



7950010

Memorandum

Date Jul - 9 1995

From Director, Office of Device Evaluation (HFZ-400)  
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Polymer Technology Division of  
Wilmington Partners L.P.'s Boston SIMPLICITY™ - ACTION

To *[Handwritten Signature]*  
The Director, CDRH  
ORA \_\_\_\_\_

**ISSUE.** Publication of a notice announcing approval of the subject PMA.

**FACTS.** Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

**RECOMMENDATION.** I recommend that the notice be signed and published.

*[Handwritten Signature]*  
Susan Alpert, Ph.D. M.D.

Attachments  
Tab A - Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. \_\_\_\_\_]

POLYMER TECHNOLOGY DIVISION OF WILMINGTON PARTNERS L.P.;  
PREMARKET APPROVAL OF BOSTON SIMPLICITY™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Polymer Technology Division of Wilmington Partners L.P., Wilmington, MA, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of Boston SIMPLICITY™. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on JUN -9 1995, of the approval of the application.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm 1-23, 12420 Parklawn Drive, Rockville, MD

FOR FURTHER INFORMATION CONTACT:

David M. Whipple,  
Center for Devices and Radiological Health (HFZ-460),  
Food and Drug Administration,  
9200 Corporate Blvd.,  
Rockville, MD 20850,  
301-594-1744.

SUPPLEMENTARY INFORMATION: On March 6, 1995, Polymer Technology Division of Wilmington Partners L.P., Wilmington, MA 01887, submitted to CDRH an application for premarket approval of Boston SIMPLICITY™. The device is a cleaning, rinsing, disinfecting and conditioning solution and is indicated for cleaning, rinsing, disinfecting and conditioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act section 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: \_\_\_\_\_.

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D. Bruce Burlington, M.D.  
Director



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Beverley A. Doyle, Ph.D.  
Senior Regulatory Affairs Associate  
Polymer Technology  
100 Research Drive  
Wilmington, MA 01887

JUN - 9 1995

RE: P950010  
Boston SIMPLICITY™  
Filed: March 6, 1995  
Amended: March 10, May 10, and June 9, 1995

Dear Dr. Doyle:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Boston SIMPLICITY™. This device is indicated for cleaning, rinsing, disinfecting and conditioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

Expiration dating for this device has been established and approved at 24 months for the 30, 60, and 120 mL bottle sizes. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

Page 2 - Beverley A. Doyle, Ph.D.

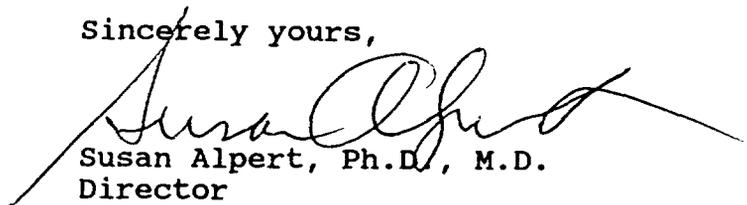
You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

If you have any questions concerning this approval order, please contact Ms. Eleanor M. Felton or Mr. David M. Whipple at (301) 594-1744.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Susan Alpert", written in dark ink. The signature is fluid and extends across several lines of text.

Susan Alpert, Ph.D., M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**CONDITIONS OF APPROVAL**

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be handled

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
  - (a) has not been addressed by the device's labeling or
  - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)  
Center for Devices and Radiological Health  
Food and Drug Administration  
1350 Piccard Drive, Room 240  
Rockville, Maryland 20850  
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems

## Summary of Safety and Effectiveness

### I. General Information

- A. Premarket Approval Application (PMA) Number: P950010  
Date Filed: March 6, 1995  
Date Approved: JUN - 9 1995
- B. Device Generic Name: cleaning, rinsing, disinfecting  
and conditioning solution
- C. Device Trade Name: Boston SIMPLICITY™
- D. Applicant's Name and Address: Polymer Technology  
Division of Wilmington Partners, L.P.  
100 Research Drive  
Wilmington, MA 01887
- E. Good Manufacturing Practice (GMP) Inspection:  
Date of Inspection: March 1, and April 6, 1994  
Conclusion: The manufacturing sites were found to be  
in compliance with device GMP requirements.

### II. Indications

Boston SIMPLICITY™ is indicated for cleaning, rinsing, disinfecting and conditioning of fluoro silicone acrylate and silicone acrylate rigid gas permeable (RGP) contact lenses.

