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

Date Issued:

September 14, 2018

Audience:

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

Medical Specialties:

Ophthalmology, Optometry, Eye Surgery

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:

This notice is to alert eye care providers and patients of the risk of eye damage in people who have the device implanted. Based on information from a post-approval study required by the FDA, Alcon (the manufacturer) is collecting all unused devices (voluntary market withdrawal) and is asking physicians to stop implanting the device.

Summary of Problem and Scope:

People who have the CyPass device implanted are at risk of losing cells in the protective outer layer of the eye (cornea). Endothelial cells line the inner surface of the eye's cornea and are important in keeping vision clear. These cells do not regrow after they are damaged. Endothelial cell loss may be associated with damage to the cornea including swelling, cloudiness, eye pain, reduction in vision, and the potential need for corneal transplant.

The FDA's approval of the CyPass device in 2016 was supported by a randomized controlled clinical study in which patients who received the device after cataract surgery were compared to a set of patients who had cataract surgery without the device. At the time of approval, patients had been followed for two years and results showed that there was no clinically significant difference in corneal cell loss between the two groups.

Although the data showed a benefit after two years, the FDA recognized the potential for adverse effects appearing later. Because these potential adverse effects may appear later, the FDA required the manufacturer to conduct a post-approval study as a condition of their approval. The manufacturer had to follow patients enrolled in the original study through five years after surgery.

Initial review of the five-year data for patients from the post-approval study shows a concerning difference in the degree of corneal cell loss in patients who received the CyPass device compared to those who did not receive it. At five years, patients who have the device had less endothelial cell density than the control group. In addition, the preliminary review shows that significantly more patients who received the device had a reduction in endothelial cell density at five years compared to the control group.

As a result of these post-approval study findings, Alcon announced a voluntary market withdrawal of the device and is asking physicians to stop implantation immediately.

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.
- Review Alcon's recommendations for evaluating and managing CyPass Micro-Stents in patients who have already received the device, such as repositioning or trimming.
- At the current time it is not known how endothelial cell density loss might continue to progress more than five years after the original surgery, and what impact surgery to remove the device may have on further endothelial cell density loss.

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:

The FDA is working closely with Alcon to further evaluate the data associated with the concerns reported. We will communicate when more information becomes available.

The CyPass Micro-Stent is one of four minimally invasive glaucoma surgery devices approved by the FDA. The FDA has no information indicating similar long-term endothelial cell loss issues with other approved minimally invasive glaucoma surgery devices, but we continue to closely monitor the progress of ongoing post-approval studies for these devices. In addition, the FDA monitors medical device reports and reviews medical literature for reports on patient outcomes following minimally invasive glaucoma surgery device implantation.

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)**

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.

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