P980006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dennis Hahn
Manager, Regulatory Affairs
Bausch & Lomb
1400 N. Goodman Street
P.O. Box 450
Rochester, NY 14603-0450

FEB - 5 1999

Re: P980006
PureVision™ (balafilcon A) Visibility Tinted Contact Lens for Extended Wear
Filed: March 6, 1998
Amended: March 16, June 10, July 17, August 21, September 30, October 8, and November 4, 1998 and January 11, 1999

Dear Mr. Hahn:

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 PureVision™ (balafilcon A) Visibility Tinted Contact Lens. This device is indicated for daily or extended wear from 1 to 7 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. 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.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

Expiration dating for this device has been established and approved at 2 years. 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).

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA

number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

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 Karen F. Warburton or James F. Saviola, O.D. at (301) 594-1744.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Issued: 3-4-98

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 briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

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.

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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:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(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 mix-up 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 applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar 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 a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

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Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

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SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

A. Device Generic Name: balafilcon A hydrophilic contact lens

B. Device Trade Name: PureVision™ Contact Lens

C. Applicant's Name and Address: Bausch & Lomb Incorporated
1400 N. Goodman Street
Rochester, NY 14692-0450

D. Premarket Approval (PMA) Application Number: P980006

E. Date of Notice of Approval to Applicant: FEB - 5 1999

II. Indications for Use

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be disinfected using either a heat or chemical disinfection system.

III. Device Description

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is manufactured from balafilcon A material, which falls into the FDA Group 3 category for a low water, ionic contact lens. The lens is tinted with up to 300 ppm of Reactive Blue 246 (1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone) which imparts a light blue color to aid the lens wearer in handling. Use of the Reactive Blue 246 is in conformance with 21 CFR Part 73.3106 where the color additive is copolymerized with 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate and N-vinyl pyrrolidone to form the contact lens material. The lens may be prescribed in powers ranging from +20.00D to -20.00D

IV. Contraindications and Warnings

Please refer to approved labeling.

V. Alternate Practices and Procedures

The alternate practices and procedures to the BAUSCH & LOMB® PureVision™ Contact Lens are other soft (hydrophilic) extended wear contact lenses, rigid gas

permeable extended wear contact lenses, radial keratotomy, photorefractive keratectomy, or spectacles.

VI. Marketing History in the United States

The PureVision™ (balafilcon A) contact lenses have been the subject of two 510(k) pre-market notification submissions:

K944895 - Bausch & Lomb received a determination of substantial equivalence for the Bausch & Lomb Premier™ 90 (balafilcon A) Contact Lens for Daily Wear on September 30, 1994 (clear version).

K972454 - Bausch & Lomb received a determination of substantial equivalence for the Bausch & Lomb OxyCor (balafilcon A) Visibility Tinted Contact Lens for Daily Wear on August 8, 1997.

Neither the clear (Premier™ 90) or the visibility tinted (OxyCor) daily wear lenses have been introduced to the market in the United States or any other country.

The PureVision™ (balafilcon A) Visibility Tinted Contact Lens (up to 7 day extended wear) received CE Mark approval from the National Standards Authority of Ireland (NSAI) on May 11, 1998.

VII. Potential Adverse Effects of the Device on Health

Potential adverse effects on health associated with extended wear contact lenses include eye problems such as corneal ulcers, epithelial microcysts, infiltrates and endothelial polymegathism. The risk of corneal ulcer has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Strict compliance with the proper lens care regimen and wearing schedule is essential in minimizing risk.

VIII. Summary of Preclinical Studies

Note: The balafilcon A material was code named RD-677 for research and development purposes.

The following tests were performed:

(1) Cytotoxicity
(2) Systemic Injection Toxicity Testing
(3) Ocular Irritation Testing
(4) Twenty-One Day Ocular Irritation Testing
(5) Leachables Testing
(6) Guinea Pig Maximization (Kligman) Testing
(7) Performance Testing

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a. Chemical, Spectral and Physical Properties Testing

Physiochemical Property	balafilcon A
Water Content (%)	36
Oxygen Permeability (10^{-11}[cm^3 O_2(STP)xcm]/(secxcm^2xmmHg)@35°C)	99
Refractive Index	1.426
Specific Gravity	1.064
Tensile Strength (g/mm^2)	50
Toughness (g/mm)	28
Modulus (g/mm^2)	130
Elongation (%)	80
Light Transmittance (CIE Value %)	96

b. Solution Compatibility Testing

(8) Shelf Life / Stability

An expiration date of two years from the month of sterilization has been established.

The results of the preclinical tests support the safety of the balafilcon A lens for its intended use.

IX. Summary of Clinical Studies

Non-Dispensing Overnight Corneal Swelling Performance of RD-677 and Control Lenses (GVC2-97-078)

The objective of this study was to measure the corneal swelling induced in adapted daily wear soft contact lens patients during overnight wear. The study was carried out under IDE G930037/S019. Thirty (30) subjects each wore an RD-677 and a control hydrophilic contact lens on the contralateral eye overnight under closed eye conditions for approximately eight hours. The swelling measured with the control contact lenses (9.1%) was significantly greater that that measured in conjunction with the RD-677 contact lenses (4.1%).

A Clinical Evaluation of the Bausch & Lomb RD-677 Contact Lens When Compared to a Control Contact Lens When Used for Extended Wear (Study #169)

(1) Study Objective

The objective of this study was to evaluate the safety and efficacy of the Bausch & Lomb RD-677 Contact Lens (test), when compared to a currently marketed Group IV, 58% water, hydrophilic contact lens (control), focusing on corneal infiltrates, slit lamp findings, patient symptoms and visual acuity as primary endpoints. This study was designed specifically to examine the difference in the rate of infiltrates between the RD-677 and the control lens. These lenses were worn by myopic phakic patients on an extended wear basis. The study was carried out under IDE G930037.

This study employed a randomized contralateral control design, in which each patient was assigned to wear one lens type (RD-677 or control lens) OD (in the right eye), and the other lens type OS (in the left eye), for the duration of the study.

The following are the safety and efficacy measures evaluated in this study:

Safety:	Efficacy:
Adverse Effects	Lens Visual Acuity
Patient Symptoms/Complaints	Lens Centration
Mire Reflex	Lens Deposits
Positive Slit Lamp Findings	Visual Acuity Line Changes
Keratometry	Lens Movement
Refractive Changes	Lens Debris
	Lens Wettability

Equivalence was defined in terms of the difference in the true frequencies of occurrences between the test and control lenses. The lenses were considered clinically equivalent if the outcome frequencies did not differ by more than 10%; this assumption determined the sample size of 200 patients (400 eyes).

(2) Study Population

A total of 400 eyes (200 patients) were enrolled by fourteen (14) Investigators into this study. Patients were fitted with a Bausch & Lomb RD-677 contact lens on one eye while the contralateral eye was fitted with a control contact lens according to randomization tables supplied to the Investigators. There were 132 females and 68 males, with a ratio of 1.94 females to every male. Their ages ranged from 18 to 52 years of age with a mean age of 33.6 years.

(3) Study Period

This was a twelve (12) month study. The study began in October 1996 and ended in October 1997.

The protocol for Study #169 (G930037/S013) specified a 12 month study with the RD-677 and control lenses being replaced every three (3) months and seven (7) days, respectively. An extension to Study #169 (G930037/S017) was approved with the objective to extend the study an additional six months and change the lens replacement cycle for both the RD-677 and control lenses to two (2) weeks). The results of the 6 month study extension are discussed separately later in this summary.

(5) Study Methods and Data Analysis Methods

The protocol specified that the patients were to wear the designated lenses on an extended wear basis. Patients were instructed to wear the lenses overnight for up to six consecutive nights per week. Both lenses had to be worn overnight at least four consecutive nights per week.

The statistical analyses utilized the study data pooled over the investigative sites. The patient bases from the sites were similar with respect to size and demographics. All investigative sites followed the same detailed investigative plan.

The statistical analyses for the frequency-of-occurrence parameters compared the RD-677 and control lenses with respect to the proportions of eyes in which particular outcome events occurred during each time frame. The time interval was defined as the end of one scheduled visit until the end of the next scheduled visit. Multiple occurrences of slit lamp findings for a given patient during the same time interval, however, were only counted once. These outcome events included:

- A score of 2 or greater on a graded slit lamp parameter
- The occurrence of a positive finding for an ungraded slit lamp parameter
- A positive symptom report
- A lens VA worsening of 2 lines or more
- Sub-optimal findings for lens centration, lens movement, lens deposits, lens debris, or lens wettability

(6) Safety Data

a. Adverse Effects

There were no unanticipated adverse effects during the course of this study. There were also no reports of corneal ulcers, anterior uveitis (iritis), or permanent loss of vision.

Anticipated adverse events were noted for 7 eyes (4 test and 3 control). There were 23 eyes (14 test and 9 control) that experienced positive slit lamp findings requiring treatment. There were 10 eyes (6 test and 4 control) with symptoms requiring treatment. The pooled summary table for slit lamp findings noted that there were 7 reports of infiltrates in 4 test eyes and 2 reports of infiltrates in 1 control eye.

b. Positive Slit Lamp Findings

Summary of Slit Lamp Findings for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
No Slit Lamp Findings	1141	55.4	1125	54.6	97	43.5	92	41.3
Epithelial Edema								
Grade 0	2030	98.6	2030	98.6	218	97.8	214	96.0
Grade 1	27	1.3	28	1.4	5	2.2	8	3.6
Grade 2 or greater	2	0.1	1	<0.05	0.0	0.0	1	0.4
Epithelial Microcysts								
Grade 0	2020	98.1	1998	97.0	217	97.3	215	96.4
Grade 1	37	1.8	55	2.7	6	2.7	7	3.1
Grade 2 or greater	2	0.1	6	0.3	0.0	0.0	1	0.4

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
Corneal Staining								
Grade 0	1573	76.4	1567	76.1	163	73.1	151	67.7
Grade 1	434	21.1	439	21.3	45	20.2	53	23.8
Grade 2 or greater	52	2.5	53	2.6	15	6.6	19	8.5
Limbal Injection								
Grade 0	1832	89.0	1822	88.5	184	82.5	184	82.5
Grade 1	220	10.7	235	11.4	36	16.1	37	16.6
Grade 2 or greater	7	0.3	2	0.1	3	1.3	2	0.8
Bulbar Injection								
Grade 0	1766	85.8	1751	85.0	176	78.9	178	79.8
Grade 1	278	13.5	300	14.6	46	20.6	44	19.7
Grade 2 or greater	15	0.7	8	0.3	1	0.4	1	0.4
Tarsal Conjunctival Ab. (TCA)								
Grade 0	1799	87.4	1817	88.2	176	78.9	182	81.6
Grade 1	224	10.9	216	10.5	27	12.1	27	12.1
Grade 2 or greater	36	1.7	26	1.2	20	9.0	14	6.3
Corneal Neovascularization								
Grade 0	2057	99.9	2058	>99.0	223	100.0	220	98.7
Grade 1	2	0.1	1	<0.05	0	0.0	2	0.9
Grade 2 or greater	0	0.0	0	0.0	0	0.0	1	0.4
Striae	0	0.0	1	<0.05	0	0.0	1	0.4
Corneal Infiltrates*	7	0.3	2	0.1	0	0.0	0	0.0
Conjunctivitis	5	0.2	6	0.3	0	0.0	0	0.0
OASA	38	1.8	35	1.7	6	2.7	6	2.7
External Adnexa Ab.	8	0.4	7	0.3	2	0.9	0	0.0

Note: Percentages are based on total eye visits for slit lamp findings.
OASA - Other Anterior Segment Abnormalities; Ab - Abnormalities
* Seven reports (4 RD-677 Eyes); Two reports (1 Control Eye)

For each of the graded slit lamp parameters, analyses were performed to compare the RD-677 and control lenses with respect to the occurrence of scores of Grade 2 or higher during each of the study time frames. Each ungraded slit lamp parameter was scored according to the presence or absence of positive findings. Completed and discontinued eyes were pooled for these analyses.

- At all visits and for all graded and ungraded slit lamp findings except TCA, no significant differences were detected between the RD-677 and control lenses.
- TCA showed significance in favor of the control lenses at the 3 month and 5 month visits.
- Over the entire study, the rate of corneal infiltrates between the RD-677 and control lenses showed no significant difference at any time interval, achieving the study primary endpoint.

c. Patient Symptoms and Complaints

Summary of Patient Symptoms/Complaints for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
No Symptom	1506	73.0	1603	77.7	120	54.1	137	61.7
Discomfort	183	8.9	85	4.1	40	18.0	25	11.3
Dryness	291	14.1	269	13.0	58	26.1	46	20.7
Burning/Itching	74	3.6	60	2.9	26	11.7	16	7.2
Blurred Vision	115	5.6	54	2.6	25	11.3	10	4.5
Variable Vision	73	3.5	40	1.9	11	5.0	8	3.6
Handling Problems	2	0.1	126	6.1	2	0.9	16	7.2
Excess Tearing	10	0.5	5	0.2	6	2.7	5	2.3
Excess Secretions	30	1.5	24	1.2	11	5.0	3	1.4
Photophobia	6	0.3	4	0.2	7	3.2	6	2.7
Other Symptoms	43	2.1	42	2.0	5	2.3	11	5.0
Total # Positive Reports	827		709		191		146	

Note 1: Multiple symptoms/complaints may have been cited for one eye.
Note 2: Percentages are based on total eye visits for symptoms/complaints.

Each symptom parameter was scored according to the presence or absence of positive findings. For each of these parameters, analyses were performed to compare the RD-677 and control lenses with respect to the occurrence of symptoms during each of the study time frames for completed and discontinued eyes pooled.

- For Lens Handling, differences between the lenses were found to be significant in favor of the RD-677 lenses at all visits.
- For Discomfort, differences between the lenses were found to be significant in favor of the control lens at or beyond the 2 month visit except for the 4 month visit.
- For Blurred Vision, outside the 24 hour visit, differences between the lenses were found to be significant in favor of the control lens at the 3 month, 5 month, 6 month and 9 month visits.
- For the remaining symptoms/complaints categories, differences between the lenses were found to be non-significant at most (10 of 12) visits.

d. Keratometry and Mire Reflex

Keratometry (K) changes from baseline to final visit were one diopter or less for 99.1% of completed test eyes, and 99.4% for controls. The overall effects to K readings were minimal. Only one completed eye from each group experienced a slightly distorted mire, rather than clear/undistorted at the final visit.

e. Lens Replacements

The pooled total of completed and discontinued eyes at both scheduled and unscheduled visits accounted for 194 replacements for the test and 65 for the control lens. There were 74 replacements in the completed test eyes and 13 in the control eyes at unscheduled visits.

Lens Replacements Most Common Reasons (pooled)

Test		Control	
Deposits	45.4%	Changed Power	33.8%
Other*	18.6%	Deposits	21.5%
Discomfort	14.4%	Damage	20.0%
@ Unscheduled visits	32.2%	@ Unscheduled visits	5.7%

* 2/3's of these were related to preventing deposits

(7) Efficacy Data

a. Refractive Changes

Baseline refractions were compared to final visit refractions for both completed and discontinued eyes. There was one refractive change of 1.63 D reported in 1 discontinued test eye.

b. Visual Acuity (VA) Results

Summary of Follow-Up Visual Acuities for Completed and Discontinued Eyes at All Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
Lens VA								
20/20 or Better	1644	84.2	1747	88.6	147	73.1	176	87.6
20/30 or Better	1934	99.0	1971	99.9	196	97.5	200	99.5
20/40 or Better	1950	99.8	1972	100.0	199	99.0	201	100.0

Note: Percentages are based on total eye visits for visual acuities.

Summary of Lens Visual Acuity Line Changes (Comparison of Follow-Up Lens VA to Initial Spherocylindrical Refractive VA) for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
VA Line Changes								
-2 Lines or More	64	3.3	25	1.3	13	6.5	8	4.0
-1 Line	349	17.9	314	15.9	46	22.9	26	12.9
No Line Change	1444	73.9	1513	76.8	131	65.2	154	76.6
+1 Line	96	4.9	119	6.0	11	5.5	13	6.5
+2 Lines or More	0	0.0	0	0.0	0	0.0	0	0.0

Note 1: – indicates a decrease in VA; + indicates improvement in VA
Note 2: Percentages are based on total eye visits for lens VA line changes.

For lens visual acuity (VA) measured on the Snellen scale (*e.g.*, 20/20, 20/30, etc.), each was categorized as to whether or not the measured lens VA was 20/40 or worse at any point during each time frame. For visual acuity (VA) line changes (changes between initial spherocylindrical visual acuity and follow-up lens visual acuity, each measured on the Snellen scale), each was scored according to the number of Snellen-chart lines by which these two scores differed.

Analysis was conducted on pooled data for completed and discontinued eyes. The data showed the control lens was more favorable than the test lens for lens VA at the 3 and 6 month visits as well as lens VA line changes at the 4 day and 6 month visits. For all other visits there was no significant difference between the test and control lens.

c. Average Wear Time

Since this was a contralateral designed study, the average wear time was the same for both groups. Average wear time was 6 days following the 2 week visit. The distribution for completed eyes was:

Extended Wear Time:			
Days	1 to 3	4 to 6	7
Percent of eyes	18.5%	46.8%	33.0%

d. Lens Centration and Movement

Pooled data for completed eyes at all visits showed Excellent Centration in 93% of test and 75.5% of control eyes. Reports of poor centration were rare. The lens movement data showed adequate movement approximately 97% of the time in both completed groups. Findings were generally consistent throughout the study.

Lens centration was scored on an ordinal categorical scale, with each eye scored as Excellent, Fair, or Poor. For this parameter, each eye was subsequently categorized as to whether or not sub-optimal findings (*i.e.*, Fair or Poor) were presented at any point during each time frame. Lens movement was scored on a categorical scale, with each eye scored as Adequate, Excessive, Insufficient, or Adherence. For this parameter, each eye was subsequently categorized as to whether or not sub-optimal findings (*i.e.*, any score other than Adequate) were presented at any point during each time frame

Analysis was conducted on pooled data for completed and discontinued eyes. The data showed the RD-677 lens was more favorable than the control lens for centration at all visits. Although the percent of "insufficient movement" was 1.5% for the control lens compared to 0.6% for the test lens there was no statistically significant difference. At all visits with respect to Lens Centration and Lens Movement, differences between the RD-677 and control lenses were either non-significant, or in favor of the RD-677 lens.

e. Lens Deposits, Lens Debris and Lens Wettability

Note: Percentages are based on total eye visits for each parameter.

Extent of Lens Deposits for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
No Deposits	1190	61.0	1650	83.8	119	59.2	152	75.6
< 6 Small Deposits	435	22.3	193	9.8	47	23.4	33	16.4
Many Small or 1 Large Deposit	187	9.6	60	3.0	18	9.0	10	5.0
Multiple Medium-Large Deposits	139	7.1	66	3.3	17	8.5	6	3.0

Extent of Lens Debris for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
No Debris	1630	83.5	1704	86.5	161	80.1	163	81.1
Small Particles	281	14.4	233	11.8	35	17.4	38	18.9
Debris Noted	40	2.0	32	1.7	5	2.5	0	0.0

Lens Wettability for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
Entire Surface Wettable	1581	81.0	1756	89.2	153	76.1	168	83.6
Small Non-Wet Areas	280	14.4	172	8.7	42	20.9	27	13.4
Some Non-Wetting	90	4.6	41	2.1	6	3.0	6	3.0

For lens deposits, each eye was categorized as to whether or not positive findings (*i.e.*, any score greater than zero) were presented at any point during each time frame. For lens debris, each eye was categorized as to whether or not positive findings (*i.e.*, any score greater than zero) were presented at any point during each time frame. For lens wettability, each eye was categorized according to the presence or absence of a score below 3 at any point during each time frame. Completed and discontinued eyes were pooled for these analyses.

- At the 4 day and from the 1 month through the end of the study, control lenses had significantly fewer Lens Deposits.
- At all visits, with respect to Lens Debris, RD-677 and control lenses showed no significant differences.
- At the 4 day, 4 month, 6 month, and 9 month visits, control lenses showed significantly better Lens Wettability Scores.

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f. Patient Assessments

Patients were asked to complete a Patient Assessment Form at each scheduled follow-up visit. An analog scale was used to rate the lens types in four different categories, with 0 being poor and 100 being excellent. The following table presents a summary of patient assessments.

Summary of Patient Assessments for Completed and Discontinued Eyes at Scheduled Follow-Up Visits

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Comfort	85.9	14.5	85.4	13.4	78.1	20.4	80.6	16.1
Visual Quality	87.5	13.0	88.6	11.4	81.4	21.5	86.3	12.6
Lens Dryness	84.9	15.4	83.7	16.1	74.2	19.4	75.4	18.2
Lens Handling	92.2	10.0	72.9	24.3	85.7	15.8	71.1	23.7

Each patient assessment parameter was scored on an analog scale from 0 to 100, with higher scores representing more favorable assessments. In accordance with the protocol, these assessments were to be made at scheduled follow-up visits only; consequently, the analyses of these parameters *did not include* any data from unscheduled visits. For each parameter, analyses were performed to compare the RD-677 and control lenses with respect to the mean scores obtained on the respective lenses at each scheduled follow-up visit for completed and discontinued eyes pooled.

- At all visits, with respect to Lens Dryness, differences between the RD-677 and control lenses were not significant. With regard to Lens Handling, the differences were in favor of the RD-677 lens.
- For 11 of 12 visits, with respect to Comfort, differences between the RD-677 and control lenses were either non-significant, or in favor of the RD-677 lenses.
- Control lenses were more favorable at 24 hour, 2 month and 3 month visits for Visual Quality.

Six Month Extension to a Clinical Evaluation of the Safety and Efficacy of the Bausch & Lomb RD-677 Contact Lens Compared to the Control Contact Lens on an Extended Wear Basis (Study #169 Extension)

(1) Study Objective

The extension to Study #169 was approved with the objective of assessing the performance of the RD-677 contact lens for an additional six months. The lens replacement interval for both the RD-677 and control lenses was redefined to two weeks, to better evaluate deposits between the study lenses on an equal basis. The study extension began in October 1997 and was completed in May 1998. The study

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was conducted under IDE G930037/S017. The investigational plans for both the original 12 month Study #169 and the Study #169 Extension were approved by the Southwest Independent Institutional Review Board in July 1996 and August 1997, respectively.

The safety and efficacy measures evaluated in this study were the same as those evaluated in the original 12 month study.

(2) Study Population

One hundred and thirty-seven (137) patients entered the 6 month Study #169 Extension from the 163 patients who completed Study #169. The ages of the 137 enrolled patients ranged from 18 to 50 years of age with a mean age of 33.7. There were 93 females and 44 males, with a ratio of 2.11 females to every male. The Investigative sites were similar with respect to the demographic characteristics of the patient bases.

(3) Study Methods and Data Analysis

The protocol specified that the patients were to wear the designated lenses on a 7-day extended wear basis. Patients were instructed to wear the lenses overnight for at least four, and at most six consecutive nights per week. Both lenses were to be replaced with a new lens every two weeks.

Each patient was assigned to wear one lens type (RD-677 or control lens) in the right eye (OD) and the other lens type in the left eye (OS), for the duration of the study. The statistical analyses were performed in the same manner as those for the 12 month study.

(4) Safety Data

a. Adverse Events

There were no reports of corneal ulcers, anterior uveitis or permanent visual loss during the study. Anticipated adverse events were noted for 3 test eyes, but no control eyes. There was 1 test eye that experienced positive slit lamp findings requiring treatment and 2 test eyes with symptoms requiring treatment. There was 1 report of an infiltrate in a completed test eye, but none in any of the control eyes.

b. Positive Slit Lamp Findings

Summary of Slit Lamp Findings for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
No Slit Lamp Findings	180	65.9	175	64.1	1	20.0	1	20.0
Epithelial Edema								
Grade 0	272	99.6	271	99.3	5	100.0	5	100.0
Grade 1	1	0.4	2	0.7	0	0.0	0	0.0
Grade 2 or greater	0	0.0	0	0.0	0	0.0	0	0.0

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
Epithelial Microcysts								
Grade 0	269	98.5	264	96.7	5	100.0	5	100.0
Grade 1	3	1.1	9	3.3	0	0.0	0	0.0
Grade 2 or greater	1	0.4	0	0.0	0	0.0	0	0.0
Corneal Staining								
Grade 0	236	86.4	230	84.2		360.0	4	80.0
Grade 1	35	12.8	38	13.9	2	40.0	1	20.0
Grade 2 or greater	2	0.7	5	1.8	0	0.0	0	0.0
Limbal Injection								
Grade 0	244	89.4	249	91.2	4	80.0	4	80.0
Grade 1	27	9.9	24	8.8	1	20.0	1	20.0
Grade 2 or greater	2	0.7	0	0.0	0	0.0	0	0.0
Bulbar Injection								
Grade 0	240	87.9	241	88.3	3	60.0	3	60.0
Grade 1	30	11.0	31	11.4	2	40.0	2	40.0
Grade 2 or greater	3	1.1	1	0.4				
Tarsal Conjunctival Ab								
Grade 0	247	90.5	247	90.5	4	80.0	4	80.0
Grade 1	19	7.0	19	7.0	0	0.0	0	0.0
Grade 2 or greater	7	2.5	7	2.6	1	20	1	20
Neovascularization								
Grade 0	273	100.0	273	100.0	5	100.0	5	100.0
Grade 1	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2 or greater	0	0.0	0	0.0	0	0.0	0	0.0
Striae	0	0.0	0	0.0	0	0.0	0	0.0
Corneal Infiltrates	1	0.4	0	0.0	0	0.0	0	0.0
Conjunctivitis	0	0.0	0	0.0	0	0.0	0	0.0
OASA	6	2.2	7	2.6	0	0.0	0	0.0
Ext Adnexa Abnormalities	1	0.4	0	0.0	0	0.0	0	0.0

Note: Percentages are based on total eye visits for slit lamp findings

OASA - Other Anterior Segment Abnormalities

The statistical analysis results for slit lamp parameters were:

- At all visits, and for all graded and ungraded slit lamp findings, no significant differences were detected between the RD-677 and control lenses.
- Over the entire study, at each time interval, the rate of corneal infiltrates between the RD-677 and control lenses showed no significant differences.

c. Patient Symptoms and Complaints

Summary of Patient Symptoms/Complaints for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
No Symptom	213	78.0	210	76.9	1	20.0	2	40.0
Discomfort	16	5.9	9	3.3	2	40.0	2	40.0
Dryness	31	11.4	35	12.8	2	40.0	2	40.0
Burning/Itching	9	3.3	6	2.2	1	20.0	1	20.0
Blurred Vision	11	4.0	7	2.6	1	20.0	1	20.0
Variable Vision	6	2.2	1	0.4	1	20.0	0	0.0
Handling Problems	0	0.0	24	8.8	0	0.0	0	0.0
Excess Tearing	3	1.1	1	0.4	1	20.0	0	0.0
Excess Secretions	3	1.1	1	0.4	1	20.0	0	0.0
Photophobia	2	0.7	1	0.4	0	0.0	0	0.0
Other Problems	4	1.5	8	2.9	0	0.0	0	0.0
Total # Positive Reports	85		93		10		6	

Note 1: Multiple symptoms/complaints may have been cited for one eye.
Note 2: Percentages are based on total eye visits for symptoms/complaints.

The statistical analysis results were:

- For Handling Problems, differences between the lenses were found to be significant in favor of the RD-677 lenses at all visits.
- For Discomfort, differences between the lenses were found to be significant in favor of the control lens at the 3 month visit only.
- For Dryness, differences between the lenses were found to be significant in favor of the RD-677 lenses at the 6 month visit only.

d. Keratometry and Mire Reflex

There were no eyes with keratometry changes of more than one diopter. One hundred percent and 99.2% of completed eyes had clear and undistorted mire reflex at the initial dispensing visit for eyes wearing the RD-677 and control lenses, respectively. Three completed control eyes had a reduction to slightly distorted at the final visit. One hundred percent of the discontinued eyes had clear and undistorted mire reflex at the initial dispensing and final visits.

f. Lens Replacements

The pooled total of replacements was 17 in the RD-677 eyes and 18 in the control eyes. There were no replacements for discontinued eyes in either group.

Lens Replacements Most Common Reasons

Test (n=17)		Control (n=18)	
Changed Power	4	Changed Power	1
Other*	13	Other*	14
Discomfort	0	Discomfort	1
@ Unscheduled visits	12	@ Unscheduled visits	12

* Primarily spare lenses were dispensed

(7) Efficacy Data

a. Refractive Changes

There were no eyes with refractive changes of more than one diopter.

b. Visual Acuity (VA) Results

Summary of Follow-Up Lens Visual Acuities for Completed and Discontinued Eyes at All Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
Lens VA								
20/20 or Better	220	82.7	231	86.5	1	25.0	2	50.0
20/30 or Better	263	98.9	266	99.6	4	100.0	4	100.0
20/40 or Better	266	100.0	267	100.0	4	100.0	4	100.0

Note: Percentages are based on total eye visits for visual acuities.

Summary of Lens Visual Acuity Line Changes (Comparison of Follow-Up Lens VA to Initial Spherocylindrical Refractive VA) for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
VA Line Changes								
-2 Lines or More	7	2.6	5	1.9	0	0.0	1	25.0
-1 Line	49	18.4	47	17.6	3	75.0	1	25.0
No Line Change	200	75.2	200	74.9	1	25.0	2	50.0
+1 Line	10	3.8	15	5.6	0	0.0	0	0.0
+2 Lines or More	0	0.0	0	0.0	0	0.0	0	0.0

Note 1: – indicates a decrease in VA; + indicates improvement in VA
Note 2: Percentages are based on total eye visits for lens VA line changes.

Analyses with respect to the occurrence of positive findings during each of the study time frames showed that for both Lens VA and Lens VA Line Changes, no significant differences were detected between the RD-677 and control lenses at any time frame.

c. Extended Wearing Time

Since this was a contralateral designed study, the average wear time was the same for both groups. Average wear time was 6.4 days. The distribution for completed eyes was:

Extended Wear Time:			
Days	1 to 3	4 to 6	7
Percent of eyes	2.9%	47.6%	49.5%

d. Lens Centration and Movement

Pooled data for completed eyes at all visits showed Excellent Centration in 96.5% of test and 80% of control eyes. There were no reports of poor centration. The lens movement data showed adequate movement approximately 98% of the time for test eyes and 96.5% for control eyes.

Lens centration and movement were recorded and scored in the same manner as the 12 month study. The statistical analysis showed that at all visits, with respect to Lens Centration, differences between the RD-677 and control lenses were in favor of the RD-677 lens. Also, at all visits, with respect to Lens Movement, differences between the RD-677 and control lenses were not significant.

e. Lens Deposits, Lens Debris and Lens Wettability

Note: Percentages are based on total eye visits for each parameter

Extent of Lens Deposits for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed RD-677		Control		Discontinued RD-677		Control	
	#	%	#	%	#	%	#	%
No Deposits	226	85.0	215	80.5	2	50.0	3	75.0
< 6 Small Deposits	29	10.9	37	13.9	0	0.0	1	25.0
Many Small or 1 Large Deposit	7	2.6	9	3.4	2	50.0	0	0.0
Multiple Medium-Large Deposits	4	1.5	6	2.3	0	0.0	0	0.0

Extent of Lens Debris for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed RD-677		Control		Discontinued RD-677		Control	
	#	%	#	%	#	%	#	%
No Debris	227	85.3	220	82.4	2	50.0	2	50.0
Small Particles	32	12.0	45	16.9	2	50.0	2	50.0
Debris Noted	7	2.7	2	0.8	0	0.0	0	0.0

Lens Wettability for Completed and Discontinued Eyes at Scheduled and Unscheduled Follow-Up Visits (Pooled)

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	#	%	#	%	#	%	#	%
Entire Surface Wettable	228	85.7	222	83.1	2	50.0	3	75.0
Small Non-Wet Areas	30	11.3	37	13.9	1	25.0	0	0.0
Some Non-Wetting	8	3.0	8	3.0	0	0.0	0	0.0

The statistical analysis for lens deposits, lens debris and lens wettability showed:

- At all visits, with respect to Lens Deposits and Lens Wettability, RD-677 and control lenses showed no significant differences.
- At the 3-Month visit, control lenses had significantly fewer lenses with Lens Debris.

f. Patient Assessments

The patient assessment form and procedures for the 12 month study were used. The following table presents a summary of patient assessments.

Summary of Patient Assessments for Completed and Discontinued Eyes at Scheduled Follow-Up Visits

	Completed				Discontinued			
	RD-677		Control		RD-677		Control	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Comfort	86.4	13.4	82.3	15.8	85.5	16.3	87.5	13.4
Visual Quality	87.0	10.9	84.8	13.7	81.0	8.5	83.0	15.6
Lens Dryness	82.9	17.2	79.8	17.3	92.0	4.2	91.0	5.7
Lens Handling	92.2	8.4	65.9	25.2	96.0	1.4	80.0	12.7

The statistical analysis for the patient assessments showed that there was no significant difference found for lens dryness at the 3 month visit, but there was at the 6 month visit, in favor of the RD-677 lens. At all visits for the other three measures, differences between the RD-677 and the control were significant in favor of the RD-677 lens.

X. Conclusions Drawn from the Studies

These studies were designed to compare the occurrence rates of specific outcome parameters between the RD-677 and control contact lenses at predetermined timeframes or visit intervals. Many differences in outcomes (e.g., lens deposits, discomfort) between the control and test lens that were noted in the 12 month study were not seen in the 6 month study extension. It is reasonable to conclude that this is the result of the different lens replacement periods for the test and control lens in the 12 month study. Overall, the clinical performance of the test lens, as measured by the safety and efficacy outcomes, was comparable to that of the control lens. Although the potential exists for minor differences in physiological response by gender for the target population, the minimal

number of clinically significant findings does not indicate that gender differences are of clinical importance for this device. The preclinical and clinical data provide reasonable assurance that the PureVision™ contact lens is safe and effective when used as indicated in accordance with the directions for use.

XI. Panel recommendation

This PMA was not referred to the Ophthalmic Devices Panel, an FDA Advisory Panel, for review and recommendation because similar information has previously been reviewed by the Panel.

XII. FDA Decision

FDA issued an approval order on FEB - 5 1999

The manufacturing facility was found to be in compliance with device Good Manufacturing Practices (GMP). Final GMP approval was dated January 5, 1999.

Table of Contents

PATIENT INFORMATION BOOKLET

PATIENT INFORMATION BOOKLET

BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses

DISPOSABLE WEAR

CAUTION: Federal (U.S.A.) Law Prohibits Dispensing Without a Prescription

INTRODUCTION:

The instructions in this booklet apply to the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses when prescribed for Disposable Wear. If you have received or are considering another brand of contact lenses, do not use this booklet. Ask your eye care practitioner for the patient booklet or instructions that apply to your brand or type of contact lenses. For BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care practitioner answer any questions, both before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to begin or to continue wearing contact lenses for daily wear or extended wear, you should discuss with your eye care practitioner the effects of contact lenses on your eyes and the risks associated with wearing contact lenses, which are greater with extended wear contact lens use. You also should read the sections of this booklet entitled "Warnings", "Adverse Reactions", "Precautions", and "Wearing Restrictions and Indications". Ask your eye care practitioner to explain anything that you do not understand, including any additional restrictions which may be given to you by your eye care practitioner.

You also need to remember that soft contact lenses, including those covered by this booklet, are made of a type of plastic that absorbs liquids, vapors, and small particles, and, for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow the instructions contained in this booklet, as well as the written information leaflets accompanying the lens care products that you buy and any other instructions given to you by your eye care practitioner. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a build-up of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule, and regular check-up visits to your eye care practitioner are also necessary for the proper and safe use of contact lenses. Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not wear your lenses for longer periods than your prescribed wearing schedule simply because they remain comfortable and you are not experiencing a problem. Only your eye care practitioner, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the section of this booklet entitled "Warnings and Adverse Reactions". (Refer to "Glossary of Medical Terms" for description of medical terms used in this booklet.) Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

WEARING RESTRICTIONS AND INDICATIONS:

When prescribed for Disposable Wear, the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is indicated for daily or extended wear from 1 to 7 days between removals for disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

Note: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

- Keep a spare pair of lenses available in case you have to remove your lenses immediately upon the appearance of a problem or symptom.
- Do not use aerosol products such as hair spray while wearing your lenses. The lenses may absorb the spray, resulting in injury to the eye and damage to the lens.
- Avoid wearing the lenses around fumes, irritating vapors, smoky or dusty conditions. The lenses may absorb the chemicals or particles, resulting in injury to the eye.
- Avoid rubbing your eyes with the lenses in, which can irritate the eye or dislodge the lens.
- Keep your eyes closed tightly when washing or showering to keep water and soaps out of the eyes, which can cause loss of the lenses, contamination or injury to the eye.
- If you get something in your eye, remove the lens immediately. Do not replace with a new lens until your eye feels normal.
- Tell your regular physician and every other doctor that you visit, that you wear contact lenses and the type of lenses that you wear. If you are admitted to a hospital, also tell your nurses that you wear contact lenses.
- Do not use any eye drops, ointments, or medicines in your eye unless they are specifically approved by your eye care practitioner or physician. Some drops, ointments, or medicines will cause injury to the eye if used by a contact lens wearer.

- Ask your eye care practitioner whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

_____

_____

_____

_____

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS:

You should be aware of and fully discuss with your eye care practitioner the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in **serious injury** to your eye. It is essential that you follow your eye care practitioner's direction and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Strict compliance with your wearing restrictions, wearing schedule, and follow-up visit schedule should be followed.

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

EXTENDED WEAR

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcycsts and infiltrates, and endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

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

PRECAUTIONS:

You should be aware of and fully discuss with your eye care practitioner the following safety precautions:

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting your lenses.

- If the lens sticks (stops moving) on your eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on your eye for the continued health of your eye. If nonmovement of the lens continues, you should **immediately** consult your eye care practitioner. Do not attempt to remove the lens, except on the instructions of your eye care practitioner.

- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in your 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.

- Do not touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.

- Carefully follow the handling, insertion, and wearing instructions in these Patient Instructions for the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens and those prescribed by your eye care practitioner.
- Never wear lenses beyond the period recommended by your eye care practitioner.
- Always handle lenses gently and avoid dropping them.
- Ask your eye care practitioner about wearing lenses during water activities and other sports.
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with your fingernails.
- Always contact your eye care practitioner before using any medicine in your eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Your eye care practitioner should provide you with a recommended follow-up schedule.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):

You should be aware 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
- Abnormal feeling of something in the eye (foreign body, 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, you should:

- **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. You should discard the lens and insert a new lens on the eye. If the problem continues, you should **immediately remove the 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 **keep the lens off your eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS AND 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 substances 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.

   - Handle your lenses with your fingertips, and be careful to avoid contact with 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 mixups.

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

   - Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly.

     a. Less than usual comfort

     b. The lens may fold on the eye

     c. Excessive lens movement on blink

d. Blurred vision

- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rewetting solution. (Refer to the Lens Rewetting Products Chart for the solutions available from BAUSCH & LOMB.) Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion.

- If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.

3. Placing the Lens on the Eye:

(Application instructions in step-by-step format with graphics will be included in Final version)

There are other methods of lens placement. If the following methods are 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 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.

  c. The lens is inside-out (it would also not be as comfortable as normal).

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

The One Hand Placement Technique

Place the lens on your index finger. With your head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment: the lens will center itself on your eye.

The Two Hand Placement Technique

With the lens on your index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of your placement hand to pull down the lower lid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.

If the Lens Feels Uncomfortable, Then:

Look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will recenter itself. If the lens still feels uncomfortable, follow the steps described in the section of this booklet entitled "Adverse Reactions."

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 one of the procedures below.

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.

  Or

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye towards the lens to place it on the center of the eye.

5. **Removing the Lens:**

Always remove the same lens first.

a. Wash, rinse, and dry your hands thoroughly.

b. Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.

c. Remove the other lens by following the same procedure.

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

6. **Care for a Sticking (Nonmoving) Lens:**

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution recommended by your eye care practitioner into your eye. Do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or drops, contact your eye care practitioner immediately. Do not attempt to remove the lens except on the advice of your eye care practitioner

7. **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 THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

LENS REWETTING PRODUCTS AVAILABLE FROM BAUSCH & LOMB:

BAUSCH & LOMB® ReNu® Lubricating and Rewetting Drops
BAUSCH & LOMB® Sensitive Eyes® Drops

EMERGENCY LENS CARE INSTRUCTIONS:

The PureVision™ (balafilcon A) Visibility Tinted Contact Lens wearing time is prescribed by the eye care practitioner. At the end of the prescribed wearing time, the lens is to be removed from the eye and discarded. However, if the lens needs to be removed before the prescribed wearing time has elapsed, and a replacement lens is not available, your contact lenses must be BOTH cleaned and disinfected before re-insertion. Failure to follow the emergency cleaning and disinfection procedures recommended by your eye care practitioner may result in development of serious eye problems and loss of vision as discussed in the "Warnings" section of this booklet. Both cleaning and disinfection are necessary. Cleaning is necessary to remove mucus and film from the lens surface. Disinfection is necessary to kill harmful germs that can lead to serious eye infections.

