Susvimo™

(ranibizumab injection)

For Susvimo ocular implant use

Instructions for Use

Initial Fill and Implant Procedure

℞ 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.

Contents

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Instructions for Use

Introduction

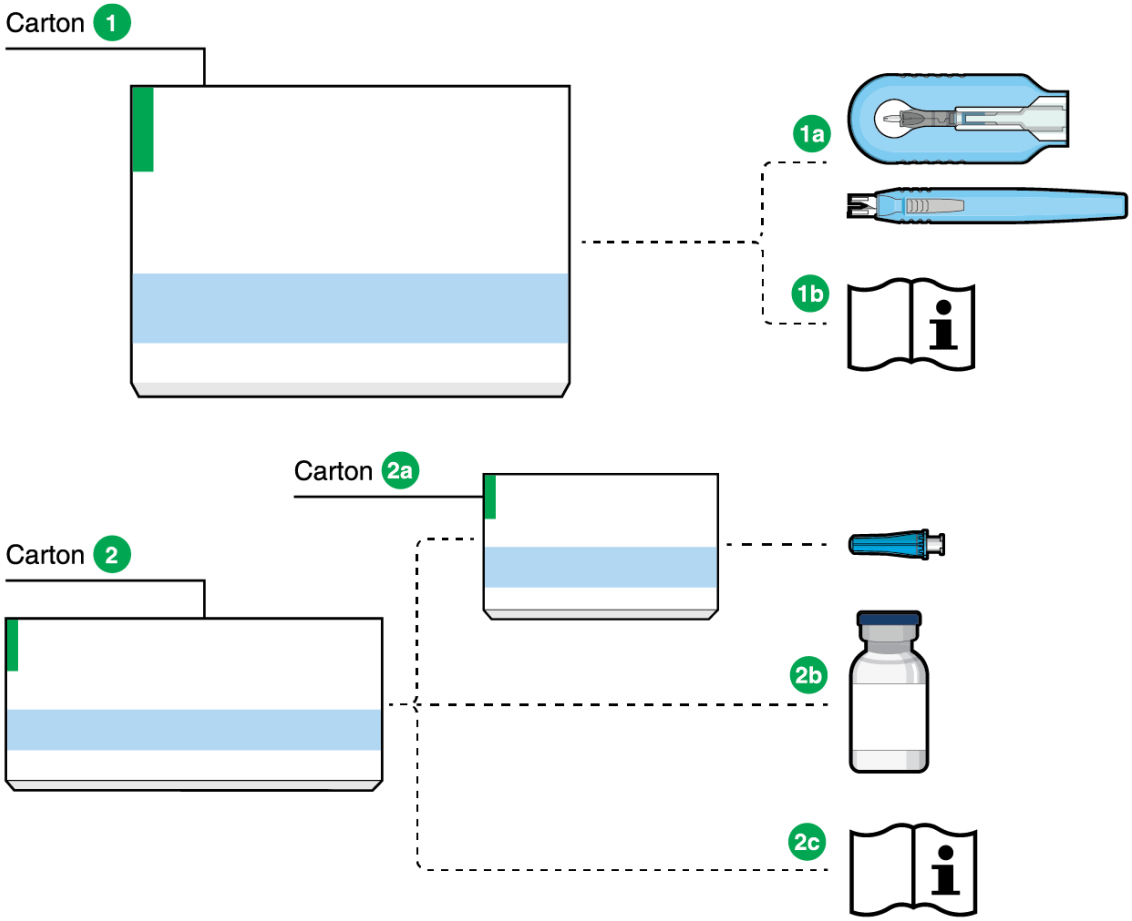
These instructions include only the procedure for filling and inserting the Susvimo implant. For more information, refer to the Susvimo prescribing information for the refill-exchange procedure and Susvimo Instructions for Use for the implant removal procedure.

Device Description

Susvimo is an intraocular drug delivery system designed to be used specifically with Susvimo (ranibizumab injection) 100 mg/mL. The system consists of an intraocular implant along with ancillary devices used to fill, insert, and explant (if needed) the implant.

The implant is a refillable drug reservoir that is inserted into the eye through the pars plana. The implant is secured within the scleral incision, with the extrascleral flange that remains visible through the conjunctiva following insertion. Once filled with ranibizumab, the implant is designed to provide continuous release of ranibizumab. The implant will be refilled with ranibizumab in an office-based setting via an administration through the conjunctiva and implant septum.

Components



1 Susvimo™ Insertion tool assembly
containing

1a Susvimo™ Insertion tool assembly in sterile blister
containing
- One insertion tool assembly
- One implant (held in insertion tool)

1b One initial fill and implant procedure IFU

+ Susvimo™ Explant tool
Available if needed

2 Susvimo™ (ranibizumab injection) and initial fill needle kit
containing

2a Susvimo™ Initial fill needle in sterile blister
containing
- One initial fill needle

2b One Susvimo™ (ranibizumab injection) 100 mg/mL vial

2c One United States Prescribing Information

Figure 1
Susvimo components for initial fill and implant procedure

Susvimo implant (packaged with insertion tool assembly)

Susvimo implant (Figure 2 and Figure 3) is a refillable reservoir inserted into the eye through the pars plana. The body of the implant, which includes the release control element, extends into the vitreous cavity.

