Alcon A Novartis Division

URGENT: VOLUNTARY FIELD SAFETY NOTICE

Commercial Name of Affected Product: **CyPass® Micro-Stent**
Reference(s): **241, 261**
FSCA Identifier: **2018.017-CORP**
Type of Action: **Voluntary Field Safety Corrective Action**

September 4, 2018

Dear Healthcare Professional,

This letter serves to advise you that Alcon has initiated a voluntary Field Safety Corrective Action (withdrawal) with respect to all models of the CyPass® Micro-Stent. In addition, Alcon is recommending that surgeons immediately cease further implantation of the CyPass® Micro-Stent, and return unused devices to Alcon.

This Field Safety Corrective Action is not related to a manufacturing or quality issue. Rather, this Field Safety Corrective Action is based on an analysis of the completed dataset from the COMPASS-XT long-term safety study. The analysis showed that the CyPass® Micro-Stent group experienced statistically significant endothelial cell loss (ECL) compared to the group who underwent cataract surgery alone.

Alcon has notified the Danish Health Authority of this voluntary Field Safety Corrective Action.

Description of the Potential Condition:

The two-year COMPASS study, that served as a basis for regulatory approval of the CyPass® Micro-Stent, included an evaluation of ECL. 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. For convenience, a copy of the IFU for the CyPass® IFU for market is included with this letter.

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 post-surgery, the CyPass® Micro-Stent group experienced statistically significant ECL compared to the group who underwent cataract surgery alone.

The CyPass® Micro-Stent features three retention rings and a proximal collar, as shown in Figure 1, below. Increased ECL was correlated with the CyPass® Micro-Stent position within the angle, with ECL increasing in relation to the number of retention rings noted on clinical examination with gonioscopy, particularly with two or more retention rings visible.

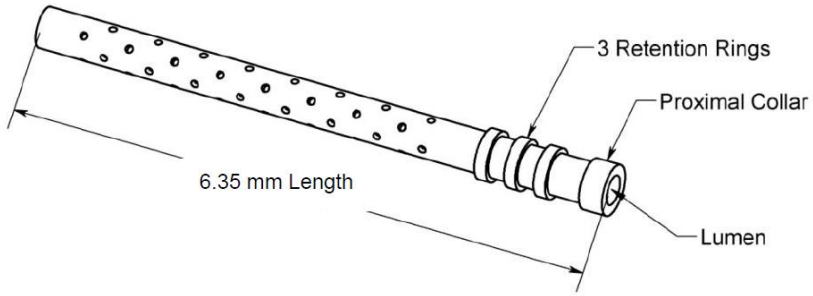

Figure 1: CyPass Micro-Stent

A healthy corneal endothelium is responsible for corneal clarity, which is necessary for good vision. Endothelial cells do not replicate, and when they are traumatized they are permanently lost. When the number of cells remaining goes below a critical threshold corneal edema (swelling) ensues. Corneal decompensation frequently follows, leading to loss of corneal clarity and a subsequent decline in vision. Treatment to regain corneal clarity often requires a corneal transplant.

Actions to be taken by the Customer / User:

1. *Cease Further Implants*

   Alcon advises surgeons to immediately cease implanting the CyPass® Micro-Stent.

2. *Locate and Return All Unused CyPass® Micro-Stent Devices*

   To assist in this voluntary market withdrawal and the return of any unused CyPass® Micro-Stent devices, please take the following steps:

   a. Review your inventory to determine if you have any unused CyPass® Micro-Stent devices.
   b. Quarantine any unused CyPass® Micro-Stent devices.
   c. Contact Alcon Customer Service at order.alcondk@alcon.com to arrange for the return of your inventory.
   d. Fill out the attached Response Form, even if you have zero units remaining in inventory.

e. Return the Response Form via fax or email to Alcon, using the contact information on the Response Form.

3. *Evaluating and Managing Patients Implanted with the CyPass® Micro-Stent*

Based on information currently available, surgeons should consider the following recommendations for evaluating and managing patients who have been implanted with the CyPass® Micro-Stent:

a. Alcon recommends that all patients who have been implanted with a CyPass® Micro-Stent undergo:

   i. post-operative gonioscopy (if not performed previously) to assess CyPass® Micro-Stent position; and
   ii. periodic assessments of endothelial cell density using specular microscopy.

b. Surgeons who are considering stent adjustment or removal should review the information in the CyPass® Micro-Stent instructions for use.
Healing response and progressive engagement of implant retention features must be factored into the decision to remove the CyPass® Micro-Stent after the immediate postoperative period (i.e., after 1 month postoperative). Surgeons should consider less invasive intervention such as positional adjustment or trimming of the CyPass® Micro-Stent proximal end as a first alternative to device removal. It is highly recommended that surgeons consult Alcon Medical Affairs at ulrika.sverkersten@alcon.com prior to device removal.

c. After the immediate postoperative period, trimming of the proximal end of the CyPass® Micro-Stent may be considered when the anterior position of the stent appears likely to compromise corneal endothelial health.

   There is limited clinical data on the effects trimming may have on ECL. Surgeons should consider the risks of further endothelial cell trauma caused by the trimming procedure against the potential benefits of the procedure. A procedure for stent trimming is set out in the CyPass® Micro-Stent IFU.

Further Distribution of this Voluntary Market Withdrawal Notice:

Please forward this information to:

- all departments within your organization who may be in possession of any CyPass® Micro-Stent devices;
- all healthcare professionals involved in the care of patients who have been implanted with a CyPass® Micro-Stent; and
- any other organization to which these devices may have been transferred.

Contact for Further Questions About this Voluntary Market Withdrawal Notice:

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

Customer Service	order.alcondk@alcon.com	*for assistance with product returns*
Medical Affairs	ulrika.sverkersten@alcon.com	*for medical information about the CyPass® Micro-Stent*
Medical Safety	complaints.nordic@alcon.com	*to report product complaints or adverse events*

We recognize the inconvenience this causes you, your staff and your patients. However, Alcon believes that this is an appropriate action to take based on the available data, and reflects Alcon's uncompromising commitment to patient safety.

Sincerely,

Thomas Gade
Quality Officer
Alvon Nordic
Edvard Thomsens Vej 14
DK-2300 Copenhagen S

Alcon A Novartis Division

RESPONSE FORM

CyPass® Micro-Stent
MA# 2018.-017- CORP

Affected Product:

Product	Lot Number	Quantity to be Returned
CyPass® Micro-Stent Models 241, 241S, 261		

Please follow these important steps:

1. Review your inventory to determine if you have any unused CyPass® Micro-Stent devices.
2. Quarantine any unused CyPass® Micro-Stent devices.
3. Contact Alcon Customer Service at order.alcondk@alcon.com to arrange for the return of your inventory.
4. Fill out this Response Form, even if you have zero units in inventory.
5. Return this Response Form via fax or email to Alcon, using the following contact information:

Email: Nordic, QA (Gen) <qa.nordic@alcon.com>

Your signature below attests that you have read and understood the information in this notice, including (i) the request that you immediately cease further implants of the CyPass® Micro-Stent; (ii) the request that you return unused CyPass® Micro-Stent devices to Alcon; and (iii) the recommendations for evaluating and managing patients who have been implanted with the CyPass® Micro-Stent.

Signature:

Printed Name:

Title:

Date: