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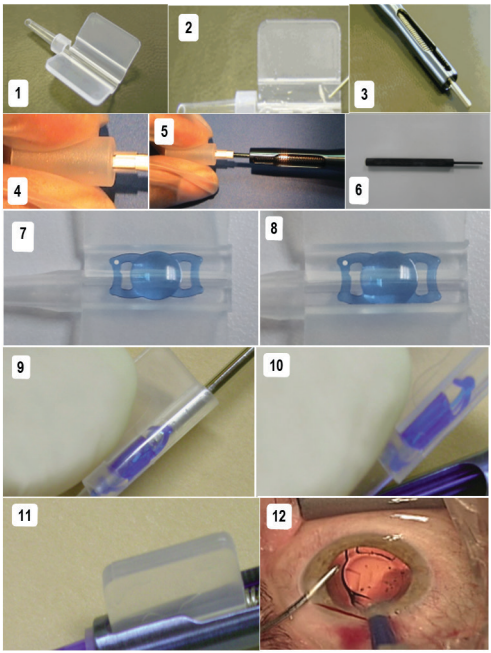
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PHYSICIAN LABELING
CLEARVIEW™ HD INTRAOCULAR LENS



STERILE

PKI51 Rev 1

Acronyms or abbreviations used throughout this Physician Labeling

ACD	Anterior Chamber Depth
AE / AEs	Adverse Event(s)
BCVA	Best Corrected Visual Acuity
CME	Cystoid Macular Edema
D	Diopter
FDA	Food and Drug Administration
HEMA	Hydroxyethyl Methacrylate
IOP	Intraocular Pressure
IOL / IOLs	Intraocular Lens(es)
ISO	International Organization for Standardization
PCIOL / PCIOLs	Posterior Chamber Intraocular Lens(es)
SE	Spherical Equivalent
SSI	Secondary Surgical Intervention
U.S.	United States
UV	Ultraviolet
YAG / Nd:YAG	Neodymium-Doped Yttrium Aluminium Garnet
°C	Degrees Celsius
°F	Degrees Fahrenheit

IMPORTANT NOTICE
It is highly recommended that the surgeon adheres to the recommendations, precautions, contraindications and warnings outlined in these instructions.

CAUTION: Federal (U.S.) law restricts this device to the sale by or on the order of a physician.

DETAILED DEVICE DESCRIPTION
The ClearView HD Posterior Chamber Intraocular Lens (PCIOL) is an ultraviolet absorbing, single-piece closed loop/modified plate intraocular lens intended for the replacement of the human crystalline lens following phacoemulsification cataract removal. The ClearView HD™ possesses a balanced aspheric optic design (containing symmetrical aspheric anterior and posterior surfaces[1]). It is offered in the dioptric power range of +5.0 to +36.0, with the +15.0 to +25.0 range being available in quarter diopter increments.

The ClearView HD combines:
- the **aspheric monofocal optic design of the Lenstec Softec HD**, and
- the **closed-loop, four-point fixation haptic platform of the ClearView™ 3**.

The ClearView HD intraocular lens is manufactured from a medical grade co-polymer of Hydrophilic Acrylic, with a polymerisable UV blocker. The hydrophilic nature of the lens material (hydrophilicacrylic) reduces the problems associated with silicone oil adhesion and silicone oil induced opacification[2-4]. Each PCIOL has a square edge design[5]. Clinical studies have not been conductedwith the aspheric IOLs to assess the effect of the aspheric surface on spherical aberration, visual acuity and contrast sensitivity.

Figure 1: Lenstec ClearView HD image

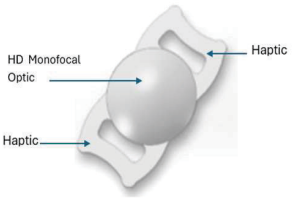


Table 1: ClearView HD Characteristics

Lens Feature	Specifications
Optic Size	5.75 mm
Optic Type	Refractive, equiconvex, aspheric
Haptic Type	Closed loop/modified plate
Length	11.00 mm
Angulation	0 Degrees
Construction	1 Piece
Optic Material	Hydrophilic acrylic (26% water content)
Haptic Material	Hydrophilic acrylic (same as optic)
Index of refraction	1.46
A Constant*	118.00 mm*
A/C Depth*	4.97 mm*

