EN

CE 0459

SINGLE-USE ONLY

280513 (H) JULY 2024

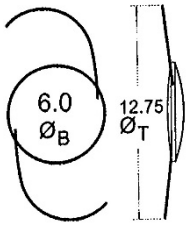
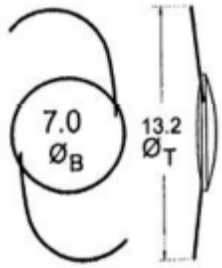
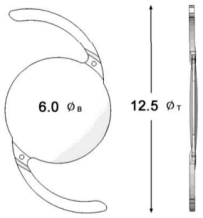
xact™

Foldable 6 and 7 mm Hydrophobic Acrylic UV-absorbing and Blue-Light Blocking Posterior Chamber Intraocular lens

MEDICAL DEVICE DESCRIPTION

All xact™ foldable intraocular lenses are Ultraviolet (UV)-Absorbing Posterior Chamber Intraocular Lenses. Many models are also Blue-Light-Blocking (BLB). They are designed to be positioned posterior to the iris where the lens replaces the natural crystalline lens of the eye and functions as a refracting medium in the correction of aphakia. However, accommodation will not be replaced. The optical portion of the lens can be folded prior to insertion.

TABLE 1: PHYSICAL CHARACTERISTICS

	Three-Piece 6 mm Models	Three-Piece 7 mm Models	Single-Piece 6 mm Model
Design			
Optic Configuration	Bi-convex, spherical	Bi-convex, spherical	Bi-convex, spherical and aspheric (posterior)
Models	X-60 and NX-60	X-70S and NX-70S	W-60R
Lens Material	Hydrophobic acrylic (hydroxyethyl methacrylate (HEMA)polyethylene glycol phenyl ether acrylate (poly(EG)PEA-styrene copolymer, crosslinked with ethylene glycol dimethacrylate), UV absorber, and Blue-Light-Blocking chromophore (NX-60, NX-70S, W-60R)		
Dioptric Powers	+10.0 to +27.0D in 0.5D increments	+5.0 to +9.0D in 1.0D increments and from +10.0D through +27.0D in 0.5D increments	+10.0 to +30.0D in 0.5D increments
Index of Refraction	1.540 @ 35 ± 2°C		
Haptic Material	Polyvinylidine Fluoride (PVDF) secured to optic body using medical-grade epoxy		Same as lens material
Body Diameter $Ø_B$	6.0 ± 0.10 mm	7.0 ± 0.10 mm	6.0 ± 0.10 mm
Clear Optic Diameter	5.16 ± 0.10 mm	6.25 ± 0.10 mm	10.0D – 17.0D: 5.50 ± 0.10 mm 17.5 – 26.5D: 5.00 ± 0.10 mm 27.0 – 30.0D: 4.75 ± 1.10 mm
Overall Length $Ø_T$	12.75 ± 0.30mm	13.19 ± 0.30 mm	12.50 +0.20mm / -0.10 mm
Haptic Angle	7°		0°
UV Transmittance 10% Cutoff	@+20.0D: 10% transmittance at 368 nm		
Suggested A-Constant (Applantation Biometry)*	118.9°		119.1°
Suggested A-Constant (Optical Biometry)*	119.3°		119.5°
Image Quality	≥ 60% or more of theoretical resolution of ideal lens that corresponds to the optical power		
*See the LENS POWER CALCULATION SECTION for more information about lens constants and calculation of lens power.			

EN

CE 0459

SINGLE-USE ONLY

280513 (H) JULY 2024

INDICATIONS

xact™ Foldable Hydrophobic Acrylic Ultraviolet-Absorbing and Blue-Light Absorbing Posterior Chamber intraocular Lens is indicated 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.

PRECAUTIONS

1. Do not attempt to resterilize the lens as this can produce undesirable side effects.
2. Do not use when product sterility or quality is thought to be compromised due to damaged packaging.
3. Do not use if there are signs of leakage (such as the loss of saline storage solution, or the presence of salt crystallization).
4. Do not reuse the lens. It is intended for permanent implantation. If explanted, sterility and proper functionality cannot be assured.

5. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
6. Do not autoclave the intraocular lens.

WARNINGS

1. The safety and effectiveness of the xact™ IOL has not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit:risk ratio before implanting a lens in a patient with one or more of these conditions. Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.

<u>Before Surgery</u>

- Previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens
- Amblyopia
- Clinically severe corneal dystrophy (e.g., 'Fuchs')
- Rubella, congenital, traumatic or complicated cataracts
- Extremely shallow anterior chamber, not due to swollen cataract
- Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g. iritis or uveitis)
- Aniridia
- Iris neovascularization
- Glaucoma (uncontrolled)
- Microphthalmos or macrophthalmos
- Optic nerve atrophy
- Previous corneal transplant
- Pre-existing ocular conditions which may negatively impact stability of the implant.

