

# Surgical Portfolio

Eighty percent of all visual impairment is avoidable – whether preventable, treatable or curable.<sup>1</sup> For more than three decades, Johnson & Johnson Vision has been innovating in ophthalmic surgery to address a full range of vision needs.<sup>2</sup> Our technologies push the boundaries of vision surgery and transform the way people see.

**CATARACTS** are the **#1** cause of preventable blindness worldwide<sup>3</sup> and impact more than **100 million** eyes.<sup>4</sup>



## Phacoemulsification

During phacoemulsification, traditional cataract surgery, a surgeon creates a small incision in the eye using a hand-held tool, inserts a small surgical instrument that applies sound waves to break the cataract into small pieces, and suctions the broken-up pieces to remove them from the eye.<sup>5</sup>

Johnson & Johnson Vision offers a versatile collection of tools that are engineered for flexibility to complement the eye surgeon's priorities and technique.<sup>6</sup>

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| <p><b>▶ WHITESTAR SIGNATURE® PRO SYSTEM</b></p>  <p>Common lens removal system that delivers clinical flexibility and high-quality performance<sup>7</sup></p> | <p><b>▶ COMPACT INTUTIV SYSTEM</b></p>  <p>Lens removal system with high functionality and enduring practicality<sup>8</sup></p> | <p><b>▶ STABLEYES CAPSULAR TENSION RING (CTR)</b></p>  <p>Maintains the integrity of the capsular bag, the sack-like structure remaining within the eye after the cataract has been removed, during phacoemulsification and intraocular lens (IOL) implantation<sup>9</sup></p> |
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## Laser Cataract Surgery

In laser-assisted cataract surgery, an imaging device maps the eye's surface to program the laser for the exact location, size and depth of the incisions. The laser is used to make the incision in the eye before an ultrasound probe breaks the lens into pieces and the pieces are suctioned out of the eye.<sup>10</sup> With Johnson & Johnson Vision image-guided laser technology, the eye surgeon can create a precise procedure and personalized patient experience.<sup>11</sup>



**▶ CATALYS® SYSTEM**

Image-guided laser technology replaces manual steps in cataract surgery for a more precise procedure and personalized patient experience<sup>11</sup>

## Ophthalmic Viscoelastic Devices (OVDs)

The HEALON® Family of OVDs are liquid polymers (gels) used to support the eye during cataract surgery, giving surgeons increased protection, control and clarity.<sup>12</sup>

# Intraocular Lenses & Implants

Intraocular lenses (IOLs) are medical devices that replace the eye's natural lens to restore vision after a cataract has been removed. IOLs are usually made of a flexible plastic with extensions called haptics that hold the lens in place once inserted into the eye. Most IOLs are rolled up and injected into the eye. Once inside, the IOL unfolds.<sup>13</sup> Johnson & Johnson Vision offers a family of IOLs that provide many options for people with cataracts to customize treatment based on vision correction and lifestyle needs.<sup>14</sup>

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| <p><b>MONOFOCAL IOLS</b></p> <p>One- and three-piece lens solutions enable surgeons to restore vision for one area of focus - usually distance.<sup>15</sup> Ninety-six percent of patients using the TECNIS® monofocal IOL had corrected 20/20 vision or better<sup>16</sup></p> | <p><b>MULTIFOCAL IOLS</b></p> <p>Offer high-quality vision at multiple distances, with enhanced vision at a distinct distance customized to suit the patient's lifestyle<sup>17</sup></p> | <p><b>EXTENDED DEPTH OF FOCUS IOLS</b></p> <p>Provide high-quality, continuous vision - from near to far and points in between<sup>18</sup></p> | <p><b>TORIC IOLS</b></p> <p>Provide options to correct astigmatism based on a patient's vision needs<sup>19</sup></p> |
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**VISION CORRECTION**