*NOTE: The 'A' Constant and ACD values printed on the outside of the package are estimates only. It is recommended that the surgeon determine his/her own values based on their individual clinical experience

Table 2: ClearView HD power offering and tolerances

Power Ranges (D)	Diopter Increments Offered In (D)	Tolerances Applied (D)
+5.0 to +10.0	1.0	(± 0.25)
+10.5 to +14.5	0.5	(± 0.25)
+15.0 to +25.0	0.25	(± 0.11)
+25.5 to +30.0	0.5	(± 0.25)
+31.0 to +36.0	1.0	(± 0.5)

Figure 2: Spectral Transmittance

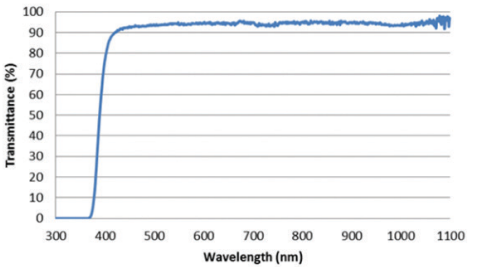


Figure 2 describes the ClearView HD spectral transmittance over the 300 nm to 1100 nm wavelengths. The % UV transmittance from 300-360 nm is 0% and the 10% cut off is 374 nm.

INDICATIONS FOR USE

The ClearView HD™ Aspheric Posterior Chamber Intraocular Lens (PCIOL) is intended for the replacement of the human crystalline lens following phacoemulsification cataract removal in adults over the age of 21. The lenses are indicated for capsular bag placement.

CONTRAINDICATIONS

Outside of general contraindications for ocular surgery, the following specific contraindications apply:
Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, potentially foreseeable post-operative complications and other conditions which an ophthalmic surgeon might identify based on their experience.

WARNINGS

The implanting ophthalmic surgeon shall consider the following warnings and identify a risk/benefit ratio prior to surgery:

1) Failure to follow the implantation instructions supplied with this lens could lead to mishandling and subsequent IOL damage prior to or during implantation.
2) There is no clinical data to support placing this lens in the ciliary sulcus.
3) ClearView HD was not evaluated in a new clinical investigation for this PMA supplement. PCO-related information for ClearView HD is based on leveraged clinical information from the previously approved parent IOLs, including the Softec HD monofocal optic and the ClearView 3 haptic platform.
4) Clinically significant posterior capsule opacification may occur following implantation of posterior chamber IOLs and may require ND:YAG posterior capsulotomy. Surgeons should monitor patients for clinically significant PCO and manage in accordance with standard clinical practice.
5) Any posterior capsulotomy opening should be limited to approximately 5 mm. Consistent with other IOLs, there is an increased risk of lens dislocation and/or secondary surgical intervention with early or large YAG capsulotomies.
6) The IOLs should not be implanted if the capsular bag is not intact or if there is significant zonular rupture/dehiscence.
7) The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been

established. As a precaution, patients should be informed that they should wear sunglasses with UV protection when in sunlight.

8) The rate of cystoid macular edema may increase with extracapsular bag placement of the haptics.
9) Patients with any of the following could be at increased risk for complication(s) following implantation of the ClearView HD: previous ocular surgery, those meeting any of the listed factors in the 'Contraindications' section of this document, non-age related cataract, vitreous loss, iris atrophy, severe aniseikonia, ocular hemorrhage, macular degeneration or suspected microbial infection.
10) Patients who present complications at the time of cataract extraction could be at increased risk for complication(s) following implantation of any IOL. This may include but is not limited to any of the following: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss.
11) The implanting surgeon shall consider whether patients in whom intraocular lens implantation would affect the ability to observe, diagnose or treat posterior segment diseases should have the ClearView HD implanted.
12) The implanting surgeon shall consider whether patients who have a distorted eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible, should have the ClearView HD implanted.
13) The implanting surgeon shall consider whether patients who have recurrent severe anterior or posterior segment inflammation or uveitis should have the ClearView HD implanted.
14) Any circumstances which could lead to damage to the corneal endothelium during implantation should be avoided.
15) Children under the age of 2 are not suitable candidates for intraocular lenses.
16) Reuse of the IOL is strictly prohibited, as it raises serious safety and effectiveness concerns.
    a. Lenstec does not provide cleaning/sterilization instructions. An improperly cleaned and/or sterilized IOL can cause significant damage to a patient's vision, due in part to cross contamination induced infection.
    b. Once removed from its original packaging, the IOL can lose traceability. In the event an IOL is re-used, it is unlikely the user will know the correct expiry date, serial number or dioptric power.
    c. Lenstec cannot guarantee stability or proper function of either haptic or optic portions in the event that an IOL is re-used. Failure of either of these components can render the IOL ineffective.
17) Failure to ensure the lens haptic or optic is properly placed in the cartridge can lead to damage during injection/implantation.

