inSight

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Market Withdrawl of Alcon CyPass® Micro-Stents

Minimally invasive glaucoma surgery (MIGS) has revolutionized the treatment of glaucoma. Surgical intervention has now become possible early in the course of the disease with less side effects. More and more patients have been able to get off their glaucoma drops without the risk associated with traditional filtering surgery.
However, progress often comes with setbacks:

A publication by the Veterans Health Administration's National Center for Patient Safety stated that Alcon decided to withdraw all versions of the Alcon CyPass® Micro-Stent (Reference 1and Figure 1) from the global market. CyPass® Micro-Stents were approved by the FDA in 2016 and have been implanted in patients' eyes for the treatment of open-angle glaucoma. The CyPass® Micro-Stents have been withdrawn from the market based on analysis of an FDA-mandated post-approval study (COMPASS-XT long-term safety study). This analysis demonstrated that patients with CyPass® Micro-Stents had a statistically significant greater loss of corneal endothelial cells at five years post-implant compared to the control group that underwent cataract surgery without implantation of CyPass® Micro-Stents. The position of the implant seems to matter. If no or just one retention ring was visible on gonioscopy, the endothelial cell loss was not greater than in the control group (Figure 1). If two or more retention rings were visible the endothelial cell loss was significantly greater (Figure 2).

It is recommended to perform specular microscopy to calculate the baseline endothelial cell density and then to follow the patient at least annually. If there is a decline in endothelial cells the shunt should be adjusted, that is trimmed with intraocular scissors.
Given the potential serious risks and complications however, explantation of the CyPass® Micro-Stents is not recommended.

Ophthalmologists considering stent adjustment should review the information in the CyPass® Micro-Stent Instructions for Use (Reference 2) and the ASCRS preliminary guidance for monitoring and treatment (Reference 3).

REFERENCES

1. FDA Safety Communication https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm620646.htm
2. Alcon CyPass® Micro-Stent Instructions for Use https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150037D.pdf
3. Preliminary ASCRS CyPass® Withdrawal Consensus Statement http://ascrs.org/CyPass_Statement

Figure 1: CyPass® Micro-Stent

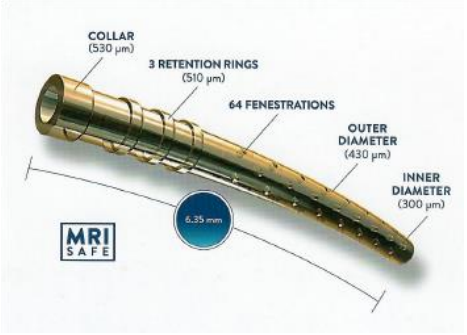
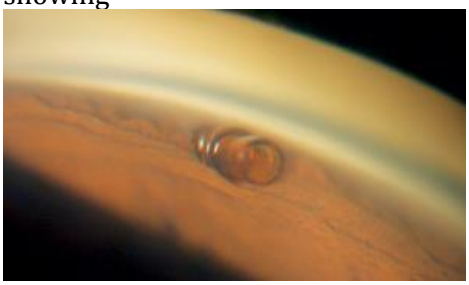


Figure 2: Two retention rings showing



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