**50%** of the world's population needs vision correction while only 10% are treated<sup>20</sup>



Myopia is predicted to rise by **34%** in the year 2020<sup>21</sup> 



# Refractive Surgery

Refractive surgery, such as LASIK, uses a laser to reshape the cornea to bend light rays to focus on the retina, reducing an individual's dependence on eye glasses or contact lenses.<sup>20</sup> **With LASIK, patients can achieve 20/20 vision.<sup>22</sup>**

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| <p><b>iDESIGN ADVANCED WAVESCAN STUDIO SYSTEM</b></p>  <p>Creates a 3-D map of the eye to measure imperfections<sup>23</sup></p> | <p><b>IFS® ADVANCED FEMTOSECOND LASER</b></p>  <p>Used to create a circular, hinged flap in the cornea, which allows the surgeon access to the tissue affecting the eye's shape<sup>24</sup></p> | <p><b>STAR S4 IR® EXCIMER LASER</b></p>  <p>Uses ultraviolet light to remove corneal abnormalities, reshaping the eye to refocus light on the retina<sup>25</sup></p> |
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**DRY EYE AND MEIBOMIAN GLAND DISEASE**

**MGD** affects approximately **86%** of dry eye patients

Meibomian Gland Dysfunction (MGD) is an abnormality of the meibomian glands that blocks the secretion of oils in the lipid layer of tear film to support natural tears.<sup>26</sup> It is the leading cause of Dry Eye, a condition in which a person is unable to produce an adequate quality or quantity of tears to lubricate and nourish the eye.<sup>27</sup>

**The Ocular Surface portfolio allows physicians to evaluate and image meibomian glands and treat MGD with a 12-minute, in-office treatment.<sup>28</sup>**

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| <p><b>LIPISCAN™</b></p>  <p>Images meibomian gland structure efficiently<sup>29</sup></p> | <p><b>LIPIVIEW® II</b></p>  <p>Measures lipid layer thickness, captures blink rate and partial blinks, and images meibomian gland structure efficiently<sup>30</sup></p> | <p><b>LIPIFLOW®</b></p>  <p>The only cleared electronic medical device for MGD shown to improve gland function by applying simultaneous heat and pressure to the eyelid to remove gland contents and obstructions while at the same time protecting delicate structures of the patient's eye<sup>28</sup></p> |
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<sup>13</sup>Vision Impairment and Blindness. World Health Organization. <http://www.who.int/mediacentre/factsheets/fs282/en>. <sup>14</sup>Surgical, Our History. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/company/history.html>. <sup>15</sup>Priority Eye Diseases." World Health Organization. <http://www.who.int/blindness/causes/priority/en/index.html>. <sup>16</sup>Vision 2020: The Cataract Challenge." National Center for Biotechnology Information. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1705965>. <sup>17</sup>Cataract Surgery. All About Vision. <http://www.allaboutvision.com/conditions/cataract-surgery.htm>. <sup>18</sup>Surgical, Phaco. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/systems/phaco.html>. <sup>19</sup>WHITESTAR SIGNATURE® PRO Manual. Compact Intuitive Owner's Manual. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/systems/phaco/compact-intuitive-system.html>. <sup>20</sup>StabilEyes Capsular Tension Ring [package insert]. Santa Ana, Calif: Johnson & Johnson Surgical Vision, Inc. <sup>21</sup>Surgical, Laser Cataract Surgery. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/systems/laser-cataract-surgery.html>. <sup>22</sup>Surgical, CATALYS® System. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/systems/laser-cataract-surgery-catalys-precision-laser-system.html>. <sup>23</sup>HEALON Family of OVDs Product DFUs. Johnson & Johnson Surgical Vision, Inc. <sup>24</sup>IntraocularLenses: How To Choose The Best IOL For Your Cataract Surgery. All About Vision. <http://www.allaboutvision.com/conditions/iols.html>. <sup>25</sup>Surgical, IOLs and Implants. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/iols.html>. <sup>26</sup>Surgical, Multifocal IOLs. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/iols/multifocal.html>. <sup>27</sup>Surgical, Extended Depth of Focus (EDOF) IOLs. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/iols/extended-depth-of-focus.html>. <sup>28</sup>Surgical, Toric IOLs. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/iols/toric.html>. <sup>29</sup>VISTAK JJVC AMO Fact Sheet. <sup>30</sup>Losing your sight is like losing a diamond. (2017) IOL. <https://www.iol.co.za/news/south-africa/western-cape/losing-your-sight-is-like-losing-a-diamond-11554625> <sup>22</sup>The LASIK Procedure: A Complete Guide. All About Vision. <http://www.allaboutvision.com/visionsurgery/lasik.htm> <sup>23</sup>Surgical, iDesign® System. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/systems/lasik/i-design-wavescan-studio-system.html>. <sup>24</sup>Surgical, iFS® Advanced Femtosecond Laser. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/systems/lasik/ifs-advanced-femtosecond-laser.html> <sup>25</sup>Surgical, STAR S4 IR® Excimer Laser. Johnson & Johnson Vision. <https://surgical.jnjvision.com/us/systems/lasik/star-s4-ir-excimer-laser.html>. <sup>26</sup>Lemp, M. A., Crews, L. A., Bron, A. J., Foulks, G. N., & Sullivan, B. D. (2012). Distribution of Aqueous-Deficient and Evaporative Dry Eye in a Clinic-Based Patient Cohort. Cornea, 31(5), 472-478. doi:10.1097/ico.0b013e318225415a <sup>27</sup>Meibomian Gland Dysfunction (MGD): The Cause Of Your Dry Eyes? All About Vision. <http://www.allaboutvision.com/conditions/meibomian-gland.htm> <sup>28</sup>Lipiflow Fact Sheet. Tear Science. <sup>29</sup>Lipiscan Fact Sheet. Tear Science. <sup>30</sup>Lipiview II Fact Sheet. Tear Science.

