

LABELING

ARTISAN® Phakic Intraocular Lens

Directions for Use

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

Description

OPHTEC's ARTISAN® Phakic Intraocular Lenses (IOLs) are single-piece lenses manufactured from Perspex CQ UV ultraviolet light absorbing polymethylmethacrylate (PMMA) with a refractive index of 1.49, which are designed for implantation into the anterior chamber of the phakic human eye for the treatment of myopia. The lenses are affixed to the anterior mid-periphery of the iris stroma by two iridoplastic bridges with enclavation mechanisms. The optic portion of the lens is available in a 5.0 mm or 6.0 mm diameter, with a convex-concave configuration. The 5.0 mm lens is available in a diopter range of -5 to -20 D. The 6.0 mm lens is available in a diopter range of -5 to -15 D. The optic carrier is elliptical in shape and has an overall length of 8.5 mm with a slight anterior vault. One fixation (enclavation) arm mechanism is located on each side of the two peripheral supports.

Indications for Use

ARTISAN® Phakic Intraocular Lenses (IOLs) are indicated for:

- the reduction or elimination of myopia in adults with myopia ranging from -5 D to -20 D with less than or equal to 2.5 D of astigmatism at the spectacle plane and whose eyes have an anterior chamber depth greater than or equal to 3.2 millimeters; and
- patients with documented stability of manifest refraction for the prior 6 months, as demonstrated by a spherical equivalent change of less than 0.50 D.

Contraindications

The ARTISAN® Phakic IOL is contraindicated in patients:

- Who are less than 21 years old
- With an anterior chamber depth (ACD) less than 3.2 mm
- With an abnormal Iris, such as peaked pupil or elevated iris margin
- Who are pregnant and nursing
- Who do not meet the minimum endothelial cell density

Endothelial Cell Density

Age	Minimum endothelial cell density
21-25	3550 cells/mm ²
26-30	3175 cells/mm ²
31-35	2825 cells/mm ²
36-40	2500 cells/mm ²
41-45	2225 cells/mm ²
> 45	2000 cells/mm ²

The table indicates the minimum endothelial cell density (ECD) per age group at time of implantation. This table was developed using a rate of 2.31% (the upper 90% confidence interval of the average cell loss for eyes with ACDs of 3.2 mm or greater.) It sets minimum endothelial cell density criteria as a function of age that should result in at least 1000 cells/mm² at 75 years of age. The patient's ECD should be monitored periodically at the physician's discretion.

Warnings

1. Do not resterilize this intraocular lens by any method. (See Returned Lens Policy.)
2. Do not store lenses at temperatures over 45°C (113°F).
3. Surgical difficulties at the time of intraocular lens implantation, which might increase the potential for complications (e.g. persistent bleeding, significant vitreous prolapse or loss).
4. The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established.
5. The long-term effect to the corneal endothelial cells has not been established.
6. The relationship between the ARTISAN® Phakic IOL and future lens opacities and retinal detachment is undetermined.
7. The effect of the ARTISAN® Phakic IOL on the future risk of glaucoma is unknown because its effects on the anterior chamber angle were not analyzed in the clinical trial. Approximately 1% of the subjects had elevated eye pressure that required glaucoma medication.
8. The long-term effect to the corneal endothelial cells has not been established.
9. The occurrence of lens opacities in the future is unknown.

Precautions

1. Prior to surgery, the surgeon must provide prospective patients with a copy of the patient information brochure for this product and inform these patients of the possible benefits and complications associated with the use of this device.
2. A high level of surgical skill and training specific to iris-fixated IOLs is required for lens implantation.
3. One or more iridotomies/iridectomies should be performed to reduce risk of pupillary block.
4. A cohesive high molecular weight viscoelastic is recommended for corneal protection and complete removal is recommended to reduce the chance of post-op intraocular pressure (IOP) spikes. Low molecular weight non-cohesive viscoelastics should not be used.
5. Patients with any of the following conditions may not be suitable candidates for this intraocular lens because the lens may exacerbate an existing

condition or may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight:

- a. Abnormality of the iris or ocular structure that would preclude fixation, such as aniridia, hemi-iridectomy, severe iris atrophy, coloboma, or microphthalmos.
 - b. Congenital bilateral cataracts.
 - c. Recurrent anterior or posterior segment inflammation.
 - d. Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases.
 - e. Previous history of retinal detachment.
 - f.
 - g. Patients with only one eye with potentially good vision.
 - h. Glaucoma.
 - i. Corneal endothelial dystrophy.
 - j. Proliferative diabetic retinopathy.
6. The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis. Annual exams are recommended.
 7. Elevated intraocular pressure has been reported occasionally in patients who received lens implants. The intraocular pressure of patients should be monitored postoperatively.
 8. Trauma is a risk factor for IOL dislocation.
 9. Visual acuity could be diminished in situations where there is low level lighting.
 10. When pupil size is greater than optic size, there may be visual aberrations.

Adverse Events and Complications

A total of 662 subjects were evaluated in the clinical trial to determine the safety of the ARTISAN® Phakic IOL.

The complications experienced during the clinical trial of the ARTISAN® Phakic IOL include (in order of frequency): Hyphema (cumulative) (0.2%), retinal detachment (cumulative) (0.6%), IOL dislocation (0.8%) and surgical reintervention (4.2%). No incidences of macular edema, endophthalmitis, hypopyon, or persistent corneal edema were reported during the study.

Incidences of complications (compared with the FDA Grid for cataract extraction and posterior chamber IOL implantation) and incidences of surgical reinterventions are shown in the following table.

