

Susvimo™
(ranibizumab injection)
For Susvimo ocular implant use
Instructions for Use

Implant Removal Procedure

R_x only

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Susvimo procedures should be performed by an ophthalmologist experienced in vitreoretinal surgery.

Refer to the Susvimo (ranibizumab injection) 100 mg/mL prescribing information for a complete list of indications, contraindications, warnings, precautions, and adverse events.

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Introduction

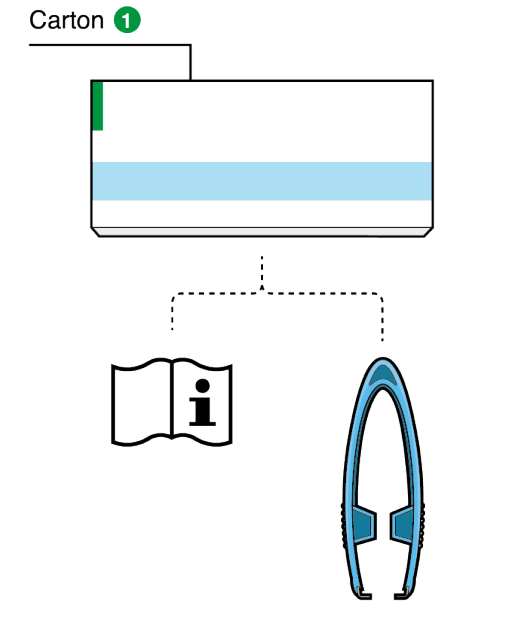
These instructions include only the implant removal procedure for the Susvimo implant. Refer to the Susvimo Instructions for Use for the initial fill and implant procedure and prescribing information for the refill-exchange procedure.

Device Description

Susvimo is an intraocular drug delivery system designed to be used specifically with Susvimo (ranibizumab injection) 100 mg/mL.

These Instructions for Use describe the required materials and steps necessary for removal of the Susvimo implant.

Components



1 Susvimo™ Explant tool

containing

- One explant tool in sterile blister
- One implant removal procedure IFU

Figure 1

Susvimo components for implant removal procedure

Susvimo explant tool

Susvimo explant tool (Figure 2) is a pair of forceps with contoured tips, which are designed to grasp underneath the implant flange to securely engage the implant during removal.

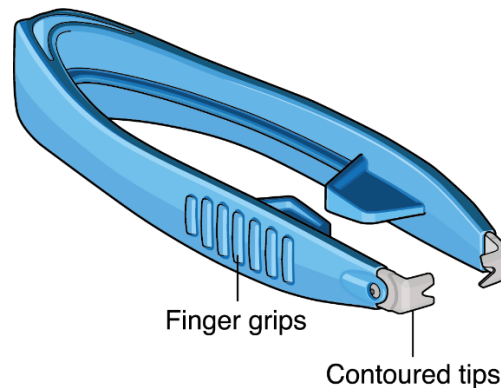


Figure 2
Susvimo explant tool

Intended Use/ Indications for Use

Susvimo explant tool is approved for use with Susvimo ocular implant. Refer to the Susvimo (ranibizumab injection) prescribing information for a complete list of indications, contraindications, warnings, precautions, and adverse events.

Warnings

- **Do not** use if the sterility has been compromised or the contents have been dropped, damaged or tampered with.
- **Do not** grasp the implant by the short axis of the implant flange. Remove the implant in a gentle manner. Perpendicular exit of the implant is important to avoid contact between the implant and intraocular structures such as the lens.

Precautions

- Read and follow all instructions, warnings, and cautions prior to use.
- Susvimo procedures should be performed by an ophthalmologist experienced in vitreoretinal surgery.
- Use Susvimo components and materials as specified in these instructions to perform the implant removal procedure.

How Supplied, Handling, and Storage

- Susvimo explant tool has been electron beam sterilized. **Do not** reprocess or resterilize.
- Susvimo explant tool is for single-use only. **Do not** reuse the Susvimo explant tool.
- **Do not** open sealed tray until time of use.
- **Do not** use if the package is damaged or broken as sterility may be compromised.