PRECAUTIONS

- The IOL must be stored in dry conditions between 0°C (32°F) and 45°C (113°F).
- Do not attempt to re-use the lens. Do not autoclave or attempt to re-sterilize the lens. Lenses requiring re-sterilization should be returned to Lenstec, Inc.
- Do not use the device if sterile packaging has been damaged or if there are traces of leakage on the bottle or pouch.
- Do not soak the intraocular lens with any solution other than a sterile balanced salt solution or saline solution.
- Once packaging has been opened the intraocular lens must be used immediately. The hydrophilic nature of the lens can cause the lens to absorb substances with which it comes into contact, such as disinfectants, medicines, blood cells, etc. This may cause a "Toxic Lens Syndrome". Rinse the lens carefully once removed from the glass vial.
- The lens must be implanted within 2 minutes following removal from its saline bath, as dehydration causes the lens material to become brittle.
- The lens must be implanted in the capsular bag.
- The lens must be implanted using only injection systems validated for use with the IOLs. These are listed in Table 3 below.
- Do not use the intraocular lens after the expiration date shown on the outside package label.
- Handle the intraocular lens carefully. Rough handling or excessive handling may damage the lens.
- The surgeon must be aware of the risk of opacification of the intraocular lens, which may necessitate lens removal[7].
    - NOTE: Although the Lenstec hydrophilic intraocular lens has a satisfactory history regarding lens opacification, there is a history of lens opacification with lenses from other manufacturers. The material used by Lenstec, unlike the materials used by other manufacturers, has not had any reported 'Adverse Events' due to material discoloration, opacification and/or other material related deficiencies which have caused post-operative patient problems. Ophthalmic surgeons should keep in mind that there have been cases of reported opacification of hydrophilic IOLs. Most, if not all of these types of cases required explantation.
- All cases of lens removal must be reported to Lenstec.
- Patients who did not meet the inclusion/exclusion criteria from the pivotal clinical trial were not studied with the IOL, therefore the safety and effectiveness of use of the ClearView HD device in these types of patients is not known. These are listed below in the section regarding study design.

ADVERSE EVENTS

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- lens epithelial cell down-growth
- corneal endothelial damage
- infection (endophthalmitis)
- retinal detachment/tear
- vitritis

- cystoid macular edema
- corneal edema
- pupillary block
- cyclitic membrane
- iris prolapse
- hypopyon
- anterior uveitis
- hyphema
- pigment dispersion
- posterior capsule opacification
- transient or persistent glaucoma
- IOL dislocation, tilt or decentration requiring repositioning
- secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration, iridotomy for pupillary block, wound leak repair and retinal detachment repair.

HOW SUPPLIED

The Lenstec ClearView HD is supplied in a 0.9% saline solution in a lens bottle contained within a sealed Tyvek sterilizable peel pouch and should only be opened under aseptic conditions.

DIRECTIONS FOR USE

Each Lenstec ClearView HD is autoclave sterilized in a lens bottle contained within a sealed Tyvek sterilizable peel pouch. The lens is held in a glass vial containing sterile 0.9% saline solution. The contents of the pouch/bottle are sterile unless the package is damaged or opened. Perform standard phacoemulsification technique. Ensure that the capsulorhexis is between 5.0 and 5.5 mm in diameter. Prior to implanting, examine the lens package for IOL, power, and expiration date. The lens should be implanted using the Directions for Folding and Inserting the Lens, listed below. If more specific instructions for use are available in the insertion system packaging, consult it. NOTE: Only folders/injectors validated for use with the Lenstec ClearView HD should be used.