Adverse Event	Cumulative % (n/N)	FDA Grid %	Persistent (3 Years) % (n/N)	FDA Grid %
Endophthalmitis	0.0 (0/662)	0.1	-	-
Hyphema	0.2 (1/662)	2.2	-	-
Hypopyon	0.0 (0/662)	0.3	-	-
IOL Dislocation	0.8 (5/662)*	0.1	-	-
Cystoid Macular Edema	0.0 (0/662)	3.0	0.0 (0/232)	0.5

Pupillary Block	0.0 (0/662)	0.1	-	-
Retinal Detachment	0.6 (4/662) [†]	0.3	-	-
Surgical Reintervention	4.2 (28/662)	0.8	-	-
Corneal Edema	-	-	0.0 (0/232)	0.3
Iritis	0.5(3/662) ^A	-	0.0 (0/232)	0.3
Raised IOP Requiring Treatment	-	-	0.0 (0/232)	0.4
Surgical Treatments Not Monitored in the FDA Grid				
Preventative Lens Repositioning	2.1 (14/662)	-	-	-
Refractive Procedures**	2.6 (17/662)	-	-	-
Nd:Yag Peripheral Iridotomy	3.0 (20/662)	-	-	-
Aqueous Release	1.8 (12/662)	-	-	-
Resuture Wound Leak	1.2 (8/662)	-	-	-

*Four events due to inadequate surgical fixation; one event due to blunt trauma

^AThere is no FDA Grid value for cumulative iritis

[†]Comparison should be made to literature for retinal detachment rates for high myopes:

- Retinal detachment rates increase with increasing myopia¹
The risk of retinal detachment within one year of implantation of this device is 0.6%. The risk of retinal detachment for high myopes following implantation is more than 10 times the risk without surgery, i.e., greater than 10-fold the background rate of retinal detachment for high myopes (greater than minus 3 diopters).
- 5.0% in myopic eyes > 6 D²
- 0.8% to 7.5% in pseudophakic eyes with high axial myopia³

¹ Ogawa, A and Tanaka, M. The relationship between refractive errors and retinal detachment, Jpn J. Ophthalmology 32:310, 1988.

² Dellone-Larkin G, Dellone CA. Retinal detachment. Available at <http://www.emedicine.com/emerg/topic504.htm>. Accessed January 13, 2004.

³ Jacobi, F and Hessemer, V. Pseudophakic retinal detachment in high axial myopia, J. Cat. Refract Surg 23:1095, 1997.

**Refractive procedures include: LASIK (11/17); AK (3/17); LRI (2/17) and PRK (1/17)

Surgical reinterventions (see table below) were not shown to have an impact on safety or efficacy.

Adverse Event	n	%*
Lens Explant	10	1.5%
High Myopia/Age Related Cataract	0	
Inflammatory Response	3	
Trauma	4	
Patient Anxiety	1	
Patient Not Satisfied	1	
Pupil Larger than Lens Optic	1	
Lens Exchange	9	1.4%
Pupil Calculation Error	6	
Pupil Larger than Lens Optic	2	
Inadequate Lens Fixation	1	
Lens Reattachment	5	0.7%
Trauma	1	
Inadequate Lens Fixation	4	
Retinal Repair	4	0.6%
Retinal Detachment	4	
Total	28	4.2%

* All Core Subjects N=662

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Other Complications

Eyes with brown irides were found to have significantly less pigment dispersion (15.3%) compared to eyes with non-brown irides (25.2%). However, eyes with brown irides had similar rates of IOP spikes greater than 30 mmHg (5.2%) compared to eyes with non-brown irides (3.9%). The interaction between pigment dispersion and brown irides was found to be a significant predictor of IOP spikes. Eyes with brown irides and pigment dispersion had a statistically significantly (Fisher's Exact Test, p=0.02) higher rate of IOP spikes (11.7%) than eyes with non-brown irides and pigment dispersion (3.1%).

Clinical Study Results

The ARTISAN® Phakic IOL was evaluated in a prospective, nonrandomized study of 662 subjects, 493 of which were followed for one year and 232 followed for three years.

The 662 subject Cohort population in the clinical trial consisted of 64.5% females (427/662) and 35.5% males (235/662). 85.0% were Caucasian, 3.2% were Black, 4.1 % were Hispanic and 6.2% were Asian. The mean age was 39.6 years.

Visual Acuity

The postoperative results demonstrated that the ARTISAN® Phakic IOL provides correction for high myopia. The visual acuities at one and three years are described in the following tables:

UCDVA=Uncorrected Distance Visual Acuity, Snellen		
Where emmetropia was the goal (+/-0.50D) and Preop Best Corrected Visual Acuity (BCVA) better than or equal to 20/20		
	1 yr	3 yr
N	204	88
20/20 or better	47.1%	44.3%
20/40 or better	93.6%	92.0%
20/80 or better	100.0%	97.7%
worse than 20/80	0.0%	2.3%

BCDVA=Best Corrected Distance Visual Acuity, Snellen		
Eyes with preoperative BCVA 20/20 or better		
	1 yr	3 yr
N	288	127
20/20 or better	95.1%	95.3%
20/40 or better	100.0%	100.0%
20/80 or better	100.0%	100.0%
worse than 20/80	0.0%	0.0%

Predictability of refraction

The refraction was predictable, with 94.5% of patients achieving ± 1.0 D from target at the one-year examination.

Spherical Equivalence (Target Variance) Distribution:		
	1 yr	3 yr
N	492	226
Plano to +/- 0.5D	72.0%	71.7%
Plano to +/- 1.0D	94.5%	94.7%

Stability of refraction

The refraction was stable, with 95.9% of patients achieving less than +/- 1.0 D of shift at 3 years.

Manifest Refraction Spherical Equivalence (MRSE) Change between visits			
	6 mo – 1 yr	1 yr – 2 yr	2 yr – 3 yr
N	485	349	215
+/- 0.5D	82.9%	85.4%	82.5%
+/- 1.0D	97.1%	97.7%	95.9%
+/- 2.0D	99.6%	99.7%	99.5%
>2.0D	0.4%	0.3%	0.5%

Endothelial Cell Density

The analysis of the change in endothelial cell (EC) density indicated that the EC density remained relatively constant over the three-year study period in relation to normal endothelial cell loss.

An endothelial cell density substudy was performed using a single reading center to minimize standard deviations inherent in this test method. For this subset of 215 subjects (315 eyes), a percent change from baseline to three years of -4.76% (SD=7.8%) was found. This result is consistent with expected normal endothelial cell loss of 1.5% to 2.0% per year. No statistically significant differences in the percent change between consecutive study intervals were found. Covariate analyses including age, anterior chamber depth, lens model, and IOP showed no significant correlations.

