DEAR HEALTHCARE PROFESSIONALS LETTER

PRODUCT SAFETY NOTICE

for selected HOYA Vivinex multiSert XY1-SP and XC1-SP IOLs

31 July 2023

To whom it may concern

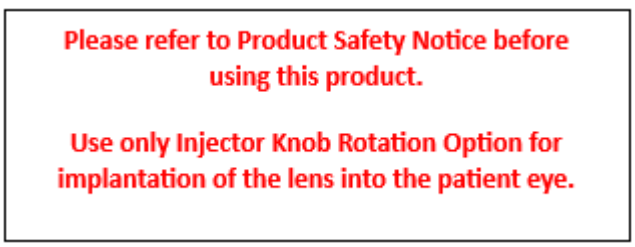
Dear Healthcare Professional,

This is to officially notify your organization, that we are issuing a Product Safety Notice of specific lots of HOYA Vivinex multiSert IOLs (Models: XY1-SP and XC1-SP). This Product Safety Notice is limited to specific lots of XY1-SP and XC1-SP models produced with injectors from a new supplier. We are contacting you as the affected products have been supplied to your organisation and have possibly been used at your organization.

We recently concluded an initial investigation into an increase in complaints related to rapid IOL release from injectors while using Push Plunger Option to implant the lenses. In several of the complaints received, the surgeons have noticed a sudden loss of control with rapid advancement of the IOL while using Push Plunger Option to implant the lenses into the patient eye, resulting in posterior capsular rupture. For more details related to patient risk please refer to Appendix 1 – Section 1.

As part of our preliminary investigation, it has been confirmed that the issue does NOT affect all units of products produced with injectors of the new supplier, it is limited to specific lots and presents itself only when using Push Plunger Option for implantation of the lens into patient eye. After extensive testing of the affected injectors, we can confirm that this issue does not affect the Injector Knob Rotation Option. Therefore, with this Product Safety Notice, we are requesting all healthcare professionals to use only Injector Knob Rotation Option during implantation of the lenses. For detailed instructions please refer to Appendix 1 – Section 2.

All product related to this Product Safety Notice will be identified with the following label, which will be attached to the outer carton:



We are taking all possible steps to contain the problem. We are investigating the potential root causes and are working step-by-step to implement corrective actions. Furthermore, we are committed to working closely with you to effectively and efficiently manage this situation.

This Product Safety Notice is limited to specific production lots of Vivinex multiSert IOLs (Models: XY1-SP and XC1-SP). It does **not** affect any other HOYA Surgical Optics IOLs that have been distributed to our customers, including Vivinex Toric, Vivinex Impress, and the Vivinex Gemetric family which are preloaded in the multiSert injector.

Please refer to Appendix 1 for the Medical Recommendations for surgeons based on Health Risk Assessment performed by HOYA Surgical Optics.

At HOYA Surgical Optics (HSO), our top priority is the health and safety of our patients. We apologize for any inconvenience this field action may cause you, and we appreciate your understanding as we undertake actions to ensure patient safety.

If you have any questions or concerns related to this matter, please contact me, who will be your point of contact on behalf of HSO.

Appendix 1 to PRODUCT SAFETY NOTICE.

Medical recommendations for the surgeons.

1. Impact on the patient.

Rapid release of the Vivinex multiSert IOLs (Models: XY1-SP and XC1-SP) using Push Plunger Option for implantation of the lens into the patient eye may result in posterior capsule rupture.

1.1. Immediate impact on patient:

Posterior capsule rupture may require anterior vitrectomy to remove vitreous strands from the anterior chamber. Posterior capsule rupture during cataract surgery is associated with significantly reduced visual acuity in the early postoperative period (1 month).

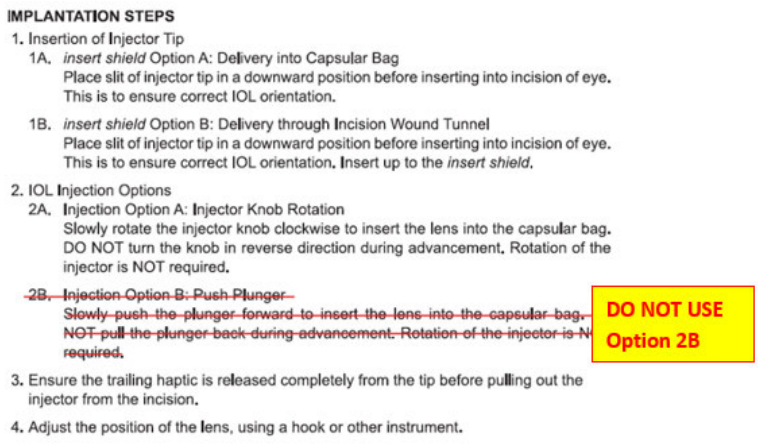
1.2. Long-Range impact on patient:

Posterior capsule rupture during cataract surgery is associated with slight reduction in visual acuity long term (5 years).

