Veterans Health Administration

Patient Safety Notice

Issued by VHA National Center for Patient Safety

N19-01 **October 04, 2018**

ITEM:
Market withdrawal of Alcon CyPass® Micro-Stents

AFFECTED PRODUCT:
All versions of the Alcon CyPass® Micro-Stent

GENERAL INFORMATION:
The National Center for Patient Safety (NCPS) received information from the Food and Drug Administration (FDA) and Alcon regarding a global market withdrawal of all versions of the Alcon CyPass® Micro-Stent (Reference 1). 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 devices have been implanted for several years, including during pre-market trials. The market withdrawal was posted to the NCPS Alerts and Recalls Web site as PRO-13430 on August 29, 2018. This posting required VHA facilities to remove all CyPass® Micro-Stents from inventory to prevent further implantation of the device. This Patient Safety Notice contains actions, developed through collaboration with the VHA National Surgery Office, the VHA Ophthalmology Service, and Alcon, for the care of VHA patients who have implanted CyPass® Micro-Stents.

The CyPass® Micro-Stents have been withdrawn from the market based on analysis of an FDA-mandated post-approval study (COMPASS-XT long-term safety study).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. An increase in endothelial cell loss may lead to damage of the cornea including swelling, cloudiness, eye pain, reduction in vision, and the potential need for corneal transplant. It is not known how endothelial cell loss might continue to progress more than five years after the original surgery or what impact surgery to remove the device may have on further endothelial cell density loss. Given the potential serious risks and complications, explant of the CyPass® Micro-Stents is not recommended.

ACTIONS:
1. By Close of Business (COB) October 12, 2018, the **Patient Safety Manager** shall contact the Ophthalmology Service (or other eye care providers if the facility does not have an

Ophthalmology Service) to identify if the facility has ever implanted Alcon CyPass® Micro-Stents or if the facility is following patients with these implants. Facilities that have not used this device - and are also not following patients with this implant - may mark this Notice as "Not Applicable."

2. By COB December 14, 2018, the **Chief of Staff** should review and ensure the following actions are implemented by Ophthalmologists (or other eye care providers if the facility does not have an Ophthalmology Service):

    - Immediately cease further implantation of CyPass® Micro-Stents and ensure the return of any unused devices to Alcon, per the instructions provided on the VHA Alerts and Recalls Web Site (PRO-13430).

    - Identify all of the facility's patients with implanted CyPass® Micro-Stents, whether implanted at the facility or elsewhere.

    - Review Alcon's recommendations in their Instructions for Use (Reference 2) for evaluating and managing CyPass® Micro-Stents in patients who have already received the device (e.g., repositioning or trimming). Preliminary guidance from the American Society of Cataract and Refractive Surgery (ASCRS) regarding monitoring and treatment options should be reviewed as well (Reference 3).

    - Ensure affected patients are contacted and scheduled to receive post-operative gonioscopy to assess CyPass® Micro-Stent position, if not completed already.

      NOTE: When contacting patients, all communication should begin with a clear description of the market withdrawal of the CyPass® Micro-Stents by the company and the recommendation for clinical follow-up as the reason for the request to schedule an appointment (clinical disclosure). Any additional guidance regarding notification to any patients that may have been affected by this issue (beyond clinical disclosure) is outside of the scope of this Patient Safety Notice. If VHA Central Office (VHACO) determines additional patient notification is necessary, guidance will be provided in a separate communication.

    - Consider follow-up gonioscopy to reassess CyPass® Micro-Stent position based on patient characteristics such as time since implantation, patient assessment, cornea endothelial cell density, and clinical need. Patients should continue to be followed by their eye care provider(s) at appropriate intervals.

NOTE: Explant of the CyPass® Micro-Stents is not recommended. Ophthalmologists considering stent adjustment or removal 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). It is highly recommended that surgeons consult Alcon at 1-800-757-9785 prior to removing an implanted CyPass® Micro-Stent. If a CyPass® Micro-Stent is explanted from a patient, the device must be retained by the facility and not returned to Alcon.

- Consider conducting periodic assessments of implant patients (e.g., annually) for endothelial cell density using specular microscopy.

3. By COB December 21, 2018, the **Patient Safety Manager** must document on the VHA Alerts and Recalls Web site (http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html) that medical center leadership has reviewed and acknowledged these recommendations. Facilities that did not utilize Alcon CyPass® Micro-Stents and do not follow patients with the implants may mark this Notice as "not applicable," including their justification.

   NOTE: When closing out this Patient Safety Notice on the VHA Alerts and Recalls Web site, it is recommended that facilities enter the total number of patients identified in Action 2 into the "estimated number of patients affected per month" field.

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

CONTACTS:

This Notice is intended to confirm awareness of this issue, share recommendations from VHA Central Office (VHACO), and learn from VHA facilities what additional problems and solutions exist for this device. If you have questions about this Notice, would like to inform us of additional issues, or have solutions that might be useful for other VHA facilities, please contact:

Dr. Bruce McIntosh, NCPS, at VHANCPSHFEREVIEW@VA.GOV or 734-930-5890

National Surgery Office at vhaco.national.surgery.office@va.gov or 202-461-7130