Mean EC density results for a consistent cohort group of 57 eyes with useable data available at postop visits are shown in the following table:

Visit	Mean	Standard Deviation	Standard Error	95% Confidence Limits	
PreOp	2818.33	425.01	56.29	2708.00	2928.67
6 Months	2812.86	465.79	61.70	2691.94	2933.78
1 Year	2768.25	460.42	60.98	2648.72	2887.77
2 Years	2760.26	478.54	63.38	2636.03	2884.50
3 Years	2692.98	478.64	63.40	2568.73	2817.24

The available 3-year data from the clinical study indicates a continual steady loss of endothelial cells of -1.8% per year and this rate has not been established as safe. If endothelial cell loss continues at the rate of 1.8% per year, 39% of patients are expected to lose 50% of their corneal endothelial cells within 25 years of implantation. The long-term effect

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on the cornea's health of a 50% loss in corneal endothelial cells is unknown.

The following table shows the predicted endothelial cell loss for the estimated proportion of patients based on percent loss and time from implantation.

Years	Percent Loss						
	10	20	30	40	50	60	70
5	48	34	22	13	7	3	1
10	57	46	36	26	18	12	8
15	63	54	44	35	27	20	14
20	67	59	50	42	34	26	20
25	71	63	55	47	39	31	24
30	74	67	60	52	44	36	29
35	77	71	63	56	48	40	32
40	80	74	67	59	51	43	36
45	82	76	70	63	55	47	39
50	84	79	73	66	58	50	42
55	86	81	75	68	61	53	44
60	88	84	78	71	64	55	47

Optical Visual Symptoms

The following table shows the postoperative outcomes by proportion as compared to preoperative levels for glare, halos and starbursts, etc., stratified by the mesopic pupil sizes measured preoperatively.

Optical Visual Symptom	Pupil Size	Questionnaire Responses*		
		Subjects with no change in symptoms preop to postop	Subjects with change in symptoms preop to postop	
			Preop NO, Postop YES	Preop YES, Postop NO
Glare	All	73.6%	13.5%	12.9%
	≤4.5 mm	70.4%	14.3%	15.3%
	>4.5 to ≤5.5 mm	71.6%	13.4%	15.1%
	>5.5 mm	76.3%	16.8% (p=0.04) [†]	6.9%
Starbursts	All	78.5%	11.8%	9.7%
	≤4.5 mm	77.8%	12.1%	10.1%
	>4.5 to ≤5.5 mm	74.5%	16.3%	9.3%
	>5.5 mm	81.2%	10.9%	7.9%
Halos	All	72.0%	18.2% (p=0.002) [†]	9.8%
	≤4.5 mm	72.8%	17.2%	10.1%
	>4.5 to ≤5.5 mm	69.2%	19.2%	11.6%
	>5.5 mm	72.2%	23.8% (p<0.001) [†]	4.0%

*412 subjects completed the questionnaire; data presented for those subjects that answered nighttime symptom questions; pupil size groups ≤4.5 mm (n=99), >4.5 to 5.5 mm (n=172), >5.5 mm (n=101).

[†] Statistically significant (McNemar's Test) for those subjects reporting a change in symptom occurrence preoperatively to postoperatively

Additional Outcome Data Including Bilateral Eyes

The following table stratifies the predictability of intended refraction for ± 0.5 and ± 1.0 D by lens power for all eyes implanted (662 subjects, 478 bilaterally implanted).

Lens Group	Exam Interval	N	MRSE vs. Intended Target		
			± 0.5 D	± 1.0 D	± 2.0 D
All Diopter Powers	1-6 Day	1037	58.0%	84.4%	92.8%
	2-3 Week	1070	67.1%	93.9%	96.4%
	4-8 Week	1086	70.2%	93.6%	96.8%
	4-6 Month	996	74.8%	95.5%	98.6%
	7-11 Month	878	76.7%	94.5%	98.4%
	1 Year	840	73.6%	95.0%	98.6%
	2 Year	604	72.0%	94.0%	98.7%
	3 Year	376	69.9%	94.7%	98.4%
-5 to -7 Diopters	1 Year	27	77.8%	100.0%	100.0%
	2 Year	14	85.7%	100.0%	100.0%
	3 Year	18	55.6%	100.0%	100.0%
>-7 to -10 Diopters	1 Year	161	73.3%	93.8%	99.4%
	2 Year	109	68.8%	94.5%	100.0%
	3 Year	69	73.9%	94.2%	100.0%
>-10 to -15 Diopters	1 Year	543	76.1%	95.6%	98.5%
	2 Year	388	74.2%	95.1%	98.5%
	3 Year	235	69.8%	94.0%	97.9%
>-15 Diopters	1 Year	109	60.6%	92.7%	97.2%
	2 Year	93	64.5%	88.2%	97.8%
	3 Year	54	70.4%	96.3%	98.1%

The following table shows the UCVA by lens power for all eyes implanted that were targeted for emmetropia.

Lens Group	Plano to:	N	20/20 or Better	20/40 or Better
All Diopter Powers	1-6 Day	720	13.1%	54.4%
	2-3 Week	686	18.8%	70.3%
	4-8 Week	687	26.5%	81.5%
	4-6 Month	623	35.0%	89.7%
	7-11 Month	556	39.6%	90.6%
	1 Year	521	39.9%	92.3%
	2 Year	379	36.9%	90.8%
	3 Year	225	35.6%	88.0%
-5 to -7 Diopters	1 Year	11	45.5%	100.0%
	2 Year	7	0.0%	85.7%
	3 Year	8	0.0%	75.0%
>-7 to -10 Diopters	1 Year	90	51.1%	93.3%
	2 Year	60	50.0%	98.3%
	3 Year	32	50.0%	96.9%
>-10 to -15 Diopters	1 Year	347	38.9%	93.1%
	2 Year	252	36.9%	89.7%
	3 Year	148	36.5%	85.8%
>-15 Diopters	1 Year	73	30.1%	86.3%
	2 Year	60	28.3%	88.3%
	3 Year	37	27.0%	91.9%

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1. Check the label on the lens package for proper lens model, dioptric power, and expiration date.
2. Inspect the blister pack. Ensure that it is not damaged.
3. Tap lightly on the lid before opening the lens container.
4. While keeping the container in a horizontal position, unscrew the cap and lift it.

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5. Grasp the lens gently with forceps.
6. Examine the lens carefully under the microscope for damage or particulate matter.
7. Rinsing the IOL with sterile balanced salt solution will remove the electrostatic charge.

NOTE: The IOL can become electrostatically charged and may stick to the lid of the lens container. The lens should be carefully examined to ensure that particles have not been attracted to it.

Calculation of Lens Power

The physician should determine preoperatively the power of the lens to be implanted.