2. Safety notice for the surgeons.

To ensure safe use of the injector in order to avoid rapid lens release and, consequently, the potential for posterior capsular rupture, please strictly follow the Instructions for Use. When preparing the injector, after removal of the injector from its case, gently push the plunger and for implantation of the lens into patient eye **use ONLY Injector Knob Rotation indicated under** "IMPLANTATION STEPS" on the IFU (see option 2A below).

Please stop implantation of the lens when noticing unusual resistance force or unsmooth movement of the IOL inside the injector.



IMPLANTATION STEPS

1. Insertion of Injector Tip
   - 1A. *insert shield* Option A: Delivery into Capsular Bag
     Place slit of injector tip in a downward position before inserting into incision of eye.
     This is to ensure correct IOL orientation.
   - 1B. *insert shield* Option B: Delivery through Incision Wound Tunnel
     Place slit of injector tip in a downward position before inserting into incision of eye.
     This is to ensure correct IOL orientation. Insert up to the *insert shield*.
2. IOL Injection Options
   - 2A. Injection Option A: Injector Knob Rotation
     Slowly rotate the injector knob clockwise to insert the lens into the capsular bag.
     DO NOT turn the knob in reverse direction during advancement. Rotation of the injector is NOT required.
   - ~~2B. Injection Option B: Push Plunger~~
     ~~Slowly push the plunger forward to insert the lens into the capsular bag.~~
     ~~NOT pull the plunger back during advancement. Rotation of the injector is N~~
     ~~required.~~

DO NOT USE Option 2B

3. Ensure the trailing haptic is released completely from the tip before pulling out the injector from the incision.
4. Adjust the position of the lens, using a hook or other instrument.

In addition, pay special attention to the following steps marked in green on the IFU:

PRECAUTIONS

1. The HOYA Vivinex™ multiSert™ lens has been validated with sodium hyaluronate Ophthalmic Viscosurgical Devices (OVDs); the use of other OVDs and lubricants may cause damage to the lens and potential complications during implantation.
2. Special attention must be paid while inserting the lens in the eye to assure the optic is positioned with the proper side up (as shown in Fig.4). In vivo studies in rabbits indicated that a reversed position would increase the rate of complications such as capsular bag distention syndrome and PCO. Read and follow all "INSTRUCTIONS FOR USE" before use. If the lens is implanted in the reversed postition, the surgeon may consider further surgical treatment options including inverting the lens in a safe manner, explantation / re-implantation or posterior capsulotomy.

Fig.4: Correct IOL haptic-optic shape in the capsular bag (surgical view)

3. Before surgery, the surgeon should consider following;
   - Inform prospective patients of the potential risk/benefit associated with this product.
   - Leave the lens for at least 30 minutes at a temperature of 18 to 25 °C to achieve optimal lens conditions for folding.
   - Handle the lens with care to prevent haptic damage due to excessive twisting, strong impact, or excessive pressure.

PRECAUTIONS (continued)

   - Avoid attempting to insert the lens forcibly through a too small incision; this may result in a torn incision and lead to possible complications.
   - Allow the OVD to attain a temperature of 18 to 25 °C prior to use (for details, consult the instructions for use attached to the OVD).
4. As a high level of surgical skill is required for IOL implantation, the surgeon should have observed and/or assisted in numerous cataract surgeries, IOL implantations, and surgical intervention techniques before attempting to implant an IOL.
5. **Do not resterilize or reuse either the injector or intraocular lens.** Reuse or resterilization may compromise the structural integrity of the devices and/or lead to device failure which, in turn, may result in patient injury or illness. Reuse or resterilization may also create a risk of contamination of the devices and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the devices may lead to injury or illness of the patient.
6. Care should be taken to remove the OVD from the eye at the end of surgery.
7. After use, discard the injector as medical waste per your local country regulations.
8. Do not store the product in direct sunlight, high humidity, or at temperatures over 25 °C.

INSTRUCTIONS FOR USE

PRELIMINARY STEPS

1. Confirm the expiration date, the dioptric power and the model of the lens.
2. Inspect the sterilization pouch carefully. DO NOT use the injector or lens if their sterility seems to be compromised due to the rupture in the pouch, etc.
3. Open the seal of the sterilization pouch. Pull the injector out of the pouch by holding the handling tab. Handle the device aseptically after opening the pouch.
4. Confirm that the injector and lens are not damaged and there are no visible foreign bodies adhering to the lens surface.

