

enVista™ Specifications

Material

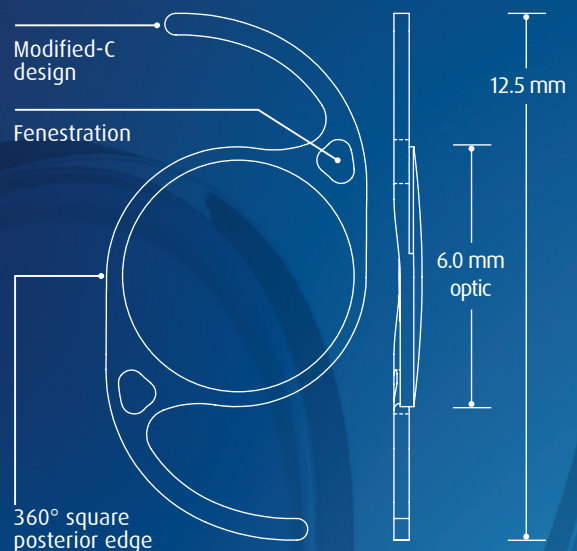
- Unique, glistening-free, hydrophobic acrylic material^{1,2}
 - Hydrated to equilibrium water content and packaged in a physiological saline solution to prevent glistening formation^{3,4}
 - Designed with a high water content to enhance flexibility and foldability
- UV protection
- More durable optical surface resists abrasion and wear⁵

Design and Range

- Modified-C, fenestrated haptics
- Designed to minimise PCO
 - 360° square posterior edge
 - Step-vaulted haptics are designed to vault the optic posteriorly for direct contact with the capsular bag and prevention of LEC migration
 - Fenestrations are designed to evenly transmit forces to the optic, promoting even pressure on the 360° square posterior edge
- Aspheric Advanced Optics deliver enhanced contrast sensitivity; uniform power, centre-to-edge; and better visual acuity⁶⁻⁸
- Polished for a smooth optic surface

Use and Implantation

- Insertion through a 2.2-mm incision
- Precise positioning in the capsular bag and removal of viscoelastic are facilitated by controlled unfolding



- Diopter range
 - 0 D to +34.0 D (0.0 D to +10.0 D in 1-D increments; +10.0 D to +30.0 D in 0.5-D increments; and +30.0 D to +34.0 D in 1-D increments)
- Applanation A-scan
 - A-Constant* 118.7
 - ACD* 5.37
 - Surgeon Factor* 1.62
- Refractive index
 - 1.54 at 35°C
- Optical biometry
 - A-Constant* 119.1
 - ACD* 5.61
 - Surgeon Factor* 1.85

new
enVista™
Glistening-free, hydrophobic acrylic IOL

Just say 'no' to glistenings.

*A-Constant, ACD, and Surgeon Factor are estimates only. It is recommended that each surgeon develop his or her own values.

1. enVista™ Directions for Use. 2. Tetz MR, Werner L, Schwahn-Bendig S, Battle JF. A prospective clinical study to quantify glistenings in a new hydrophobic acrylic IOL. Paper presented at: American Society of Cataract and Refractive Surgery (ASCRS) Symposium & Congress; April 3-8, 2009; San Francisco, CA. 3. Mentak K, Elachchabi A, Goldberg E. Hydrophobic character and aqueous wettability of hydrophobic acrylic IOLs. Paper presented at: XXVI Congress of the European Society of Cataract and Refractive Surgery; September 13-17, 2008; Berlin, Germany. 4. Summary of Safety and Effectiveness (SSED). PMA P080021. Food and Drug Administration website. http://www.accessdata.fda.gov/cdrh_docs/pdf/8/p080021b.pdf. Accessed July 28, 2011. 5. Mentak K, Martin P, Elachchabi A, Goldberg EP. Nanoindentation studies on hydrophobic acrylic IOLs to evaluate surface mechanical properties. Paper presented at: XXV Congress of the European Society of Cataract and Refractive Surgery; September 8-12, 2007; Stockholm, Sweden. 6. Santhiago MR, Netto MV, Barreto J Jr, et al. Wavefront analysis, contrast sensitivity, and depth of focus after cataract surgery with aspherical intraocular lens implantation. *Am J Ophthalmol.* 2010;149(3):383-389.e1-2. 7. Pepose JS, Qazi MA, Edwards KH, Sanderson JP, Sarver EJ. Comparison of contrast sensitivity, depth of field and ocular wavefront aberrations in eyes with an IOL with zero versus positive spherical aberration. *Graefes Arch Clin Exp Ophthalmol.* 2009;247(7):965-973. 8. Johansson B, Sundelin S, Wikberg-Matsson A, Unsbo P, Behndig A. Visual and optical performance of the Akreos® Adapt Advanced Optics and Tecnis Z9000 intraocular lenses: Swedish multicenter study. *J Cataract Refract Surg.* 2007;33(9):1565-1572.

INDICATIONS: Indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed by an extracapsular cataract extraction method. The lens is intended for placement in the capsular bag. **WARNINGS:** Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio: 1. Recurrent severe anterior or posterior segment inflammation or uveitis. 2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases. 3. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (eg, persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss). 4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible. 5. Circumstances that would result in damage to the endothelium during implantation. 6. Suspected microbial infection. 7. Children under the age of 2 years are not suitable candidates for intraocular lenses. 8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support. **PRECAUTIONS:** Do not attempt to resterilize the lens as this can produce undesirable side effects. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline. Do not store the lens at a temperature greater than 43°C (110°F). DO NOT FREEZE. Do not autoclave the intraocular lens. Do not reuse the lens. It is intended for permanent implantation. If explanted, sterility and proper function cannot be assured. For complete physician labeling information, refer to the enVista™ product package insert.

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