Lens power calculation methods are described in the following reference:

- van der Heijde, G.L., Some optical aspects of implantation of an IOL in a myopic eye, *European Journal of Implant Refractive Surgery*, Vol 1, Dec 1989, pgs 245-248

Physicians requiring additional information on lens power calculation should contact OPHTEC.

Patient Registration Instructions and Reporting Registration

Each patient who receives an ARTISAN® Phakic IOL must be registered with OPHTEC at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to OPHTEC. Patient registration is essential for OPHTEC's long-term patient follow-up program and will assist OPHTEC in responding to Adverse Reaction Reports and/or potentially sight-threatening complications.

An Implant Identification Card is supplied in the lens package. 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.

Reporting

Adverse Reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported to OPHTEC immediately but no later than 10 days after occurrence. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation, especially in younger patients.

Physicians must report these events in order to aid in identifying emerging or potential problems with ARTISAN® Phakic IOLs. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOLs in general.

Physicians should use the following number when reporting adverse reactions or potentially sight

threatening complications involving OPHTEC intraocular lenses. **National:** (561) 989-8767.

How Supplied

The IOL is supplied sterile and dry in a lens container, which is sealed in a blister pack and placed in a box together with the identifying labels.

Expiration Date

Sterility is guaranteed unless the sterile 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.

Returned 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 if not opened or damaged.

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ARTISAN[®] PHAKIC IOL

FACTS YOU NEED TO KNOW ABOUT IMPLANTATION OF THE ARTISAN[®] PHAKIC IOL (-5 TO -20 D) FOR THE CORRECTION OF MYOPIA (Nearsightedness)

PATIENT INFORMATION BROCHURE

This brochure is designed to help you and your ophthalmologist decide whether or not to have surgery for implantation of the ARTISAN[®] PHAKIC IOL. Please read this entire brochure. Discuss its contents thoroughly with your ophthalmologist so that you have all of your questions answered to your satisfaction. Ask any questions before you agree to the surgery.

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1. Introduction

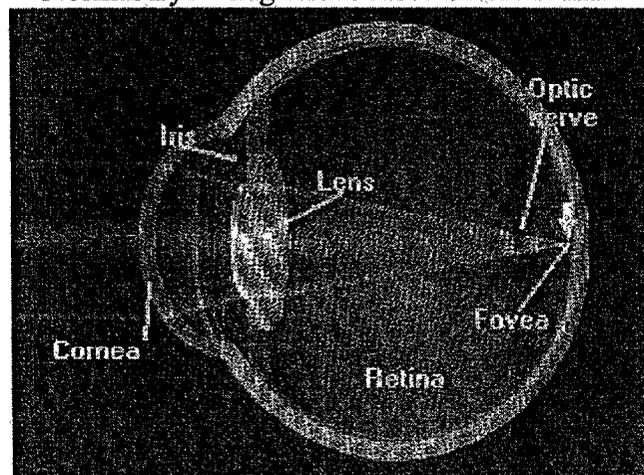
This brochure provides information to help you decide whether to undergo implantation of the ARTISAN[®] Phakic Intraocular Lens (IOL) for the correction of your nearsightedness (myopia). An IOL is not required to correct nearsightedness. For instance, you may be able to wear glasses or contact lenses instead to correct your vision. Depending on the degree of your nearsightedness and other conditions of your eye, there may also be different refractive surgery options available to correct your vision including Laser Assisted In-Situ Keratomileusis (LASIK).

Please read this brochure carefully and discuss the information with your ophthalmologist and their staff. Your ophthalmologist can determine if you are a suitable candidate for the ARTISAN[®] Phakic IOL. However, you are the only one who can decide whether the surgery is right for you. The information in this brochure should help you make your decision. You should also discuss your decision with your ophthalmologist, and make sure that all of your questions have been answered to your satisfaction before deciding to proceed with surgery.

2. How the Eye Functions

Your eye focuses light to form images or “pictures” of everything around you, much like a camera. Your eye changes these images into electrical signals and sends them to your brain.

Normal Eye – Light is focused on the retina



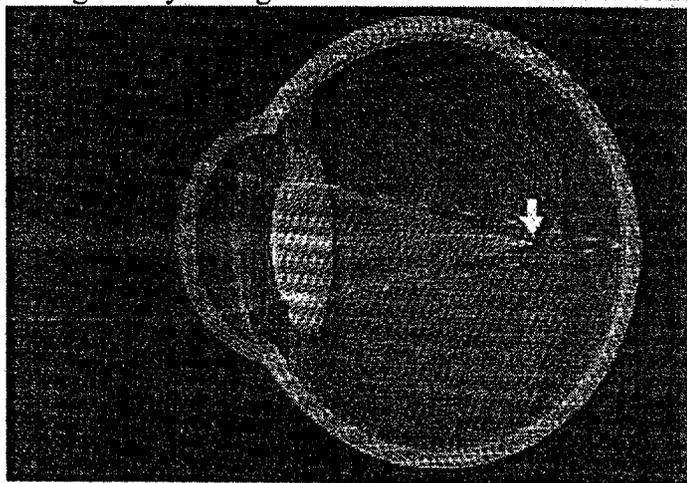
There are several structures in your eye responsible for forming the images that you see. The cornea and crystalline lens focus light by bending it as it enters the eye so the light rays form an image on the retina. The cornea is the clear outermost layer of your eye.

The crystalline lens inside the eye also bends light rays as they pass through the eye. The cornea provides two-thirds of the focusing power of the eye, and the crystalline lens provides the other third. The retina is the part of the eye that transmits information to the brain, allowing you to “see” images. The fovea is the central point on the retina that produces the sharpest vision.

The eye focuses incoming light by bending all the light rays to meet at a single point on the retina. When all of the light rays meet on the retina, it gives you a clear, sharp image of the object at which you are looking. However, if the light focuses behind the retina or in front of the retina, the image you see will be blurred. Depending on where the image focuses, you may be nearsighted or farsighted.

Since the cornea has the greatest bending (focusing) power, it is the cornea’s shape that determines the eye’s focusing power. In normal eyes, the cornea is able to bend light rays to focus on your retina. In nearsighted eyes, the eye is too long and light is focused in front of the retina. In farsighted eyes, the eye is too short and light is focused in back of the retina. There is another condition that also causes blurry vision. If the cornea is shaped irregularly, like an egg, light rays do not come to a single focus point. This condition is called astigmatism.

