



## Memorandum

Date • DEC 22 1997

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

Subject Premarket Approval of Mentor Corporation's MemoryLens™ Model U940A Ultraviolet-Absorbing Hydrophilic Posterior Chamber Intraocular Lens - ACTION

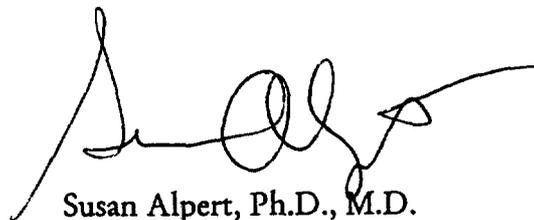
To The Director, CDRH  
ORA \_\_\_\_\_

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

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

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

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



Susan Alpert, Ph.D., M.D.

Attachments  
Tab A - Notice  
Tab B - Order  
Tab C - S & E Summary

### DECISION

Approved \_\_\_ Disapproved \_\_\_ Date \_\_\_\_\_

Prepared by Kesia Alexander, Ph.D, CDRH, HFZ-460, 08/11/97, 594-2053

**DRAFT**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

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

Mentor Corp.; Premarket Approval OF Memorylens™ MODEL U940A  
Ultraviolet-Absorbing Hydrophilic Posterior Chamber Intraocular  
Lens

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Mentor Corp., Santa Barbara, CA for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of MemoryLens™ Model U940A ultraviolet-absorbing hydrophilic posterior chamber intraocular lens. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of, December 22, 1997, of the approval of the application.

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

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Kesia Alexander,  
Center for Devices and Radiological Health (HFZ-460),  
Food and Drug Administration,  
9200 Corporate Blvd.,  
Rockville, MD 20850,  
301-594-2053.

SUPPLEMENTARY INFORMATION: On October 1, 1996, Mentor Corp., Santa Barbara, CA 93111, submitted to CDRH an application for premarket approval of MemoryLens™ Model U940A ultraviolet-absorbing hydrophilic posterior chamber intraocular lens. The device is a posterior chamber intraocular lens and is indicated for primary implantation for the visual correction of aphakia in patients sixty years of age or older where a cataractous lens has been removed by an extracapsular cataract extraction method. The lens is intended for placement in the capsular bag.

On July 10 1997, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On December 22, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

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

device and the docket number found in brackets in the heading of this document.

#### Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified

with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

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

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

DEC 22 1997

Mr. Clarke Scherff  
Director, Corporate Regulatory Affairs/  
Quality Assurance  
Mentor Corporation  
5425 Hollister Avenue  
Santa Barbara, CA 93111

Re: P960036  
MemoryLens™ Model U940A Ultraviolet-Absorbing Hydrophilic  
Posterior Chamber Intraocular Lens  
Filed: October 1, 1996  
Amended: December 16, 1996; (3) January 21, February 24, March 19, May 15,  
(2) May 23, May 28, August 4, August 8, and August 11, 1997

Dear Mr. Scherff:

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 MemoryLens™ Model U940A ultraviolet-absorbing hydrophilic posterior chamber intraocular lens. This device is indicated for primary implantation for the visual correction of aphakia in patients sixty years of age or older where a cataractous lens has been removed by an extracapsular cataract extraction method. The lens is intended for placement in the capsular bag. 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 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

1. Registration of all patients receiving the above-referenced intraocular lens must be continued and the data base shall be maintained indefinitely, or until the applicant is otherwise notified.
2. A way of facilitating adverse reaction reporting, such as an 800 telephone number, must be maintained.

3. FDA notes your agreement that you will continue postoperative follow-up for three years on 500 subjects derived from the core subjects (and modified core, if necessary) to assess further the long-term safety and effectiveness of hydrogel IOLs. At the completion of the postapproval study, you must submit the clinical data and update your labeling accordingly.
4. Advertising and other printed materials prepared by your firm or its distributors will not include indications or claims not included in the FDA-approved labeling for the device, e.g., that the use of this lens (or that small incision surgery) results in more rapid visual recovery, decreased surgically-induced astigmatism, improved overall quality of vision, or similar claims.