The procedures in this booklet are recommended by Bausch & Lomb for the emergency care of your PureVision™ (balafilcon A) Visibility Tinted Contact Lenses. Cleaning and disinfecting lens care solutions and other care products are provided with instructions and warnings for their use, which should be read and followed. Your eye care practitioner will recommend the emergency care products that are right for you.

Emergency lens care should be used **only in an emergency**, you should always have a replacement lens on hand.

Basic Precautions for Cleaning and Disinfecting

- Wash and rinse your hands before handling your contact lenses.
- Do not use hard contact lens solutions not indicated for use with soft contact lenses. Serious injury to the eye can result from wearing a soft contact lens that has been soaked in a hard contact lens solution.
- Bausch & Lomb recommends that you use the lens care system recommended by your eye care practitioner, either heat (thermal) or chemical (not heat). Unless specifically indicated in the labeling; do not alternate, mix or change lens care systems for the same pair of lenses. Changing or mixing the two systems can damage the lenses and injure your eyes.

INSTRUCTIONS FOR THE MONOVISION WEARER:

- You should be aware that as with any type of lens correction, there are advantages and disadvantages to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks.

- Some patients have experienced difficulty adapting to monovision contact lens therapy. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.

- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.

- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

* **The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.**

PERSONAL WEARING SCHEDULE RECORD

Your eye care practitioner will prescribe your own individual lens wearing schedule and lens replacement schedule. Use the space below to record your schedule and wearing record.

DAY	DATE	HOURS TO BE WORN	HOURS WORN
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			

CHECK-UP VISITS

Regular check-up examinations by your eye care practitioner are an important part of wearing contact lenses. It is recommended that you follow your eye care practitioner's directions for follow up examinations. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care practitioner to refer you to a contact lens practitioner in your new location. Use the space below to record your appointments.

VISIT SCHEDULE

1. _____ Date _____ Time
2. _____ Date _____ Time
3. _____ Date _____ Time
4. _____ Date _____ Time
5. _____ Date _____ Time
6. _____ Date _____ Time
7. _____ Date _____ Time
8. _____ Date _____ Time
9. _____ Date _____ Time
10. _____ Date _____ Time

Eye Care Practitioner Information
(Please fill out for ready use)

Name: _____
Address: _____
Phone: _____
Other Information: _____
_____
_____

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

NAME AND ADDRESS OF MANUFACTURER:
Bausch & Lomb Incorporated
Rochester, New York 14692

Glossary of Medical Terms

Ametropia	Abnormal vision requiring correction for proper focus
Myopia	Nearsighted
Hyperopia	Farsighted
Aphakic	Lacking a crystalline lens (focusing lens inside the eye)
Non-aphakic	Not lacking a crystalline lens
Acute inflammation	Sudden swelling, redness and pain
Subacute inflammation	Gradual swelling, redness and pain
Anterior chamber	Internal portion of the eye, between the cornea and iris
Cornea	Clear, front covering of the eye
Conjunctiva	Membrane that lines the eyelids and the white part of the eye
Corneal ulcer	A sore or lesion on the cornea, which left untreated could lead to a permanent loss of vision
Ulcerative keratitis	An infected corneal ulcer
Hypoxia	Lack of oxygen
Epithelial	Layer of cells on the surface of the cornea
Epithelial microcysts	A small abnormal structure (cyst) in the front surface of the eye
Endothelial polymegathism	Irregular cell size and shape
Neovascularization	Small blood vessels growing into the cornea
Iritis	Internal inflammation of the colored part of the eye (iris)

Store lenses at room temperature (60°F - 80°F, 15°C - 25°C)

Patent Number:
Patent information
placed here
part number

BAUSCH & LOMB INCORPORATED
Rochester, NY 14692

month/year of issue

Printed in U.S.A.

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PATIENT INSTRUCTIONS

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PATIENT INFORMATION BOOKLET

BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses

FREQUENT/PLANNED REPLACEMENT WEAR

CAUTION: Federal (U.S.A.) Law Prohibits Dispensing Without a Prescription

INTRODUCTION:

The instructions in this booklet apply to the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses, when prescribed in a Frequent/Planned Replacement Program. If you have received or are considering another brand of contact lenses, do not use this booklet. Ask your eye care practitioner for the patient booklet or instructions that apply to your brand or type of contact lenses. For BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care practitioner answer any questions, both before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to begin or to continue wearing contact lenses for daily wear or extended wear, you should discuss with your eye practitioner the effects of contact lenses on your eyes and the risks associated with wearing contact lenses, which are greater with extended wear contact lens use. You also should read the sections of this booklet entitled "Warnings", "Adverse Reactions", "Precautions", and "Wearing Restrictions and Indications". Ask your eye care practitioner to explain anything that you do not understand, including any additional restrictions which may be given to you by your eye care practitioner.

You also need to remember that soft contact lenses, including those covered by this booklet, are made of a type of plastic that absorbs liquids, vapors, and small particles, and, for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow the instructions contained in the sections of this booklet entitled "Personal Cleanliness and Lens Handling", as well as the written information leaflets accompanying the lens care products that you buy and any other instructions given to you by your eye care practitioner. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a build-up of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule and replacement schedule, and regular check-up visits to your eye care practitioner are also necessary for the proper and safe use of contact lenses. Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not wear your lenses for longer periods than your prescribed wearing schedule simply because they remain comfortable and you are not experiencing a problem. Only your eye care practitioner, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the section of this booklet entitled "Warnings" and "Adverse Reactions". (Refer to "Glossary of Medical Terms" for description of medical terms used in this booklet). Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

WEARING RESTRICTIONS AND INDICATIONS:

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

Note: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

The lens may be disinfected using either a heat or chemical disinfection system. Eye Care Practitioners may prescribe the lens for a frequent/planned replacement wearing schedule; with cleaning, disinfection and scheduled replacement of the lens.

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner.

- Keep fresh solution accessible when you wear your lenses, in case you have to remove your lenses immediately upon the appearance of a problem or symptom.
- Do not use aerosol products such as hair spray while wearing your lenses. The lenses may absorb the spray, resulting in injury to the eye and damage to the lens.
- Avoid wearing the lenses around fumes, irritating vapors, smoky or dusty conditions. The lenses may absorb the chemicals or particles, resulting in injury to the eye.
- Avoid rubbing your eyes with the lenses in, which can irritate the eye or dislodge the lens.
- Keep your eyes closed tightly when washing or showering to keep water and soaps out of the eyes, which can cause loss of the lenses, contamination or injury to the eye.
- If you get something in your eye, remove the lens immediately. Do not replace the lens until your eye feels normal, and, after you have cleaned and disinfected the lens.
- Tell your regular physician and every other doctor that you visit, that you wear contact lenses and, the type of lenses that you wear. If you are admitted to a hospital, also tell your nurses that you wear contact lenses.

- Do not use any eye drops, ointments, or medicines in your eye unless they are specifically approved by your eye care practitioner or physician. Some drops, ointments, or medicines will cause injury to the eye if used by a contact lens wearer.
- Ask your eye care practitioner whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

_____

_____

_____

_____

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that 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 the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS:

You should be aware of and fully discuss with your eye care practitioner the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to your 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**.

- Strict compliance with your lens care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be followed.

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

EXTENDED WEAR

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcycsts and infiltrates, and endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

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

PRECAUTIONS:

You should be aware of and fully discuss with your eye care practitioner the following lens care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
  - Never use solutions recommended for conventional hard contact lenses only.
  - Chemical disinfection solutions should not be used with heat **unless** specifically indicated on product labeling for use in both heat and chemical disinfection.
  - Always use **fresh unexpired** lens care solutions.
  - Always follow directions in the package inserts for the use of contact lens solutions.
  - 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 your lenses.
  - Always keep your lenses completely immersed in the recommended storage solution when your lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for "Care for a Dehydrated Lens" if the lens surface does become dried out.
- If the lens sticks (stops moving) on your eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on your eye for the continued health of your eye. If nonmovement of the lens continues, you should **immediately** consult your eye care practitioner. Do not attempt to remove the lens, except on the instructions of your eye care practitioner.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in your 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.
- Do not touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in these Patient Instructions for the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens and those prescribed by your eye care practitioner.
- Never wear lenses beyond the period recommended by your eye care practitioner.
- Always handle lenses gently and avoid dropping them.

