



October 2022

Subject: Voluntary recall of the SUSVIMO™ Ocular Implant

Dear Health Care Provider:

The purpose of this letter is to inform you that Genentech has initiated a voluntary recall of the Susvimo Ocular Implant and Insertion Tool Assembly, including the Susvimo (ranibizumab) drug vial and initial fill needle (lot numbers 3499188 and 3523071) which are sold together.

The recall will not include the SUSVIMO (ranibizumab injection) 100 mg/ml drug vial for refill-exchange and Refill Needle in order to allow for continued refill-exchange procedures in eligible patients who already have an implant. This recall will not include the SUSVIMO (ranibizumab injection) Explant Tool. The US Food and Drug Administration (FDA) has been informed and is aligned with this approach.

During an investigation into septum dislodgement cases in the Port Delivery System with ranibizumab (PDS) phase III clinical trial program, we identified a need for additional testing of the commercial implant supply. This additional testing of our commercial supply involved repeatedly puncturing Susvimo implants with a needle, to evaluate performance of the septum of the implant over the long-term via multiple refills. The results showed that some implants did not perform to our standards. Hence, a pause in all new implantations is required.

Patient safety and the highest quality of our products are an utmost priority for Genentech and we are committed to continue monitoring and improving device performance and ensuring patient safety.

Indications and Background

SUSVIMO is indicated for the treatment of adult patients with Neovascular (wet) Age-related Macular Degeneration who have previously responded to intravitreal vascular endothelial growth factor inhibitor medication. In clinical trials, a type of implant damage where the septum has dislodged into the implant body has been reported. The USPI lists septum dislodgement under Warnings and Precautions and provides instructions to physicians to examine the implant carefully prior to and after each refill-exchange procedure to monitor for the occurrence of septum dislodgement. As of 31 August 2022, there have been 33 reported cases of septum dislodgement in approximately 1,419 patients with implants (2.3%, includes re-implantations) and 5,236 refill-exchange procedures (0.63%) across PDS clinical trials. To date, no cases of septum dislodgement have been reported in patients implanted with the Phase 2 implants (195 implants). In addition, no cases of septum dislodgement have been reported with implants from the commercial supply to date. As of

September 30th 2022, there have been 219 implantations and 24 refill-exchange procedures in the commercial setting.

Prescriber Action

Counsel patients about the risks and benefits of SUSVIMO, specifically about the risk of septum dislodgement and about the recall.

For patients who have not experienced septum dislodgement:

- In discussion with the patient, refill-exchange procedures of ranibizumab can continue to provide visual and anatomical benefits of continuous delivery of ranibizumab. We believe that the benefit-risk for these patients has not been impacted.
- Per the USPI, careful examination of the implant in the vitreous cavity through the dilated pupil is required prior to and after the refill-exchange procedure to check the appearance of the implant and its components.

For patients who have experienced septum dislodgement:

- Further refill-exchange procedures should not be performed because normal device functioning cannot be assured after the septum dislodgement.
- Whether to remove or keep the implant with a dislodged septum in place, is an individual choice for the physician and patient based on a discussion about the potential risks and benefits, including, among other considerations, the risks associated with undergoing an explantation procedure.
- The long-term risks of retaining vs. removing an implant with a dislodged septum are not well characterized at this time.
- **Action for physician:**
 - Please discuss the various patient management options with the patient keeping in mind the benefits and risks of each option.
 - Monitor the patient for signs of disease worsening and per physician judgment, the patient may be started on an appropriate intravitreal therapy for nAMD.

Patients should be encouraged to review the Medication Guide and immediately report any side effects to their doctor.

Reporting Adverse Events / Product Complaints and Company Contact

Health Care Providers should report any adverse events or product complaints suspected to be associated with the use of SUSVIMO to Genentech at 833-EYE-GENE. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Should you have any questions about the information in this letter, returning the product, or the safe and effective use of SUSVIMO, please contact us at 833-EYE-GENE.

This letter is not intended as a complete description of the benefits and risks related to the use of SUSVIMO. Please refer to the enclosed full [prescribing information](#) for additional information.

Sincerely,



Jamie Freedman MD, PhD
Head of U.S. Medical Affairs