LENSTEC SOFTEC HD FDA IDE 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	58.2%
Male	41.8%
Race	
Caucasian	85.6%
Black	2.8%
Asian	1.5%
Mixed	1.0%
Other	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

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%).

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 Len (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

Non-IOL Grid AEs included 9 haptic break AEs at the time of the initial surgery and 1 subretinal hemorrhage.