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URGENT: VOLUNTARY FIELD SAFETY NOTICE

Commercial Name of Affected Product: **CyPass® Micro-Stent**
Reference(s): **241 (8065754001)**
FSCA Identifier: **2018.017-CORP**
Type of Action: **Voluntary Field Safety Corrective Action**

29th August 2018

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»
«Contact_Name»

Attention <<Enter Customer Information>>:

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 Health Products Regulatory 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® Micro-Stent System 241 IFU 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.

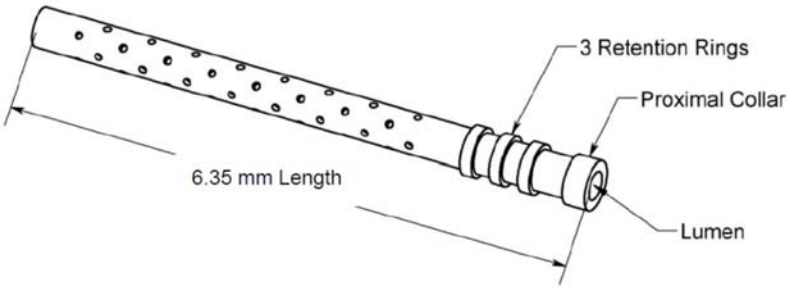


Figure 1: CyPass Micro-Stent

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 using the below contact details to arrange for the return of your inventory.

Tel: +353 214865194 **E-mail:** irl.customerservice@alcon.com

d. Fill out the attached Response Form, even if you have zero units remaining in inventory.
e. Return the Response Form via 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 Information using the below contact details prior to device removal.

   Tel: +44 345 266 9363 **Email:** gb.medicaldepartment@alcon.com

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	Tel: +353 21 486 5194 E-mail: irl.customerservice@alcon.com	*for assistance with product returns*
Medical Information	Tel: +44 345 266 9363 Email: gb.medicaldepartment@alcon.com	*for medical information about the CyPass® Micro-Stent*
Medical Safety	Tel: +44 371 376 1402 E-mail: gb.adr@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,

James Comper
Head of Regulatory Affairs UK and Ireland

RESPONSE FORM

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

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»
«Contact_Name»

Affected Product:

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

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 using the below contact details to arrange for the return of your inventory.
   Tel: +353 21 486 5194 **E-mail:** gb.customerservice@alcon.com
4. Fill out this Response Form, even if you have zero units in inventory.
5. Return this Response Form via email to Alcon, using the following contact information:
   Email: gb.medicaldepartment@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:

INSTRUCTIONS FOR USE

CyPass® system 241

A. DEVICE DESCRIPTION

The CyPass® system consists of the CyPass® Micro-Stent, which is contained in a loading device (loader), and the CyPass® applier.
The CyPass® Micro-Stent (Figure 1) is a polyimide tube with a fenestrated lumen. The stent has a single piece design and is 0.25" (6.35 mm) long. The inner diameter of the stent is 0.012" (0.30 mm) and the outer diameter is 0.017" (0.43 mm). The CyPass® Micro-Stent is designed for placement in the angle of the eye, with the proximal end extending from the angle into the anterior chamber (AC) and the distal end residing in the supraciliary space.