Nearsighted eye – Light is focused in front of the retina

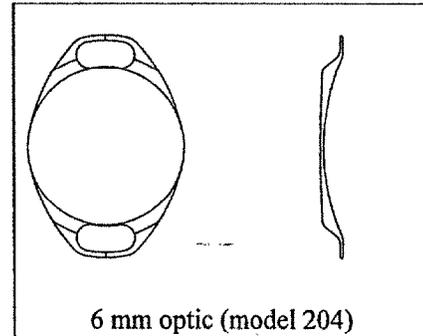
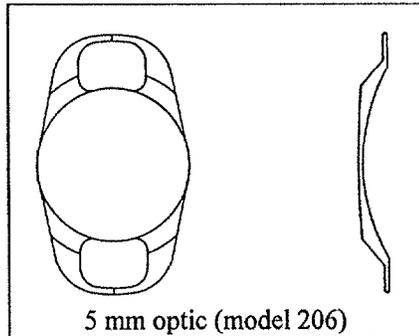


When you have an eye examination, your ophthalmologist is able to determine whether you are nearsighted, farsighted, and/or astigmatic. During the eye exam, your ophthalmologist will measure where your eye focuses light.

If it is determined that you are nearsighted, your ophthalmologist will discuss different treatment options with you. The ARTISAN[®] Phakic IOL is just one option.

3. What is the ARTISAN[®] Phakic IOL?

The ARTISAN[®] Phakic IOL is an intraocular lens that is inserted in front of your natural lens, between the cornea and the iris, during a surgical procedure. This type of lens is called a phakic IOL, because the eye still has its natural lens in place. The IOL is made of the same type of plastic that has been used to make intraocular lenses for cataract surgery. The plastic has a long history of use in these types of products.



The goal of placing the ARTISAN[®] Phakic IOL into your eye is to correct your nearsightedness. The ophthalmologist will select the appropriate lens power (diopter) to correct your nearsightedness. Once the ARTISAN[®] Phakic IOL has been implanted in your eye and your eye has healed, the light coming into your eye can correctly focus on the retina, resulting in improved vision.

The ARTISAN[®] Phakic IOL does not eliminate the need for reading glasses. In some cases, you may need reading glasses after surgery even if you did not need them before.

The ARTISAN[®] Phakic IOL may be implanted in one eye at a time. Your second eye may receive an implant after your ophthalmologist determines that your first eye has healed sufficiently. It is common to perform the second eye implant surgery within 3 months of the first eye. You should discuss this with your ophthalmologist.

The ARTISAN[®] Phakic IOL has been tested and successfully used in Europe since 1990 on thousands of patients. In the United States, clinical studies of the ARTISAN[®] Phakic IOL procedure began in 1997 and ended in 2003. During that time, over 1000 lenses were implanted in over 500 patients. During the U.S. study, over 84% of subjects achieved 20/40 vision or better without the use of glasses or contact lenses.

4. Are You a Good Candidate for the ARTISAN[®] Phakic IOL?

Candidates for the ARTISAN[®] Phakic IOL must meet the following criteria:

- At least 21 years of age;
- Healthy eyes with no eye disease, iris or corneal abnormality (for example, infection);
- Nearsightedness that can be corrected with lenses between -5 to -20 diopters with up to 2.5 diopters of astigmatism;
- Stable refraction, as determined by your ophthalmologist (this is a test to determine that your nearsightedness has not changed more than 0.50 diopters for 6 months prior to surgery);
- Informed of the ARTISAN[®] Phakic IOL's risks and benefits compared with other available treatment options;
- Understand and sign the informed consent form for refractive surgery with the ARTISAN[®] Phakic IOL.

5. Benefits of the ARTISAN[®] Phakic IOL

The ARTISAN[®] Phakic IOL is effective in correcting nearsightedness that can be corrected with lenses between -5 and -20 diopters. If you have nearsightedness in this range, the ARTISAN[®] Phakic IOL may improve your distance vision without glasses or contact lenses.

6. Risks of the ARTISAN[®] Phakic IOL

Implantation of an ARTISAN[®] Phakic IOL is a surgical procedure, and as such, carries potentially serious risks. Please review this brochure and discuss the risks with your ophthalmologist.

The clinical study of the ARTISAN[®] Phakic IOL included the following postoperative vision-threatening events:

- retinal detachment
- cataract development
- lens opacities
- corneal edema

Retinal detachment is a separation of the retina from its connection at the back of the eye. The separation usually results from a tear in the retina. Patients with moderate to high levels of nearsightedness have a higher risk for retinal detachment when compared with the general population. This risk level may be increased with the implantation of the ARTISAN[®] Phakic IOL. This is because inflammation as a result of the surgical

procedure could lead to accelerated cataract development, which has implications for retinal detachment.

A **cataract** is a clouding of the crystalline lens, which impairs normal vision. Patients with high levels of nearsightedness are at an increased risk for cataract development. This risk level may be increased with the implantation of the ARTISAN[®] Phakic IOL. The ARTISAN[®] Phakic IOL is affixed (“clipped”) to the iris which is located in front of the natural crystalline lens. This IOL has a vaulted design so that the back portion of the IOL does not touch the natural lens. However, if the IOL were to come into contact with the lens, cataract development could be induced.

The relationship between the ARTISAN[®] Phakic IOL and future lens opacities and retinal detachment is undetermined.

Corneal edema occurs when the cornea takes on more water than it can absorb, which means the cornea swells and becomes less transparent. Endothelial cells play a role in keeping the cornea healthy. The available 3-year data from the clinical study indicates a continual steady loss of endothelial cells of -1.8% per year and this rate has not been established as safe. If endothelial cell loss continues at the rate of 1.8% per year, 39% of patients are expected to lose 50% of their corneal endothelial cells within 25 years of implantation. The long-term effect on the cornea’s health of a 50% loss in corneal endothelial cells is unknown. However, if too many cells are lost you may need a corneal transplant. Therefore, it is very important that your endothelial cell density is periodically monitored.

Based on the data obtained from the clinical study of the ARTISAN[®] Phakic IOL, it is impossible to predict the effect that this IOL will have on the corneal endothelium. The endothelium is a layer of cells which lines the undersurface of the cornea, and it regulates corneal water content. The endothelium works as a pump, removing excess water as it is absorbed into the stroma, the surface behind the epithelium. If the water content isn’t regulated, the stroma could become saturated, resulting in a hazy and opaque appearance, which would reduce vision.