INSTRUCTIONS FOR IMPLANTATION OF THE ClearView HD

CALCULATION OF LENS POWER:

It is recommended that the surgeon uses a power calculation method with which they are most comfortable. In general, the power of the lens for each patient can be calculated from the keratometry measurements and axial length of the eye according to formulas in relevant literature. An A Constant of 118.00 and an anterior chamber depth (ACD) of 4.97 are the manufacturer suggested values for the Lenstec ClearView HD when using partial coherence interferometry. Additional reference to this topic can be found at http://www.doctor-hill.com/iol-master/lens_constants.htm.

NOTE: These manufacturers suggested values are estimates. It is recommended that the surgeon determine their own values based on their own individual clinical experience.

PRE-SURGICAL PREPARATION:

a. Determine the lens power from the preferred IOL formula.
b. Determine the expected post-operative target refraction (SE).

DIRECTIONS FOR FOLDING AND INSERTING THE LENS (Refer to diagrams on the cover of this DFU document):

1. Prepare injector cartridge (1) by opening the cartridge wings and injecting viscoelastic down the barrel, both channels on each side and across the ridge between the channels (2).
2. Obtain the injector (3). Expose its plunger tip and use the applicator (4) to affix the silicone tip onto the plunger tip (5) and then retract the plunger as far as it will go.
3. Remove the lens bottle from the Tyvek pouch. Firmly hold the bottle in one hand and unscrew the cap. Remove the stopper and then carefully remove the lens holder from the vial. Retract the plunger to release the holding pins from the lens. Using toothless forceps grasp the lens by the haptic and place the lens on the cartridge as shown in (7). Inspect the lens for debris and damage.
4. Using a partially open pair of sterile angled toothless forceps, gently compress the lens (including both haptics and the full optic) into the chamber channels of the cartridge below the level of the flaps (8).
5. Slowly close the cartridge, keeping gentle pressure on the optic with the forceps, and ensure that the optics and haptics are not pinched in the flaps of the cartridge as it closes. Visually inspect the closed cartridge to ensure that the lens is not trapped between the flaps. Introduce the plunger end of the Lens Loader II (6) into the back of the closed cartridge chamber (9) and slowly advance the lens from the chamber to the barrel (feel for any resistance which could indicate the lens is trapped between the flaps). Ensure that the Lens Loader II is advanced to its farthest depth so that the lens is in the tip of the nosecone (10). The lens should move freely. If it does not, one (or both) of the haptics or optic is pinched by the wings of the cartridge. If the lens does not move freely, open the cartridge and repeat steps 4 and 5. If the lens moves freely, the cartridge is ready to load in the injector.
6. Place the cartridge into the housing of the injector and push it in as far as it will go (11). Depress the injector plunger

so that the silicone tip fits into the back of the cartridge chamber and advance it forward until you can just see the tip in the barrel.

7. Carefully introduce the loaded injector tip into the anterior chamber with the bevel facing down, assisting with delivery into the capsular bag, until the tip of the cartridge is near the mid-pupil margin. Gently inject the lens into the anterior chamber. If the IOL is twisting, rotate the injector, if necessary, to ensure the IOL remains orientated correctly as it emerges from the cartridge. Ensure the leading haptic is in the bag. Gently withdraw the cartridge from the eye as the trailing haptic emerges from the cartridge (12). Reconfirm that the anterior chamber is deep, and if not, introduce additional saline or viscoelastic. Using a tapered "pusher", insert the trailing haptic into the capsular bag if needed.
8. Immediately after lens insertion, visually confirm correct placement of the four footplates by manipulating the lens once it is fully inside the capsule. The amount of manipulation will depend on where the surgical incision was made and if any rotation has occurred during implantation.
9. Irrigate and aspirate the saline or viscoelastic from the anterior chamber and from behind the lens.
10. Close the wound as desired.

The table below describes the injection systems which are approved for use with the ClearView HD.

