

To date, FDA has approved labeling claims related to PCO for certain Alcon Laboratories and Allergan Inc.'s intraocular lenses. Attached are excerpts from Alcon and Allergan's PMA-approved labeling that include the claims related to posterior capsule opacification. This labeling is being provided for background purposes. Any recommendations you make concerning PCO clinical studies or labeling claims should be independent of the information conveyed in this labeling. In other words, we are interested in your views, whether or not they are consistent with the labeling that follows.

You should also note the literature upon which these studies are based (copies of these articles are provided in the literature section of the mailout) :

Alcon Laboratories

Hollick, E.J., et al. #1. The effect of PMMA, silicone and polyacrylic intraocular lenses on posterior capsule opacification three years after cataract surgery. *Ophthalmology*, 1999; 106:49-55.

Hollick, E.J., et al. #2. Lens epithelial cell regression on the posterior capsule with different IOL materials. *British J Ophthal.*, 1998; 82:1182-1188.

Pande, M.V., et al. High-resolution digital retroillumination imaging of the posterior capsule after cataract surgery. *J. Cataract Refract. Surg.* 23:1521-1527, 1998.

Ursell, P.G., et al. Anterior capsule stability in eyes with intraocular lenses made of Poly(Methylmethacrylate), Silicone and AcrySof. *J. Cataract Refract. Surg.* 23:1532-1538, 1997.

Ursell, P.G., et al. Relationship between intraocular lens biomaterials and posterior capsule opacification. *J. Cataract Refract. Surg.*, 1998; 24:352-360.

Allergan, Inc.

Hayashi, H. et al. Quantitative Comparison of Posterior Capsule Opacification After Polymethylmethacrylate, Silicone and Soft Acrylic Intraocular Lens Implantation. *Arch. Ophthalmol.* 1998;116, pp. 1579-82.

Hayashi, K., et al. In vivo quantitative measurement of posterior capsule opacification after extracapsular cataract surgery. *Am J Ophthalmol* 1998; 125:837-843.

Hayashi, K., et al. Reproducibility of posterior capsule opacification measurement using Scheimpflug videophotography system. *J Cataract Refract Surg* 1998; 24: 1632-1635.

LABEL CLAIMS ADDED OCTOBER 1998

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**SUPPLEMENTAL PUBLISHED DATA**

A prospective, well-controlled and randomized study (Unsell et al, 1998; Hollick et al. #1, 1998) with ACRYSOF lenses utilizing a uniquely-developed ooidal illumination method linked to a novel computerized digital imaging system (Panda et al, 1998) was conducted with a total of 90 eyes (30 ACRYSOF, 30 PMMA and 30 silicone), with all lenses implanted unfolded using a planned ECCE procedure with continuous curvilinear capsulorhexis (CCC). There were no statistical differences in best corrected visual acuity and contrast sensitivity established between ACRYSOF and the PMMA and silicone lenses studied.

This study demonstrated a statistically significant reduction in the area of lens epithelial cells computed at 6 months and 1, 2 and 3 years postoperative in comparison with specific models of silicone and PMMA lenses of similar design (Table 7). Lens epithelial cells, or LECs, are believed to be the major contributor to posterior capsule opacification, or PCO.

**Table 7**  
Percentage of Area Opacified\*  
Median and Range

Follow-up	6 months	1 year	2 years	3 years
<b>ACRYSOF</b>				
Median	8.2	10.7	11.8	10.2
Range	4.1 - 34.7	1.1 - 34.4	2.8 - 52	3.4 - 53.7
N	21	25	16	18
<b>Silicone</b>				
Median	20.1	22.2	33.5	39.9
Range	7.7 - 59.4	6.8 - 61.2	4.7 - 75.6	5.5 - 74.3
N	24	23	21	21
<b>PMMA</b>				
Median	19.9	28.1	43.7	56.1
Range	1.3 - 86	9.5 - 54.1	3.9 - 67	4.8 - 94.2
N	25	21	24	21
P value	0.0003	0.0001	0.0001	0.0001

\*Area of opacification is defined as the boundary of the posterior lens capsule within the border of the anterior capsulorhexis exhibiting a relative difference in brightness in forward light scatter.