- **Do not** use past the expiration date printed on the label.
- Susvimo explant tool should be stored at a room temperature 15°C to 25°C (59°F to 77°F).

Instructions for Use

Introduction and Materials

Removal of the Susvimo implant requires a surgical procedure that is performed in an operating room.

Materials List

Materials that are required and provided for the procedure are listed in Table 1.

Table 1 Susvimo sterile components that are provided for implant removal

Item Description
Susvimo explant tool

Materials required but not provided are listed in Table 2.

Table 2 Additional materials required but not provided for implant removal

Item Description
Surgical microscope
Vitrectomy surgical control system
Standard 25 G or 27 G vitrectomy set up
Standard vitrectomy tray (<i>including 0.12 straight toothed forceps and blunt wescott scissors</i>)
Cauterization equipment (<i>including standard fine tip diathermy and eraser tip wet-field cautery</i>)
Ophthalmic broad-spectrum microbicide solution
Surgical scalpel blade #15
Non-absorbable sutures for sclera (<i>suggested Nylon</i>)
Gut or Vicryl sutures for conjunctival tissues (<i>suggested 7-0 to 9-0: monofilament recommended</i>)
Indirect ophthalmoscope and lens
Drapes

Preparatory Procedures

1. Inspect and open sterile packaging

- Prior to use in the operating room, inspect the sterile packaging of the explant tool for damage.
- Check the expiration date printed on the label.
- Open sterile packaging and using aseptic technique, remove the explant tool from the tray.
- Inspect the explant tool and place onto sterile surface.

Warning

Do not use if the sterility has been compromised or the contents have been dropped, damaged, or tampered with.

2. Patient Preparation

- Dilate the pupil of the eye.
- Place the patient in a supine position on the operating table.
- Implant removal is a surgical procedure and therefore requires sterile controls (i.e. use of ophthalmic broad-spectrum microbicide solution on eye including lids and lashes and draping) be in place to minimize the risk of ocular infection.
- Perform the procedure under local anesthesia using either peribulbar, retrobulbar, or sub-Tenon's technique.
- Place lid speculum.

Implant Removal

Perform the implant removal procedure under the microscope. Consider placing a traction suture for better visualization of the superotemporal quadrant throughout the entire implant removal procedure.

1. Place infusion line

- Place an infusion cannula in the inferotemporal quadrant via an angled entry wound.
- Attach the infusion line, however keep the infusion off.

2. Perform conjunctival peritomy

- Create at least a 6 mm by 6 mm peritomy of the conjunctiva and Tenon's capsule around the implant flange (Figure 3).

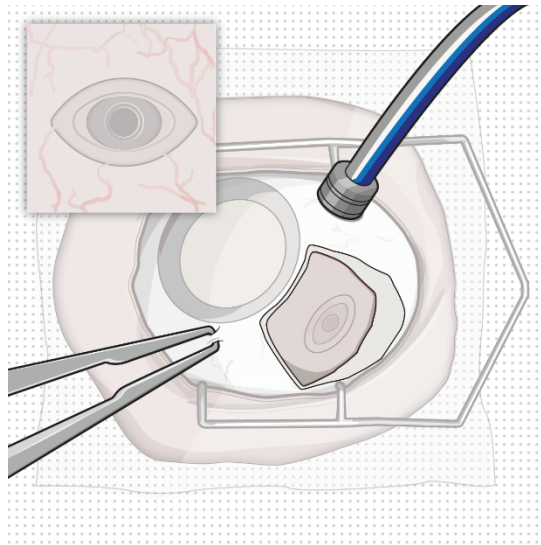


Figure 3
Conjunctival peritomy

3. Remove fibrous capsule covering implant

- Remove any fibrous capsule or scar tissue that may have formed over the implant flange and septum (Figure 4 and Figure 5).
 - To expose the implant, use a scalpel to make an incision in the tissue around the entire circumference of the implant (Figure 4).
 - Use forceps to carefully dissect the implant flange and neck from the surrounding tissue so that the edges of the flange are completely exposed and the implant is free of any adherent tissue (Figure 5).

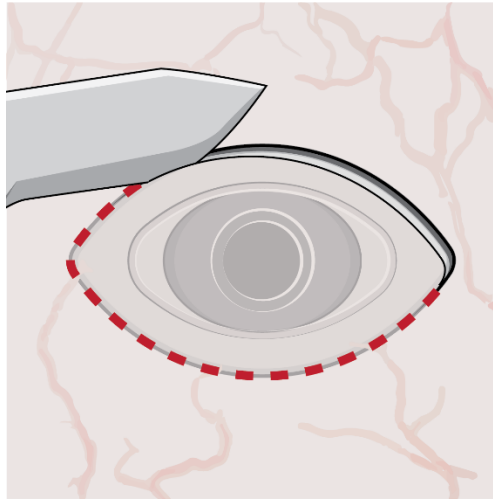


Figure 4

Incision to remove tissue that may be covering the implant flange and septum

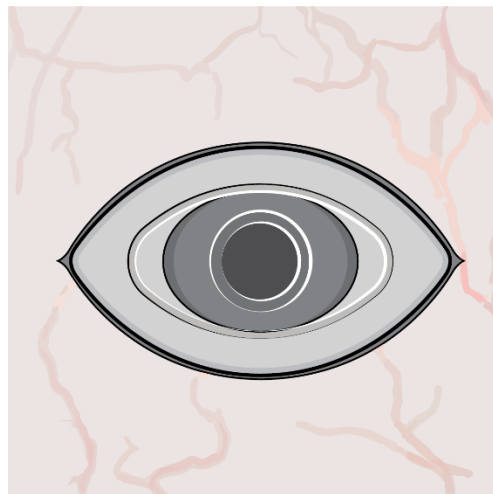


Figure 5

Exposed implant

4. Stabilize the globe and align the explant tool

- Stabilize the globe with forceps to prevent unwanted eye movement.
- With the explant tool oriented perpendicular to the globe, **align the contoured tips with the long axis of the implant flange** (Figure 6).

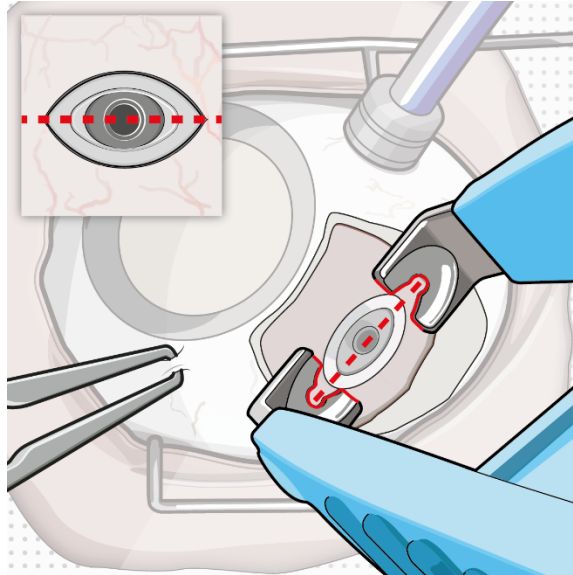


Figure 6

Align the explant tool along the long axis of the implant flange

5. Grasp the implant

Warning

Do not grasp the implant by the short axis of the implant flange. Remove the implant in a gentle manner. Perpendicular exit of the implant is important to avoid contact between the implant and intraocular structures such as the lens.

- Use the contoured tips of the explant tool to gently grasp underneath the long axis of the implant flange (Figure 7).