Expiration dating for this device has been established and approved at 1 year.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, 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 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.

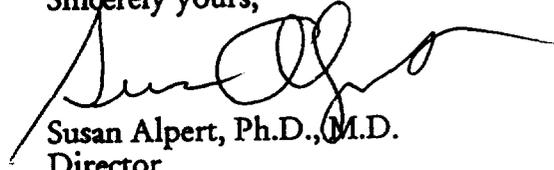
All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

Page 3 - Mr. Clarke Scherff

If you have any questions concerning this approval order, please contact  
Kesia Alexander, Ph.D. at (301) 594-2053.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Susan Alpert', with a long horizontal flourish extending to the right.

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

Enclosure

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## 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 Effectuated" 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 Effectuated." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

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

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

- (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 mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
  - (a) has not been addressed by the device's labeling or
  - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the 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, and requires that all manufacturers and importers of medical devices, including *in vitro* diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

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

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

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

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

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)  
Center for Devices and Radiological Health  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

# SUMMARY OF SAFETY AND EFFECTIVENESS DATA

## I. GENERAL INFORMATION

- A. Premarket Approval Application (PMA) Number: P960036  
Date Filed: October 14, 1996  
Date Approved: DEC 22 1997
- B. Generic Name of Device: Ultraviolet-Absorbing Hydrophilic  
Posterior Chamber Intraocular Lens (IOL)
- C. Trade Names of Device: MemoryLens®
- D. Applicant's Name and Address:  
Mentor Corporation  
5425 Hollister Avenue  
Santa Barbara, CA 93111
- E. Good Manufacturing Practice (GMP) Inspection Dates:  
Date of Inspection (Cidra, Puerto Rico Facility): May 14, 1996  
Conclusion: The manufacturing site was found to be in compliance with device  
GMP requirements.
- F. Ophthalmic Devices Panel (Panel): July 1997  
Date Reviewed: July 10, 1997  
Recommendation: Approvable

## II. INDICATIONS

The MemoryLens is intended to be used for primary implantation for the visual correction of aphakia in patients sixty years of age or older where a cataractous lens has been removed by an extracapsular cataract extraction method. The lens is intended for placement in the capsular bag.

### III. SUMMARY

Two separate clinical investigations of the MemoryLens were conducted to investigate the safety and efficacy of the MemoryLens (360 patients) and the Mentor Pre-Rolled MemoryLens (190 patients) posterior chamber intraocular lenses. The cohort populations of 360 and 190 represent the total number of completely followed patients. The core populations of 616 and 226 represent the total number of patients enrolled in the studies, respectively. Data on 360 and 190 patients followed postoperatively for 12-14 months were clinically and statistically evaluated against historical controls. The population at risk for developing visually-disabling cataracts and needing cataract surgery is typically elderly; the elderly population has a slightly higher proportion of females to males. The average age of the 360 cohort subjects was 73 years (72.6 years, 190 cohort) at the time of surgery; 62.5% of the 360 cohort subjects (61.1%, 190 cohort) were female and 37.5% were male (38.9%, 190). The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The study population was 96.7% Caucasian for the 360 cohort (99.1% for the 190 cohort); 2.5% African-American, and 0.8% other for the 360 cohort (0.9% other for the 190 cohort). In this study, which began in 1989, all patients who met the inclusion criteria were included in the study.

In 1983 Stark et. al. (Ophthalmology, 90(4): 311-317) published a grid of historical clinical data established from review of 45,543 eyes implanted with IOLs PMA-approved before 1982. FDA adopted the grid, which includes adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models. Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of Model U940A compares favorably with the grid of historical data (refer to Section IV.B. Safety and Effectiveness Data). The cumulative rate of hyphema in the 360 cohort was higher than reported in the Stark grid; however, this complication did not persist. The cumulative rates of pupillary block, endophthalmitis, macular edema, lens dislocation, and retinal-detachment in the 360 cohort were below Stark grid rates. However, in the case of persistent secondary glaucoma, four of the five patients reporting secondary glaucoma had an investigational viscoelastic known to increase intraocular pressure used during surgery. If the data from the viscoelastic patients are excluded from the analysis, the rate of persistent secondary glaucoma is 0.3% which is below the Stark grid rate. The rate for intraocular infection in the 360 cohort exceeded the grid value but was not statistically significant. In the 190 cohort, all rates of adverse reactions and sight-threatening complications were less than the FDA grid.

