R&D to Manufacturing from Lenstec

Lenstec... for True Innovation
Lenstec, Inc. is a medical device corporation serving the global ophthalmic surgical market. Founded in 1993, the company designs, manufactures and distributes a wide range of intraocular lens implants and lens injection systems, and has an established reputation for rapid prototype design and development, and high quality/low cost manufacturing.

At Lenstec we continuously strive to improve vision possibilities through research, testing and partnerships with the world’s leading ophthalmologists. We welcome your interest in the company and any questions you may have about our products and services or opportunities to partner with us.

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ISO 13485:2003
FM 38446

Lenstec is an ISO 13485 Registered company manufacturing CE Marked products.

US Patent 7,350,918 B2

Designed to be the World’s

...Most Accurate Bi-Aspheric IOL

Bi-Aspheric
Quarter Diopter IOL

Exact emmetropia is now the requisite refractive starting point, yet it cannot be achieved except by pure luck with the standard IOL labeling.
Diopter Size Does Matter

0.25 Diopter vs. 0.50 Diopter...that's only half the story

- Many surgeons do not know that a great degree of error potentially exists within the labeling of every "standard" IOL manufactured in the United States today.
- For any given patient, the labeling of standard IOLs introduces a potentially significant discrepancy between the targeted and the labeled IOL power.

Industry Standard - 0.4 Tolerance

Softec HD New Gold Standard - 0.11 D Tolerance - 3x More Precise!

Optical Prescription Selection and Tolerance
Example: eye requires 24.25D Prescription to achieve optimal vision.

<table>
<thead>
<tr>
<th>Diopter</th>
<th>Variance from Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>0D to 15D</td>
<td>+/- .3D</td>
</tr>
<tr>
<td>15D to 24.50D</td>
<td>+/- .4D</td>
</tr>
<tr>
<td>25 to 29.50D</td>
<td>+/- .5D</td>
</tr>
<tr>
<td>30D and up</td>
<td>+/- 1D</td>
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When it comes to power, what you see is definitely not what you get with standard IOLs

- The tolerance for error in most IOL labeling is now obsolete, and it fails today's refractive accuracy test. With standard IOLs, efforts at refractive recalibration will be hostage to this outdated industry standard. 1
- This is an untenable risk for surgeons who are expected to deliver uncorrected vision. 1
- The most commonly used implant powers lie between 15D and 25D, surgeons are most often dealing with an error range of ±0.4D — far above the tolerance required by current refractive expectations.

IOL power tolerances published by ISO
(The current standards for IOL tolerances were established by the International Organization for Standardization and the American National Standards Institute.)
Softec HD is the only IOL designed to address both Spherical Aberration and Defocus

- 0.25D of defocus is a more significant aberration than spherical aberration; in fact 0.25D of defocus is more significant than all Higher Order Aberrations added together.  
- Defocus is invariant with pupil diameter – this is not true with spherical aberration which varies with pupil size – small pupils have nearly zero aberrations.

Defocus is a more significant aberration than Spherical Aberration

The average amount of higher order aberrations present for a 7.5 mm pupil was equivalent to the wave-front error produced by less than 1/4D of defocus.

Softec HD: The Total Package

Bi-Aspheric Equal Conic Zero aberration IOL
Softec HD addresses the issue of spherical aberration inherent in conventional monofocal spherical IOLs by adjusting the optic with a patented design on both the anterior and posterior surfaces.

Studies have shown that Aspheric IOLs provide patients with significant optical benefits over traditional spherical IOLs.  

Softec HD performs exceptionally over a wider range of corneal shapes and alignment errors than Negative Aspheric IOLs.

Astigmatism: negative aspheric surface on posterior of optic, sensitive to decentration and tilt, less effective for corneas with negative surface and small pupils.

AMO: negative aspheric surface on anterior of optic, sensitive to decentration and tilt, less effective for corneas with negative surface and small pupils.

Staar: conflicting literature on negative surface location.

Natural “Decentration” is inherent in all eyes and may contribute to poor vision with Negative aspheric IOLs. Angle Kappa, a misalignment of the visual axis and pupillary axis, may contribute to alignment errors. Based on bell curve distribution approximately 8 – 10% of patients have severe anatomical “decentration.”
YAG Laser Capsulotomy Occurrence *

Significant Outcomes
Mean refractive outcome was found to be closer to intended outcome. Depth of field was significantly improved, and Critical print size for fluent reading was smaller when compared to a standard monofocal IOL.  

Advantages of Hydrophilic

- Hydrophilic IOLs have been reported to have lower inflammatory response making them ideal for diabetic, uveitis, and glaucoma patients.  
- Lenstec manufactures Lathe cut lenses which provides superior optic and high resolution efficiency  
- Lenstec has no reported incidence of glinting or vacuoles in more than 5 million implants over 5 years  
- Lenstec Hydrophilic material has few dysphotopsia due to lower refractive index which minimizes problems with glare and halos.

References:
8. FDA Data, On the Net.
11. Data is all asters.