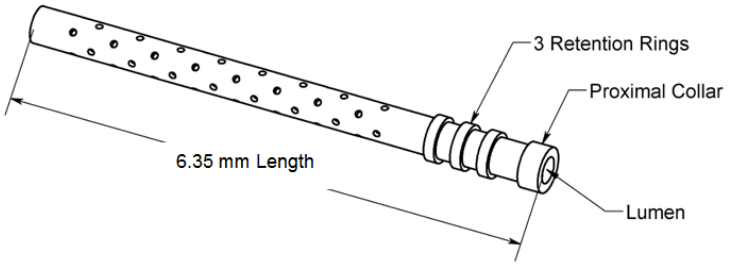


Figure 1: CyPass® Micro-Stent

When properly implanted, the CyPass® Micro-Stent is intended to allow outflow of aqueous fluid from the AC, where the device proximal end resides, through and around the fenestrated lumen and distal end of the tube into the supraciliary and suprachoroidal space via the uveoscleral pathway.
The CyPass® applier (Figure 2) is the hand-held surgical instrument used to implant the CyPass® Micro-Stent. The applier consists of a medical-grade polymer handpiece with a guidewire assembly. The guidewire assembly includes a Nitinol implant delivery guidewire extending from inside the handpiece through and beyond the distal end of a stainless steel tube (guidewire tube) that supports the guidewire. The guidewire is 0.011" (0.28 mm) in diameter and formed with a 0.48" (12 mm) radius of distal curvature and a blunt distal tip to facilitate location and blunt dissection of the plane between the ciliary body and sclera. The CyPass® applier delivers the CyPass® Micro-Stent to the desired location within the eye.

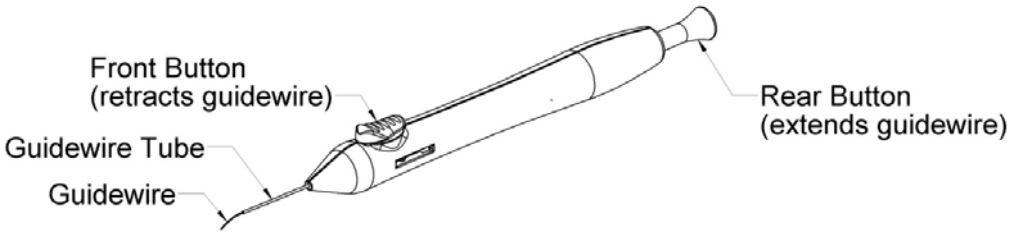


Figure 2: CyPass® applier with Guidewire Extended

The CyPass® Micro-Stent is loaded onto the guidewire before insertion into the eye (Figure 4). Once the guidewire has positioned the CyPass® Micro-Stent at the desired location within the eye, the implant is released from the guidewire using the front button on the CyPass® applier. This action withdraws the guidewire back into the guidewire tube, leaving the CyPass® Micro-Stent in position in the eye.

B. INDICATIONS

The CyPass® system is intended:

- For use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma
- For use in conjunction with cataract surgery or in a standalone procedure for the reduction of IOP in adult patients with primary open-angle glaucoma where previous medical treatments have failed

C. CONTRAINDICATIONS

Use of the CyPass® Micro-Stent is contraindicated under the following circumstances or conditions:

1. In children
2. In eyes with angle closure glaucoma
3. In eyes with traumatic, malignant, uveitic or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle.
4. In patients with known intolerance or hypersensitivity to topical anesthetics, miotics, mydriatics, or polyimide.

D. WARNINGS

1. Since implantation is performed under direct gonioscopy, clear media for adequate gonio visualization is required. The following conditions may prohibit sufficient visualization of the angle required for safe and successful implantation of the CyPass® Micro-Stent: corneal haze, corneal opacity or any other conditions that may inhibit gonioscopic view in the intended implant location.
2. The surgeon should perform gonioscopy prior to surgery to exclude congenital anomalies of the angle, peripheral anterior synechiae (PAS), angle closure, rubeosis and any other angle abnormalities that could lead to improper placement of the stent and pose a hazard.
3. The surgeon should monitor the patient postoperatively for proper maintenance of IOP. If IOP is not adequately maintained after surgery, the surgeon should consider appropriate additional therapy to maintain target IOP.
4. Caution is indicated in eyes with evidence of corneal compromise (e.g., corneal guttae or low endothelial cell density) and in eyes with risk factors for corneal compromise following cataract surgery (e.g., advanced age, severe nuclear sclerosis).
5. Do not re-use. The CyPass® Micro-Stent, applier, and loader are for single use only.
6. Do not re-sterilize.