Most MemoryLens™ patients achieved a visual acuity of 20/40 or better. The rates for both overall and best-case visual acuity for both the 360 and 190 cohorts of 20/40 or better exceed the FDA grid values.

Statistical analyses were conducted in an effort to assure similarity of the data sets and to assure acceptable accountability of the core populations. Overall, the safety and effectiveness profiles of the two studies, MemoryLens (360 patients) and Pre-Rolled MemoryLens (190 patients) are comparable and compare favorably to the FDA grid.

#### IV. SAFETY AND EFFECTIVENESS DATA

##### A. Nonclinical Studies

The applicant has performed nonclinical studies on this device in accordance with the FDA guidance document for testing intraocular lenses dated June 9, 1980. The applicant conducted a battery of in vivo and in vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material and overall device design for use in an intraocular lens. The adequacy of the manufacturing processes, including sterilization, was established through review of the manufacturing information in the PMA as well as through on-site inspections. Nonclinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

Page 4 - Summary of Safety and Effectiveness Data

B. Clinical Studies

	<u>Overall Visual Acuity (20/40 or better).</u>		<u>FDA Grid</u>
	<u>*Cohort =360</u>	<u>**Cohort =190</u>	
Age < 59 Years	100.0%[20/20]	100.0%[13/13]	93.7
Age 60-69 Years	97.3% [73/75]	94.3% [33/35]	90.8
Age 70-79 Years	93.5% [144/154]	98.9% [94/95]	88.6
Age > 80 Years	88.7% [94/106]	100.0%[47/47]	75.2%
All Ages Combined	93.2% [331/355]	98.4% [187/190]	88.0%
♦ Best Case, All Ages Combined	97.6%[239/245]	99.3%[143/144]	94.0%
<small>*Flat Configuration: 5 patients had no visual acuity reported at Form 6</small>			
<small>**Pre-rolled Configuration</small>			

Adverse Reactions

	<u>Core=616</u>	<u>Core=226</u>	<u>FDA Grid</u>
Hypopyon	0.3%[02]	0.0%[0]	0.4%
Intraocular Infection	0.2%[01]	0.0%[0]	0.1%
Acute Corneal Decompensation	0.0%[00]	0.0%[0]	0.2%
Surgical Reintervention	1.6%[10]	1.3%[3]	2.0%

Postoperative Complications

	<u>Cohort=360</u>	<u>Cohort=190</u>	<u>FDA Grid</u>
Cumulative Hyphema	3.9% [14]	0.0%[0]	1.0%
Cumulative Macular Edema	1.4% [05]	1.6%[3]	3.5%
Persistent Macular Edema	0.6% [02]	0.5%[1]	0.8%
Cumulative Pupillary Block	0.0% [00]	0.0%[0]	0.3%
Persistent Secondary Glaucoma	1.4% [05]	0.0%[0]	0.5%
Persistent Cyclitic Membrane	0.0% [00]	0.0%[0]	<0.1%
Persistent Vitritis	0.0% [00]	0.0%[0]	0.1%
Cumulative Retinal Detachment	0.3% [01]	0.5%[1]	0.5%
Cumulative Endophthalmitis	0.0% [00]	0.0%[0]	<0.1%
Persistent Corneal Edema	0.3% [01]	0.0%[0]	0.6%
Persistent Iritis	0.6% [02]	0.5%[1]	1.0%
Cumulative Lens Dislocation	0.3% [01]	0.0%[0]	0.4%

♦ Best Case: Excludes patients with preoperative ocular pathology, macular degeneration, abnormal cornea, or endothelial disease at any time.

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) and the Panel reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. CDRH approved this PMA in a letter to the PMA applicant dated DEC 22 1997 and signed by the Director, Office of Device Evaluation.