Patients with high levels of nearsightedness are also at an increased risk for the development of glaucoma. Glaucoma is an increase in the pressure of the eye caused by slowed fluid drainage from the eye. The effect of the ARTISAN[™] Phakic IOL on the future risk of glaucoma is unknown because its effects on the anterior chamber angle were not analyzed in the clinical trial. Approximately 1% of the subjects had elevated eye pressure that required glaucoma medication long term.

Complications associated with the implantation procedure and/or the lens itself are rare. During the clinical trial for this product, the following types of events were reported:

- 1.36% of patients had their IOL exchanged (due to inadequate surgical fixation, the lens optic size was smaller than their pupil size, or a power calculation error).
- 1.51% of patients had their IOL removed (due to inflammatory response, patient anxiety, the lens optic was smaller than their pupil size, postoperative trauma, or surgical trauma).
- 0.60% of patients had to have their IOL reattached (due to inadequate surgical fixation or postoperative trauma).
- 0.45% of patients required repair of their retina
- 0.15% of patients experienced surgical trauma which required retinal repair

The following table shows the percentage of patients from the clinical trial who achieved vision of 20/20 or better, and 20/40 or better. Most patients were able to achieve vision of 20/40 or better.

Lens Group	Plano to:	N	20/20 or Better	20/40 or Better
All Diopter Powers	1 Year	521	39.9%	92.3%
	2 Year	379	36.9%	90.8%
	3 Year	225	35.6%	88.0%
-5 to -7 Diopters	1 Year	11	45.5%	100.0%
	2 Year	7	0.0%	85.7%
	3 Year	8	0.0%	75.0%
>-7 to -10 Diopters	1 Year	90	51.1%	93.3%
	2 Year	60	50.0%	98.3%
	3 Year	32	50.0%	96.9%
>-10 to -15 Diopters	1 Year	347	38.9%	93.1%
	2 Year	252	36.9%	89.7%
	3 Year	148	36.5%	85.8%
>-15 Diopters	1 Year	73	30.1%	86.3%
	2 Year	60	28.3%	88.3%
	3 Year	37	27.0%	91.9%

The following table shows the outcomes for optical visual symptoms for the patients in the clinical trial. This table compares the patients' preoperative levels for glare, halos and starbursts with their postoperative levels. Most patients experienced no change in these symptoms.

Optical Visual Symptom	Pupil Size	Questionnaire Responses*		
		Subjects with no change in symptoms preop to postop	Subjects with change in symptoms preop to postop	
			Preop NO, Postop YES	Preop YES, Postop NO
Glare	All	73.6%	13.5%	12.9%
	≤4.5 mm	70.4%	14.3%	15.3%
	>4.5 to ≤5.5 mm	71.6%	13.4%	15.1%
	>5.5 mm	76.3%	16.8% (p=0.04) [†]	6.9%
Starbursts	All	78.5%	11.8%	9.7%
	≤4.5 mm	77.8%	12.1%	10.1%
	>4.5 to ≤5.5 mm	74.5%	16.3%	9.3%
	>5.5 mm	81.2%	10.9%	7.9%
Halos	All	72.0%	18.2% (p=0.002) [†]	9.8%
	≤4.5 mm	72.8%	17.2%	10.1%
	>4.5 to ≤5.5 mm	69.2%	19.2%	11.6%
	>5.5 mm	72.2%	23.8% (p<0.001) [†]	4.0%

*412 subjects completed the questionnaire; data presented for those subjects that answered nighttime symptom questions; pupil size groups: ≤4.5 mm (n=99), >4.5 to 5.5 mm (n=172), >5.5 mm (n=101).

[†] Statistically significant (McNemar's Test) for those subjects reporting a change in symptom occurrence preoperatively to postoperatively

It is possible that a secondary procedure may have to be performed to fine tune your vision. During the clinical trial of this lens, the following secondary procedures were performed.

- Lens repositioning
- Secondary refractive procedures (LASIK, AK, LRI or PRK).
- Resuturing of the wound leak, aqueous release, or insertion of punctual plugs

It is normal to expect that signs associated with inflammation may be noticed by your ophthalmologist following your surgery. These types of symptoms usually are present after surgery because they are part of the normal healing process; however they will decrease as time goes on, with most being completely resolved by 6 months after your implant.

If your results with the ARTISAN® Phakic IOL are not satisfactory, there may be a need for an additional surgical procedure to adjust the lens, exchange the lens or remove the lens.

In some cases, you may need reading glasses after implantation of the ARTISAN® Phakic IOL even if you did not need them before.

7. What to Expect

Before the ARTISAN® Phakic IOL Surgery

If you are interested in receiving an ARTISAN® Phakic IOL, you will need a qualification examination to determine if your eye is healthy and suitable for surgery. This will include a complete eye history, and a thorough examination of both eyes.

Prior to surgery, you will undergo an examination to determine your general health that will assist the surgery staff in preparing for any special needs. Your ophthalmologist may prescribe eye drops or other medication to be taken prior to surgery and you may also be asked to obtain medications for your postoperative care.

Before treatment, be sure to tell your ophthalmologist about any medication you take or allergies you have. You will receive instructions from the ophthalmologist and the surgery center regarding preparation prior to surgery (e.g., food/drink, transportation, arrival time). In all cases, you will need to arrange for someone to drive you home after surgery and to your next appointment. You will not be able to drive until you receive permission from your ophthalmologist.

The Day of Your ARTISAN® Phakic IOL Surgery

If you are a contact lens wearer, you will need to stop wearing your contact lenses during your baseline refraction and on the day of surgery. After you arrive and complete the surgery center check-in, you will be taken to the preoperative area and readied for the surgery (this process varies by site).

Depending on the type of anesthesia to be administered, you will be prepared for anesthesia. You may also receive an intravenous drip (I.V.), depending on your needs. Your eye will be prepared to receive the lens implant, and drops will be placed in your eye to make your pupil smaller.

You will be taken to the operating room suite where your eye will be cleaned and prepared to receive the lens. A drape will be placed over you to keep the area around your eye clean. The ophthalmologist will place an instrument in your eyelids to assist in stabilizing your eye. This instrument is used to hold the eyelids apart, to give better access to the eyeball. This can be uncomfortable but most patients tolerate the discomfort for the short surgery.