E. PRECAUTIONS

1. The safety and effectiveness of the CyPass® Micro-Stent has not been established as an alternative to the primary treatment of glaucoma with medications.
2. The safety and effectiveness of the CyPass® Micro-Stent has not been established in patients with the following circumstances or conditions:
    - In eyes with significant prior trauma
    - In eyes with abnormal anterior segment
    - In eyes with chronic inflammation
    - In eyes with glaucoma associated with vascular disorders
    - In eyes with uveitic glaucoma
    - In eyes with pseudoexfoliative or pigmentary glaucoma
    - In eyes with other secondary open angle glaucomas
    - In eyes that have undergone prior incisional glaucoma surgery
    - In the setting of complicated cataract surgery with iatrogenic injury to the anterior or posterior segment
3. The safety and effectiveness of use of more than a single CyPass® Micro-Stent has not been established.
4. Adverse Reactions
   Potential intraoperative adverse effects may include, but are not limited to: choroidal detachment, choroidal hemorrhage or effusion, difficulty with CyPass® Micro-Stent implantation, hyphema obscuring the surgeon's view, inability to implant the CyPass® Micro-Stent, inadvertent perforation of sclera, loss of vitreous not associated with the cataract procedure, posterior capsular rupture with or without vitreousloss resulting from cataract surgery, significant corneal damage, significant iris injury or trauma, and zonular dialysis.
   Potential postoperative adverse effects may include, but are not limited to: AC cell and flare requiring either extension of the standard postoperative steroid regimen or re-initiation of steroids after steroid regimen completion; AC flattening with lens/cornea touch; AC shallowing with iridocorneal apposition; atrophy/phthisis; choroidal hemorrhage or effusion; chronic pain in the implanted eye; corneal edema; corneal opacification; corneal decompensation; CyPass® Micro-Stent malposition, dislodgement or movement; CyPass® Micro-Stent obstruction; elevated IOP requiring treatment with oral or intravenous medications or with surgical intervention; endophthalmitis; hypotonic maculopathy; increase in C:D ratio; loss of best-corrected visual acuity (BCVA);

persistent significant foreign body sensation; persistent hyphema; persistent hypotony; maculopathy; retinal complications (dialysis, flap tears, retinal detachment or proliferative vitreoretinopathy); significant ptosis; worsening in visual field loss; wound dehiscence (persistent aqueous leak or fistula formation) unplanned secondary ocular surgical intervention, including, but not limited to, glaucoma surgery, surgery to correct CyPass® device positioning, surgery to occlude CyPass® lumen and surgery to explant CyPass®.

F. DIRECTIONS FOR USE

CyPass® Micro-Stent Implantation

As with all new procedures, there is a learning curve associated with this procedure. Outcomes can be affected by the surgeon's level of experience. Surgeons must be adequately trained in this procedure prior to use of the CyPass® system.

The implantation procedure is performed as follows. In the case of implantation in conjunction with cataract surgery, the following steps should be performed after completion of cataract extraction and intraocular lens implantation.

1. Instill a miotic agent to constrict the pupil.
2. Tilt the microscope approximately 35 - 45° towards the surgeon and rotate the patient's head approximately 10° away from the surgeon to facilitate direct visualization of the anterior angle.
3. Verify the AC angle is open.
4. Open the tray containing the CyPass® system onto a sterile field. DO NOT USE either the CyPass® Micro-Stent or the CyPass® applier if the packaging has been opened or damaged.
5. Remove the CyPass® applier from the sterile tray and examine its condition. First, press the rear button on the handle and verify the guidewire extends from the guidewire tube. Then, press the front button on the handle and confirm the guidewire fully retracts into the guidewire tube.
6. Remove the loader containing the CyPass® Micro-Stent (Figure 3) from the sterile tray.