*Draft Edition of Product Insert Data Sheet  
August, 1997*

## **MEMORYLENS® HYDROPHILIC INTRAOCULAR LENS Model U940A**

### **Mentor Ophthalmics Surgical Products**

**CAUTION: Federal (United States) law restricts this device to sale by, or on the order of, a physician.**

#### **General Description**

The MemoryLens Model U940A is an ultraviolet-absorbing, hydrophilic, posterior chamber intraocular lens (IOL) consisting of a biconvex optic with two supporting haptics in a modified "C" configuration.

The thermoplasticity of the MemoryLens material enables the Model U940A to be rolled without damage to the lens. The lens, as rolled and presented from the delivery system, can be inserted through a 3.5 mm phacoemulsification incision.

#### **Indications**

The MemoryLens is used for primary implantation for the visual correction of aphakia in patients sixty years of age and older where a cataractous lens has been removed by an extracapsular cataract extraction method. The lens is intended for placement in the capsular bag.

#### **Contraindications**

The safety and effectiveness of the lens has not been established for secondary implantation or for intracapsular cataract extraction methods.

#### **Warnings**

**DO NOT FREEZE.**

Do not resterilize this IOL by any method. If the pouch is open or damaged upon receipt, return the lens to MENTOR OPHTHALMICS.

Additional rinsing is not necessary; however, if desired, use only cold, sterile intraocular irrigating solutions less than 15°C (59°F).

Mentor Corporation  
MemoryLens® PMA

Long-term effects of intraocular lens implants have not been determined. Therefore, the physician should continue to monitor implant patients postoperatively on a regular basis.

The safety and effectiveness of this lens if placed in the anterior chamber has not been established. Implantation of posterior chamber lenses within the anterior chamber have been shown in some cases to be unsafe. Such implantation should take place only under an approved investigational protocol. This lens is for posterior chamber implantation only.

The need for a secondary iridectomy for pupillary block may be prevented by one or more iridectomies at the time of IOL implantation.

A high level of surgical skill is required for IOL implantation. It is highly recommended that a surgeon should observe and/or assist in numerous implantation procedures and attend one or more courses on IOL implantation prior to implanting IOLs.

### Precautions

Keep cold. Refrigerate at 2-10°C (36-50°F). The two temperature dots supplied with the outer shipping carton should be white. If either dot is any shade of blue or black or if the lens vial has been cracked or shattered, do not use the lens. Return the affected lens shipment to Mentor Ophthalmics. Return individual lenses to MENTOR OPHTHALMICS if any lens has been inadvertently frozen.

The lens should be handled carefully.

The lens should be carefully examined in the operating room prior to implantation.

The effectiveness of the UV absorbing lens in reducing the incidence of retinal disorders has not been established.

### Adverse Reactions

Adverse reactions reported from the implantation of an IOL include procedural and lens related events.

Adverse reactions were reported at the following rates during the MemoryLens clinical study:

Mentor Corporation  
MemoryLens® PMA

**Adverse Reactions (Core Study)  
(N= 616)**

<b>ADVERSE REACTIONS</b>	<b>NUMBER OF PATIENTS</b>	<b>PERCENTAGE</b>
Hypopyon	2	0.32%
Intraocular Infection	1	0.16%
Acute Corneal Decompensation	0	0.00%
Secondary Surgical Reintervention	10	1.62%

**Complications**

Complications reported from the implantation of an IOL include procedural and lens related events. There are risks associated with the medications and the materials implanted in the eye.

The following sight-threatening complications occurred following cataract extraction and intraocular lens implantation in the MemoryLens cohort patient population (N=360).

Postoperative Complications	Cumulative	Persistent
Corneal Edema	142 (39.4%)	1 (0.28%)
Iritis	237 (65.8%)	2 (0.56%)
Uveitis	14 (3.89%)	2 (0.56%)
Hyphema	14 (3.89%)	0 (0.0%)
Secondary Glaucoma	16 (4.44%)	5 (1.39 %)*
Macular Edema	5 (1.39%)	2 (0.56%)
Pupillary Block	0 (0.0%)	0 (0.0%)
Cyclitic Membrane	0 (0.0%)	0 (0.0%)
Vitritis	2 (0.56%)	0 (0.0%)
Endophthalmitis	0 (0.0%)	0 (0.0%)
Retinal Detachment	1 (0.28%)	0 (0.0%)
Lens Dislocation	1 (0.28%)	0 (0.0%)

\*Four of the five patients had an investigational viscoelastic known to increase intraocular pressure used during surgery. If the data from these four patients are excluded, the rate of persistent secondary glaucoma is 0.28%.