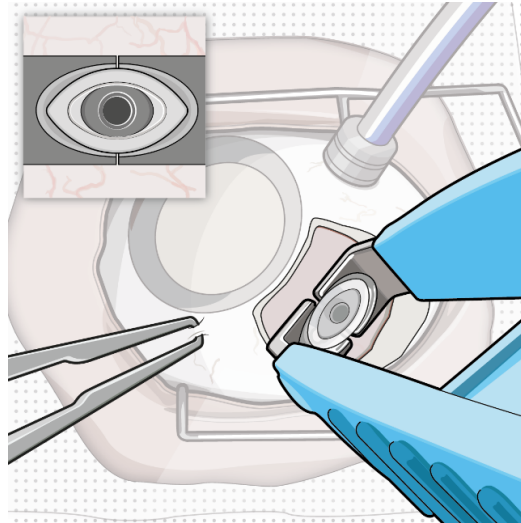


Figure 7

Grasp underneath the long axis of the implant flange

6. Remove the implant

- Once the implant is secured in the explant tool, in a gentle manner pull the implant from the eye in a perpendicular motion to avoid contact with adjacent intraocular structures.
- During removal, use forceps to stabilize the globe and provide counter traction to help release the surrounding tissue (Figure 8).
- During removal, continue to maintain perpendicular orientation of the implant relative to the globe (Figure 9).

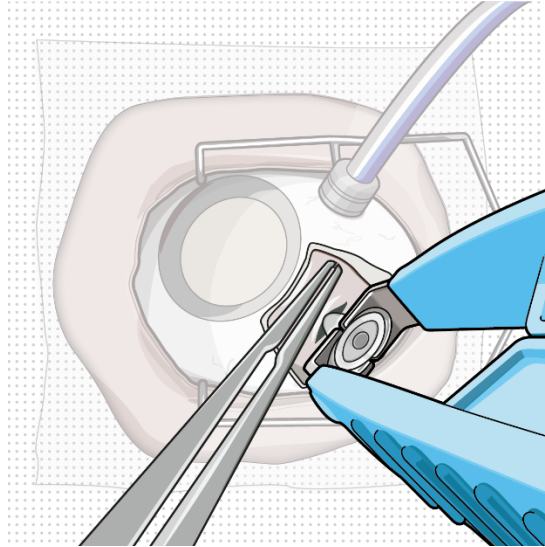


Figure 8
Implant removal

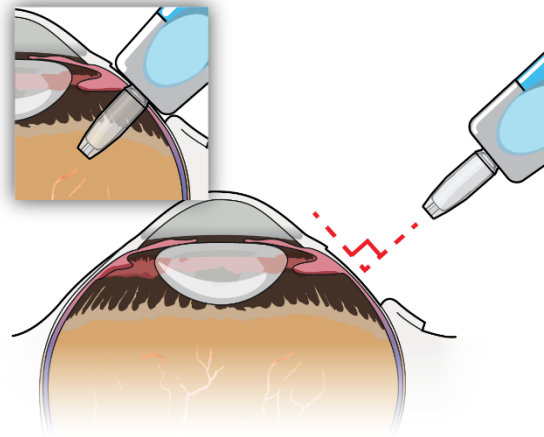


Figure 9
Perpendicular exit of the implant

- If needed per the surgeon's discretion, the infusion line on the vitrectomy surgical system can be turned on during implant removal.
- Control any scleral or conjunctival bleeding, using cauterization if needed, and clear any vitreous prolapse present within or around the scleral wound using a vitrectomy setup.

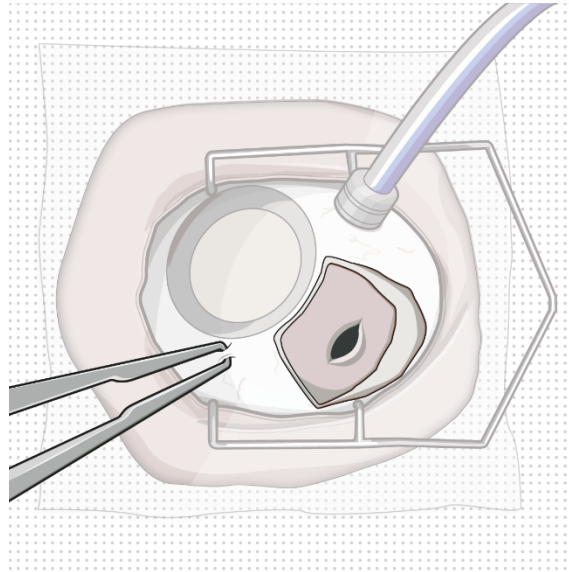


Figure 10

Appearance of the scleral wound after implant removal

7. Suture the sclera

- **Completely close** the scleral incision with non-absorbable (suggested Nylon) sutures (Figure 11). More than one suture will be needed to close the wound. It is recommended to place equally spaced partial thickness interrupted sutures.
- Ensure that the knots are buried.