Table 3: IOL Injection System Compatibility Guide

	IOL Injection Systems			
IOL Model	LC Injection Systems		Disposable Softip Injection System (Asico LLC)	
	Injector	Cartridge & Power Range (D)	Injector	Cartridge & Power Range (D)
ClearView HD	I-9011S	LC16: 10.0 to 26.0	AS-9300	LC16I: 10.0 to 26.0
		LC1620: 10.0 to 26.0		LC1620I: 10.0 to 26.0
		LC24: 10.0 to 36.0		CART45S: 10.0 to 26.0
		LC2420: 10.0 to 36.0		CART20S: 10.0 to 26.0
		CART45S: 10.0 to 26.0		
		CART20S: 10.0 to 26.0		
	I-9012/ I9012FS	LC16: 10.0 to 30.0	AS-9310	LC24I: 10.0 to 36.0
		LC2420: 10.0 to 30.0		LC2420I: 10.0 to 36.0
		CART45S: 10.0 to 26.0		CART45S: 10.0 to 26.0
		CART20S: 10.0 to 26.0		CART20S: 10.0 to 26.0

SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the parent optic lens, Softec HD. A summary of the clinical study is presented below.

CLINICAL OUTCOMES

The multi-center U.S. Softec HD™ PCIOL Clinical Investigation was conducted at 8 clinical centers with Softec HD™ PCI-OL implantations occurring between December 13, 2006 and June 9, 2008. One year postoperative follow-up provides documented evidence of the safety andeffectiveness of the Softec HD™ PCIOL for the indications for use stated in this physician labeling.

Patient Population

Three hundred and ninety eyes of 390 study subjects were implanted with the Softec HD™ PCIOL. The Softec HD™ Study Cohort consisted of 227 females and 163 males; 334 were Caucasian, 11 Black, 6 Asian, 4 Mixed and 35 "Other". The mean age for the study cohort was 70.8 years. One year follow-up was collected for 366 eyes of 366 study subjects.

Table 1 – Patient Population – Softec HD™ PCIOL
n = 390 eyes in 390 study subjects

Patient Population		Population Description
Mean Age (years)		70.8 yrs
Patients with Pre-existing Macular Degeneration		3.1 %
Other Patients with Pre-existing Conditions		30.5%
Gender	Female Male	58.2% 41.8%
Race	Caucasian Black Asian Mixed Other	85.6% 2.8% 1.5% 1.0% 9.0%

Visual Acuity

Table 2 summarizes the postoperative visual acuity outcomes at the 1 year visit (330-420 days) for the Softec HD™ PCIOL Study Group who did *not* have a preoperative ocular pathology or postoperative macular degeneration ("Best Case" Cohort).

Table 2 – BEST CORRECTED DISTANCE VISUAL ACUITY at 1 Year (Form 5)
Best Case Analysis – Stratified by Age (Years)

	< 60	60 to < 70	70 to <80	≥ 80
20/10 or better	0 / 32 (0%)	0 / 118 (0%)	0 / 135 (0%)	0 / 42 (0%)
20/16 or better	5 / 32 (15.6%)	12 / 118 (10.2%)	4 / 135 (3%)	2 / 42 (4.8%)
20/20 or better	24 / 32 (75%)	79 / 118 (66.9%)	68 / 135 (50.4%)	21 / 42 (50%)
20/25 or better	30 / 32 (93.8%)	100 / 118 (84.7%)	108 / 135 (80%)	31 / 42 (73.8%)
20/30 or better	32 / 32 (100%)	115 / 118 (97.5%)	127 / 135 (94.1%)	39 / 42 (92.9%)
20/40 or better	32 / 32 (100%)	117 / 118 (99.2%)	132 / 135 (97.8%)	42 / 42 (100%)
20/50 or better	32 / 32 (100%)	117 / 118 (99.2%)	133 / 135 (98.5%)	42 / 42 (100%)
20/60 or better	32 / 32 (100%)	117 / 118 (99.2%)	134 / 135 (99.3%)	42 / 42 (100%)
20/80 or better	32 / 32 (100%)	117 / 118 (99.2%)	134 / 135 (99.3%)	42 / 42 (100%)
20/100 or better	32 / 32 (100%)	117 / 118 (99.2%)	135 / 135 (100%)	42 / 42 (100%)
20/200 or better	32 / 32 (100%)	117 / 118 (99.2%)	135 / 135 (100%)	42 / 42 (100%)
Worse than 20/200	0 / 32 (0%)	1 / 118 (0.8%)	0 / 135 (0%)	0 / 42 (0%)
Not Reported	0	0	0	0
Total	32	118	135	42

Table 3 for "All Eyes" Cohort in the Softec HD™ PCIOL Study Group.
Note: 30 study subjects had YAG capsulotomies 12 months or earlier; 17 six months or less, YAG capsulotomy is anticipated to produce an improved BCVA outcome versus a pre-YAG outcome.