### Clinical Experience

A clinical trial of MemoryLens was initiated in 1989. The results in 360 cohort patients followed for one year or more provide the basis for the data which were used to determine that this IOL design is safe and effective for the visual correction of aphakia.

- Patient Population

The core population in the clinical trial consisted of 616 patients. 59.7% (368) were female and 40.3% (248) were male; 94.5% (582) were Caucasian, 3.4% (21) were African-American; 1.5% (9) were noted as "Other"; and 0.6% (4) had no information entered for race. The mean age for the total population was 73.3 years.

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MemoryLens® PMA

Of the cohort patients, 96.7% were Caucasian, 2.5% were African-American, and 0.8% were noted as "Other." The average age of the 360 cohort patients was 73.0 years.

**TABLE 1**

**VISUAL ACUITY  
Best Case Cohort\*  
N=360**

The following is a summary of final visual acuity (one year postoperatively) achieved by Cohort subjects who did not have a preoperative ocular pathology or postoperative macular degeneration (Best Case Cohort).

Age Group (years)	n	20/40 or better	20/41 - 20/80	20/81 or worse
		No. (%)	No. (%)	No. (%)
59 or less	18	18 (100%)	0 (0.0%)	0 (0.0%)
60 - 69	64	62 (96.9%)	2 (3.1%)	0 (0.0%)
70 - 79	107	104 (97.2%)	2 (1.9%)	1 (0.9%)**
80 or greater	56	55 (98.2%)	1 (1.8%)	0 (0.0%)
Total	245	239 (97.6%)	5 (2.0%)	1 (0.4%)**

\*Cohort is defined as having Form 1, 2, or 3; 4 or 5; and 6.

\*\* One patient had a visual acuity of worse than 20/200.

TABLE 2

**VISUAL ACUITY OUTCOME OF ALL COHORT PATIENTS  
N=360**

The following is a summary of final visual acuity (one year postoperatively) achieved by all cohort patients (n=360\*).

Age Group	n	20/40 or better		20/41 - 20/80		20/81 or worse	
		No.	(%)	No.	(%)	No.	(%)
59 or less	20	20	(100%)	0	(0.0%)	0	(0.0%)
60 - 69	75	73	(97.3%)	2	(2.7%)	0	(0.0%)
70 - 79	154	144	(93.5%)	8	(5.2%)	2	(1.3%)**
80 or greater	106	94	(88.7%)	7	(6.6%)	5	(4.7%)***
Total	355	331	(93.2%)	17	(4.8%)	7	(2.0%)

\*Cohort is defined as having Form 1, 2, or 3; 4 or 5; and 6.

\*\* Two patients had visual acuities worse than 20/200.

\*\*\*One patient had a visual acuity between 20/81-20/100, two patients had visual acuities between 20/101 and 20/200, and two patients had visual acuities worse than 20/200.

**Detailed Description**

The optic of the MemoryLens is manufactured from a proprietary polymer consisting of methyl methacrylate (MMA), 2-hydroxyethyl methacrylate (HEMA), and ethylene glycol dimethacrylate (EGDMA). MMA and HEMA are highly integrated into a three-dimensional covalent network which gives the polymer unique thermomechanical properties. The composition of the lens is 80% polymer and 20% water by total weight.

