Cataract Surgery Important Safety Information

RISKS

There are risks to routine cataract surgery. This is irrelevant to the lens you choose. The problems could be minor, temporary, or affect your vision permanently. Complications are rare. These may include are worsening of your vision, bleeding, or infection. Pre-existing diseases or conditions may place you at higher risk of experiencing complications (e.g., more difficult recovery) after routine cataract surgery. Examples of pre-existing diseases or conditions are diabetes, heart disease and previous trauma to your eye.

With some IOLs, you may experience some loss in the sharpness of your vision, even with glasses. With these IOLs, you may have more difficulty driving at night or in poor visibility conditions This can affect your ability to detect road hazards as quickly at night or in fog. You may also experience halos (rings around light), glare (reflected light, making it difficult to see) and starbursts (rays around light). A small number of patients may want to have their IOL removed. This can be due to lens-related optical/visual symptoms. You should discuss all risks and benefits with your eye doctor before surgery.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS® 1-PIECE IOL

INDICATIONS

The 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

The product may not be suitable for everyone. Physicians considering lens implantation under any of the circumstances described in the TECNIS® 1-Piece IOL labeling should weigh the potential risk/benefit ratio for patients.

ATTENTION

Consult the labeling for a listing of indications and important safety information. Always read and follow the directions in the labeling.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS® Toric 1-Piece IOL and TECNIS® Toric II 1-Piece IOL

INDICATIONS FOR USE

The TECNIS® Toric 1-piece and TECNIS® Toric II 1-piece posterior chamber intraocular lenses are indicated for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction 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

Routine cataract surgery risks, which are not related to the intraocular lens ("IOL"), could include minor, temporary, or permanently impact your vision. While rare, complications could include worsening of vision, bleeding, or infection. Please discuss all risks and benefits with your Eye Care Professional before lens selection and surgery. If you have a pre-existing eye condition (including glaucoma), your vision may not be good even after cataract removal, as you will not be able to benefit fully from the insertion of the IOL. Before surgery, your Eye Care Professional will check for any eye diseases. Once the IOL has been inserted, your vision may not be good enough to perform detailed 'up-close' work without glasses. While rare, in some cases certain types of retinal treatment (e.g., retinal tear repair) may become more difficult to repair. You should avoid any activity that could harm your eye(s) while you are recovering from surgery. Your Eye Care Professional will advise which activities to avoid while you are recovering from surgery.

A Toric IOL corrects astigmatism when it is placed correctly in the eye. There is a chance that the Toric IOL could be placed incorrectly during the surgery or could move within the eye following the surgery. If the Toric IOL is not placed correctly, this may lead to visual distortions. A subsequent surgery may be required to adjust the position of the IOL.

SIDE EFFECTS

Side effects of cataract surgery with TECNIS® Toric 1-piece and TECNIS® Toric II 1-piece posterior chamber IOLs may include the need for a second surgery to reposition the lens or repair the retina, thickening of the retina, and separation of the retina from the surrounding tissues.

ATTENTION

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS® Eyhance™ IOL

INDICATIONS FOR USE
The TECNIS® Eyhance™ IOL, Model ICB00, is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens extends the depth of focus, which improves vision for intermediate tasks, and provide similar distance vision as compared to a standard aspheric monofocal IOL. The lens is indicated for placement in the capsular bag only.

CONTRAINDICATIONS
There are no known conditions under which the TECNIS® Eyhance™ IOL should not be used.

RISKS
There are risks to routine cataract surgery. This is irrelevant to the lens you choose. The problems could be minor, temporary, or affect your vision permanently. Complications are rare. These may include worsening of your vision, bleeding, or infection. Similar to other monofocal IOLs, patients implanted with the TECNIS® Eyhance™ IOLs may require glasses for some tasks. Discuss all risks and benefits with your eye doctor prior to surgery.

WARNINGS
Pre-existing diseases or conditions may place you at higher risk of experiencing complications (e.g., more difficult recovery) after routine cataract surgery. Examples of pre-existing diseases or conditions include, but are not limited to: ocular inflammation, surgical difficulties at the time of cataract extraction, suspected eye infection, congenital bilateral cataract, history or predisposition to retinal detachment, patients with only one good eye with potentially good vision, medically uncontrollable glaucoma, diabetes, heart disease, and previous trauma to your eye. These lenses have not been evaluated for use in children.

