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.

OPTIBLUE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM, MODELS DFW100, DFW150, DFW225, DFW300 AND DFW375

INDICATIONS FOR USE: 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.

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 implanting, examine the lens package for proper lens model, dioptric power, and expiration date. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve centration of the intraocular lens. When the insertion system is used improperly, the haptics of the IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Safety and effectiveness in patients 21 years or younger have not been established in clinical studies. The intraocular pressure of implanted patients with glaucoma should be carefully monitored for postoperative changes.

WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio. The lens should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. Well-informed patients with well-defined visual needs and preferences should be selected for lens model ZFW implantation. The patients should be informed of the possibility of visual effects (such as halo or glare) in nighttime or poor visibility conditions. 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. 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. The lens model ZFW 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.

Rotation of toric lens model ZFW from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as

possible prior to lens encapsulation. Carefully remove all viscoelastic from the capsular bag. Residual viscoelastic may allow the lens to rotate, causing misalignment of the toric lens model ZFW with the intended axis of placement.

ADVERSE EVENTS: Potential adverse events during or following cataract surgery with implantation of the IOL may include but are not limited to: Endophthalmitis/intraocular infection, IOL dislocation, Persistent cystoid macular edema, Persistent corneal stromal edema, Persistent raised intraocular pressure (IOP) requiring treatment, Secondary surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure). Adverse events can lead to permanent visual impairment and may require secondary surgical intervention, including intraocular lens exchange or explantation.

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

OPTIBLUE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM, MODELS DFW100, DFW150, DFW225, DFW300 AND DFW375

INDICATIONS FOR USE: 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.

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 implanting, examine the lens package for proper lens model, dioptric power, and expiration date. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve centration of the intraocular lens. When the insertion system is used improperly, the haptics of the IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Safety and effectiveness in patients 21 years or younger have not been established in clinical studies. The intraocular pressure of implanted patients with glaucoma should be carefully monitored for postoperative changes.

WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio. The lens should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. Well-informed patients with well-defined visual needs and preferences should be selected for lens model ZFW implantation. The patients should be informed of the possibility of visual effects (such as halo or glare) in nighttime or poor visibility conditions. 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. 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. The lens model ZFW 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.

Rotation of toric lens model ZFW from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation. Carefully remove all viscoelastic from the capsular bag. Residual viscoelastic may allow the lens to rotate, causing misalignment of the toric lens model ZFW with the intended axis of placement.

ADVERSE EVENTS: Potential adverse events during or following cataract surgery with implantation of the IOL may include but are not limited to: Endophthalmitis/intraocular infection, IOL dislocation, Persistent cystoid macular edema, Persistent corneal stromal edema, Persistent raised intraocular pressure (IOP) requiring treatment, Secondary surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure). Adverse events can lead to permanent visual impairment and may require secondary surgical intervention, including intraocular lens exchange or explantation.

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

INDICATIONS and IMPORTANT SAFETY INFORMATION FOR TECNIS SYNERGY OPTIBLUE EXTENDED RANGE OF VISION IOL

Rx Only

INDICATIONS FOR USE: The Model ZFR00V 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.

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 implanting, examine the lens package for proper lens model, dioptric power, and expiration date. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve centration of the intraocular lens. When the insertion system is used improperly, the haptics of the IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Safety and effectiveness in patients 21 years or younger have not been established in clinical studies. The intraocular pressure of implanted patients with glaucoma should be carefully monitored for postoperative changes.

WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio. The lens model ZFR00V should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. Well-informed patients with well-defined visual needs and preferences should be selected for lens model ZFR00V 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 ZFR00V implantation since they may not fully benefit in terms of potential spectacle independence. The lens model ZFR00V 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.

ADVERSE EVENTS: Potential adverse events during or following cataract surgery with implantation of the IOL may include but are not limited to: Endophthalmitis/intraocular infection, IOL dislocation, Persistent cystoid macular edema, Persistent corneal stromal edema, Persistent raised intraocular pressure (IOP) requiring treatment, Secondary surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure). Adverse events can lead to permanent visual impairment and may require secondary surgical intervention, including intraocular lens exchange or explantation.

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

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

ATTENTION

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

INDICATIONS

The TECNIS® Toric 1-Piece and TECNIS® Toric II 1-Piece posterior chamber 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 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.

WARNINGS

Physicians considering lens implantation should weigh the potential risk/benefit ratio as described in the TECNIS® Toric 1-Piece and TECNIS® Toric II 1-Piece IOL Directions for Use. Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the TECNIS® Toric 1-Piece and TECNIS® Toric II 1-Piece IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of TECNIS® Toric 1-Piece and TECNIS® Toric II 1-Piece IOLs after implantation. TECNIS® Toric 1-Piece and TECNIS® Toric II 1-Piece IOLs should not be placed in the ciliary sulcus. Rotation of TECNIS® Toric II 1-Piece and TECNIS® Toric 1-Piece IOLs away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. All viscoelastic should be removed carefully from the capsular bag. Residual viscoelastic may allow the lens to rotate, causing misalignment of the TECNIS Toric 1-piece and TECNIS Toric II 1-piece IOLs with the intended axis of placement.

