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

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%

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
**All unrelated to Softec HD™ PCIOL

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.

EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. Do not use the IOL after the expiration date.

RETURNS POLICY

Contact your Lenstec representative regarding the return goods policy. Return the lens with full identification and the reason for the return. Label the return package as a biohazard.

PATIENT REGISTRATION AND REPORTING

A Patient Identification Card is included in the package. This is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye practitioner the patent consults in future. Self-adhesive lens identification labels are provided for use on the Patient Identification Card and other clinical records.

Adverse events/complaints 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 Lenstec (Barbados) Inc., Airport Commercial, Pilgrim Road, Christ Church, Barbados: Tel: 246-420-6795 • Fax: 246-420-6797; Email: Feedback@Lenstec.com or contact your Lenstec representative.

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7 ISO 11979-7 Ophthalmic Implants – Intraocular lenses – Part 7: Clinical Investigations; 2006.

LENS TEC™
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INSTRUCTIONS FOR USE
SOFTEC HD™, SOFTEC HDO™, SOFTEC I™ AND SOFTEC HDM™
POSTERIOR CHAMBER INTRAOCULAR LENSES (PCIOLs)

CE 2797 STERILE

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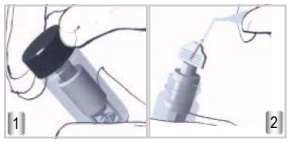
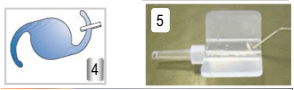




INSTRUCTIONS FOR USE
SOFTEC HD™, SOFTEC HDO™, SOFTEC I™ AND SOFTEC HDM™ POSTERIOR CHAMBER INTRAOCULAR LENSES (PCIOLs)

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.

DEVICE DESCRIPTION
The LENSTEC Softec series of Posterior Chamber Intraocular Lenses (PCIOLs) are ultraviolet absorbing, single-piece "C" loop intraocular lenses intended for the replacement of the human crystalline lens following phacoemulsification cataract removal. The Softec 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 Softec HDO™ possesses the same aspheric design, with the optic being ovoid rather than circular. It is offered in the same dioptric range as Softec HD™. The Softec I™ has an optic designed with a balanced spherical optic. It is offered in the dioptric power range of +5.0 to +36.0. The Softec HDM™ possesses a balanced aspheric optic design with a reduced central optic thickness and tapered haptics. It is offered in the same dioptric power range as Softec HD™.
Each of the Softec series of intraocular lenses is manufactured from a medical grade co-polymer of Hydrophilic Acrylic, with a polymerisable UV blocker. The hydrophilic nature of the lens material (hydrophilic acrylic) 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 conducted with the aspheric IOLs to assess the effect of the aspheric surface on spherical aberration, visual acuity and contrast sensitivity.

INDICATIONS FOR USE
The LENSTEC Softec HD™ Aspheric, Softec HDO™ Aspheric, Softec I™ and Softec HDM™ Posterior Chamber Intraocular Lenses (PCIOLs) are 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. Any posterior capsulotomy opening should be limited to approximately 4 mm. Consistent with other IOLs, there is an increased risk of lens dislocation and/or secondary surgical reintervention with early or large YAG capsulotomies.
4. The IOLs should not be implanted if the capsular bag is not intact or if there is significant zonular rupture/dehiscence.
5. 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.
6. The rate of cystoid macular edema may increase with extracapsular bag placement of the haptics.
7. Patients with any of the following could be at increased risk for complication(s) following implantation of any of the IOLs: 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.
8. Patients who present complications at the time of cataract extraction could be at increased risk for complication(s) following implantation of any of the IOLs. This may include, but is not limited to: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss.
9. The implanting surgeon shall consider whether patients in who intraocular lens implantation would affect the ability to observe, diagnose or treat posterior segment diseases, should have any of the IOLs implanted.
10. 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 any of the IOLs implanted.
11. The implanting surgeon shall consider whether patients who have recurrent severe anterior or posterior segment inflammation or uveitis, should have any of the IOLs implanted.
12. Any circumstances which could lead to damage to the corneal endothelium during implantation should be avoided.
13. Children under the age of 2 are not suitable candidates for intraocular lenses.
14. Reuse of the IOL is strictly prohibited, as it raises serious safety and effectiveness concerns.
    - 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.
    - 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.
    - LENSTEC can not 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.

