UPDATE: Potential Eye Damage from Alcon CyPass Micro-Stent Used to Treat Open-Angle Glaucoma: FDA Safety Communication

Date Issued

October 24, 2018

Audience

- People who have a CyPass Micro-Stent to treat open-angle glaucoma during cataract surgery
- Eye care providers

Medical Specialties

Ophthalmology, Optometry

Device

Alcon's CyPass Micro-Stent is a small tube with tiny holes that is surgically placed (implanted) in the eye. The device is used to drain fluid that causes high eye pressure and vision loss in people with glaucoma. In 2016, the device was approved by the U.S. Food and Drug Administration (FDA) for use during cataract surgery to reduce eye pressure in adults with the most common type of glaucoma, open-angle glaucoma (https://nei.nih.gov/eyedata/glaucoma).

Purpose

The FDA is issuing this communication to provide additional information regarding corneal endothelial cell loss in patients who have received the Alcon CyPass Micro-Stent. This communication also contains updated recommendations to clinicians who care for patients implanted with the device as well as information related to its recall.

Summary of Problem and Scope

On August 29, 2018, Alcon announced an immediate, voluntary market withdrawal of the CyPass Micro-Stent from the global market. In addition, Alcon advised surgeons to immediately cease further implantation with the CyPass Micro-Stent and to return any unused devices to Alcon. This action was based on an analysis of five-year post-surgery data from the FDA-mandated post-approval safety study.

On September 14, 2018, the FDA issued a Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm620646.htm) to alert eye care providers and patients of the risk of damage to the cells lining the cornea of the eye in people who have the CyPass Micro-Stent implanted. The communication, based on preliminary review of longer-term data from an ongoing FDA-mandated post-approval study, cited concerns regarding significant endothelial cell loss and reductions in endothelial cell density (ECD), and provided preliminary recommendations. Since then, the FDA has received additional post-approval study data that confirm the recommendations made in September. Our review also supports the three new recommendations to eye care providers that we are adding in this update. Key findings from our review include:

- At five-year follow-up, 27.2 % (44/162) of implanted patients had more than 30% loss in endothelial cell density.
- Data suggests a correlation between the amount the CyPass device extends into the anterior chamber of the eye, assessed by the number of visible retention rings on the device, and the rate of endothelial cell loss. Of the patients that had ECD data at both two and five years after implantation, mean loss in ECD over this three-year period was 3.1% when 0 rings were visible (55 patients), 8.4% with one ring visible (65 patients), 21.0% with two rings visible (26 patients) and 31.4% with three rings visible (8 patients).
- Data on surgical intervention to trim CyPass devices that were identified to be in suboptimal position (that is, more than 2 retention rings visible) was very limited in the study. As a result, no conclusions could be made regarding the impact of trimming on endothelial cell loss progression.
- The five-year endothelial cell loss data suggest that the general rate of cell loss does not plateau at five years post-implant.

Recommendations for Eye Care Providers

- Do not implant CyPass Micro-Stents and return unused devices to Alcon. Call Alcon at 1-800-862-5266 for directions on how to return the device.
- All patients that have the CyPass device should be evaluated periodically for endothelial cell density using specular microscopy until the rate of loss stabilizes.
- Eye care providers should evaluate all patients with CyPass to assess device positioning by visualization of the number of retention rings visible on the proximal end of the device. Patients with two or more rings visible upon examination should be evaluated for endothelial cell loss as soon as possible.
- Based on the endothelial cell density levels, and other factors such as age and time post-implantation, the surgeon should determine if additional surgical interventions (that is, trimming, repositioning, removal) are appropriate.

Recommendations for Patients

- If you have a CyPass Micro-Stent implanted, you should make an appointment with your eye care provider as soon as possible. Your eye care provider will explain your options and help you decide what to do.

FDA Actions

Since our September 14, 2018 communication, the FDA has classified the firm's market withdrawal of the CyPass Micro-Stent as a Class I recall (/MedicalDevices/Safety/ListofRecalls/ucm624282.htm). Class I recalls represent a situation

where there is a reasonable chance that the product will cause serious health problems.

The FDA will review new information related to the Alcon CyPass Micro-Stent as it becomes available. In addition, the FDA continues to evaluate data related to the long-term loss of ECD being collected in post-approval studies for other minimally invasive glaucoma devices. The risk of endothelial cell loss after implant of a minimally invasive glaucoma device may depend on factors such as device design and site of implantation, and at the current time,data do not suggest a similar concern with other minimally invasive glaucoma products. The FDA will update the public as new information regarding the CyPass or other minimally invasive glaucoma devices warrants.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with this device, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home). Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Additional Resources

- Alcon Press Release (August 29, 2018) (https://www.novartis.com/news/media-releases/alcon-announces-voluntary-global-market-withdrawal-cypass-micro-stent-surgical-glaucoma)
- Alcon CyPass Micro-Stent Premarket Approval (PMA) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150037)
- CyPass Micro-Stent Patient Information Brochure (https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150037C.pdf)
- Alcon Dear Healthcare Professional Letter (https://www.alcon.com/sites/www.alcon.com/files/CyPass_US_Customer_Letter-8-29_Final.pdf)

Contact Information

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

2018 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)

2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)