more mid-peripheral bearing. Try a larger diameter.
<b>Induced Against-The-Rule Astigmatism:</b> Typically caused by a tight low riding lens or	<b>Determine if tight or loose:</b> Steepen or flatten Alignment Curve as necessary. Try a larger diameter.

a sloppy loose low riding lens.	
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**RECOMMENDED INITIAL WEARING SCHEDULE:**

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wear time to the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

**Nighttime Wear:**

If prescribing nighttime wear, schedule follow-ups at the earliest possible time of the day.

**Daily Wear:**

**Note: The following daily wear schedule depends upon the professional judgment of the eyecare practitioner and should be modified according to the response to the initial lenses.**

**Maximum wearing time:**

Day	Wearing Time (Hours)
1 .....	3
2 .....	6
3 .....	7
4 .....	8
5 .....	9
6 .....	10
7 .....	15
8 And After .....	All Hours Awake

**Nighttime Retainer Lens Schedule:**

The retainer wear schedule for nighttime wear will vary based on the original degree of refractive error and other physical properties of each individual cornea. The average nighttime retainer wear time is all sleeping hours. Patients with higher degrees of refractive error may need to wear their CONTEX OK®-B, D & BB Series™ lenses a few hours prior to and following their sleep to obtain maximum results.

**Daily Wear Retainer Lens Schedule:**

The retainer lens schedule must be customized for each patient. The retainer lens wearing time begins with the same wearing time required for the last fitted CONTEX OK® lenses. There is considerable variability, as many patients require several hours more or less than the averages. After a period of several weeks or months, the retainer lens wearing time can be reduced daily by intervals of one hour. This may continue for as long as the patient can see clearly for the remainder of the day following lens removal. When it is found that the patient experiences a visual decrement following lens removal, the previous wearing time is then followed on a daily basis.

**HANDLING OF LENSES:**

Standard procedures for rigid gas permeable lenses may be used.

**Caution: CONTEX OK® (Orthokeratology) contact lenses are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.**

**PATIENT LENS CARE DIRECTIONS:**

Please see package insert.

**VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS:**

Standard charts may be used.

**REPORTING OF ADVERSE REACTIONS:**

All serious adverse experiences and adverse reactions observed in patients wearing the lenses should be reported to:

Contex, Inc.  
4505 Van Nuys Blvd.  
Sherman Oaks,  
CA 91403  
Phone 1-818-788-5836

**HOW SUPPLIED:**

Each lens is supplied non-sterile in an individual flat pack case containing one or two lenses. The container is marked with the base curve, distance power, diameter, center thickness, color, and lot number.

**TECHNICAL ASSISTANCE:**

For further technical assistance please contact one of the friendly knowledgeable Contex Orthokeratology Consultants.