# Indications and Important Safety Information for the Catalys® Precision Laser System

## Rx Only INDICATIONS

The OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

## CONTRAINDICATIONS

The CATALYS® System is contraindicated in patients with corneal ring and/or inlay implants, severe corneal opacities, corneal abnormalities, significant corneal edema or diminished aqueous clarity that obscures OCT imaging of the anterior lens capsule, patients younger than 22 years of age, descemetocele with impending corneal rupture, and any contraindications to cataract surgery.

## WARNINGS

Prior to INTEGRAL GUIDANCE System imaging and laser treatment, the suction ring must be completely filled with sterile buffered saline solution. If any air bubbles and/or a meniscus appear on the video image before treatment, do not initiate laser treatment. Before initiating laser treatment, inspect images created from the OCT data, surface fits, and overlaid pattern in both axial and sagittal views, and review the treatment parameters on the Final Review Screen for accuracy. Safety margins for all incisions are preserved only if Custom Fit Adjustments to ocular surface(s) are applied in accordance with the instructions for use. Purposeful misuse of the Custom Fit Adjustment to ocular surfaces can result in patient injury and complication(s), and therefore must be avoided. Standard continuous curvilinear capsulorrhexis (CCC) surgical technique must be used for surgical removal of the capsulotomy disc. The use of improper capsulotomy disc removal technique may potentially cause or contribute to anterior capsule tear and/or a noncircular, irregularly shaped capsulotomy. Verify that the suction ring is correctly connected to the disposable lens component of the LIQUID OPTICS Interface during the initial patient docking procedure.