A statistically significant difference in Nd:YAG capsulotomy rate was observed between ACRYSOF and a similarly designed PMMA lens ( $p=0.02$ ), but not between ACRYSOF and a silicone lens ( $p=0.23$ ) at 3 years postoperative (Table 8).

**Table 8**  
Posterior (Nd:YAG) Capsulotomy Rates  
IOL Material @ 3 years

	ACRYSOF	Silicone	PMMA
N	0/19	3/22	6/23
%	0%	14%	26%
P value	NA	0.23	0.02

In addition, the reduced area of LECs observed in this study was associated with decreased lens epithelial cell proliferation (Hollick et al, #2, 1998) and anterior capsule movement (Unsell et al, 1997) for ACRYSOF lenses as compared to the models of similarly designed silicone and PMMA lenses.

**HOW SUPPLIED**

These posterior chamber intraocular lenses are supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions (See DIRECTIONS FOR USE).

**EXPIRATION DATE**

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (See RETURNED GOODS POLICY).

**RETURNED GOODS POLICY**

Returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc. Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon's Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Account Manager or Customer Service Representative.

**CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.**

## FDA-APPROVED LABELING FOR ALLERGAN SILICONE POSTERIOR CHAMBER IOLS, MODELS SI40NB AND SI55NB

**Clinical Experience**

Clinical trials of the SI20NB and SI22NB silicone posterior chamber lenses began on November 3, 1986. The results achieved by the Core patients successfully followed for one year indicate that the SI20NB and SI22NB silicone posterior chamber intraocular lenses are safe and effective devices for the visual correction of aphakia.

\*

In a randomized, prospective trial, visual acuity loss from best postoperative acuity, incidence of Nd:YAG capsulotomy, and "PCO value" were all significantly lower at two years ( $p < 0.001$ ) in eyes implanted with SLM-2/UV silicone posterior chamber IOLs vs. eyes with a single piece PMMA IOL (12.5 mm overall diameter, 5° haptic angulation). The "PCO value" was determined by calculating an average opacification density of the 4 meridians (0°, 45°, 90° and 135°) using axial densitometry of the Scheimpflug videophotography system.

**Patient Population**

The population in the clinical trials consisted of 64.4% females and 35.6% males (1.3% non-reported), 92.1% were Caucasian, 4.5% were Black, and 3.3% were "Other". The mean age for the total population was 74.0 years.

**How Supplied**

Allergan Posterior Chamber IOLs are supplied as individual sterile units. Each sterile lens is enclosed in its own case within a double aseptic transfer peel pouch, the contents of which are sterile unless the packages are damaged or opened. The external surfaces of the double aseptic transfer peel pouch are not sterile. The product labels are enclosed in a non-sterile pouch.

**Expiration Date**

Sterility is guaranteed unless the double aseptic transfer peel pouch is damaged or opened. In addition, there is a sterility expiration date that is clearly indicated on the outside of the shelf-pack. The lens should not be used after the indicated date.

**Return Lens Policy**

The lens may be returned to the manufacturer for credit within 30 days of purchase. After 30 days it can be replaced or exchanged at no charge.

**Patient Information**

It is recommended that each patient receive information regarding intraocular lenses 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 should also be provided by the physician.

Allergan has a patient brochure available that may be used to help the patient make an informed decision regarding the mode of treatment of aphakia, and to provide postoperative self-care guidance. It is suggested that the surgeon discuss the material in this brochure with the patient at some time prior to surgery.

**Caution**

Federal (USA) law restricts this device to sale by, or on the order of, a physician.

**Symbol/Explanation**

SYMBOL	ENGLISH
	Sterilized by ethylene oxide
	DO NOT REUSE
	USE BY (YYYY-MM: year-month)
	SEE INSTRUCTIONS FOR USE
	Not Sterile