

Alcon Research, LTD. Recalls CyPass® Micro-Stent Systems Due to Risk of Endothelial Cell Loss

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product(s)

- CyPass® System 241-S, CYPASS® MICRO-STENT, CYPASS® LOADED, CYPASS® APPLIER
- CyPass® System 241, Intraocular Pressure Lowering Implant, CYPASS® MICRO-STENT, CYPASS® APPLIER
- CyPass® ULTRA SYSTEM, CYPASS® MICRO-STENT, CYPASS® APPLIER
- CyPass® System 241, Intraocular Pressure Lowering Implant, CYPASS® MICRO-STENT, CYPASS® APPLIER

Device Use

The CyPass® System is used in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild to moderate primary open-angle glaucoma. The primary users of this device are ophthalmologists.

The CyPass® Micro-Stent is a small tube with tiny holes that is surgically placed (implanted) in the eye. The CyPass® Micro-Stent, when implanted as directed, is designed to drain fluid from the anterior chamber of the eye that causes high eye pressure and vision loss in people with glaucoma.

Reason for Recall

On August 29, 2018, Alcon Research, LTD issued a [press release \(https://www.novartis.com/news/media-releases/alcon-announces-voluntary-global-market-withdrawal-cypass-micro-stent-surgical-glaucoma\)](https://www.novartis.com/news/media-releases/alcon-announces-voluntary-global-market-withdrawal-cypass-micro-stent-surgical-glaucoma) to announce a voluntary market withdrawal of the CyPass® Micro-Stent from the global market. The firm announced that the voluntary market withdrawal was based on five-year post-surgery data from the COMPASS-XT long-term safety study. The study demonstrated a clinically and statistically significant increase in corneal endothelial cell loss reported in the CyPass® Micro-Stent group compared to the cataract surgery-only control group.

Based on preliminary review of the data from the COMPASS-XT study, the FDA issued a [Safety Communication \(https://www.fda.gov/medical-devices/safety/alerts-and-notices/ucm620646.htm\)](https://www.fda.gov/medical-devices/safety/alerts-and-notices/ucm620646.htm), notifying physicians and patients of the risk of eye damage in people who the device implanted and recommendations for physicians to stop implanting the device.

Who May be Affected

- Patients who have a CyPass® Micro-Stent System
- Physicians who use the CyPass® Micro-Stent System to treat open-angle glaucoma during cataract surgery.

What to Do

Alcon Research, LTD. sent an [Urgent: Voluntary Medical Device Market Withdrawal letter \(https://www.alcon.com/sites/www.alcon.com/files/CyPass_US_Customer_Letter-8-29_Final.pdf\)](https://www.alcon.com/sites/www.alcon.com/files/CyPass_US_Customer_Letter-8-29_Final.pdf) dated August 29, 2018, to inform surgeons of the safety concern regarding endothelial cell loss. The letter provided the following recommendations about the CyPass® Micro-Stent System:

- Surgeons should immediately stop further implantation of the CyPass® Micro-Stent. The letter directed the users to identify and quarantine any unused CyPass® Micro-Stent devices and to return the unused devices to Alcon through Alcon Customer Service.
- All patients who were implanted with CyPass® Micro-Stent should be assessed for post-operative device positioning (via gonioscopy) and have periodic assessments of endothelial cell density performed using specular microscopy.

- Surgeons who are considering removal of the device after the immediate postoperative period (i.e., after 1 month postoperative) should consider less invasive intervention such as positional adjustment or trimming of the proximal end of the CyPass® Micro-Stent device as a first alternative to device removal. Alcon notes that there is limited clinical data on the effects trimming may have on endothelial cell loss. Surgeons should consider the risks of further endothelial cell trauma caused by trimming against the potential benefits of the procedure.

Additionally, the letter informed surgeons to forward the letter to all departments within the organization who may be in possession of any CyPass® Micro-Stent devices, all health care professionals involved in care of patients who have received the CyPass® Micro-Stent and any organizations to which these devices may have been transferred.

Contact Information

Customers who have questions about this recall should contact Alcon Research LTD's Customer Service line at 1-800-862-5266.

Date Recall Initiated

August 28, 2018

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)

(<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?>

[action=reporting.home](#)). Health care professionals employed by facilities that are subject to the [FDA's user facility reporting requirements](#)

(<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm>) should follow the reporting procedures established by their facilities.

[More in Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](#)

[2018 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm590900.htm\)](#)

[2017 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm535289.htm\)](#)

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](#)