## PRECAUTIONS

The CATALYS® System has not been adequately evaluated in patients with a cataract greater than Grade 4 (via LOCS III); therefore no conclusions regarding either the safety or effectiveness are presently available. Cataract surgery may be more difficult in patients with an axial length less than 22 mm or greater than 26 mm, and/or an anterior chamber depth less than 2.5 mm due to anatomical restrictions. Use caution when treating patients who may be taking medications such as alpha blockers (e.g. Flomax®) as these medications may be related to Intraoperative Floppy Iris Syndrome (IFIS); this condition may include poor preoperative dilation, iris billowing and prolapse, and progress intraoperative miosis. These conditions may require modification of surgical technique such as the utilization of iris hooks, iris dilator rings, or viscoelastic substances. Surgical removal of the cataract more than 30 minutes after the laser capsulotomy and laser lens fragmentation has not been clinically evaluated. The clinical effects of delaying surgical removal more than 30 minutes after laser anterior capsulotomy and laser lens fragmentation are unknown. The LIQUID OPTICS Interface is intended for single patient use only. Full-thickness corneal cuts or incisions should be performed with instruments and supplies on standby, to seal the eye in case of anterior chamber collapse or fluid leakage. Patients who will undergo full-thickness corneal incisions with the CATALYS® System should be given the same standard surgical preparation as used for patients undergoing cataract surgery for the removal of the crystalline lens. During intraocular surgery on patients who have undergone full-thickness corneal incisions with the CATALYS® System, care should be taken if an eyelid speculum is used, in order to limit pressure from the speculum onto the open eye. Patients who will be transported between

the creation of a full-thickness corneal incision and the completion of intraocular surgery should have their eye covered with a sterile rigid eye shield, in order to avoid inadvertent eye injury during transport. Patients must be able to lie flat and motionless in a supine position and able to tolerate local or topical anesthesia.

## ADVERSE EFFECTS

Complications associated with the CATALYS® System include mild Petechiae and subconjunctival hemorrhage due to vacuum pressure of the LIQUID OPTICS Interface Suction ring. Potential complications and adverse events generally associated with the performance of capsulotomy and lens fragmentation, or creation of a partial-thickness or full-thickness cut or incision of the cornea, include: Acute corneal clouding, age-related macular degeneration, amaurosis, anterior and/or posterior capsule tear/rupture, astigmatism, capsulorrhexis notch during phacoemulsification, capsulotomy/lens fragmentation or cut/incision decentration, cells in anterior chamber, choroidal effusion or hemorrhage, conjunctival hyperemia/injection/erythema/chemosis, conjunctivitis (allergic/viral), corneal abrasion/depithelization/epithelial defect, corneal edema, cystoid macula edema, Descemet's detachment, decentered or dislocated intraocular lens implant, diplopia, dropped or retained lens, dry eye/superficial punctate keratitis, edema, elevated intraocular pressure, endothelial decompensation, floaters, glaucoma, halo, inflammation, incomplete capsulotomy, intraoperative floppy iris syndrome, iris atrophy/extrusion, light flashes, meibomitis, ocular discomfort (e.g., pain, irritation, scratchiness, itching, foreign body sensation), ocular trauma, petechiae, photophobia, pigment changes/pigment in corneal endothelium/foveal region, pingueculitis, posterior capsule opacification, posterior capsule rupture, posterior vitreous detachment, posteriorly dislocated lens material, pupillary contraction, red blood cells in the anterior chamber (not hyphema), residual cortex, retained lens fragments, retinal detachment or hemorrhage, scar in Descemet's membrane, shallowing or collapsing of the anterior chamber, scoring of the posterior corneal surface, snail track on endothelium, steroid rebound effect, striae in Descemet's, subconjunctival hemorrhage, thermal injury to adjacent eye tissues, toxic anterior shock syndrome, vitreous in the anterior chamber, vitreous band or loss, wound dehiscence, wound or incision leak, zonular dehiscence.

## CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician. The system should be used only by qualified physicians who have extensive knowledge of the use of this device and have been trained and certified.

## ATTENTION

Reference the labeling for a complete listing of Indications and Important Safety Information.



# Indications and Important Safety Information

## Rx Only

**ATTENTION:** Reference the labeling for a complete listing of Indications and Important Safety Information.

### WHITESTAR SIGNATURE PRO System

**INDICATIONS:** The AMO WHITESTAR Signature PRO Phacoemulsification System is a modular ophthalmic microsurgical system that facilitates anterior segment (i.e., cataract) ophthalmic surgery. The modular design allows the users to configure the system to meet their surgical requirements. **IMPORTANT SAFETY INFORMATION:** Risks and complications of cataract surgery may include broken ocular capsule or corneal burn. This device is only to be used by a trained licensed physician.