The Model U940A has the following characteristics:

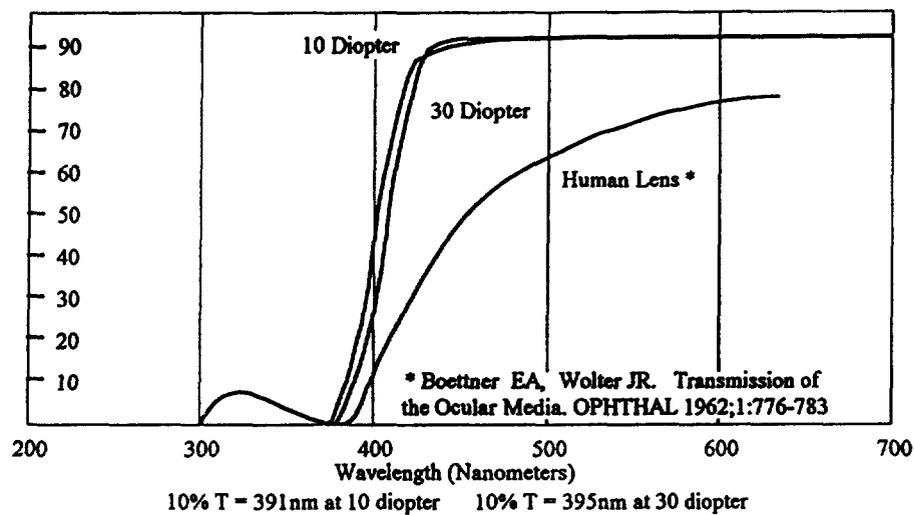
**LENS OPTIC:**

1. Light transmittance: See transmission curve below
2. Specific gravity: 1.19



The cut-off wavelengths and spectral curves below represent the range of transmittance values of IOLs made with this material.

## MemoryLens UV Transmittance Curves

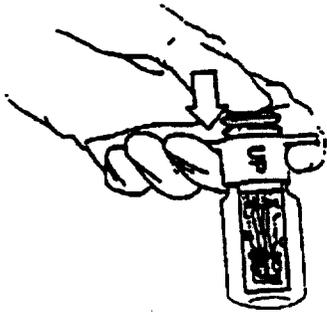


### Instructions For Use

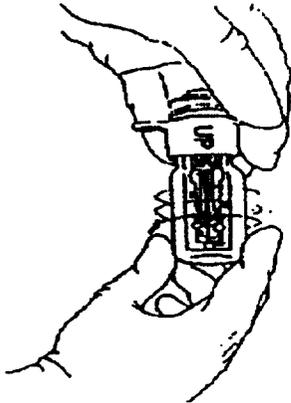
1. Examine the label on the lens package for proper diopter power.
2. The MemoryLens package should be refrigerated at 2-10°C (36-50°F) until the surgeon is ready to implant the lens.
3. The MemoryLens should be placed in the OR Pak immediately after removal from the refrigerator and prior to surgery. The MemoryLens may remain in the OR Pak for up to ten (10) hours.
4. At the time of implantation, examine the outside label on the lens package to confirm the lens model, diopter and expiration date.
5. Remove the sealed pouch from the lens package. The pouch contains the prerolled MemoryLens within a retainer in a glass vial filled with sterile balanced salt solution.

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6. Using the sterile technique, open the pouch and transfer the glass vial containing the prerolled MemoryLens into the sterile field.
7. Push the bellows on the top of the cap down to move the prerolled MemoryLens to the bottom of the retainer where it is accessible for removal.

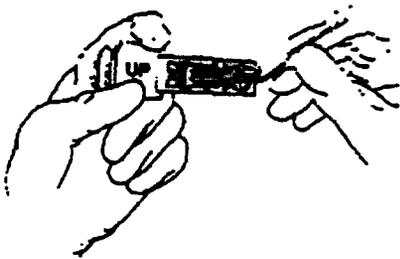


8. Unscrew the glass vial from the cap to separate the cap/retainer/lens from the vial of saline.



9. To remove the lens, grasp the optic with a smooth tipped forceps (Faulkner, Kelman-McPhersen or equivalent), and lift the prerolled MemoryLens out of the retainer.

*Note: A thin, translucent white Teflon membrane surrounds the lens in the retainer. This membrane is expected to remain in the retainer when the lens is removed. Should the membrane be present with the lens, remove it before implanting.*



10. It is not necessary to rinse the MemoryLens prior to implantation. However, if the lens is rinsed, cold sterile intraocular irrigating solution less than 15°C (59°F) should be used.

