FIRST GLAUCOMA STENT FOR CATARACT SURGERY

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FDA approves first glaucoma stent for use with cataract surgery

Today, the iStent Trabecular Micro-Bypass Stent System, Model GTS100R/L, was approved by the U.S. Food and Drug Administration. This is the first device approved for use in combination with cataract surgery to reduce pressure inside the eye (intraocular pressure) in adult patients with mild or moderate open-angle glaucoma and a cataract who are currently being treated with medication to reduce intraocular pressure.

Glaucoma, a group of diseases that damage the optic nerve, is one of the leading causes of vision loss and blindness. Open-angle glaucoma is the most common form of glaucoma.

In a healthy eye, clear fluid flows continuously into and out of the anterior chamber of the eye, the fluid filled space between the iris and the cornea. Fluid drains from the anterior chamber through a meshwork of tissue along the outer edge of the iris, where the iris and cornea meet, and into a canal called Schlemm's canal that drains the fluid out of the eye.

In open-angle glaucoma, the meshwork may become blocked or drain too slowly. Since fluid cannot leave the eye or leave it quickly enough, pressure builds up inside the eye and can rise to a level that may damage the optic nerve, resulting in vision loss.

The iStent® is a small titanium tube placed through the meshwork of tissue. This creates an opening between the eye's anterior chamber and Schlemm's canal that allows fluid to drain, potentially decreasing intraocular pressure.

"The iStent® is a new option that may be considered in the treatment of open-angle glaucoma in patients needing cataract extraction," said Christy Foreman, director of the Office of Device Evaluation at FDA's Center for Devices and Radiological Health. "This option may be considered earlier in the disease process than some other types of surgical glaucoma treatments."

The FDA reviewed effectiveness data from a study total of 240 eyes for 239 participants (one participant had both eyes evaluated). The FDA also reviewed the safety data for these and an additional 50 participants. At one year following the procedure, 68 percent of participants with the iStent had the study target pressure of 21 millimeters of mercury or lower without the use of eye pressure-lowering medication, compared to 50 percent of participants who underwent cataract surgery alone.

Because the iStent® was implanted in combination with cataract surgery during the study, it was not possible to attribute all complications in theiStent® -implanted participants to just the cataract procedure or just the iStent® device. Among the participants who underwent surgery to implant the iStent®, the following complications were directly linked to the device: unsuccessful or difficulty implanting, poor positioning of the stent, the stent touching the iris or cornea during surgery, the device being dropped into the eye prior to implantation, and the stent becoming blocked after surgery.

The iStent® Trabecular Micro-Bypass Stent System is manufactured by Glaukos Corporation of Laguna Hills, Calif.

For more information:

- FDA: Medical Devices
- FDA: Device Approvals and Clearances

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.