### COMPACT INTUITIV System

**INDICATIONS:** The COMPACT INTUITIV System is an ACpowered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract. The Single-Use Pack is used with the COMPACT INTUITIV System. The Single-Use Pack is sterilized using Ethylene Oxide and is designed for single use only. **IMPORTANT SAFETY INFORMATION:** Risk and complications may include broken ocular capsule, corneal burn and iris depigmentation. Consult the Operator's Manual for a complete listing of warnings and risks.

### STABLEYES CAPSULAR TENSION RING

**INDICATIONS:** CTRs are indicated for the stabilization of weakened, broken or missing zonules that are suspected or observed during cataract extraction using phacoemulsification and continuous curvilinear capsulorhexis techniques in adults. **CONTRAINDICATIONS:** CTRs should not be used in the presence of a torn or compromised capsular bag or significant, progressive pseudoexfoliation. CTRs should not be used in patients 12 years old or younger due to the developing eye. **WARNINGS:** The long-term effects of progressive zonular stability following implantation of a CTR are not known. Patients with pseudoexfoliation syndrome or an otherwise compromised zonule due to trauma exhibit a wide variety and degree of intraoperative and postoperative complications that must be taken into consideration by the surgeon prior to using the CTR. All subjects with a compromised zonule may not be suitable to receive a CTR. The medical literature has reported that eyes with pseudoexfoliation syndrome and a shallow (below average) anterior chamber depth may exhibit a greater tendency to develop zonular instability, intraoperative and postoperative complications. The use of a CTR in patients less than 18 years of age may increase the risk of radial tears of the capsulorhexis as reported in the medical literature. The safety of the CTR in cases of zonulolysis greater than 33% has not been established. **ADVERSE EVENTS:** Potential adverse events during or following cataract surgery with the use of a capsular tension ring may include but are not limited to: intraoperative vitreous loss requiring a vitrectomy, zonular instability, zonular dehiscence requiring suturing of IOL, corneal transplant rejection/graft, or retinal detachment. The most frequently reported cumulative adverse event that occurred during the StabilEyes Capsular Tension Ring clinical trial was intraoperative vitreous loss requiring a vitrectomy which occurred at a rate of 2.2%.

### HEALON FAMILY OF OVDs

**INDICATIONS for HEALON EndoCoat OVD:** HEALON EndoCoat OVD is an ophthalmic viscoelastic containing 3% sodium hyaluronate indicated for use as a surgical aid in patients undergoing ophthalmic anterior segment procedures including: Cataract surgery with an intraocular lens, Cataract surgery without an intraocular lens, Secondary intraocular lens implantation. HEALON EndoCoat OVD maintains a deep chamber during anterior segment surgery, aids in tissue manipulation during surgery, enhances visualization during the surgical procedure and protects the corneal endothelium and other ocular tissue. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery. It may also be used to coat intraocular lenses and insertion instruments prior to intraocular lens implantation. **INDICATIONS for HEALON5 OVD:** HEALON5 OVD is

