If You Need **Cataract Surgery** and Have **Glaucoma**, The **iStent supra®** may be Right for You

A Prospective, Randomized, Single-Masked, Controlled, Parallel Groups, Multicenter Clinical Investigation of The **Glaukos® Suprachoroidal Stent** in Conjunction with Cataract Surgery
Talking Points

1. Eye Pressure
   - Glaucoma can permanently impair vision and ultimately cause blindness, if untreated
   - iStent supra is an investigational medical device that is permanently implanted and designed to work continuously to effectively control your eye pressure

2. The Device
   - Highlight the small size: it is one of the smallest medical devices known to be placed in the human body
     - To demonstrate the actual size of the device, please show patient the acrylic model.

3. How it works
   - iStent supra is inserted in the eye in a specific location where fluid flows out of the eye
   - Once it’s inserted, you will not be able to feel or see the device in the eye
   - The device provides a channel for fluid to move out of the front chamber of the eye
   - It can help restore the natural flow of fluid in the eye
   - Reducing the amount of fluid in the anterior chamber lowers pressures in the eye

4. Animation
   - Use the animation to demonstrate the entire iStent supra Procedure.
The Goal of iStent supra is to LOWER YOUR EYE PRESSURE

The Device

- iStent supra—one of the smallest medical devices ever designed

How It Works

- iStent supra provides a channel for fluid to move out of the front chamber of the eye
- Less fluid = lower pressure
Talking Points

Screening
Initial screening is conducted to make sure patients are qualified to participate in the study. The doctor or staff will advise you when to stop using your regular glaucoma medication(s). This will be done long enough to be able to measure the untreated eye pressure.

Baseline Evaluation
Eye pressure measurements will be taken over the course of a single day at

☐ 8 AM  ☐ 12 PM  ☐ 4 PM

Cataract Surgery
On the day of your procedure, you will come to the surgery center just as you would with a standard cataract surgery.
The procedure with the iStent supra only takes a few minutes longer than standard cataract surgery, and requires no additional sedation.
Your post-op recovery will be basically the same as cataract surgery, and you will return home later that day.

Follow Up Visits
To ensure that your glaucoma is being closely monitored, you will have periodic scheduled doctor visits throughout the Glaukos research study.

• Your study visit exams will only take approx. 1 hour and consists of a standard eye exam and glaucoma testing

• Months 6, 12, & 24 you will have your eye pressure taken the same way as your baseline visit ( 8 am, 12 pm, 4 pm)
Over the course of the study, you will receive exceptional medical care. We will make sure to get you in and out as quickly as possible.
Group Assignment

If you are participating in the study, you will be assigned into one of two groups.

- One group (3/4 of subjects) will receive the iStent *supra* after successful cataract surgery.

- The other group (1/4 of subjects) will receive cataract surgery, but not the iStent *supra*.

The groups are randomly assigned just after your cataract surgery is completed. The doctor and staff cannot influence, select, or predict your group assignment.

During the course of the study, you will not be informed which group you are in, but your doctor and staff will know.
Two Treatment Groups

**Group 1**
Cataract Surgery + iStent supra

**Group 2**
Cataract Surgery Only

Groups are randomly assigned – 3:1 ratio. You will not know which treatment group you are in for the 24 months of the study.
Cataract Surgery

- Cataract surgery is very common and usually very safe—almost 4 million cataract surgeries are performed each year in the US alone
- After the procedure, patients sometimes report a scratchy sensation in their eyes, slight redness, or pain
- If you experience any of these issues, we can help manage that with medication and/or eye drops

Note: It may help to talk about what you have seen or heard patients in your practice say after the procedure.

iStent supra

- This device is an investigational medical device
- Your doctor will go over all possible risks and discomforts so you can make an informed decision.
Potential Risks

Cataract Surgery
One of the most frequently performed procedures in the US
- Following surgery your eye may have a scratchy sensation and slight redness
- You may feel pain in the eye after surgery

iStent supra
Review the Informed Consent Form for an outline of potential complications associated with the study device

MRI
The iStent supra contains implant grade titanium. Therefore, if you are in the study and an MRI (Magnetic Resonance Imaging) is prescribed for you, please notify your study doctor before having it done.
The Study:
• Everything related to the study is completely free
• You will not be charged for study-related visits before or after surgery
• You will have NO out-of-pocket expenses for the study device or the study procedure

Payment for Participation
Everyone who qualifies to participate in the study will receive up to $1,000 over the 24 months of the study, as long as all study related visits are completed.

Other Considerations
Patients may also ask about the following:
• Travel
• Food prior to/during IOP checks

Costs of Participation

Cataract Surgery:
• The only costs for participation in the study will be for the cataract surgery itself
• The costs of the cataract surgery and medications are typically covered by insurance
• If your insurance coverage does not cover cataract surgery, or you select a premium lens option, you are responsible for those costs
Costs of Participation

Patient Expense:
- Cataract Surgery and Medication (typically covered by insurance)

No Cost:
- Study-related visits before and after surgery
- Study device
- Study procedure

Payment for Participation

Qualified participants will receive up to $1,000 over 24 months to compensate you for your time and inconvenience*

*All study related follow up visits must be kept to receive the full payment of $1,000
Ready to Enroll?

- If the study device is able to reduce pressure inside your eye, you may be able to:
  - reduce ocular hypotensive medications (eye drops)

OR

- stop taking your eye drops all together

- Plus, you’ll be helping test a glaucoma treatment that may help thousands of patients

Get Started

- Do you think you are interested in participating in the study?
- If so, I’ll let the doctor know to go over the procedure with you and explain the potential outcomes in greater detail
- We will schedule your initial screening appointment (or perform the screening for eligibility today)

Note: Have the folder ready with the brochure, FAQs, etc.
Ready to Enroll?

Get Started!
Let the practice staff know that you are interested in participation to be screened for study eligibility.