### III. Summary

The applicant performed non-clinical and clinical testing on the device in accordance with the FDA Testing Guidelines for Class III Soft (Hydrophilic) Contact Lens Solutions dated July 1985. The non-clinical testing supports the safety and effectiveness of the device from microbiology, toxicology, chemistry and manufacturing perspectives. Data from a controlled, randomized, double-masked, multicenter parallel group clinical study consisting of 428 eyes in the Test Group using the subject device and 454 eyes in a Control Group using the Boston Conditioning Solution. The subjects in both groups were followed for 6 months and clinically evaluated. The Test Group included 35 males and 179 females and the Control Group included 32 males and 195 females which is representative of the contact lens wearing population in the

IV. Safety and Effectiveness Data

A. Non-clinical Data

The applicant conducted a battery of in-vivo and in-vitro acute toxicology studies that support the safety and biocompatibility of the solution with fluoro silicone acrylate and silicone acrylate RGP contact lens materials. Additionally, chemistry and manufacturing information was submitted demonstrating that the solution is suitable for use to clean, rinse, and condition fluoro silicone acrylate and silicone acrylate lens materials. The adequacy of the manufacturing process, including sterilization and shelf-life expiration dating, was established through a review of the manufacturing and microbiology data submitted in the PMA as well as through an on-site GMP inspection. Additionally, microbiology data were submitted demonstrating that the solution is effective in disinfecting fluoro silicone acrylate and silicone acrylate RGP lenses.

B. Clinical Data (Test Group)

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Accountability (478 eyes enrolled): 428 completed and  
50 discontinued\*

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Visual Acuity:	<u>Initial Visit with Lens</u>	<u>Final Visit with Lens</u>
20/30 or better	428	411
20/40 or worse	0	11
Not Reported	0	6

Wear Time:	<u>Initial Adapted (1 week)</u>	<u>Final (6 months)</u>
Daily	13.8 hours	13.8 hours

Adverse Reactions: 2 reported\*\*

Slit Lamp Findings:	<u>Initial Visit</u> (201/428 eyes)=47.0%	<u>Final Visit</u> (177/428 eyes)=41.4%
Staining (Total)	134	102
> grade 2	0	2
Injection (Total)	35	49
> grade 2	0	1

C. Clinical Data (Control Group)

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Accountability (480 eyes enrolled): 454 completed and  
26 discontinued\*

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Visual Acuity:	<u>Initial Visit with Lens</u>	<u>Final Visit with Lens</u>
20/30 or better	454	438
20/40 or worse	0	12
Not Reported	0	4

Wear Time:	<u>Initial Adapted (1 week)</u>	<u>Final (6 months)</u>
Daily	14.0 hours	14.0 hours

Adverse Reactions: None reported for all eyes enrolled

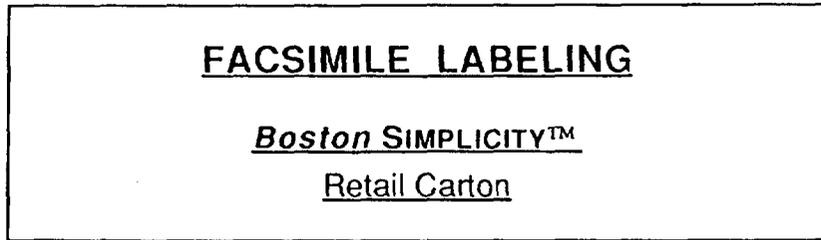
Slit Lamp Findings:	<u>Initial Visit (266/454 eyes)=58.6%</u>	<u>Final Visit (203/454 eyes)=44.7%</u>
Staining (Total)	183	123
> grade 2	0	2
Injection	54	48
Tarsal Abnormalities	10	15
Other	19	17

Symptoms, Problems, Complaints: (1889 reports/4100 exams)=46.1%  
Categories reported=13  
Vision Related (e.g. variable vision) (477/1889)=25.3%  
Comfort (e.g. dryness, pain, itching) (1164/1889)=61.6%  
All Other (248/1889)=13.1%

Lens Replacements: (105 replaced/454 dispensed)=23.1%  
Categories reported=9  
Vision Related (e.g. fit, blur) (20/105)=19.0%  
Lens Related (e.g. warpage) (24/105)=22.9%  
Other (e.g. breakage, lost) (61/105)=58.1%

\*None associated with pathology

V. Conclusion



Side (left):

New! (flag)  
**Boston SIMPLICITY™**  
**Multi-Action Solution**

Cut along line for directions and important safety information printed on inner carton.

PACKAGE MADE FROM RECYCLED PAPERBOARD(symbol)

(Olympic Rings) Polymer Technology, a division of Wilmington Partners L.P., a Bausch & Lomb affiliate

Questions or Comments : 1-800-333-4730(telephone symbol) HOURS.:9am-5pm EST  
© 1995 Made in USA

US Patents Pending

Top Flap:

TAMPER EVIDENT SEAL  
Do not use if imprinted neck band on bottle is missing or broken.