### Suggested Implantation Technique

After removing the MemoryLens from the delivery system, with the instrument of your choice, visually inspect the lens under the operating room microscope.

#### Step A

A viscoelastic should be used to expand the capsular bag and lubricate the lens and the incision. Initiation of insertion is accomplished by placing the leading edge of the optic into the wound allowing the inferior haptic to self-position along the left edge of the optic. The haptic will remain in this position until the majority of the optic and entire haptic are clear of the internal incision and are directed posteriorly into the capsular bag.

Before releasing the lens, place the leading edge of the optic beneath the capsulorhexis near the 6:00 position.

#### Step B-1 – Compression Technique

Again, with the instrument of your choice, engage the superior haptic approximately 3mm from the distal end and compress the haptic towards the center of the optic.

When the haptic-optic junction elbow clears the superior capsulorhexis border, direct the haptic posteriorly, into the capsular bag.

The haptic can now be released with the lens and haptics placed in the capsular bag.

#### Step B-2 – Dialing Technique

Using your selected instrumentation, engage the superior haptic approximately 3mm from the distal end and into the capsular bag.

Using a lens manipulator, or a “Y” hook, engage the superior haptic-optic junction.

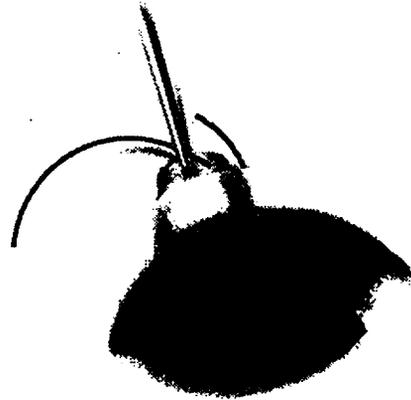
Applying a slight pressure posteriorly, direct the leading optic edge under the inferior capsulorhexis border and dial clockwise until the superior portion of the optic and the superior haptic are position in the capsular bag.

#### Step C

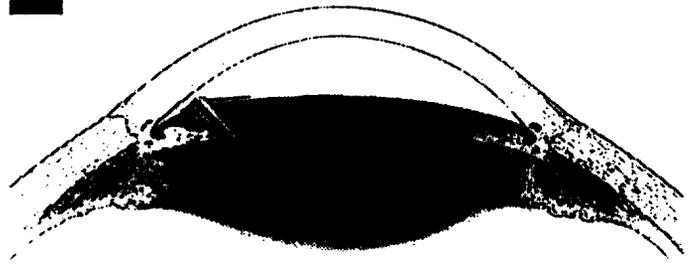
The lens may be repositioned with a lens manipulator to the optimal position.

Prior to complete unfolding, easy access is offered for the removal of any viscoelastic or cortical remnants.

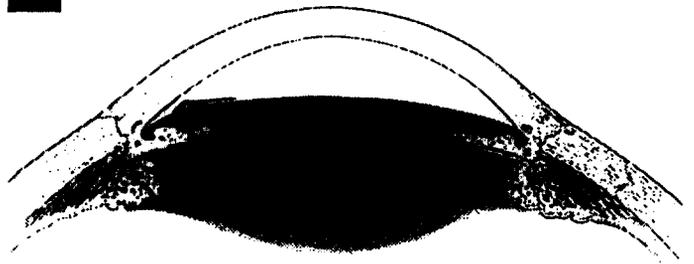
A



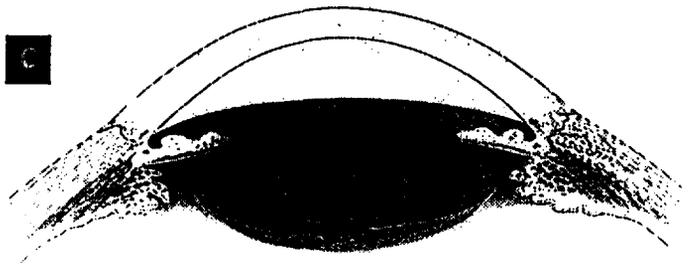
B-1



B-2



C



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### **Calculation of Lens Power**

The physician should determine preoperatively the power of the lens to be implanted by using a calculation method of his/her preference. Lens power calculation methods are described in the following references:

*Binkhorst, R.D. Intraocular Lens Power Calculation Manual, New York, 1978.*

*Retzlaff, J. Sanders, D., Kraff, M. Lens Implant Power Calculation, 3rd edition, 1990.*

Formula results may vary by surgeon and surgical technique. Physicians requiring additional information on lens power calculation should contact Mentor Ophthalmics.