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 include the Softec IOL Injection System (Lenstec Inc), Viscoject 1.8™ Injector Set, Model# LP604350 (Medicel AG) and the Softip injection system, Model# AS-9300 (ASICO).
- 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.
  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[6]. 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.

HOW SUPPLIED
The IOLs are 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
LENSTEC IOLs are autoclave sterilized in a lens bottle contained within a sealed Tyvek sterilizable peel pouch. The contents of the pouch/bottle are sterile unless the package is damaged or opened. NOTE: A blue IOL was used only to aid in contrasting the lens from the cartridge in the attached photograph.

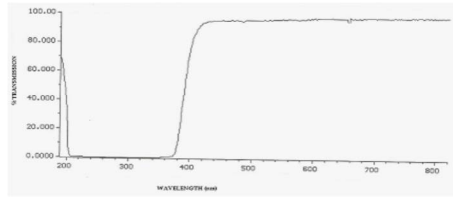
INSTRUCTIONS FOR IMPLANTATION: SOFTEC PCIOL

Calculation of Lens Power:
It is recommended that the surgeon uses a power calculation method with which they are 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 published literature. Additional reference to this topic can be found at http://www.doctor-hill.com/iol-master/lens_constants.html
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.

Pre-Surgical Preparation:
a. Determine the lens power from IOL Refractive Calculation Equation-Holladay or SRK/T.
b. Determine the Expected Post-operative Target Refraction (SE).

SURGICAL TECHNIQUE
a. Ensure capsulorhexis is up to 5.5 mm in diameter.
b. Perform standard phacoemulsification technique.
c. Unscrew the cap from the glass vial. See Figure 1.
d. Remove the Delivery System from the glass vial using forceps. See Figure 2.
e. Turn the Delivery System upside-down, so that the lens is uppermost. Retract the plunger slightly (about 5mm). See Figure 3.
f. Using toothless forceps, remove the lens by either the haptics or the optic, taking care not to cause damage to the lens. See Figure 4.
g. If using the Medicel Viscoject 1.8™ Injector Set, Model# LP604350 or the ASICO Softip injection system, Model# AS-9300, proceed as directed in the respective injection system's DFU. A copy of the DFU is supplied with each of those injection systems. NOTE: The Softec HDO™ is only validated for use with the Lenstec Softec IOL Injection system. If using the Lenstec Softec IOL Injection system, proceed as follows: Prepare the injector cartridge (LENSTEC Softec IOL Injection System) with viscoelastic. Open the cartridge flaps and inject viscoelastic down each side of the chamber, and into the tip (nosecone). See Figure 5.
h. Load the implant.
   - Obtain the Injector (LENSTEC Softec IOL Injection System) and make sure that the tip is exposed. Use the applicator to affix the silicone tip onto the injector tip and then pull its plunger back as far as it will go. See Figure 6.
   - Holding the flaps of the cartridge open as far as possible, place the lens in the cartridge chamber as indicated in Figure 7. Ensure that the trailing haptic is 'tucked' within the boundaries of the chamber prior to closing.
   - Close the injector cartridge, using the fork end of the fork loader to keep gentle pressure down on the optic to ensure that the lens does not shift. Make sure the optic and/or haptics are not pinched in the wings of the cartridge.
   - Place the flat (loading) end of the fork loader into the back of the cartridge chamber while the flaps are still closed and advance the lens from the chamber to the tip (nosecone) (see Figure 8).
     - Ensure that the loading end of the fork loader is advanced to its farthest depth, so that the lens is in the tip (nosecone). 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, please open the cartridge and repeat this step. If the lens moves freely, the cartridge is ready to load in the injector. See Figure 8.
       NOTE: FAILURE TO ENSURE THE LENS HAPTIC OR OPTIC IS PROPERLY PLACED IN THE CARTRIDGE CAN LEAD TO DAMAGE DURING INJECTION/IMPLANTATION.
i. Load the cartridge into the injector. See Figures 9 & 10
   - Ensure that the plunger is retracted as far as possible. Place the cartridge tip (nosecone) first into the housing and push it in as far as it will go.
   - 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 silicone tip in the cartridge tip (nosecone).
   - The injector is now ready to use.
j. Carefully introduce the loaded injector tip into the anterior chamber (bevel facing down to avoid touching the endothelium) until the opening of the cartridge is beyond the distal pupil margin. Gently inject the lens. Rotate the injector counterclockwise if necessary to ensure the IOL remains orientated correctly as it emerges from the cartridge. Ensure the leading haptic is in the bag and the lens haptic is orientated correctly. See Figure 11.
k. Gently withdraw the cartridge from the eye as the trailing haptic emerges from the cartridge.
l. Reconfirm that the anterior chamber is deep, and if not, introduce additional viscoelastic material.
m. Using a tapered "pusher" insert the trailing haptic if protruding from the section and let it drop into the bag.
n. Irrigate out the viscoelastic from the anterior chamber and from behind the IOL.
o. Hydrate the edges of the section to seal it. No sutures are normally required but if the section appears leaky or the chamber remains shallow, a suture may be advisable.