**CONTEX** INC.

*Inventors of  
Reverse Geometry OK® Lenses  
For Orthokeratology*

**4505 Van Nuys Blvd  
Sherman Oaks, CA 91403 USA**

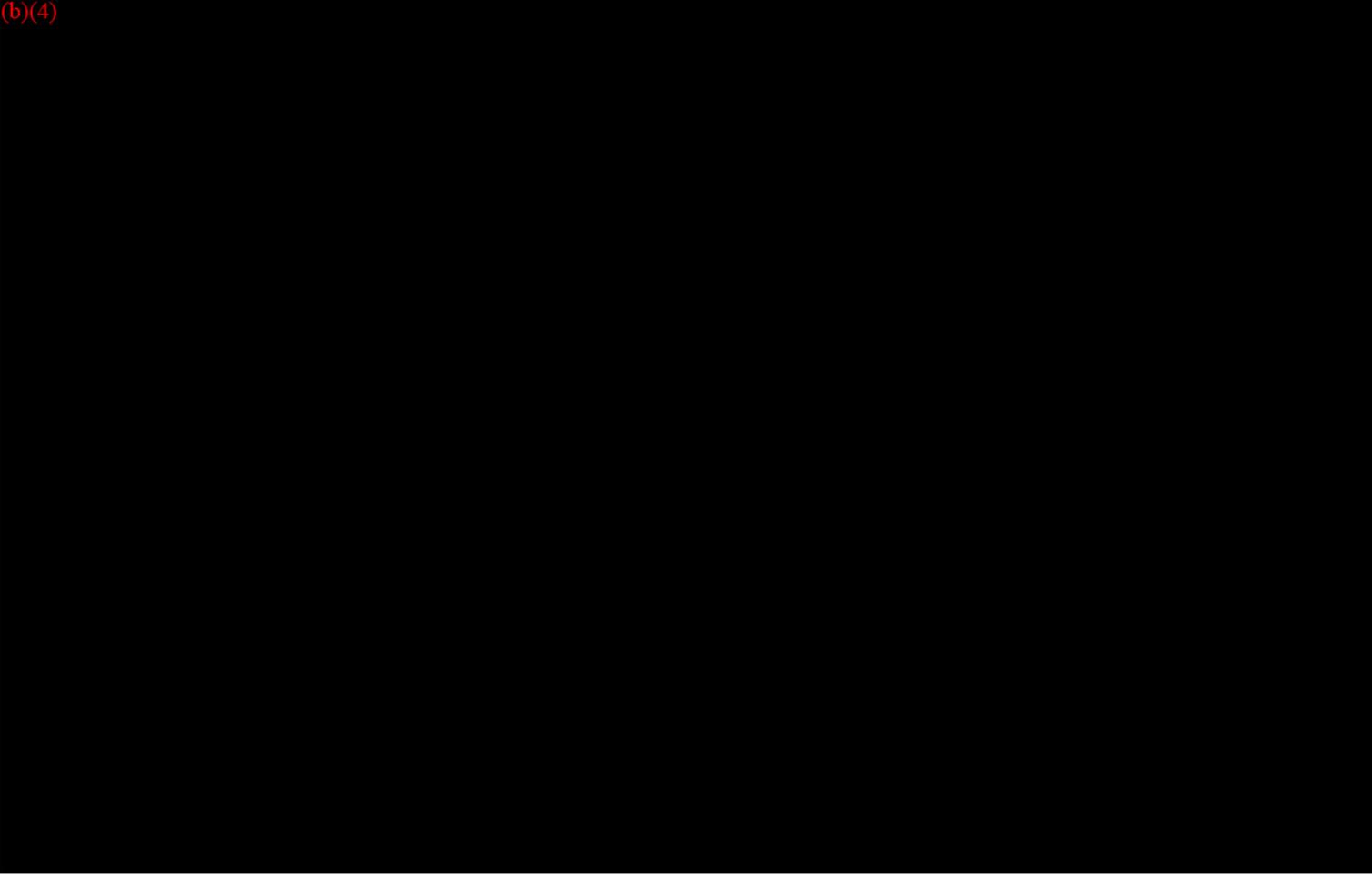
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**510(K) PREMARKET NOTIFICATION**  
**BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology**

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**Appendix 3**

**510(k) Summary of Safety And Effectiveness**

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

### FOR

### BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

1. **SUBMITTER INFORMATION:**

Polymer Technology  
Global Vision Care  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

2. **CONTACT PERSON:**

	Debra L.B. Ketchum
	Manager, Regulatory Affairs
Address:	1400 North Goodman Street
	P.O. Box 30450
	Rochester, New York 14603-0450
Telephone No.:	(716) 338-8638
Fax No.:	(716) 338-0702
E-mail Address:	dketchum@bausch.com

3. **DEVICE IDENTIFICATION:**

Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens

Proprietary Name: BOSTON XO (hexafocon A) Contact Lens  
for Orthokeratology

Common Name: Fluoro silicone acrylate rigid gas permeable contact lens  
material

4. **PREDICATE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocin A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

**5. DESCRIPTION OF THE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206. The hexafocon A material has an oxygen permeability (Dk) of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN)

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is hexafocon A, is a fluoro silicone acrylate material.

**6. INDICATIONS FOR USE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens must be disinfected using a chemical disinfection system only.

**7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:**

The safety and efficacy of *BOSTON XO (hexafocon A) Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K000795, cleared on May 26, 2000. Also, the use of a rigid gas permeable contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology 510(k) Premarket Notification No. K973697, cleared on April 8, 1998.

**8. SUBSTANTIAL EQUIVALENCE**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

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