During the surgical procedure, your ophthalmologist will make an incision in your eye to insert the lens. After the incision is made, a gel-like solution (viscoelastic) is placed into the eye to help during insertion of the lens. The lens is inserted, positioned and then fixed into place in the following manner: The ophthalmologist will insert the lens into the front part (anterior chamber) of your eye between your cornea and the colored central portion of your eye (iris). The ARTISAN[®] Phakic IOL is “clipped” to your iris so it will remain in place after surgery. If any of the gel-like solution remains in your eye, it will be removed by suction (aspiration). Your ophthalmologist will close the incision.

A temporary shield will be placed over the eye to protect it during the immediate postoperative period. You will be transported to a recovery area until you have stabilized and are ready to go home (after approximately one hour). After you have stabilized from the surgery you will be asked to go home and relax for the rest of the day (no lifting, exercise, or other strenuous activity).

Immediately After Surgery

After the surgical procedure, you will be allowed to go home, usually within 60 minutes, but you may not drive yourself. Your ophthalmologist may give you eye drops to use when you return home, with instructions on when and how to use the eye drops. You should only have minor discomfort after the ARTISAN[®] Phakic IOL procedure, but if you do experience pain, be sure to contact your ophthalmologist.

You will return for an evaluation the day after surgery to determine the results of your surgery. At that time, your ophthalmologist will explain to you the care of your eye, precautions and schedule your next follow-up visit. Follow all postoperative instructions given to you by your ophthalmologist and the surgery center. Do not rub your eye(s) as this may cause disruption of the wound or corneal edema.

Some discomfort is normal during the healing process and your ophthalmologist will discuss this with you. Any unexpected pain, discomfort, discharge, trauma or other condition should be reported immediately to your ophthalmologist. If you cannot contact your ophthalmologist you should seek alternative care. Contact your ophthalmologist or the surgery center immediately if your discomfort is greater than expected for the normal healing process.

The First Week Following Surgery

You will return to your ophthalmologist the day after your surgery for an examination. The shield will be removed and your eye will be observed under a special microscope to make sure the lens is positioned correctly and that there are no complications. Although there may be some improvement in your vision at this time, the visual effects of the surgery take 2-4 weeks to stabilize. Most patients are able to return to work and can resume normal non-strenuous activities.

Your ophthalmologist will instruct you to return for additional follow up visits to monitor your progress. Standard postoperative exams are performed postoperatively at 1 day, 1 week, 1 month, 3-6 months and yearly thereafter. It is important to attend all of these visits. If you experience any pain, trauma or unusual discomfort during the postoperative period, immediately contact your ophthalmologist for instructions.

8. Contraindications

You should NOT have the ARTISAN[®] Phakic IOL implanted if:

- You are less than 21 years of age
- You are a woman who is pregnant or nursing
- Your ophthalmologist determines you have an abnormal iris, pupil or cornea
- Your ophthalmologist determines you have an anterior chamber depth of less than 3.2 mm
- Your ophthalmologist determines your endothelial cell density does not meet the minimum recommended density in the following table.

Age	Minimum endothelial cell density
21-25	3550 cells/mm ²
26-30	3175 cells/mm ²
31-35	2825 cells/mm ²
36-40	2500 cells/mm ²
41-45	2225 cells/mm ²
> 45	2000 cells/mm ²

The table indicates the minimum endothelial cell density per age at time of implantation. It sets minimum endothelial cell density criteria as a function of age that will result in at least 1000 cells/mm² at 75 years of age.

9. Precautions

Read this brochure thoroughly prior to making the decision to have the ARTISAN™ Phakic IOL lens implanted in your eye. Be sure your ophthalmologist has informed you of all of the possible risks and benefits with this surgery and you have had all of your questions answered.

If you have any of the following conditions, be sure to discuss them with your ophthalmologist, as you may not be a suitable candidate for this procedure:

- Abnormality of the iris
 - Congenital bilateral cataracts (cataracts in both eyes due to a genetic disorder)
 - Recurrent ocular inflammation
 - History of ocular diseases
 - Previous history of retinal detachment
 - Only one eye with potentially good vision
 - Glaucoma
 - Corneal endothelial dystrophy (a condition in which one or more parts of the cornea lose their normal clarity due to a buildup of cloudy material)
 - Diabetic retinopathy (a common complication of diabetes affecting the blood vessels in the retina; if untreated, it may lead to blindness)
-
- Elevated intraocular pressure has been reported occasionally in patients who receive lens implants. The intraocular pressure of patients should be monitored postoperatively.
 - Individuals participating in activities that would jostle the head or lead to a concussion are at greater risk of sustaining traumatic dislocation of the ARTISAN® Phakic IOL and this may result in the necessity for secondary surgical intervention or potentially loss of vision.
 - Patients could theoretically have problems with glare, halos, and night driving if the patient's dilated pupils are larger than the largest available optic size (6 mm).
 - Visual acuity could be diminished in situations where there is low level lighting.
 - The long-term effect to the corneal endothelial cells has not been established.
 - When pupil size is greater than optic size, there may be visual aberrations.
 - The occurrence of lens opacities in the future is unknown.

10. Questions to Ask Your Ophthalmologist

Ask your ophthalmologist the following questions in order to help you decide whether the ARTISAN™ Phakic IOL is right for you:

- What other options are available for correcting my nearsightedness?
- Will I need to limit my activities after treatment? If yes, for how long?
- What are the benefits of the ARTISAN® Phakic IOL for my amount of nearsightedness?
- What quality of vision can I expect in the first few months after surgery?
- How is the ARTISAN® Phakic IOL likely to affect my need to wear glasses or contact lenses as I grow older?
- Should I have the ARTISAN® Phakic IOL implanted in my other eye?
- How long will I have to wait before having surgery on my other eye?
- What vision problems might I experience if I have the ARTISAN® Phakic IOL only on one eye?
- How much will the surgery and follow-up cost? Will my health insurance cover this surgery?
- Will there be additional costs if I need an additional procedure to fine tune my vision?

