

	< 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



http://www.lenstec.com  
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**INSTRUCTIONS FOR USE**  
**SOFTEC HD™, SOFTEC HDO™, SOFTEC I™ AND SOFTEC HDM™**  
**POSTERIOR CHAMBER INTRAOCULAR LENSES (PCIOLs)**



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%

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 patient 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](mailto:Feedback@Lenstec.com) or contact your Lenstec representative.

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

**IMPLANT CARD**

- All fields present on the ID card must be completed by the healthcare institution/provider.
- It is the responsibility of the healthcare institution/provider to attach the label sticker with the etched 'LENSTEC' logo to the reverse (unprinted) face of the patient ID card, and provide this to the patient as a record of their implant.



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