New! (flag)  
**Boston SIMPLICITY™**  
**Multi-Action Solution**

Front:

New! (flag)  
**Boston SIMPLICITY™**  
**Multi-Action Solution**

- Convenient, Effective  
CLEANING

Top Dust Flaps

See Package Inner Carton for Directions and Important Safety Information

Side (right):

New!

**Boston SIMPLICITY™**  
**Multi-Action Solution**

**WARNINGS:** To avoid contamination, never touch dropper tip of the container with your hands or to any surface. Keep bottle tightly closed when not in use.

**Contraindications:** Do not use this solution if you are allergic to any ingredient in this product. Not For Use With Soft (hydrophilic) Contact Lenses.

Discard solution ninety (90) days after opening. Record date opened in space provided on bottle label. Note: When used daily, BOSTON SIMPLICITY Solution will be depleted before 90 days.

We recommend that you store this solution at room temperature. Avoid freezing.

Back:

**New from the makers of the leading Doctor Recommended Solutions\*.** BOSTON SIMPLICITY™\*\* Solution is a very convenient RGP regimen which is proven clinically effective for lens care. The care of your contact lenses is now this simple with cleaning, rinsing, disinfecting and conditioning in one solution. This unique formula combines a cushioning and wetting solution with an effective cleaning system. It's all you need for convenient RGP lens cleaning and conditioning in one bottle. In patient surveys, new BOSTON SIMPLICITY Solution was preferred over their current two product regimen of separate cleaner/conditioning solution.

Unique to RGP solutions, new BOSTON SIMPLICITY Solution contains a wetting agent\*\* that assists in the cleaning process of your RGP lenses. Elements of this wetting agent help to neutralize the irritating potential of the surfactants without compromising their cleaning efficacy. This unique ingredient, in combination with a dual action cleaning system, removes protein and lipids from the lens surface and also helps keep stubborn deposits away from lenses. This solution is also designed for rinsing lenses, which eliminates loosened deposits

**Active Ingredients:**

BOSTON SIMPLICITY™ Solution is a sterile, buffered, slightly hypertonic solution. Only this unique formula\*\* contains a combination of the following effective ingredients:

Cleaning Agents:

- PEO sorbitan monolaurate
- Betaine surfactant

Wetting & Cushioning Agents:

- Silicone glycol copolymer\*\*
- Derivatized polyethylene glycol
- Cellulosic viscosifier

Preservatives:

- Polyaminopropyl biguanide (0.0005%)
- Chlorhexidine gluconate (0.003%)
- Edetate disodium (0.05%)

\* HPR Data

\*\* Patent Pending

Polymer Technology  
a division of Wilmington Partners L.P.  
Wilmington, MA 01887

**Boston SIMPLICITY™** is a trademark of Polymer Technology, a division of Wilmington Partners L.P.

Part #

Bottom:

Expiration Date

Lot #

**FACSIMILE LABELING****Boston SIMPLICITY™****Retail Bottle Label****Front:**

New!  
**Boston SIMPLICITY™**  
**Multi-Action Solution**

Cleaning • Rinsing • Disinfecting • Conditioning

For Rigid Gas Permeable Contact Lenses  
See Inner Carton or Insert For Lens List, Directions and Important Safety Information

4 FL OZ (120 ml)  
Sterile                  Patent Pending                  Part #

**Back:****DIRECTIONS**

To ensure proper disinfecting, all steps listed below must be followed:

- Wash your hands with mild soap
- Rub both sides of the lenses carefully with two (2) to four (4) drops of BOSTON SIMPLICITY™ Solution in the palm of your hand for twenty (20) seconds. No separate daily cleaner is required.
- Rinse for approximately five (5) seconds with BOSTON SIMPLICITY Solution to eliminate loosened surface deposits. (Note: This product removes the need for a tap water rinse).
- Place lenses in lens case and fill with fresh BOSTON SIMPLICITY Solution. Soak lenses

**Contraindications:** Do not use this solution if you are allergic to any ingredient in this product. Not For Use With Soft (hydrophilic) Contact Lenses.

**Active Ingredients:** A sterile, buffered, slightly hypertonic solution containing PEO sorbitan monolaurate and a betaine surfactant as cleaning agents; a silicone glycol copolymer, a cellulosic viscosifier and a derivatized polyethylene glycol as wetting and cushioning agents; preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%) and edetate disodium (0.05%).

**Do not use if imprinted neck band on bottle is missing or broken.**

Polymer Technology  
a division of Wilmington Partners L.P.  
Wilmington, MA 01887

Questions or Comments : 1-800-333-4730      HOURS: 9AM-5PM EST

MADE IN USA      © 1995

US Patents Pending  
EXP. DATE/LOT NO.

