CLAREON® IOL WITH THE CLAREON® MONARCH® IV DELIVERY SYSTEM

TECHNICAL SPECIFICATIONS

CLAREON® IOL TECHNICAL SPECIFICATIONS[2]

Attribute	Clareon® IOL
Model Number	SY60WF
Spherical Powers (D)	+6.0 to +30.0 D (0.5 D increments)
Optic Type	Asymmetric biconvex optic[1]
Optic Material	Hydrophobic acrylic (1.5% water content)[1,2]
Optic Diameter	6.0 mm[1]
Overall Length	13.0 mm[1]
Asphericity	-0.20 µm (anterior surface)[3]
Haptic Configuration	STABLEFORCE® Modified L Haptics[1]
Haptic Angulation	0° planar[1]
Photoprotection	UV blocking and blue light filtration[1]
Refractive Index	1.55 at 35°C[1]
A-Constant (suggested starting point)	119.1 (Optical Biometry) 118.8 (Ultrasound)

Where a personalized A-constant has been established for AcrySof® Model SN60WF/SA60WF; the initial Clareon® A-constant may be estimated by adding 0.2 to the personalized A-constant for AcrySof® SN60WF/SA60WF.

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Clareon® Monarch® IV
IOL DELIVERY SYSTEM

CLAREON® MONARCH® IV TECHNICAL SPECIFICATIONS[2]

Attribute	Clareon® Monarch® IV
Model Number	8065977774
Material	Titanium
Overall Length	158.5 mm
Grip Diameter	12.66 mm
Weight	31 g
Center of Gravity (dwell position)	82 mm from cartridge tip
Color	Silver/Gray
Plunger Tip Extension	7 mm
Approved OVDs	ProVisc®, VisCoat®, DisCoVisc®
Approved Cartridges	MONARCH® III D, MONARCH® III C, MONARCH® II B
Approved IOL Material	Clareon®

CLAREON® MONARCH® IV STERILIZATION TEMPERATURES AND TIME SETTINGS[4]

Cycle Type	Sample Configuration	Temperature	Mininmum Exposure Time	Minimum Drying Time
Gravity	Wrapped	132°C (270°F)	15.0 minutes	45.0 minutes
Gravity	Unwrapped	132°C (270°F)	10.0 minutes	—
Pulsing Prevacuum	Unwrapped	132°C (270°F)	4.0 minutes	—
Pulsing Prevacuum	Wrapped	132°C (270°F)	4.0 minutes	30.0 minutes
Pulsing Prevacuum	Wrapped	135°C (275°F)	3.0 minutes	16.0 minutes
Pulsing Prevacuum	Wrapped	134°C – 137°C (273°F – 279°F)	3.0* minutes	30.0 minutes
*Several European national health authorities recommend a minimum sterilization time of 18 minutes at 134°C (273°F).				

Any deviation from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. Please refer to nationally recognized standards, such as AAMI Standards (2, 3, 4) or to your facility's standard procedures.

Important Product Information

CLAREON® ASPHERIC FAMILY OF HYDROPHOBIC ACRYLIC IOLS
CAUTION: Federal law restricts this device to sale by or on the order of a physician. **INDICATIONS:** The Clareon® Aspheric Hydrophobic Acrylic IOLs include the Clareon® Aspheric and Clareon® Aspheric Toric IOLs and are indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed. In addition, the Clareon® Aspheric Toric IOL is indicated to correct pre-existing corneal astigmatism. **WARNINGS/PRECAUTIONS:** The Clareon® IOL is intended for implantation in the capsular bag only. Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio: Patients in whom the posterior capsule is ruptured, zonules are damaged, or primary posterior capsulotomy is planned. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting the IOL in a patient with any of the conditions described in the Directions for Use. For the Clareon® Aspheric Toric IOLs, rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract and/or IOL implantation surgery may include, but are not limited to, the following: lens epithelial cell on- growth, corneal endothelial cell damage, infection (endophthalmitis), toxic anterior segment syndrome (TASS), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, anterior uveitis, hyphema, pigment dispersion, posterior capsule opacification, transient or persistent glaucoma, and secondary surgical interventions. 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. Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with this IOL as well as the risks and benefits associated with cataract surgery. After surgery, physicians should provide an implant card to patients regarding the IOL implanted. DO NOT re-sterilize the Clareon® IOL by any method. The device is for single use only. **ATTENTION:** Refer to the Directions for Use labeling for a complete list of indications, warnings and precautions.

CLAREON® MONARCH® IV IOL DELIVERY SYSTEM
CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician. **INDICATIONS:** The CLAREON® MONARCH® IV IOL Delivery System is for implantation of qualified Alcon foldable IOLs. No unqualified lenses should be used with the CLAREON® MONARCH® IV IOL Delivery System. **WARNINGS:** Consult the product labeling for the complications associated with the CLAREON® MONARCH® IV IOL Delivery System used in conjunction with cataract surgery and IOL implantation. HANDPIECE PRECAUTIONS: 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. Read all instructions prior to use. The handpiece is non-sterile and must be cleaned and sterilized prior to each use (refer to Handpiece Preparation section of this Instructions for Use). Failure to properly sterilize handpiece could result in serious infection (e.g., endophthalmitis and systemic infection). Use of hydrogen peroxide may discolor titanium instruments. Mixing titanium and stainless-steel instruments during sterilization may result in discoloration of the instruments. If a patient with a prion-related disease undergoes a procedure which, in the medical opinion of the physician, poses a high risk of instrument contamination, the instrument should be destroyed or processed according to local requirements. **ATTENTION:** Reference the Directions for Use labeling for a complete listing of indications and precautions.

REFERENCES: 1. Clareon® IOL Directions for Use. 2. Alcon Data on File. 2016. 3. Alcon Data on File. 2015. 4. Clareon® Monarch® IV IOL Delivery System Directions for Use.

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