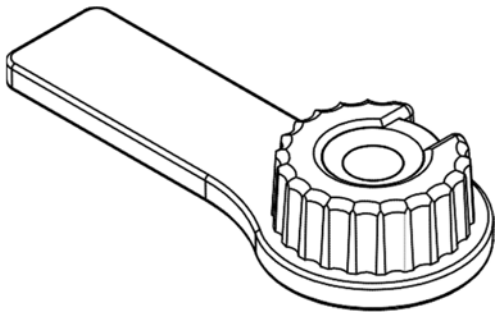


Figure 3: CyPass® Micro-Stent is packaged in the loader

7. Rotate the cap of the loader clockwise until the opening is aligned with the CyPass® Micro-Stent.
8. Confirm the CyPass® applier guidewire is fully retracted into the guidewire tube.
9. Push the distal tip of the guidewire tube into the loader until it contacts the CyPass® Micro-Stent and stops. Push the applier rear button to extend the guidewire into the Micro-Stent. Remove the CyPass® applier with loaded CyPass® Micro-Stent.
10. Examine the assembly. Confirm the condition of the CyPass® Micro-Stent and that the guidewire is fully exposed at the distal end (Figure 4). If either the CyPass® Micro-Stent or the CyPass® applier guidewire is damaged, DO NOT USE and contact Alcon.

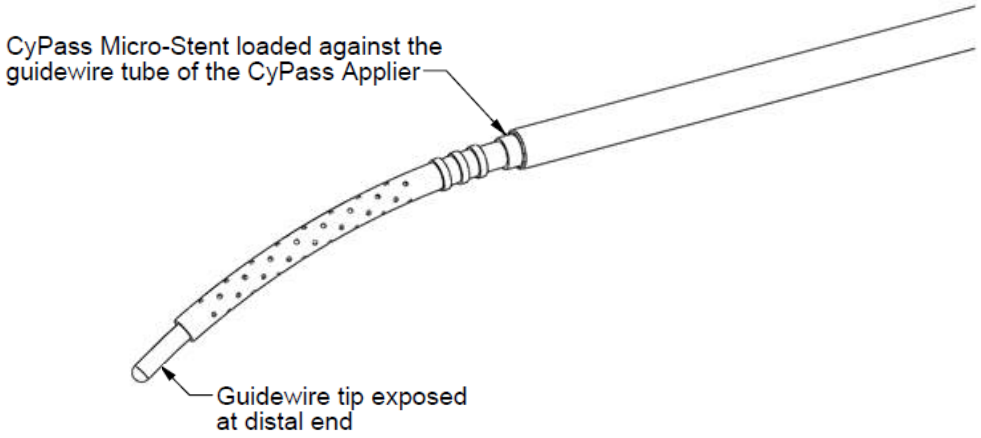


Figure 4: CyPass® Micro-Stent loaded onto CyPass® applier guidewire

11. Examine the AC and the angle under the microscope. Take note of angle anatomy and configuration to identify the best implantation site. Avoiding the area of the anterior ciliary arteries at 3, 6, 9 and 12 o'clock may help reduce the possibility of significant bleeding.
12. When implanted as a standalone procedure, create a minimum 1.5 mm corneal incision opposite the intended site of implantation.
13. Fill the AC with ophthalmic viscoelastic and use additional viscoelastic as necessary to maintain a deep, stable AC during the CyPass® Micro-Stent implantation process. (Only sodium hyaluronate, methylcellulose, and chondroitin sulfate ophthalmic viscoelastics have been used in clinical studies of CyPass®).
14. Introduce the loaded CyPass® applier guidewire tube through the corneal incision and advance towards the intended site of implantation until the guidewire tube and sleeve have cleared the corneal incision. When CyPass® is implanted in conjunction with cataract surgery, the cataract incision should be used. When crossing the AC, rotate the CyPass® applier guidewire such that its curvature is parallel to the iris plane. Take particular care not to cross over the center of the pupil and the visual axis to avoid touching the lens.
15. Position the CyPass® applier guidewire radially toward the scleral spur/ciliary body interface. Care should be taken to align the curvature of the CyPass® on the guidewire with the curvature of the sclera bordering the supraciliary space to reduce the possibility of encountering resistance during insertion. To gain access, place the distal end of the guidewire at the scleral spur/ciliary body interface and smoothly advance the guidewire through the tissue plane between the ciliary body and the adjacent sclera to separate the ciliary body from the sclera at the point of implantation.
16. Continue to advance the guidewire until only the most proximal retention ring and the collar of the CyPass® Micro-Stent are located in the AC (Figure 5). An additional confirmatory placement landmark is when the top of the CyPass® Micro-Stent collar is even with Schwalbe's line. In this position, the distal tip of the Micro-Stent should be resting against the sclera in the supraciliary space anterior to both retinal and choroidal tissues.

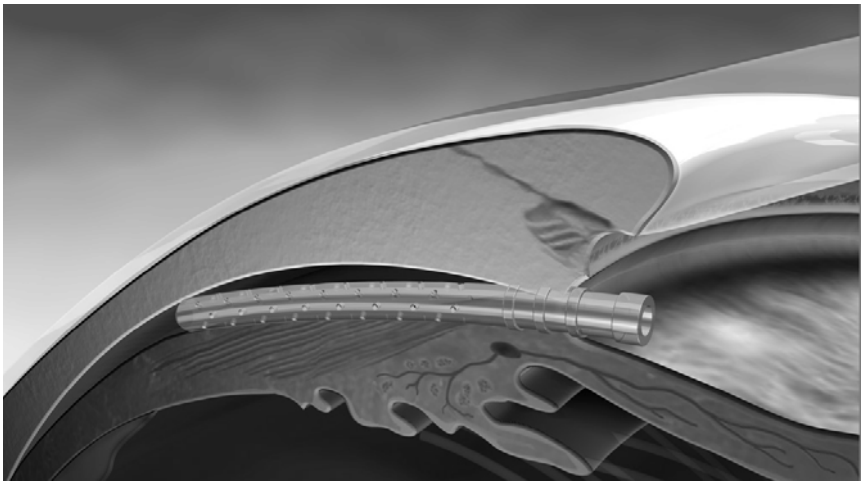


Figure 5: CyPass® Micro-Stent at Implant Site

17. If resistance is encountered or adequate implantation is not achieved at the initial implant site, implantation at a location at least 2 clock hours away from any area of ciliary body disinsertion can be considered if there is no significant iris trauma, the CyPass® Micro-Stent remains properly positioned on the guidewire and adequate hemostasis and visualization can be maintained. Make sure that the position of the patient's head and the tilt of the microscope allow adequate gonioscopic visualization of the angle structures. Increase magnification and fine focus the microscope as needed. Additional viscoelastic tamponade may be needed to assure hemostasis and maintain visibility during CyPass® Micro-Stent implantation. Align the curvature of the CyPass® on the guidewire with the curvature of the sclera bordering the supraciliary space to reduce the possibility of encountering resistance during insertion.
18. Hold the CyPass® applier stationary and carefully press the front button on the CyPass® applier to allow the guidewire to completely retract into the guidewire tube, leaving the Micro-Stent anchored between the sclera and ciliary body.
19. Remove the CyPass® applier from the eye.
20. Termination of the procedure should be considered after 2 failed attempts at device placement or if adequate visibility cannot be maintained during implantation.
21. Use gonioscopy to confirm CyPass® Micro-Stent position. Optimal position of the CyPass® Micro-Stent is when only the collar and the first retention ring are visible in the AC. Anterior positioning with more than 2 retention rings visible in the AC can be associated with corneal endothelial cell loss. Posterior positioning such that the collar is not visible can be associated with reduced device effectiveness.
    a. If the CyPass® Micro-Stent appears to be too anterior, use the guidewire tube of the applier to gently push the device deeper into the supraciliary space until it is optimally positioned. If the proximal end of the CyPass® Micro-Stent appears to be too posterior, use a micro-forceps to grasp the CyPass® Micro-Stent collar and gently pull it into the AC until it is optimally positioned. DO NOT USE the irrigation/aspiration (I/A) tip for Micro-Stent positioning.
    b. If proper placement cannot be achieved, implant removal should be considered. Use direct gonioscopy visualization and supplementary viscoelastic for safe removal.
22. Since retained viscoelastic can lead to elevated IOP in the early postoperative period, irrigate and aspirate viscoelastic from the AC, taking care to avoid I/A tip proximity to the CyPass® Micro-Stent.
23. Because the flow of irrigation fluid near the Micro-Stent may cause implant movement, after completion of I/A, verify CyPass® Micro-Stent location and confirm the absence of CyPass® Micro-Stent lumen obstruction.
24. Confirm that the surgical incision is sealed by either pressure challenge testing or Seidel testing. Use a suture or ocular sealant for closure, if needed.