intended for use in anterior segment ophthalmic surgical procedures of the human eye. The HEALON5 OVD is designed to create and maintain a deep anterior chamber which facilitates manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The HEALON5 OVD can also be used to efficiently separate and control ocular tissues. The HEALON5 OVD is not designed to have any pharmacological effect. **INDICATIONS for HEALON OVD:** The HEALON OVD is indicated for use as a surgical aid in cataract extraction (intra- and extracapsular), IOL implantation, corneal transplant, glaucoma filtration and retinal attachment surgery. In surgical procedures in the anterior segment of the eye, instillation of the HEALON OVD serves to maintain a deep anterior chamber during surgery, allowing for efficient manipulation with less trauma to the corneal endothelium and other surrounding tissues. Furthermore, its viscoelasticity helps to push back the vitreous face and prevent formation of a postoperative flat chamber. In posterior segment surgery the HEALON OVD serves as a surgical aid to gently separate, maneuver and hold tissues. The HEALON OVD creates a clear field of vision thereby facilitating intra- and postoperative inspection of the retina and photocoagulation. **INDICATIONS for HEALON GV OVD:** The HEALON GV OVD is indicated for use in anterior segment ophthalmic surgical procedures. The HEALON GV OVD creates and maintains a deep anterior chamber, to facilitate manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The HEALON GV OVD also can be used to efficiently maneuver, separate and control ocular tissues. **CONTRAINDICATIONS:** There are no known contraindications to the use of HEALON OVDs when used as recommended.

### IMPORTANT SAFETY INFORMATION for the family of HEALON Products

**PRECAUTIONS:** Remove carefully and completely from the eye by irrigating or aspirating to reduce the risk of early postoperative intraocular pressure (IOP) spikes. Patients with preexisting glaucoma, other causes of compromised outflow, higher preoperative intraocular pressure and surgical complications are more susceptible to postoperative IOP and should be treated with additional care. Carefully monitor intraocular pressure and treat with pressure lowering therapy if required. In posterior segment procedures with HEALON OVD in aphakic diabetic patients, special care should be exercised to avoid using large amounts of the product. Express a small amount of product prior to use and carefully examine the remainder as it is injected into the eye. Because HEALON OVDs contain trace amounts of protein from avian tissues, physicians should be aware of potential allergic risks, such as postoperative inflammation, that may occur with the injection of biological materials. **WARNINGS:** The HEALON EndoCoat OVD delivery system is not designed or intended to be attached to instruments other than the one provided with the product, as it may cause cannula detachment. When using HEALON EndoCoat OVD for surgery, the eye should not be irrigated with any solution containing benzalkonium chloride, because the mixing of quaternary ammonium salts, such as benzalkonium chloride, with sodium hyaluronate results in the formation of a precipitate. **ADVERSE EVENTS:** Increased intraocular pressure has been reported after use of HEALON OVDs. In rare instances, postoperative inflammatory reactions as well as corneal edema and corneal decompensation have been reported. Conjunctival hemorrhage has been reported for HEALON5 OVD.

### TECNIS 1-Piece Intraocular Lens

**INDICATIONS:** TECNIS 1-piece lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag. **IMPORTANT SAFETY INFORMATION:** Physicians considering lens implantation under any of the conditions described in the Directions for Use should weigh the potential risk/benefit ratio prior to implanting a lens that could increase complications or impact patient outcomes. Do not place the lens in the ciliary sulcus. The most commonly reported adverse events of cataract surgery with the 1-Piece IOL included macular edema.

### **TECNIS Multifocal Family of 1-Piece IOLs**

**INDICATIONS:** The TECNIS Multifocal 1-Piece IOLs are indicated for primary implantation for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag. **IMPORTANT**

**SAFETY INFORMATION:** Inform patients of possible contrast sensitivity reduction and increases in visual disturbances that may affect their ability to drive at night or in poor visibility conditions. The lenses should not be placed in the ciliary sulcus. Weigh the potential risk/benefit ratio for patients with conditions that could be exacerbated or may interfere with diagnosis or treatment. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma.

### **TECNIS Toric 1-Piece IOL**

**INDICATIONS:** The TECNIS Toric 1-Piece posterior chamber lenses are indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision. The device is intended to be placed in the capsular bag. **IMPORTANT SAFETY INFORMATION:** Rotation can reduce astigmatic correction. Misalignment greater than 30° may induce refractive error. Accurate keratometry, biometry and [www.TecnisToricCalc.com](http://www.TecnisToricCalc.com) are recommended to optimize visual outcomes. Weigh the potential risk/benefit ratio that could increase pre-existing complications or impact patient outcomes. Variability in any preoperative measurements can influence outcomes.