**FACSIMILE LABELING*****Boston SIMPLICITY™*****Retail Package Insert (Front)****NEW! *Boston SIMPLICITY™*  
Multi-Action Solution**

For Cleaning, Rinsing, Disinfecting and Conditioning Fluoro Silicone Acrylate and Silicone Acrylate Rigid Gas Permeable Contact Lenses

(The following captions are shown beneath illustrations:)

**DIRECTIONS FOR USE**

To ensure proper disinfecting, all steps listed below must be followed:

1. Wash your hands with mild soap
2. Rub both sides of the lenses carefully with two (2) to four (4) drops of BOSTON SIMPLICITY™ Solution in the palm of your hand for twenty (20) seconds. No separate daily cleaner is required.
3. Rinse for approximately five (5) seconds with BOSTON SIMPLICITY Solution to eliminate loosened surface deposits. (Note: This product removes the need for a tap water rinse).
4. Place lenses in lens case and fill with fresh BOSTON SIMPLICITY Solution. Soak lenses for at least four (4) hours (or overnight) before wearing. Always use fresh solution for soaking and storing lenses.
5. After removing lenses from the lens case, apply fresh BOSTON SIMPLICITY Solution to wet the lenses for additional cushioning, if desired, and insert.

**FACSIMILE LABELING****Boston SIMPLICITY™****Retail Package Insert (Back)**

**Description:** *Boston SIMPLICITY™* Solution is a sterile, buffered, slightly hypertonic solution containing PEO sorbitan monolaurate and a betaine surfactant as cleaning agents; a silicone glycol copolymer, a cellulosic viscosifier and a derivatized polyethylene glycol as wetting and cushioning agents, preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%) and edetate disodium (0.05%).

**Actions:** This solution removes protein and lipids from the lens surface and also helps keep stubborn deposits away from lenses. This solution is also designed for rinsing lenses, which eliminates loosened surface deposits from the lens.

A multi-polymer cushioning system conditions the lens to provide cushioning upon insertion and enhanced uniform wetting. A patented humectant maintains lens wettability. This formula is designed to provide a soothing effect to your eyes. It also contains a preservative system proven effective in destroying harmful organisms. This solution is effective both in cleaning and disinfecting, yet is compatible with the eye upon lens insertion.

**Indications:** BOSTON SIMPLICITY Solution is indicated for cleaning, rinsing, disinfecting and conditioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

**Contraindications:** This solution is not for use with soft (hydrophilic) contact lenses. Do not use this solution if you are allergic to any ingredient in this product.

**Warnings:** To avoid contamination, never touch dropper tip of the container with your hands or to any surface. Keep bottle tightly closed when not in use.

Contact lenses and solutions, if not handled properly can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and loss of vision may result from using contaminated solutions or from wearing contaminated or damaged contact lenses.

**PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD**

**Precautions:** To ensure proper hygiene and handling of contact lenses and contact lens solutions, always follow label directions carefully.

- Never reuse this solution.
- Always wash your hands before handling your lenses.
- Store solutions at room temperature. Avoid freezing.
- After inserting your lenses, always thoroughly clean the interior of the lens case with hot water and air dry after each use.
- Always use fresh solution for soaking and storing lenses.
- Use before expiration date on the container.
- **ALWAYS RINSE LENSES THOROUGHLY WITH BOSTON SIMPLICITY™ SOLUTION AFTER CLEANING TO ELIMINATE LOOSENED SURFACE DEPOSITS**
- **SOAK LENSES IN BOSTON SIMPLICITY SOLUTION FOR AT LEAST FOUR (4) HOURS (OR OVERNIGHT) BEFORE WEARING.**
- **Keep out of reach of children**

Discard solution ninety (90) days after opening. Record date opened in space provided on bottle label.

Note: When used daily, BOSTON SIMPLICITY Solution will be depleted before 90 days.

**Adverse Effects: The following problems may occur:**

- Eyes stinging, burning, itching (irritation)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above conditions, immediately remove and examine the lenses. If the problem stops and the lenses appear to be undamaged, thoroughly clean, rinse and disinfect the lenses and reinsert. If the problem continues or if a lens appears to be damaged DO NOT REINSERT. Contact your eye care professional immediately. If any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and treatment to avoid serious eye damage.

**How Supplied:** BOSTON SIMPLICITY™ Solution is supplied sterile in 4 fluid ounce (120 ml) and 2 fluid ounce (60 ml) bottles. All retail Boston® solutions are packed in unit cartons. Bottles are sealed with an imprinted neck band and marked with a lot number and expiration date.

**Do not use if imprinted neck band on bottle is missing or broken.**

\*\* Patent Pending

Part #

Print Date Mth/Yr.

Made in USA

© 1995

Manufactured for:

Polymer Technology, a division of Wilmington Partners L.P., Wilmington, MA 01887

Questions or Comments : 1-800-333-4730 HOURS: 9AM-5PM EST

***Boston®*** and ***Boston SIMPLICITY™*** are trademarks of Polymer Technology, a division of Wilmington Partners L.P.