Postoperative Instructions

Manage patients postoperatively for IOP changes that may occur in the early postoperative period as a possible sequelae following intraocular surgery in patients with glaucoma.

Perform gonioscopy to assess CyPass® Micro-Stent position postoperatively. Anterior positioning of the CyPass® Micro-Stent such that more than 2 retention rings are visible in the AC may result in reduced endothelial cell density

and a need for secondary surgical intervention (e.g., device repositioning, device trimming, or device removal). If the CyPass® Micro-Stent is close to the corneal endothelium, consider early (e.g., within 1 month postoperative) repositioning or removal of the CyPass® Micro-Stent and closely monitor corneal status.
If ciliary body edema is suspected due to forward movement of the ciliary body-lens diaphragm, ultrasound biomicroscopy (UBM) may be a useful adjunctive diagnostic aid in the evaluation of the ciliary body and suprachoroidal space.

Postoperative CyPass® Adjustment or Removal
Situations that may merit consideration of CyPass® Micro-Stent position adjustment or removal include, but are not limited to: contact between the CyPass® Micro-Stent and the corneal endothelium; significant decrease in endothelial cell density that appears related to CyPass® Micro-Stent positioning or stability; iris-cornea touch; persistent hypotony; persistent uncontrolled uveitis; recurrent or persistent hyphema with IOP elevation above target pressure; or any anatomic or functional clinical sequelae of the anterior or posterior segment that may cause a threat to vision. Variations in gonioscopic visualization or other alterations in angle anatomy may be interpreted as micro-movement of the CyPass® Micro-Stent; however, in the absence of clinical sequelae, device adjustment or removal is not recommended.
Healing response and progressive engagement of implant retention features must be factored into the decision to remove the CyPass® Micro-Stent after the immediate post-operative period (e.g., after 1 month postoperative). It is advised to consider less invasive intervention, such as positional adjustment or trimming of the CyPass® Micro-Stent proximal end (if the device is considered too anteriorly positioned) as a first alternative to device removal. It is also highly recommended that Alcon be contacted prior to device removal.

- **Procedure for CyPass® Micro-Stent Repositioning or Removal**

Surgical access for CyPass® Micro-Stent repositioning or removal is primarily *ab-interno* through a minimum 1.5 mm clear cornea incision under direct gonioscopy and AC viscoelastic stabilization. Use of retinal micro-forceps and retinal instrumentation is recommended for optimal surgical control and access. The steps for this procedure are as follows:

1. Instill a miotic agent to constrict the pupil. Construct the clear corneal incision and instill ophthalmic viscoelastic into the AC.
2. Utilizing a gonioprism for visualization, grasp the CyPass® Micro-Stent with toothed micro forceps around the anterior rim and gently either reposition until optimal positioning is achieved, or remove the device from its position. Carefully observe any tension or traction on surrounding tissues.
3. Remove remaining ophthalmic viscoelastic from the AC and adjust the tension in the eye by injecting and/or allowing egress of BSS; then close the incision.