PRECAUTIONS
Increased spectacle independence has not been determined for the TECNIS® Eyhance™ IOL compared to commercially available monofocal lenses. There is an anticipated potential for some level of distance vision compromise that is known for this type of extended depth of focus IOL. If your eye is not healthy (including glaucoma), your vision may not be good even after your cataract is removed. In this case, you may not get the full benefit of the TECNIS® Eyhance™ IOL. Before surgery, your eye doctor will check if you have any eye diseases that may influence your IOL selection. In rare instances, the TECNIS® Eyhance™ IOL may make some types of retinal treatment (e.g., retinal tear repair) more difficult. Take all prescribed medicines and apply eye drops as instructed to avoid inflammation and infection. Your eye doctor may tell you if you should avoid certain activities after surgery.

SIDE EFFECTS
Side effects of cataract surgery with the TECNIS® Eyhance™ IOL may include swelling/thickening of an area of the retina, and/or the need for a second surgery to reposition the lens, repair the retina, or remove the new lens.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS® SYNERGY™ OPTIBLUE AND TECNIS® SYNERGY™ TORIC II OPTIBLUE™ IOL WITH TECNIS® SIMPLICITY™ DELIVERY SYSTEM, MODEL DFW

INDICATIONS FOR USE
The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS® Synergy™ OptiBlue™ IOL which is indicated for primary implantation for the visual correction of aphakia in adult patients with or without presbyopia, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing vision far through near and reduced spectacle dependence across a range of distances.

The TECNIS® Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS® Synergy™ Toric II OptiBlue™ IOLs which are indicated for primary implantation for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing vision far through near, a reduction of residual refractive cylinder and reduced spectacle dependence across a range of distances.
The lenses are intended to be placed in the capsular bag.

CONTRAINDICATIONS
None

RISKS
Routine cataract surgery risk, irrelevant to lens selection, could be minor, temporary, or affect patients' vision permanently. Rare complications are worsening of vision, bleeding, or infection. Risks related to use of this lens include halo or glare in nighttime or poor visibility conditions. These may be perceived as an annoyance or hindrance, which on rare occasions, may be significant enough for the patient to request removal of the IOL. Patients should discuss all risks and benefits with their eye doctor before surgery.

PRECAUTIONS
Recent contact lens usage may affect the patient's refraction; therefore, in contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient. Safety and effectiveness in patients 21 years or younger have not been established in clinical studies. A patient implanted with an intraocular lens should be monitored on a regular basis for long-term postoperative follow-up. The intraocular pressure of implanted patients with glaucoma should be carefully monitored for postoperative changes.

WARNINGS
Physicians considering lens implantation should weigh the potential risk/benefit ratio. Well-informed patients with well-defined visual needs and preferences should be selected for lens implantation. The patients should be informed of the possibility of visual effects (such as halo or glare) in nighttime or poor visibility conditions. Patients may perceive these visual effects as an annoyance or hindrance, which, on rare occasions, may be significant enough for the patient to request removal of the IOL. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for lens model ZFW implantation since they may not fully benefit in terms of potential spectacle independence. The lens may affect image quality and lead to some reduction of contrast sensitivity compared to a monofocal lens. Therefore, patients should exercise caution when driving at night or in poor visibility conditions.

ATTENTION
Reference the Directions For Use for a complete listing of indications and safety information.

INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS® Eyhance™ and TECNIS® Eyhance™ Toric II IOLs with TECNIS Simplicity® Delivery System

INDICATIONS FOR USE
The TECNIS® Eyhance™ IOL is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens extends the depth of focus, which improves vision for intermediate tasks, and provide similar distance vision as compared to a standard aspheric monofocal IOL. The lens is indicated for placement in the capsular bag only.

The TECNIS® Eyhance™ Toric II IOL is indicated for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision compared to a non-toric IOL. The lens also extends the depth of focus, which improves vision for intermediate tasks, and provides similar distance vision as compared to a standard aspheric monofocal IOL. The lens is indicated for placement in the capsular bag only.

CONTRAINDICATIONS
There are no known conditions under which the TECNIS® Eyhance™ and TECNIS® Eyhance™ Toric II IOLs should not be used.

RISKS
There are risks to routine cataract surgery. This is irrelevant to the lens you choose. The problems could be minor, temporary, or affect your vision permanently. Complications are rare. These may include worsening of your vision, bleeding, or infection. Similar to other monofocal IOLs, patients implanted with the TECNIS® Eyhance™ or TECNIS® Eyhance™ Toric II IOLs may require glasses for some tasks. Discuss all risks and benefits with your eye doctor prior to surgery.