<u>During Surgery</u>

- Mechanical or surgical manipulation required to enlarge the pupil
- Vitreous loss (significant)
- Anterior chamber bleeding (significant)
- Uncontrollable positive intraocular pressure
- Complications in which the IOL stability could be compromised

2. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
3. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
4. Care should be taken to remove viscoelastic from the eye at the close of surgery.

EN

CE 0459

SINGLE-USE ONLY

280513 (H) JULY 2024

CLINICAL SUMMARY

Long-term clinical safety and efficacy of the hydrophobic acrylic xact™ X-60 three-piece UV-absorbing IOL was confirmed in a three-year, two-phase, multi-center, unilateral, prospective trial in the US. This study established that both the primary efficacy and safety endpoints were satisfied. Subsequent clinical trials followed 100 patients for six months and found that the X-60 was free of *in vivo* glistenings. The X-60 serves as the other 3-piece models' parent. Bausch + Lomb's enVista® model MX60 is manufactured from xact™ UV-absorbing hydrophobic material and serves as the parent model for the xact™ single-piece IOLs. Evidence of its clinical safety and effectiveness for the visual correction of aphakia was confirmed in a multi-center six-month prospective study.

CONTRAINDICATIONS

1. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
2. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
3. Circumstances that would result in damage to the endothelium during implantation.
4. Suspected microbial infection.

5. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support for placement in the capsular bag.
6. Diabetic retinopathy.
7. Retinal detachment.
8. Patients lacking sufficient anatomical clearance for the implant.
9. Pregnant or nursing women.

COMPLICATIONS THAT MAY OCCUR

1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
3. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, uveitis, diabetic retinopathy congenital eye abnormality, shallow anterior chamber, microphthalmus, cornea dystrophy, atrophy of optic nerve, ocular hypertension, mydriasis, amblyopia, cornea transplant, iritis, corneal abnormality, macular degeneration, retinal degeneration disease, atopic disease, pseudoexfoliation syndrome and weak zonule structures, zonular plasmotomy and dislocation of lens (including subluxation), iris neoangiogenesis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

PACKAGING/STERILIZATION

The xact™ IOL is individually packaged in the sterile barrier pouch and plastic vial that should be opened under sterile conditions. The lens is stored in 0.9% sterile saline solution within the top cavity of the vial. An implant card and self-adhesive labels are supplied to provide traceability of the IOL. The xact™ IOL is sterilized by gamma irradiation.

DIRECTIONS FOR USE

1. This product must be inserted into the posterior capsular bag. Safety and efficacy of insertion into the anterior chamber has not been confirmed.
2. Prior to implanting, examine the lens package for type, power, and proper configuration.
3. Open the peel pouch and remove the vial in a sterile environment.
4. Remove the lid from the vial.
5. With a pair of smooth forceps, remove the lens from the vial by gently grasping the lens haptic.
6. If you rinse this device before insertion, rinse only with sterile balanced salt solution or sterile normal saline.
7. Examine the lens thoroughly to ensure particles have not become attached to it and examine the lens optical surfaces for other defects.
8. The lens may be soaked in sterile balanced salt solution until ready for implantation.
9. Viscoelastic should be used for lubrication of the injector when inserting the IOL.
10. If you fold this device for insertion, choose a proper device and become familiar with its use. Confirm that the tip of the inserter is smooth and free of nicks, notches, or damage.
11. The manufacturer recommends using an approved delivery system and to take care when loading and delivering the intraocular lens. Follow the inserter instructions carefully.

CE 0459

SINGLE-USE ONLY

280513 (H) JULY 2024

12. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery. Post-surgical and periodic follow-up examinations should be scheduled to confirm successful implantation.
13. Implant cards are provided with each intraocular lens and should be completed and provided to your patients to present to other medical facilities or physicians, if needed.