- **Procedure for CyPass® Micro-Stent Proximal End Trimming**

After the immediate postoperative period, trimming of the proximal end of the CyPass® Micro-Stent may be considered when anterior positioning of the CyPass® is likely to compromise corneal endothelial health. The steps for this procedure are as follows:

1. Instill a miotic agent to constrict the pupil. Construct 2 clear corneal incisions under ophthalmic viscoelastic, utilizing either direct observation or a gonioprism for visualization.
2. Hold the proximal portion of the CyPass® Micro-Stent with micro-forceps, and incise distally with micro-scissors.
3. Remove the separated proximal portion through the corneal incision.
4. Inspect the remaining distal portion of the CyPass® Micro-Stent with a gonioprism to confirm optimal positioning.
5. Remove remaining ophthalmic viscoelastic from the AC utilizing irrigation alone or automated irrigation/aspiration, then adjust the tension in the eye by allowing egress of aqueous and seal the incision.

After surgery, monitor patients for IOP changes that may occur as possible sequelae following intraocular surgery in patients with glaucoma, and for corneal status.

G. REPORTING

Adverse events that may reasonably be regarded as CyPass® System-related should be reported to Alcon Laboratories, Inc.

By Phone:
In USA – (800) 757-9780

International: Contact the local country office.

Website:
http://www.alcon.com/contact-us

Each CyPass® System is identified by a lot number which provides traceability and this information should be given to Alcon.

H. HOW SUPPLIED

The CyPass® system is supplied sterile and non-pyrogenic in a sealed tray. The sealed tray is placed in a unit box containing product labeling and product information. The CyPass® system has been sterilized using irradiation and must only be opened under aseptic conditions (see Section F. Directions for Use).
The CyPass® Micro-Stent is MR Safe: the implant is constructed of polyimide material, a non-conducting, non-metallic, non-magnetic polymer that poses no known hazards in all magnetic resonance imaging environments.
The CyPass® Micro-Stent and applier are designed for single use only, and are intended to be used only on a single patient. The safety and effectiveness of cleaning, re-sterilization and/or reuse has not been evaluated and may adversely impact device integrity and patient safety.
Used CyPass® appliers should be discarded only in a suitable, biohazardous sharps container.
The Patient Identification Card included in the package is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any health care practitioner that the patient consults in the future.

I. EXPIRATION DATE

The sterility expiration date is clearly indicated both on the sealed tray and the outside of the unit box. Sterility is assured until the expiration date as long as the tray seal is not punctured or damaged. The CyPass® system should not be used past the date indicated.

J. RETURN GOODS

Contact local Alcon offices or distributors regarding the applicable returned goods policy.

K. PHYSICIAN TRAINING

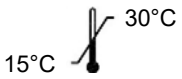
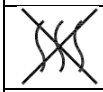
Physician training by certified Alcon personnel is required prior to use of this device. Training consists of three main parts:

- Didactic session
- Simulated implantation of CyPass® Micro-Stent
- Supervised CyPass® Micro-Stent implantation clinical cases until implantation proficiency is demonstrated.

CE 0123

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

EC REP
Alcon Laboratories, (UK) Ltd.
Frimley Business Park
Frimley Camberley
Surrey GU16 7SR
United Kingdom

SYMBOLS/ ABBREVIATIONS	DEFINITION
L	Left
R	Right
	Caution
	Consult instructions for use
	Catalogue number
	Batch code
	Quantity
	Date of manufacture (YYYY-MM-DD: Year-Month-Day)
	Manufacturer
	Use-by date (YYYY-MM-DD: Year-Month-Day)
	Sterilized using irradiation
	Do not reuse
	Do not resterilize
	Do not use if package is opened or damaged
	Authorized Representative in the European Community
	Lower and Upper limit of temperature
	MR Safe. The CyPass® Micro-Stent poses no known hazards in all magnetic resonance imaging environments
	Non-pyrogenic
	Does not contain dry natural rubber or natural rubber latex