 **Caution**

Do not overtighten the scleral sutures, to minimize excessive tensions on the sclera or cornea.

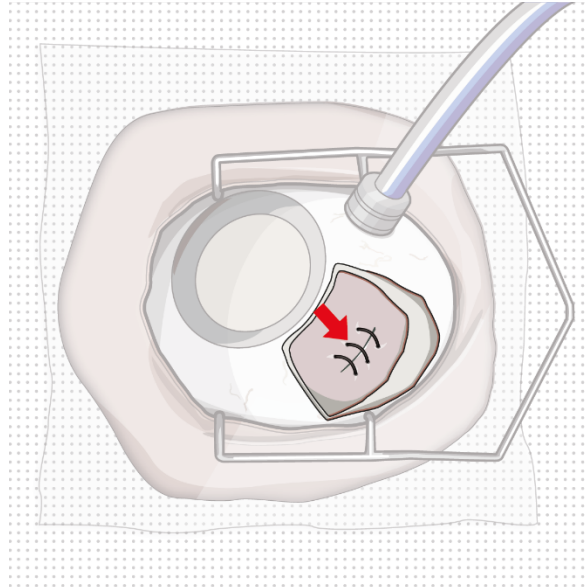


Figure 11

Suture scleral wound using multiple sutures

8. Suture conjunctiva

- Close Tenon's capsule and conjunctiva to completely cover the scleral incision (Figure 12).

Caution

Completely close Tenon's capsule and conjunctiva to minimize potential post-removal complications.

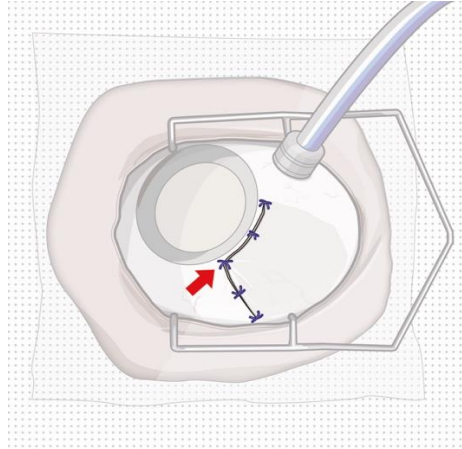


Figure 12

Suture conjunctiva post-removal

9. Remove infusion cannula

- If the infusion was previously turned on, then set the infusion pressure to 20 mmHg before removing the infusion cannula.
- Place suture at infusion cannula site as needed.

10. Check Intraocular Pressure (IOP) using digital palpation

11. Perform indirect ophthalmoscopy to examine for the presence of any complications

Disposal and Post-removal Procedures

1. Dispose of the used components

- Dispose of the used explant tool together with the implant in a biohazard waste container or in accordance with local requirements.

2. Perform post-removal procedures










- Post-removal procedures are consistent with standard post-surgical procedures.

3. Post-removal patient instructions

- Provide the patient with the following post-operative instructions:
 - Positioning:
 - Keep head above shoulder level for the rest of the day.
 - Sleep with head elevated on 3 or more pillows if lying down during the day and night after implant removal.
 - Information on caring for the eye after the procedure, including but not limited to:
 - Monitor for symptoms that may require immediate attention.
 - Wear an eye shield at bedtime for at least 7 nights.
 - **Do not** participate in strenuous activities until 14 days following the implant removal procedure.
 - Administer all post-operative anti-inflammatory and antimicrobial drops, as directed by their physician.

Explanation of symbols on product or package labeling

Table 3 Symbols on blister tray and carton

Symbol	Title
	Manufacturer
	Prescription only
	Do not re-use
	Do not use if package is damaged
	Consult Instructions for Use
	Sterilized by irradiation
	Temperature limit
	Expiration date/ Use by date
	Lot/Batch number

Manufactured by:

Genentech, Inc.

A Member of the Roche Group

1 DNA Way

South San Francisco, CA 94080-4990

U.S. License No.: 1048

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Approved: 10/2021