WARNINGS
Pre-existing diseases or conditions may place you at higher risk of experiencing complications (e.g., more difficult recovery) after routine cataract surgery. Examples of pre-existing diseases or conditions include, but are not limited to: ocular inflammation, surgical difficulties at the time of cataract extraction, suspected eye infection, congenital bilateral cataract, history or predisposition to retinal detachment, patients with only one good eye with potentially good vision, medically uncontrollable glaucoma, diabetes, heart disease, and previous trauma to your eye good eye with potentially good vision, medically uncontrollable glaucoma, diabetes, heart disease, and previous trauma to your eye. The TECNIS® Eyhance™ Toric II IOL corrects astigmatism when it is placed correctly in the eye. There is a chance that the TECNIS® Eyhance™ Toric II IOL could be placed incorrectly or could move within the eye, resulting in visual distortions. A second surgery may be needed to properly position the lens. These lenses have not been evaluated for use in children.

PRECAUTIONS
Increased spectacle independence has not been determined for the TECNIS® Eyhance™ IOL compared to commercially available monofocal lenses. There is an anticipated potential for some level of distance vision compromise that is known for this type of extended depth of focus IOL. If your eye is not healthy (including glaucoma), your vision may not be good even after your cataract is removed. In this case, you may not get the full benefit of the TECNIS® Eyhance™ and TECNIS® Eyhance™ Toric II IOLs. Before surgery, your eye doctor will check if you have any eye diseases

that may influence your IOL selection. In rare instances, the TECNIS® Eyhance™ and TECNIS® Eyhance™ Toric II IOLs may make some types of retinal treatment (e.g., retinal tear repair) more difficult. Take all prescribed medicines and apply eye drops as instructed to avoid inflammation and infection. Your eye doctor may tell you if you should avoid certain activities after surgery.

SIDE EFFECTS
Side effects of cataract surgery with the TECNIS® Eyhance™ and TECNIS® Eyhance™ Toric II IOLs may include swelling/thickening of an area of the retina, and/or the need for a second surgery to reposition the lens, repair the retina, or remove the new lens.

ATTENTION
Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS® SYM*F*ONY™ EXTENDED RANGE OF VISION IOLs

INDICATIONS

The TECNIS® Symfony™ IOL, Model ZXR00, is indicated for primary implantation for the visual correction of aphakia in adult patients with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens is intended to correct presbyopia by providing improved vision over a continuous range of distances including far, intermediate and near, and decreased spectacle dependence. The lens is intended for capsular bag placement only. The TECNIS® Symfony IOLs, Models ZXT100, ZXT150, ZXT225, ZXT300, ZXT375, ZXT450, ZXT525, and ZXT600 are indicated for primary implantation for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction, and aphakia following refractive lensectomy in presbyopic adults, who desire useful vision over a continuous range of distances including far, intermediate and near, a reduction of residual refractive cylinder, and increased spectacle independence. These devices are intended to be placed in the capsular bag

IMPORTANT SAFETY INFORMATION

The product may not be suitable for everyone. Physicians considering lens implantation under any of the circumstances described in the TECNIS® Symfony™ labeling should weigh the potential risk/benefit ratio as some patients may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight.

ATTENTION

Consult the labeling for a listing of indications and important safety information. Always read and follow the directions in the labeling.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS® MULTIFOCAL 1-PIECE IOLs

INDICATIONS FOR USE
TECNIS® multifocal intraocular lenses 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.

RISKS
No matter what lens you choose, there are risks or problems that can happen with cataract surgery. The problems could be minor, temporary, or affect your vision permanently. Complications are rare and may include the worsening of your vision, bleeding, or infection. There are also tradeoffs with receiving a multifocal lens. Whereas your use of glasses may decrease, it may come at the cost of some sharpness of your vision. Even with glasses, this loss of sharpness may become worse under poor visibility conditions such as dim light or fog. You may also notice more halos (rings of light around a light source) or glare (scattered light effect around a light source), which are more common with multifocal IOLs than monofocal IOLs. Call your eye doctor right away if you experience any itching, pain, flashing lights, “floaters,” redness, severe headache, nausea/vomiting, light sensitivity, or watery eyes after surgery.