Fig.5: Step 1 - Infuse OVD

Fig.6: Step 2 - Remove cover

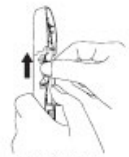


Fig.7: Step 3 - Push slider slowly

INJECTOR PREPARATION STEPS

1. Infuse the sodium hyaluronate OVD into the injector through the infusion port (Fig.5). Fill up the area indicated by the dotted lines in Fig.5 with the OVD, and confirm the OVD has reached the entire optic.
2. Press the release tabs, lift up and remove the cover from the injector case (Fig.6).
3. Hold injector body with thumb and slowly push the slider forward in an even manner for about 3 seconds, without applying upward or downward pressure, until it stops (Fig.7). Verify the slider stops at the injector case (as indicated in Fig. 8, by the dotted line). DO NOT pull the slider back. After slider advancement, implant the IOL within 3 minutes.
4. Remove the injector from its case (Fig.9). Go immediately to Step 5 once removed.
5. Gently advance the plunger forward in one smooth, continuous motion until haptic tucking state reaches the specific position as illustrated in figure (Fig.10). This plunger advancement should require about 5 seconds.

   DO NOT pull the plunger back AT ANY TIME.

   Pay special attention that the trailing haptic is tucked correctly as the rod advances to the back edge of the optic. As the lens advances further confirm that the leading and trailing haptic are tucked correctly, and that the rod tip pushes the edge of the optic in the center (Fig. 10). If no issues are observed, go immediately to Step 6. If *insert shield* is not used, go to Step 6A. If *insert shield* is used, go to Step 6B.

   DO NOT proceed if the leading and / or trailing haptics are not in correct position, or the rod tip does not push the edge of the optic in the center (Fig.11).

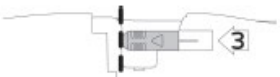


Fig.8: Step 3 - Confirm slider

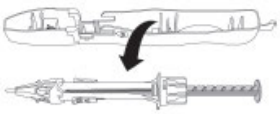


Fig.9: Step 4 - Remove from the case

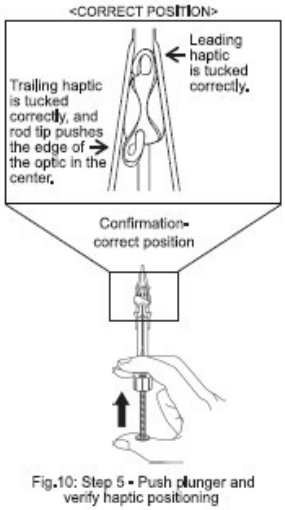


Fig.10: Step 5 - Push plunger and verify haptic positioning

<WRONG POSITION>

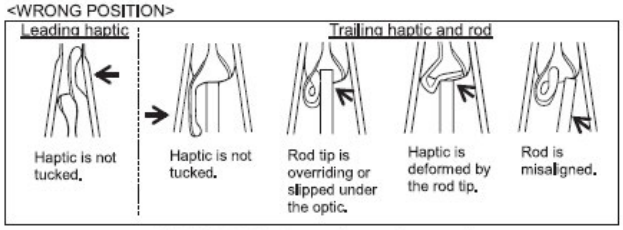


Fig.11: Step 5 - Do not proceed in case of wrong position

5. Insertion Depth Options of Injector Tip

6A. *insert shield* Option A: Delivery into Capsular Bag
Use injector without moving *insert shield* from its default position. Go immediately to IMPLANTATION steps 1 through 4.

NOTE: *insert shield* is pre-attached to the injector and CANNOT be removed.

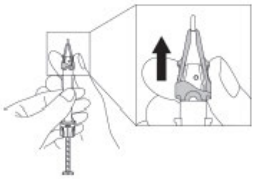


Fig.12: Step 6B - Advance *insert shield*

6B. *insert shield* Option B: Delivery through Incision Wound Tunnel
Hold the injector body and slide the *insert shield* gently forward until it stops with a click at the final position (Fig.12). DO NOT pull the *insert shield* back. Go immediately to IMPLANTATION steps 1 through 4.

IMPLANTATION STEPS

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   1B. *insert shield* Option B: Delivery through Incision Wound Tunnel
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2. IOL Injection Options
   2A. Injection Option A: Injector Knob Rotation
   Slowly rotate the injector knob clockwise to insert the lens into the capsular bag. DO NOT turn the knob in reverse direction during advancement. Rotation of the injector is NOT required.

   ~~2B. Injection Option B: Push Plunger~~
   ~~Slowly push the plunger forward to insert the lens into the capsular bag. NOT pull the plunger back during advancement. Rotation of the injector is N required.~~

DO NOT USE Option 2B

3. Ensure the trailing haptic is released completely from the tip before pulling out the injector from the incision.

4. Adjust the position of the lens, using a hook or other instrument.