PRECAUTIONS

When the insertion system is used improperly, the haptics of the TECNIS® Toric 1-Piece and TECNIS® Toric II 1-Piece IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system.

ADVERSE EVENTS

The most frequently reported cumulative adverse event that occurred during the TECNIS® Toric 1-Piece IOL clinical trial was surgical re-intervention which occurred at a rate of 3.4% (lens repositioning procedures and retinal repair procedures).

INDICATIONS and IMPORTANT SAFETY INFORMATION FOR TECNIS SYNERGY OPTIBLUE WITH TECNIS SIMPLICITY DELIVERY SYSTEM, MODEL DFR00V

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 lens is intended to be placed in the capsular bag.

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 implanting, examine the lens package for proper lens model, dioptric power, and expiration date. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve centration of the intraocular lens. When the insertion system is used improperly, the haptics of the IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Safety and effectiveness in patients 21 years or younger have not been established in clinical studies. The intraocular pressure of implanted patients with glaucoma should be carefully monitored for postoperative changes.

WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio. The lens model ZFR00V should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. Well-informed patients with well-defined visual needs and preferences should be selected for lens model ZFR00V 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 ZFR00V implantation since they may not fully benefit in terms of potential spectacle independence. The lens model ZFR00V 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.

ADVERSE EVENTS: Potential adverse events during or following cataract surgery with implantation of the IOL may include but are not limited to: Endophthalmitis/intraocular infection, IOL dislocation, Persistent cystoid macular edema, Persistent corneal stromal edema, Persistent raised intraocular pressure (IOP) requiring treatment, Secondary surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure). Adverse events can lead to permanent visual impairment and may require secondary surgical intervention, including intraocular lens exchange or explantation.

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS FAMILY OF 1-PIECE IOLs

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.

INDICATIONS FOR USE: The TECNIS® Multifocal 1-Piece 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 TECNIS® Multifocal Toric 1-Piece lens is indicated for the primary implantation for the visual correction of aphakia and pre-existing corneal astigmatism in astigmatic adult patients with and without presbyopia in whom a cataractous lens has been removed by Phacoemulsification, who desire improved uncorrected vision, reduction of residual refractive cylinder, useful near vision and reduced spectacle dependence across a range of distances.

INDICATIONS FOR USE*:* The TECNIS Symfony® Extended Range of Vision 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 TECNIS Symfony® Toric Extended Range of Vision 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. The lenses are intended to correct presbyopia by providing improved vision over a continuous range of distances including far, intermediate and near, a reduction of residual refractive cylinder, and decreased spectacle dependence.

INDICATIONS: The TECNIS® Toric 1-Piece and TECNIS Toric II 1-Piece Posterior Chamber 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 phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision.

INDICATIONS: 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 provides similar distance vision as compared to a standard aspheric monofocal IOL.

INDICATIONS: The TECNIS Synergy® OptiBlue IOL, model ZFR00V 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.

CONTRAINDICATIONS: None.

IMPORTANT SAFETY INFORMATION: Routine cataract surgery risks, irrelevant to lens selection, could be minor, temporary, or affect patients' vision permanently. Rare complications are worsening of vision, bleeding, or infection. Discuss all risks and benefits with your eye doctor before surgery. If the patient's eye is unhealthy (including glaucoma), vision may not be good even after cataract removal; patients may not get full benefit of the TECNIS Sym*f*ony IOL. Before surgery, the eye doctor will check for any eye diseases. Patients' vision with the IOL may not be good enough to perform detailed 'up-close' work without glasses, and rarely, may make some types of retinal treatment (e.g., retinal tear repair) more difficult. You should avoid any activity that could harm your eye while you are recovering from surgery. Your doctor will tell you what activities to avoid while you are recovering from surgery. TECNIS Multifocal and TECNIS Symfony IOLs: Risks related to use of this lens include a slight loss in vision sharpness with decreased use of glasses. Even with glasses, loss of sharpness may worsen under poor visibility conditions such as dim light or fog. Patients may also notice halos, starbursts, glare, and other visual symptoms with extended range of vision and multifocal IOLs. This may lead to driving difficulties, and not detecting road hazards as quickly at night or in fog. This may impact patients when there are bright lights at night. Therefore, you may need to take extra care when driving, especially in poor light conditions. A small number of patients may want their TECNIS Sym*f*ony or TECNIS Multifocal IOL removed because of lens-related optical/visual symptoms. TECNIS Toric IOLs: 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 or could move within the eye. Your doctor may need to move the lens to the right position following surgery. If the Toric lens is not placed correctly, you may have visual distortions. A second surgery may be needed to properly position the lens. TECNIS Eyhance IOLs: 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.

SIDE EFFECTS: Side effects of cataract surgery with the TECNIS Family of 1-Piece 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 Eyhance™ IOL

Rx Only

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.

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