

**Notification of Competent Authorities about Product hold
related to selected HOYA Vivinex Multisert IOLs**

To whom it may concern

12 June 2023

Dear Sir or Madam,

This is to officially inform you that HOYA Surgical Optics (HSO) is temporary putting our distributed inventory on hold to perform additional investigation of selected **HOYA Vivinex Multisert Intraocular Lenses ("IOLs")**.

The hold is specific to Vivinex Multisert IOLs produced with injector parts provided by a new supplier during the manufacturing period of February 2023. As some of the stock potentially affected has been shipped to the country under your jurisdiction, we would like to inform you about this hold.

Background: within the last two weeks we have received 12 complaints of rapid IOLs release. Some cases led to capsular bag rupture. These complaints are from France and Switzerland only. All required cases have been filed as adverse events ("AEs") and submitted to the relevant Competent Authorities, according to the vigilance reporting requirements in each country.

We are conducting an urgent investigation into these complaints to further investigate the root cause of these cases and define if they are linked to user error or product malfunction.

We take our responsibility to manufacture safe and quality medical devices seriously and we are committed to high quality standards. Our manufacturing plants and processes are ISO 13485:2016 and MDSAP (Medical device single audit program) certified and regularly audited by Competent Authorities/Notifying Bodies as well as internally monitored. Our product review processes enabled us to identify this issue and to take early action. While our analysis has shown that not every device is affected, we prioritize patient safety above all else and have therefore initiated this investigation.

In addition, we are taking every possible step to contain the problem and have asked our distributors to immediately hold products to prevent any further risks for our patients.

We target to complete the initial investigation and confirm the scope **by 19th of June**. Based on the results of this investigation, HSO will inform the relevant Competent Authorities about suggested field actions as required.

At HOYA Surgical Optics, our top priority is the health and safety of our patients. We are committed to implementing all required actions and improvements to minimize any future risk.

If you have any questions or concerns related to this matter, please contact me directly. I will be your point of contact on behalf of HOYA Surgical Optics.

Kind regards

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