### **Patient Information**

It is recommended that each patient receive information regarding intraocular lenses and preoperative instructions in a manner that is suitable to the patient. This information should be provided prior to the decision to implant an intraocular lens. Postoperative information and instructions should also be provided to the patient by the physician.

### **Patient Registration Instructions and Reporting**

Each patient who receives a MENTOR OPHTHALMICS Intraocular Lens must be registered with MENTOR OPHTHALMICS at the time of implantation.

Registration may be achieved by completing and returning the Implant Registration Card enclosed within the lens box to MENTOR OPHTHALMICS. This registration is important for the MENTOR OPHTHALMICS patient registry program.

An Implant Identification Card is supplied in the lens packaging. This card should be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

### **Adverse Event Reporting**

MENTOR OPHTHALMICS requests that any complications resulting from the use of this device be brought to the immediate attention of the Product Evaluation Department at MENTOR OPHTHALMICS, 3000 Longwater Drive Norwell, MA 02061-1610 USA, (617) 871-6950, FAX (617) 871-7785.

### **How Supplied**

The prerolled MemoryLens is distributed cold and must be refrigerated at 2-10°C (36-50°F). DO NOT FREEZE. If inadvertently frozen, do not use; return to MENTOR OPHTHALMICS.

MemoryLens is packaged in a glass vial containing sterile balanced salt solution and is terminally heat sterilized in a tyvek pouch. The contents of the pouch are sterile unless the package is damaged or opened.

MemoryLens is rolled and packaged by the manufacturer and supplied to the physician in the rolled configuration. The lens is intended for rolled implantation and single use only.

### **Expiration Date**

MemoryLenses are sterile unless the sterility pouch is damaged or opened. In addition, there is a sterility expiration date on the outside of the package. The lens should not be used after the expiration date.

### **Return Lens Policy**

#### **U.S. Customers**

MENTOR OPHTHALMICS will accept its lenses for exchange when accompanied by a Lens Return Authorization Form in accordance with the MENTOR OPHTHALMICS Return Lens Policy. For additional information on lenses requiring an exchange, please contact your MENTOR OPHTHALMICS representative or contact MENTOR OPHTHALMICS directly.

#### **International Customers**

Authorization for return of lenses should be obtained from your respective dealer. Other conditions noted above also apply.

### **Disclaimer of Liability**

MENTOR OPHTHALMICS shall not be liable for any injury or damage suffered by a patient as a result of any implantation method or technique used by a physician to implant the IOL or any prescription or selection and use of this lens for a particular patient. The prescribing physician bears full responsibility for the proper selection of the lens and the technique of implantation for each patient.

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**Product Information Disclosure**

MENTOR OPHTHALMICS expressly disclaims all warranties, whether written or oral, statutory, express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness or design. MENTOR OPHTHALMICS shall not be liable for any direct, incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by MENTOR OPHTHALMICS for any purpose. MENTOR OPHTHALMICS neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

**Product Order Information**

**U.S. Customers**

To order directly in the USA , please contact the MENTOR OPHTHALMICS Products Customer Service Department at MENTOR OPHTHALMICS, 5425 Hollister Avenue, Santa Barbara, CA 93111. Toll free telephone (800)423-1887. FAX (805)964-2712.

**International Customers**

For product information or to order directly, contact your local Mentor Ophthalmics products distributor or the International Customer Service Department at Mentor Ophthalmics, 5425 Hollister Avenue, Santa Barbara, CA 93111. Telephone (805)681-6000. FAX (805)964-2712.

This product is covered by one or more of the following patents: U.S. Patent Number 4,731,079.

**MENTOR OPHTHALMICS CORPORATION**

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