Table 3 – BEST CORRECTED DISTANCE VISUAL ACUITY at 1 Year (Form 5) Stratified by Age (Years)				
	< 60	60 to < 70	70 to < 80	≥ 80
20/10 or better	0 / 36 (0%)	0 / 128 (0%)	0 / 155 (0%)	0 / 47 (0%)
20/16 or better	6 / 36 (16.7%)	12 / 128 (9.4%)	4 / 155 (2.6%)	2 / 47 (4.3%)
20/20 or better	26 / 36 (72.2%)	85 / 128 (66.4%)	78 / 155 (50.3%)	22 / 47 (46.8%)
20/25 or better	33 / 36 (91.7%)	110 / 128 (85.9%)	121 / 155 (78.1%)	33 / 47 (70.2%)
20/30 or better	36 / 36 (100%)	125 / 128 (97.7%)	143 / 155 (92.3%)	41 / 47 (87.2%)
20/40 or better	36 / 36 (100%)	127 / 128 (99.2%)	152 / 155 (98.1%)	45 / 47 (95.7%)
20/50 or better	36 / 36 (100%)	127 / 128 (99.2%)	153 / 155 (98.7%)	47 / 47 (100%)
20/60 or better	36 / 36 (100%)	127 / 128 (99.2%)	154 / 155 (99.4%)	47 / 47 (100%)
20/80 or better	36 / 36 (100%)	127 / 128 (99.2%)	154 / 155 (99.4%)	47 / 47 (100%)
20/100 or better	36 / 36 (100%)	127 / 128 (99.2%)	155 / 155 (100%)	47 / 47 (100%)
20/200 or better	36 / 36 (100%)	127 / 128 (99.2%)	155 / 155 (100%)	47 / 47 (100%)
Worse than 20/200	0 / 36 (0%)	1 / 128 (0.8%)	0 / 155 (0%)	0 / 47 (0%)
Not reported	0	0	0	0
Total	36	128	155	47

ADVERSE EVENTS
Cumulative adverse events consist of all adverse events (AEs) that occurred at any point in postoperative follow-up during the first year after Softec HD™ PCIOL surgery.
Table 4 presents all cumulative adverse events through the 1 year visit (330-420 days); **Table 5**, all persistent adverse events at 6 months (120-180 days) and 1 year visits. The overall incidence of cumulative and persistent IOL Grid adverse events in the Softec HD™ PCIOL Study Group (n=366) was 2.2% (CME 0.8%, secondary surgical interventions 0.8%, iritis 0.3% and raised IOP requiring treatment 0.3%)
Non-IOL Grid AEs included 9 haptic break AEs at the time of the initial surgery and 1 sub-retinal hemorrhage.

Table 4 – Patient Population **Softec HD™ PCIOL** n = 366 eyes in 366 study subjects with 1 year follow-up		
Cumulative Adverse Event through 1 year	**Softec HD™ PCIOL Incidence**	**FDA PCIOL Grid n = 300**
Cystoid Macular Edema	0.8%*	6.0%
Hypopyon	0%	1.8%
Endophthalmitis	0%	1.0%
Dislocated Lens (from Posterior Chamber)	0%	1.0%
Pupillary Block	0%	1.0%
Retinal Detachment	0%	1.8%
Secondary Surgical Intervention**	0.8%	2.6%

**Identical cases reported in persistent & cumulative CME rows*
***All unrelated to Softec HD™ PCIOL*

Table 5		
Persistent Adverse Event at 6 mths and/ or 1 year	**Softec HD™ PCIOL Incidence**	**FDA PCIOL Grid n = 300**
Corneal Stromal Edema	0%	1.8%
Cystoid Macular Edema	0.8%*	2.2%
Iritis	0.3%*	1.8%
Raised IOP Requiring Treatment	0.3%	1.8%

**Identical cases reported in persistent & cumulative CME rows*

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