- Ask your eye care practitioner about wearing lenses during water activities and other sports.
- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with your fingernails.
- Always discard lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by your eye care practitioner.
- Always contact your eye care practitioner before using any medicine in your eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Your eye care practitioner should provide you with a recommended follow-up schedule.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):

You should be aware 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
- Abnormal feeling of something in the eye (foreign body, 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, you should:

- **Immediately remove your lenses.**

- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, you should **immediately remove the 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 **keep the lens off your eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS AND 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 substances 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.
   - Handle your lenses with your fingertips, and be careful to avoid contact with 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 mixups.
   - Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
   - Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly.

     a. Less than usual comfort

     b. The lens may fold on the eye

     c. Excessive lens movement on blink

d. Blurred vision

- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rinsing or storing solution. (Refer to the Lens Care Products Chart for the solutions available from BAUSCH & LOMB.) Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion.

- If this gentle rubbing does not work, soak the lens in the recommended solution in your lens case until the lens has resumed its normal shape. If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.

- Keep the lens wet in the solutions recommended by your eye care practitioner.

- Never place a lens on the eye unless it has been fully hydrated (wet) with the recommended rinsing or storing solution. (Refer to the Lens Care Products Chart for the solutions available from BAUSCH & LOMB.)

3. Placing the Lens on the Eye:

(Application instructions in step-by-step format with graphics will be included in Final version)

There are other methods of lens placement. If the following methods are 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 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.

  c. The lens is inside-out (it would also not be as comfortable as normal).

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

The One Hand Placement Technique

Place the lens on your index finger. With your head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment: the lens will center itself on your eye.

The Two Hand Placement Technique

With the lens on your index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of your placement hand to pull down the lower lid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.

If the Lens Feels Uncomfortable, Then:

Look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will recenter itself. If the lens still feels uncomfortable, follow the steps described in the section of this booklet entitled "Adverse Reactions."

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 one of the procedures below.

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.

  Or

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye towards the lens to place it on the center of the eye.

5. Removing the Lens:

Always remove the same lens first.

a. Wash, rinse, and dry your hands thoroughly.

b. Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.

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 **first clean and rinse, then disinfect** [and neutralize (for hydrogen peroxide systems)] your lenses after each removal, using the lens care regimen recommended by your eye care practitioner. **Cleaning and rinsing** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. **Disinfecting** is necessary to destroy harmful germs.

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

If you require only vision correction, but will not or cannot adhere to a recommended lens care regimen, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure to practice putting on your lenses and removing them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of these Patient Instructions for the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens.

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, either heat (thermal) or 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.

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

- Lenses prescribed in a frequent replacement program should be thrown away after the expiration of the wearing period prescribed by your eye care practitioner.

- Never rinse your lenses in water from the tap. There are two reasons for this:

  a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.

  b. You might lose the lens down the drain.

- **Clean** one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, and rinsing, **disinfect** lenses using the system recommended by your eye care practitioner. Follow the instructions provided in the disinfection solution labeling.

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.

- 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** storage solution. Replace lens case at regular intervals.

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

2. **Thermal (Heat) Lens Disinfection:**

- **After cleaning** and thoroughly rinsing contact lenses with recommended solutions, prepare the empty lens storage case. **To keep the lenses wet during disinfection,** use the solution that is recommended by your eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.
- Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless your eye care practitioner recommends rinsing.

3. **Emergency (Alternate) Method for Heat (Thermal) Disinfection:**

- If a heat disinfection unit is not available, place the tightly closed storage container which contains the lenses into a pan of already boiling water. Leave the closed lens case in the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes.) Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lens.

Note: Use of heat disinfection unit should be resumed as soon as possible.

- ~~Leave the lenses~~ in the unopened storage case until ready to put on your eyes
- Before reinsertion of the lenses, no rinsing is necessary unless your eye care practitioner recommends #. rinsing.

4. **Chemical (Not Heat) Disinfection:**

- Clean the contact lenses with the cleaning solution recommended by your eye care practitioner and thoroughly rinse them with the recommended rinsing solution.
- **After cleaning**, and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by your eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the closed storage case until ready to put on your eyes.
- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to your eyes. A thorough rinse in fresh sterile saline solution prior to placement on your eye should reduce the potential for irritation.

5. **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.

6. **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 each time you remove the contact lenses from it. Lens cases should be replaced at regular intervals.

7. **Care for a Sticking (Nonmoving) Lens:**

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution recommended by your eye care practitioner into your eye. Do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or drops, contact your eye care practitioner immediately. Do not attempt to remove the lens except on the advice of your eye care practitioner

8. **Care for a Dehydrated Lens:**

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply the recommended rinsing solution before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour until it returns to a soft state.
- Clean lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, if the surface remains dry, DO NOT USE THE LENS UNTIL IT HAS BEEN EXAMINED BY YOUR EYE CARE PRACTITIONER.

9. **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 THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

LENS CARE PRODUCTS CHART

The following solutions are available from Bausch & Lomb for use with all Bausch & Lomb Contact Lenses; however, eye care practitioners may recommend alternative products and procedures which should be followed by the patient. BAUSCH & LOMB® Care Kits are available for lens disinfection, cleaning, and storage.

Thermal (Heat) Lens Care System

Action	Care Product
Cleaning	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Rinsing, Disinfecting & Storing	Commercially Available Heat Disinfection Unit for Contact Lenses used with: BAUSCH & LOMB® Sensitive Eyes® Saline Solution BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray BAUSCH & LOMB® SENSITIVE EYES Plus® Saline Solution
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner BAUSCH & LOMB® SENSITIVE EYES® Enzymatic Contact Lens Cleaner

Chemical Lens Care System

Action	Care Product
Cleaning	BAUSCH & LOMB® ReNu MultiPlus™ Multi-Purpose Solution
	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Disinfecting & Storing	BAUSCH & LOMB® ReNu MultiPlus™ Multi-Purpose Solution
	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
Rinsing	BAUSCH & LOMB® ReNu MultiPlus™ Multi-Purpose Solution
	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray
	BAUSCH & LOMB® SENSITIVE EYES Plus® Saline Solution
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® SENSITIVE EYES® Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® ReNu® [illegible] Enzymatic Contact Lens Cleaner

All Lens Care Systems

Action	Care Product
Rewetting	BAUSCH & LOMB® ReNu® Lubricating and Rewetting Drops
	BAUSCH & LOMB® SENSITIVE EYES® DROPS

- Note: Some solutions may perform more than one function in the care regimen, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

INSTRUCTIONS FOR THE MONOVISION WEARER:

- You should be aware that as with any type of lens correction, there are advantages and disadvantages to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks.

- Some patients have experienced difficulty adapting to monovision contact lens therapy. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.

- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this option with your eye care practitioner.

- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

* **The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.**

PERSONAL WEARING SCHEDULE RECORD

Your eye care practitioner will prescribe your own individual lens wearing schedule and lens replacement schedule. Use the space below to record your schedule and wearing record

DAY	DATE	HOURS TO BE WORN	HOURS WORN
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			

CHECK-UP VISITS

Regular check-up examinations by your eye care practitioner are an important part of wearing contact lenses. It is recommended that you follow your eye care practitioner's directions for follow up examinations. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care practitioner to refer you to a contact lens practitioner in your new location. Use the space below to record your appointments.

VISIT SCHEDULE

1. _____ Date _____ Time
2. _____ Date _____ Time
3. _____ Date _____ Time
4. _____ Date _____ Time
5. _____ Date _____ Time
6. _____ Date _____ Time
7. _____ Date _____ Time
8. _____ Date _____ Time
9. _____ Date _____ Time
10. _____ Date _____ Time

Eye Care Practitioner Information
(Please fill out for ready use)

Name: _____
Address: _____
Phone: _____
Other Information: _____
_____
_____

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

NAME AND ADDRESS OF MANUFACTURER:
Bausch & Lomb Incorporated
Rochester, New York 14692

Glossary of Medical Terms

Ametropia	Abnormal vision requiring correction for proper focus
Myopia	Nearsighted
Hyperopia	Farsighted
Aphakic	Lacking a crystalline lens (focusing lens inside the eye)
Non-aphakic	Not lacking a crystalline lens
Acute inflammation	Sudden swelling, redness and pain
Subacute inflammation	Gradual swelling, redness and pain
Anterior chamber	Internal portion of the eye, between the cornea and iris
Cornea	Clear, front covering of the eye
Conjunctiva	Membrane that lines the eyelids and the white part of the eye
Corneal ulcer	A sore or lesion on the cornea, which left untreated could lead to a permanent loss of vision
Ulcerative keratitis	An infected corneal ulcer
Hypoxia	Lack of oxygen
Epithelial	Layer of cells on the surface of the cornea
Epithelial microcysts	A small abnormal structure (cyst) in the front surface of the eye
Endothelial polymegathism	Irregular cell size and shape
Neovascularization	Small blood vessels growing into the cornea
Iritis	Internal inflammation of the colored part of the eye (iris)

Store lenses at room temperature (60°F - 80°F, 15°C - 25°C)

Patent Number:
Patent information
placed here
part number

BAUSCH & LOMB INCORPORATED
Rochester, NY 14692

month/year of issue

Printed in U.S.A.

BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses

PACKAGE INSERT AND FITTING GUIDE

CAUTION:

Federal (U.S.A.) Law Prohibits Dispensing Without Prescription.

IMPORTANT:

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens and to illustrate fitting procedures. It is effective as of (date) and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide 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 and the recommended wearing schedule.

DESCRIPTION:

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is soft hydrophilic contact lens which is available as a spherical lens. The lens material, balafilcon A, is a copolymer of a silicone vinyl carbamate, N-vinyl-pyrrolidone, a siloxane crosslinker and a vinyl alanine wetting monomer, and is 36% water by weight when immersed in a sterile borate buffered saline solution. This lens is tinted blue with up to 300 ppm of Reactive Blue Dye 246.

The physical / optical properties of the lens are:

Specific Gravity:	1.064
Refractive Index:	1.426
Light Transmittance:	C.I.E. value - at least 95%
Water Content:	36%
Oxygen Permeability:	99×10^{-11} [$cm^3 O_2$(STP) x cm]/(sec x cm^2 x mmHg) @ 35°C (Polarographic Method)

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens may be prescribed for Frequent/Planned Replacement or Disposable Wear.

1276 61

LENS PARAMETERS AVAILABLE:

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	13.5mm to 15.0mm
Center Thickness:	0.05mm to 0.50mm
Base Curve:	7.5mm to 9.5mm
Powers (Spherical):	+20.00D to -20.00D

HOW THE LENS WORKS (ACTIONS):

In its hydrated state, the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

INDICATIONS

The BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

Note: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

FREQUENT/PLANNED REPLACEMENT WEAR

When prescribed for Frequent/Planned Replacement Wear, the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using either a heat or chemical disinfection system.

DISPOSABLE WEAR

When prescribed for Disposable Wear, the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that 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 the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS:

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing practitioner of all the risks with contact lens wear. Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's 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.**
- When prescribed for Frequent/Planned Replacement Wear, the need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

EXTENDED WEAR

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcycsts and infiltrates, and epithelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

  The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods from 1 to 7 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.

- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS:

Precautions for Eye Care Practitioners:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing eye care practitioner.

- Fluorescein should not be used while the patient is wearing the lenses, because the lenses will become discolored. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before reinserting the lenses. If replaced too soon, the lenses may absorb residual fluorescein.

- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Precautions for Frequent/Planned Replacement Wear:

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.

  - Never use solutions recommended for conventional hard contact lenses only.

  - Chemical disinfection solutions should not be used with heat **unless** specifically indicated on product labeling for use in both heat and chemical disinfection.

  - Always use **fresh unexpired** lens care solutions.

  - Always follow directions in the package inserts for the use of contact lens solutions.

  - 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. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.

Precautions for Disposable Wear:

- If the lenses are prescribed for disposable wear, they are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens. If replacement lenses are not available, the patient should refer to the emergency lens care directions in the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lens - Disposable Wear Patient Information Booklet.

Precautions for Frequent/Planned Replacement and Disposable Wear:

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner. Do not attempt to remove the lens, except on the instructions of the eye care practitioner.

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.

- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Information Booklet and those prescribed by the eye care practitioner.

- Never wear lenses beyond the period recommended by the eye care practitioner.

- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

- Always handle lenses gently and avoid dropping them.

- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Ask the eye care practitioner about wearing lenses during water activities and other sports.

- Inform the doctor (health care practitioner) about being a contact lens wearer.

- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

- Do not touch the lens with fingernails.

- Discard disposable lenses and lenses worn on a frequent/planned replacement wearing schedule after the recommended wearing schedule prescribed by the eye care practitioner.

- Always contact the eye care practitioner before using any medicine in the eyes.

- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

- Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing, and eye care practitioners should conduct early and frequent follow-up examination to determine ocular response to extended wear.

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

ADVERSE REACTIONS:

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, 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 the patient notices any of the above, he or she should be instructed to:

- **Immediately remove the lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult his or her eye care practitioner.**

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lenses and contact his or her eye care practitioner** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

SELECTION OF PATIENTS:

Persons who require vision correction and who would not or could not adhere to a recommended care or replacement regimen for BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the patient should be instructed to contact his or her eye care practitioner.

FITTING PROCEDURE:

1. **Pre-Fitting Examination**

   A pre-fitting patient history and examination are necessary to:

   - determine whether a patient is a suitable candidate for contact lenses (consider patient hygiene and mental and physical state),
   - make ocular measurements for initial contact lens parameter selection, and
   - collect and record baseline clinical information to which post-fitting examination results can be compared.

   A prefitting examination should include spherocylinder refraction and VA, keratometry, and biomicroscopic examination.

2. **Initial Lens Power Selection**

   a. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the appropriate lens and place on the eye.

   b. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

   c. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. **Initial Lens Evaluation**

a. To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.

- Movement: The lens should provide discernible movement with:
  - Primary gaze blink
  - Upgaze blink
  - Upgaze lag
- Centration. The lens should provide full corneal coverage.

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, a the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

4. **Criteria of a Well-Fitted Lens**

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed.

5. **Characteristics of a Tight (Steep) Lens**

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

6. **Characteristics of a Loose (Flat) Lens**

If the lens is too flat, it will:

- Decenter, especially on post-blink.
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

7. **Follow-up Care**

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow up.

- 3 or 4 days post-dispensing
- 10 days
- 1 month
- 3 months
- every six months thereafter

At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

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 might be occurring related to contact lens wear.

c. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.

2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.

3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

PRACTITIONER FITTING SETS

Lenses must be discarded after each use.

WEARING SCHEDULE:

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, are extremely important.

Daily Wear:

There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Extended Wear (Greater than 24 hours or while asleep):

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Bausch & Lomb recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear to determine the corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the Warnings section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care practitioner.

MONOVISION FITTING GUIDELINES:

1. **Patient Selection**

   A. Monovision Needs Assessment

   For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses.

   Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

   (1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

   (2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. **Eye Selection**

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sighting dominant eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. **Special Fitting Considerations**

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. **Near Add Determination**

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. **Trial Lens Fitting**

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and than graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. **Adaptation**

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. **Other Suggestions**

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions.

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

* **The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.**

* **All patients should be supplied with a copy of the PureVision™ (balafilcon A) Visibility Tinted Contact Lens Frequent/Planned Replacement Wear Patient Information Booklet or the PureVision™ (balafilcon A) Visibility Tinted Contact Lens Disposable Wear Patient Information Booklet.**

HANDLING OF LENSES

Patient Lens Care Directions:

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care practitioner should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the practitioner, the specific instructions for such products and the particular characteristics of the patient.

Frequent/Planned Replacement Wear: For complete information concerning the care, cleaning and disinfection of contact lenses refer to the PureVision™ (balafilcon A) Visibility Tinted Contact Lens Frequent/Planned Replacement Wear Patient Information Booklet.

Disposable Wear: For complete information concerning emergency lens care, refer to the PureVision™ (balafilcon A) Visibility Tinted Contact Lens Disposable Wear Patient Information Booklet

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to **not** use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution, and to not attempt to remove the lens except on the advice of the eye care practitioner.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing BAUSCH & LOMB® PureVision™ (balafilcon A) Visibility Tinted Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
Rochester, New York 14692
Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720

HOW SUPPLIED:

Each sterile lens is supplied in a glass vial package containing borate buffered saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter and expiration date. Store lenses at room temperature (60°F - 80°F, 15°C - 25°C)

Patent Number:
Patent information
placed here

BAUSCH & LOMB INCORPORATED
Rochester, NY 14692

part number month/year of issue Printed in U.S.A.