11. Summary of Important Information

- The ARTISAN[®] Phakic IOL is intended to be a permanent procedure. While the lens can be removed, vision may not return to what it was prior to surgery.
- The ARTISAN[®] Phakic IOL may not eliminate the need for glasses.
- Your vision should be stable for at least six months prior to surgery. Your ophthalmologist should verify that your nearsightedness has not changed more than 0.50 diopters in the past six months.
- The surgery and implantation of the ARTISAN[®] Phakic IOL is not risk-free. Please review this entire brochure, paying special attention to the risk and benefit sections before agreeing to treatment.
- Alternatives to the ARTISAN[®] Phakic IOL include, but are not limited to, glasses or contact lenses.
- Before considering the ARTISAN[®] Phakic IOL surgery, you should have a complete eye examination and talk with at least one ophthalmologist about the time required for healing and the potential benefits, complications, and risks of the ARTISAN[®] Phakic IOL.
- You should NOT have the ARTISAN[™] Phakic IOL implanted if:
 - You are less than 21 years of age
 - You are a woman who is pregnant or nursing
 - Your ophthalmologist determines you have an abnormal iris, pupil or cornea
 - Your ophthalmologist determines you have an anterior chamber depth of less than 3.2 mm
 - Your ophthalmologist determines your endothelial cell density does not meet the minimum density in the table on page 12 of this brochure.
- If you have any of the following conditions, be sure to discuss them with your ophthalmologist, as you may not be a suitable candidate for this procedure:
 - Abnormality of the iris
 - Congenital bilateral cataracts (cataracts in both eyes due to a genetic disorder)
 - Recurrent ocular inflammation
 - History of ocular diseases
 - Previous history of retinal detachment
 - Only one eye with potentially good vision

- Glaucoma
- Corneal endothelial dystrophy (a condition in which one or more parts of the cornea lose their normal clarity due to a buildup of cloudy material)
- Diabetic retinopathy (a common complication of diabetes affecting the blood vessels in the retina; if untreated, it may lead to blindness)

12. Patient Assistance Information

To be completed by you or your Primary Eye Care Professional as a reference.

PRIMARY EYE CARE PROFESSIONAL:

Name: _____

Address: _____

Telephone No: _____

SURGEON IMPLANTING THE ARTISAN™ PHAKIC IOL:

Name: _____

Address: _____

Telephone No: _____

SURGERY LOCATION:

Name: _____

Address: _____

Telephone No: _____

LENS INFORMATION:

Lens Model Number: _____

Lens Power: _____

IOL MANUFACTURER:

OPHTEC BV
Groningen, The Netherlands
<http://www.OPHTEC.com>

North America

OPHTEC USA, Inc.
6421 Congress Ave., Suite 112
Boca Raton, FL 33487
561-989-8767

13. Glossary of Terms

AK	Arcuate Keratotomy. A method of flattening a part of the cornea with a curved corneal incision, intended to reduce astigmatism. Same as LRI, Limbal Relaxing Incision
Anterior chamber:	The space in the eye that is behind the cornea and in front of the iris
Astigmatism:	A common form of visual impairment in which part of an image is blurred, due to an irregularity in the curvature of the front surface of the eye, the cornea.
Cataract:	A clouding of the lens of the eye. The normally clear aspirin-sized lens of the eye starts to become cloudy which will eventually impair normal vision.
Contraindication:	A condition which makes a particular treatment or procedure inadvisable.
Cornea:	The clear front window of the eye that transmits and focuses light into the eye.
Crystalline lens:	A transparent, colorless body located in the front third of the eyeball, behind the iris, that helps bring rays of light to a focus on the retina.
Diabetic retinopathy:	A common complication of diabetes affecting the blood vessels in the retina. If untreated, it may lead to blindness
Diopter:	Unit of measure for optical strength or refractive power of glasses or contact lenses.
Endothelial cells:	Refers to the cells that make up the thin, innermost layer of the cornea. Endothelial cells are essential in keeping the cornea clear.
Endothelial dystrophy:	A condition in which one or more parts of the cornea lose their normal clarity due to a buildup of cloudy material. The endothelial cells in the cornea gradually deteriorate.

Excimer laser:	A laser that emits very concentrated light in the ultraviolet (UV) region of the spectrum which is used for treating various refractive errors, such as nearsightedness or farsightedness.
Farsightedness (hyperopia):	The ability to see distant objects more clearly than close objects.
Glaucoma:	A common eye condition in which the fluid pressure inside the eyes rises because of slowed fluid drainage from the eye. If untreated, it may damage the optic nerve and other parts of the eye, causing the loss of vision or even blindness.
Halos:	Hazy ring around bright lights seen by some patients with refractive error or optical defects (e.g., cataracts or corneal swelling). This symptom may occur after surgery.
Intraocular pressure (IOP):	Pressure caused by the fluid inside the eye; it helps to maintain the shape of the eye.
Iris:	Circular, colored portion of the eye. Its opening forms the pupil. The iris helps regulate the amount of light that enters the eye.
LASIK:	A laser assisted surgical procedure to correct for the refractive error of the cornea
LRI	Limbal Relaxing Incision. A method of flattening a part of the cornea with a curved corneal incision, intended to reduce astigmatism. Same as AK, Arcuate Keratotomy.
Nearsightedness (myopia):	The ability to see close objects more clearly than distant objects. In this type of refractive error, light is focused in front of the retina. Correction of nearsightedness brings the light to focus on the retina.
Ophthalmologist:	A medical doctor (M.D.) specializing in refractive, medical, and surgical treatment of eye diseases and disorders.
Phakic	Refers to an eye that possess its natural lens.
Pupil:	

diameter depending upon the brightness of the light coming into the eye.

PRK: An acronym for “photorefractive keratectomy”. This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is reshaped by an excimer laser in a predetermined manner to correct refractive errors of the eye.

Refractive surgery: Refers to many different procedures used for correcting the refractive error of an eye.

Retina: The thin membranous lining of the rear two-thirds of the eye that converts images from the eye’s optical system into electrical impulses sent along the optic nerve for transmission to the brain.

Retinal detachment: A separation of the retina from its connection at the back of the eye. The separation usually results from a tear in the retina.

RK: An acronym for radial keratotomy. This is a surgical procedure whereby radial superficial incisions are made on the cornea to correct refractive error.

Uncorrected visual acuity (UCVA) The measurement of visual acuity (such as 20/20) without wearing glasses or contact lenses

Visual aberrations: A defect of focus, such as blurring in an image.

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