SERIOUS INCIDENT REPORTING

Serious incidents 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 Advanced Vision Science, Inc. and to the Competent Authority of the Member State in which the patient and/or user is established.
(1) Corneal edema
(2) Corneitis (includes corneal erosion)
(3) Corneal endothelial dysfunction
(4) Acute corneal defect (
5) Descemet's membrane detachment

(6) Conjunctival inflammation, subconjunctival hemorrhage
(7) Hyphema
(8) Hypopyon
(9) Damage of iris
(10) Iritis (iridocyclitis)
(11) Adhesion of iris
(12) Iris prolapse
(13) Pupillary abnormalities (block, capture, deformation, dilated, etc.)
(14) Uveitis
(15) Zonule plasmotomy
(16) Cyclitis
(17) Posterior capsule rupture
(18) After-cataract
(19) Vitreitis
(20) Vitreous hemorrhage, vitreous opacity
(21) Vitreous prolapse
(22) Detachment, hole or broken hole of retinal tissue (macular, etc.)
(23) Retinal detachment
(24) Choroidal detachment
(25) Choroidal hemorrhage
(26) Edema or denaturation of macular
(27) Expulsion hemorrhage
(28) Intraocular inflammation
(29) Fibrin precipitation
(30) Secondary glaucoma
(31) Elevation of intraocular pressure (includes transient increased intraocular pressure and ocular hypertension)
(32) Hypotonia bulbi
(33) Chromatopsia
(34) Decreased visual performance (eyesight, contrast sensitivity)
(35) Predicted refractive value error
(36) Open macular hole

MANUFACTURER

Manufactured in the U.S.A.
Advanced Vision Science, Inc. 5743 Thornwood Dr., Goleta, CA U.S.A.
Office Tel. +1-805-683-3851 FAX +1-805-964-3065 Website: www.advancedvisionscience.com

www.advancedvisionscience.com/Incident-Reporting/ or to Advanced Vision Science's authorized representative in Europe.

EC REP AF Pharma Service Europe SL
Muntaner 281, Barcelona
08021, España

EN

CE 0459

SINGLE-USE ONLY

280513 (H) JULY 2024

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

STORAGE RECOMMENDATIONS

Do not store the lens at a temperature greater than 43°C (110 °F), or in direct sunlight. DO NOT FREEZE.

LENS POWER CALCULATIONS

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

- Hoffer K J. The Hoffer Q formula: a comparison of theoretic and regression formulas, Journal of Cataract and Refractive Surgery Vol. 19, pp. 700-712, 1993; ERRATA, Vol. 20, pp. 677, 1994.

- Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, Ruiz RS. A three-part system for refining intraocular lens power calculations. Journal of Cataract and Refractive Surgery, Vol. 14, pp. 17-24, 1988.
- Norrby NES. Unfortunate Discrepancies, Letter to the Editor and Reply by Holladay JT. Journal of Cataract and Refractive Surgery, Vol. 24, pp. 433-434, 1998. • Olsen T, Olesen H, Thim K, and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. Journal of Cataract and Refractive Surgery, Vol. 18, pp. 280-285, 1992. • Retzlaff JA, Sanders DR, Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract and Refractive Surgery, Vol. 16, pp. 333-340, 1990; ERRATA, Vol. 16, pp. 528, 1990.
- Haigis W: The Haigis Formula. In: Intraocular lens power calculations. H. John Shammas (eds), Slack Incorporated, Thorofare, NJ, USA, pp. 39-57, 2004.

The recommended A-constant on the outside of the box is intended for use with axial length measurements obtained by optical biometry.

Table 2: **RECOMMENDED LENS CONSTANTS** (SURGEON'S FACTORS)

FORMULAR		Applantation Biometry	Optical Biometry
Holladay 1 Surgeon Factor		1.85	2.07
SRK/T A-Constant		119.1	119.5
SRK II A-Constant		119.1	119.5
Hoffer QpACD		5.61	5.84
Haigis	a0	1.96	1.64
	a1	0.40	0.40
	a2	0.10	0.10

WARRANTY

Advanced Vision Science Incorporated warrants that the intraocular lens, when delivered, will conform to all applicable laws and the manufacturer's then current version of the published specifications for such intraocular lens in all material respects and will be free from defects in material and workmanship. ADVANCED VISION SCIENCE INCORPORATED DISCLAIMS ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR BY OPERATION OF LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ADVANCED VISION SCIENCE INCORPORATED SHALL NOT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT OR EXEMPLARY DAMAGES OF ANY KIND, DIRECTLY OR INDIRECTLY ARISING FROM THE PURCHASE OR USE OF THIS PRODUCT EVEN IF ADVANCED VISION SCIENCE INCORPORATED HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, DAMAGE OR EXPENSE.

RETURN/EXCHANGE POLICY

Please contact your distributor regarding lens return or exchange.

EN

CE 0459

SINGLE-USE ONLY

280513 (H) JULY 2024

ABBREVIATIONS

Abbreviation	Meaning
IOL	Intraocular Lens
UV	Ultraviolet
D	Diopter
$Ø_B$	Body Diameter (Optic Diameter)
ØT	Overall Diameter (Overall Length)
SN	Serial Number
|CH|REP|	Swiss Authorized Representative