DETAILED DEVICE DESCRIPTION
- Construction: Single Piece
- Material: 26% Water Content HEMA (Hydroxyethyl methacrylate)
- Light transmittance:



- Index of refraction: 1.460

	Softec HD™, Softec I™, Softec HDM™	Softec HDO™
Optic Size	5.75mm (circle)	5.75 x 6.50mm (oval)
Optic Type	Equiconvex	Equiconvex
Length	12.00mm	12.50mm
Angulation	0 degrees	0 degrees
Construction	1 Piece	1 Piece
Position Holes	0 Holes	0 Holes
Optic/Haptic Material	HEMA (26% water content)	HEMA (26% water content)
A-Constant*	118.0**	118.0**

The lens specifications for the LENSTEC Softec series of Posterior Chamber Intraocular Lenses are as follows:

Intraocular Lens Specifications

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

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

*Guidelines for Calculation of Implant Power
**See above section titled 'Calculation of Lens Power'.

The Softec HD™, Softec HDO™, Softec I™ and Softec HDM™ Posterior Chamber Intraocular Lenses are manufactured in the following dioptric ranges:

***Internal manufacturing/sorting tolerance

COMPATIBILITY GUIDE

IOL Model	IOL Injection Systems					
	Softec		Viscoject		Softip	
	Validated for Use	Power range (D)	Validated for Use	Power range (D)	Validated for Use	Power range (D)
Softec HD™	✔	I-9011S/ LC1620: 5.0 to 26.0 I-9011S/ LC2420: 5.0 to 36.0	✔	5.0 to 26.0	✔	5.0 to 26.0
Softec HDO™	✔	I-9011S/ LC1620: 5.0 to 20.0 I-9011S/ LC2420: 5.0 to 36.0	✘	N/A	✘	N/A
Softec I™	✔	I-9011S/ LC1620: 5.0 to 26.0 I-9011S/ LC2420: 5.0 to 36.0	✔	5.0 to 26.0	✔	5.0 to 26.0
Softec HDM™	✔	I-9011S/ LC16: 5.0 to 36.0	✘	N/A	✘	N/A

CLINICAL OUTCOMES
The multi-center U.S. Softec HD™ PCIOL Clinical Investigation was conducted at 8 clinical centers with Softec HD™ PCIOL implantations occurring between December 13, 2006 and June 9, 2008. One year postoperative follow-up provides documented evidence of the safety and effectiveness 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 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 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