WARNINGS
A very small number of patients may be dissatisfied and request removal of their multifocal IOL. Under poor visibility conditions, your vision may be reduced more than it would be with a monofocal IOL. Under these conditions, you may have more difficulty recognizing some traffic signs and hard-to-see objects in the road. Therefore, you
may need to take extra care when driving, especially in poor light conditions. In rare instances, multifocal IOLs may make some types of retinal surgery more difficult. You should not receive this device if you have had previous trauma to your eye. Children under the age of 2 should not receive this device.

PRECAUTIONS
If your eye is not healthy (including glaucoma), your vision may not be good even after your cataract is removed. In this case, you may not get the full benefit of the multifocal IOL. Before surgery, your eye doctor will check to see if you have any eye diseases. There is a chance that your vision with a multifocal IOL may not be good enough to perform very near or detailed “up-close” work without glasses. Depending on the type of TECNIS® Multifocal 1-Piece IOL you choose, the lens is designed for near vision from 13 to 20 inches. Take all prescribed medicines and apply eye drops as instructed. You should avoid any activity that could harm your eye while you are recovering from surgery. Your eye doctor will tell you what activities you should avoid. If you wear contact lenses, your eye doctor may ask you to stop wearing them before being tested for the multifocal IOL.

SIDE EFFECTS
Multifocal IOL implants may be inadvisable in patients with conditions such as macular degeneration, retinal pigment epithelium changes, and glaucoma. In rare cases, severe incidents of halos and/or glare may result in the multifocal IOL being explanted and replaced with another type of IOL.

ATTENTION

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS® MULTIFOCAL TORIC IOLs

INDICATIONS

The TECNIS® Multifocal Toric 1-piece intraocular lens is indicated for the primary implantation for the visual correction of aphakia and pre-existing corneal astigmatism in [1] astigmatic adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and [2] aphakia following refractive lensectomy in astigmatic presbyopic adults, who desire improved uncorrected vision, reduction of residual refractive cylinder, useful near vision and reduced spectacle dependence across a range of distances. The intraocular lenses are intended to maintain rotational stability after implantation in the capsular bag.

IMPORTANT SAFETY INFORMATION

Routine cataract surgery risks, which are not related to the intraocular lens ("IOL"), could include minor, temporary, or permanently impact your vision. While rare, complications could include worsening of vision, bleeding, or infection. Please discuss all risks and benefits with your Eye Care Professional before lens selection and surgery. If you have a pre-existing eye condition (including glaucoma), your vision may not be good even after cataract removal, as you will not be able to benefit fully from the insertion of the IOL. Before surgery, your Eye Care Professional will check for any eye diseases. Once the IOL has been inserted, your vision may not be good enough to perform detailed 'up-close' work without glasses. While rare, in some cases certain types of retinal treatment (e.g., retinal tear repair) may become more difficult to repair. You should avoid any activity that could harm your eye(s) while you are recovering from surgery. Your Eye Care Professional will advise which activities to avoid while you are recovering from surgery.

A Toric IOL corrects astigmatism when it is placed correctly in the eye. There is a chance that the Toric IOL could be placed incorrectly during the surgery or could move within the eye following the surgery. If the Toric IOL is not placed correctly, this may lead to visual distortions. A subsequent surgery may be required to adjust the position of the IOL.

WARNINGS

Mild visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos or glare around lights under nighttime conditions. In a small percentage of patients, the observation of such phenomena may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions these visual effects may be significant enough that patients will be dissatisfied and request removal of the TECNIS® Multifocal Toric 1-Piece IOL.

PRECAUTIONS

If your eye is not healthy (including glaucoma), your vision may not be good even after your cataract is removed. In this case, you may not get the full benefit of the multifocal IOL. Before surgery, your eye doctor will check to see if you have any eye diseases. There is a chance that your vision with a multifocal IOL may not be good enough to perform very near or detailed "up-close" work without glasses. Depending on the type of TECNIS® Multifocal 1-Piece IOL you choose, the lens is designed for near vision from 13 to 20 inches. Take all prescribed medicines and apply eye drops as instructed. You should avoid any activity that could harm your eye while you are recovering from surgery. Your eye doctor will tell you what activities you should avoid. If you wear contact lenses, your eye doctor may ask you to stop wearing them before being tested for the multifocal IOL.

SIDE EFFECTS
Multifocal IOL implants may be inadvisable in patients with conditions such as macular degeneration, retinal pigment epithelium changes, and glaucoma. In rare cases, severe incidents of halos and/or glare may result in the multifocal IOL being explanted and replaced with another type of IOL.

ATTENTION
Reference the Directions for Use for a complete listing of Indications and Important Safety Information.