Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

August 29, 2018

Dear Colleagues,

Today, Alcon announced an immediate, voluntary market withdrawal of all versions of the *CyPass® Micro-Stent* from the global market.

This market action is not related to a manufacturing or quality issue. Rather, we are undertaking this action based on an analysis of the completed dataset from the COMPASS-XT long-term safety study. That analysis showed that, over time, the *CyPass® Micro-Stent* group experienced statistically significant endothelial cell loss (ECL) compared to the group who underwent cataract surgery alone.

By way of background, the two-year COMPASS study that served as a basis for FDA approval of the *CyPass® Micro-Stent* included an evaluation of ECL. As noted in the *CyPass® Micro-Stent* instructions for use, at two years post-surgery there was little difference in ECL between the *CyPass® Micro-Stent* and cataract surgery-only groups, and results were consistent with peer-reviewed literature benchmarks of cataract-related ECL.

The COMPASS-XT study was designed to collect safety data on the subjects who participated in the COMPASS study for an additional three years, with analysis of the completed dataset at five years post-surgery. At five years, the *CyPass® Micro-Stent* group experienced statistically significant ECL compared to the group who underwent cataract surgery alone. Increased ECL was correlated with the *CyPass® Micro-Stent* position within the angle. Specifically, ECL increased in relation to the number of retention rings noted on clinical examination with gonioscopy, particularly when two or more retention rings were visible.

Based on this new information, we are advising surgeons to immediately cease further implants with the *CyPass® Micro-Stent* and to return any unused devices to Alcon. Our Quality group will be communicating directly with *CyPass® Micro-Stent* implanters with instructions for returning unused devices, and recommendations for evaluating and managing those patients who have already received a *CyPass® Micro-Stent*.

Although we are removing the product from the market now out of an abundance of caution, we intend to partner with the FDA and other regulators to explore labeling changes that would support the reintroduction of the *CyPass® Micro-Stent* in the future.

We recognize the inconvenience this causes you, your staff and your patients. However, we believe that this is the right thing to do based on the available data, and that this action is a reflection of Alcon's uncompromising commitment to patient safety.

Please contact the following Alcon departments if you have questions about this communication, or if you would like to report product complaints or adverse events:

Customer Service	1-800-268-4574	*for assistance with product returns*
Medical Information	1-800-613-2245	*for medical information about the CyPass® Micro-Stent*
Medical Safety	1-800-613-2245	*to report product complaints or adverse events*

Kind regards,

Stephen S. Lane, MD
Chief Medical Officer