# Procedure Consent Form



### WHAT IS IDOSE TR?

iDose TR is a prescription medicine (prostaglandin analog) and drug delivery system for the eye approved to lower eye pressure in patients with open angle glaucoma or high eye pressure (ocular hypertension). iDose TR is gently implanted directly inside your eye and will release the drug slowly over time. iDose TR, when placed in the eye, can help lower pressure inside the eye by releasing an already approved drug called travoprost. This drug has been approved by the U.S. Food and Drug Administration (FDA).

### **IDOSE TR IS CONTRAINDICATED IN PATIENTS WITH:**

- An infection or suspected infection in your eye or the area surrounding your eye
- Corneal endothelial cell dystrophy, a condition in which the clear front layer of your eye (cornea) has lost its ability to work normally as this can cause vision problems
- · A corneal transplant or cells transplanted to the inner layer of the cornea (endothelial cell transplant)
- · Allergies to any of its ingredients
- Narrow angles (the iris and the cornea are too close together)

#### **RISKS:**

- The most common side effect of iDose TR was increased eye pressure. Other common side effects were inflammation of the iris, dry eye, a loss of part of the usual field of vision, eye pain, eye redness, and reduced clearness of vision.
- Dislocation of the iDose TR has been observed in clinical trials, you should inform your healthcare provider if you observe any changes.
- Macular edema (swelling of the retina), including cystoid macular edema, has been reported during treatment with ophthalmic travoprost, including iDose TR intracameral implant.
- There is a possibility of increased brown pigmentation of the iris, which may be permanent. Pigmentation has been observed with topical ophthalmic travoprost.
- iDose TR is MR Conditional (as noted on your Patient ID card). If you require magnetic resonance imaging (MRI), you should inform your healthcare provider that you have an iDose TR implanted in your eye.
- iDose TR may also have risks commonly associated with eye surgery in general, such as infection, blurred vision, or dry eye.
- Please see full Prescribing Information by visiting www.idosetr.com.
- You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You may also call Glaukos at 1-888-404-1644.

## **CONSENT:**

By signing, I am voluntarily consenting to have the iDose TR procedure performed on me. I acknowledge that my healthcare practitioner has recommended iDose TR for me and that the procedure and potential side effects have been fully explained to me. I also confirm that I have read the above, understand it, and that my questions have been answered satisfactorily by my healthcare practitioner. I accept the risks and complications of the procedure and I understand that no guarantees are implied as to the outcome of the procedure. I understand that any treatment performed is between me and my healthcare practitioner, and I will direct all post-operative questions or concerns to them. I confirm that I do not have any of the above contraindications of treatment, and that I will notify my healthcare practitioner immediately if I experience any side effects.

OD (right eye)

OS (left eye)

Patient/Authorized Person Signature Print Name Date