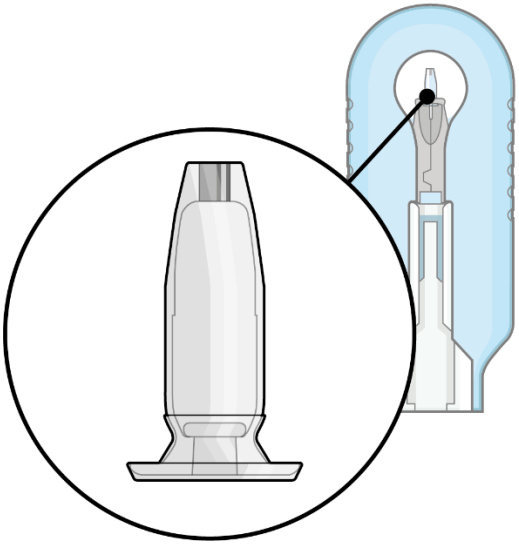


Figure 2
Susvimo implant

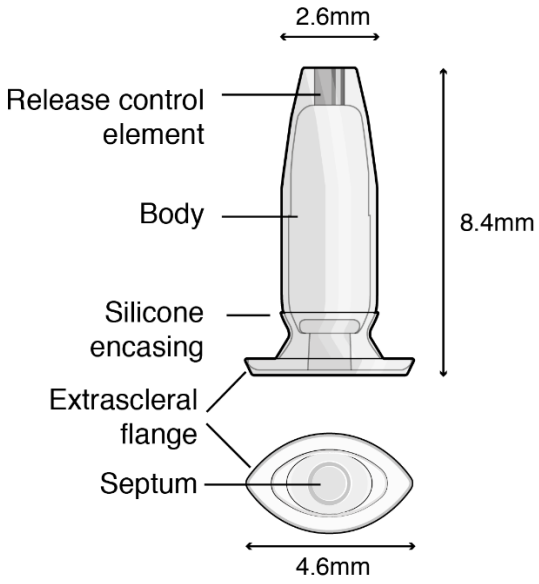


Figure 3
Susvimo implant detail

Table 1 Susvimo implant component description

Implant components	Description
Extrascleral flange	The extrascleral flange provides secure anchoring of the implant within the scleral incision and is encased in silicone.
Septum	The septum is a self-sealing interface through which ranibizumab is administered into the implant both prior to insertion and during subsequent refills in an office-based setting.
Body	The body of the implant contains a hollow drug reservoir, capable of holding 0.02 mL of drug.
Release control element	The titanium release control element controls the rate of ranibizumab diffusion from the drug reservoir into the vitreous.

Susvimo insertion tool assembly

Susvimo insertion tool assembly is designed to facilitate handling of the implant during the initial fill and implant procedure. The insertion tool assembly is comprised of a carrier and handle (Figure 4 and Figure 5), described in more detail below:

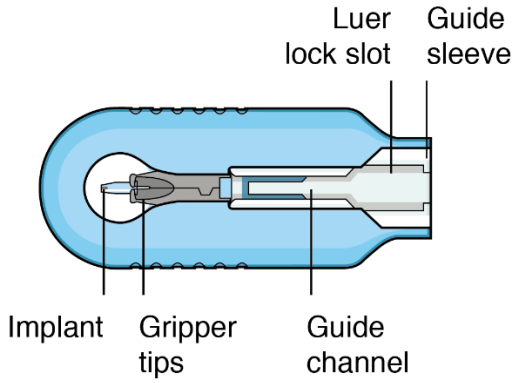


Figure 4
Susvimo insertion tool carrier

Figure 5
Susvimo insertion tool handle

Table 2 Susvimo insertion tool assembly component description

Insertion tool assembly components	Description
Gripper tips	The implant is provided pre-positioned in the insertion tool assembly gripper tips. After initial fill of the implant with ranibizumab, the implant and gripper tips are transferred from the insertion tool carrier to the insertion tool handle.
Luer lock slot	The syringe is loaded into the insertion tool carrier by aligning the syringe Luer lock with the insertion tool carrier Luer lock slot.
Guide channel	The guide channel serves to direct the syringe and initial fill needle in the insertion tool carrier during the initial fill of the implant.
Release button	Pressing the release button on the insertion tool handle will open the gripper tips and release the implant.

Susvimo (ranibizumab injection) 100 mg/mL vial

Susvimo (ranibizumab injection) (Figure 6) is used to fill the implant prior to insertion or during subsequent refill-exchange in an office-based setting.

Figure 6

Susvimo (ranibizumab injection) 100 mg/mL vial

Susvimo initial fill needle

Susvimo initial fill needle (Figure 7) is designed to fill the implant with ranibizumab prior to implant insertion. The initial fill needle is distinguished by its blue cap.

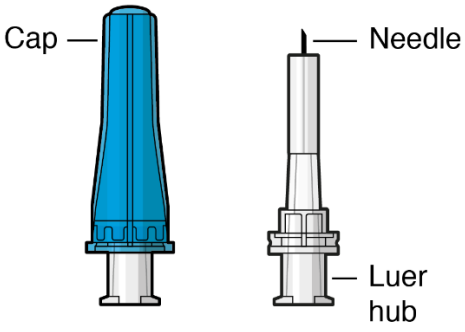


Figure 7

Susvimo initial fill needle

Table 3 Susvimo initial fill needle component description

Initial fill needle components	Description
Needle	34 G needle
Integrated filter	Integrated 5 µm filter within needle hub

Intended Use/Indications for Use

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

Contraindications

Susvimo is contraindicated in patients with ocular or periocular infections, with active intraocular inflammation, or with known hypersensitivity to ranibizumab or any of the excipients in Susvimo (ranibizumab injection) 100 mg/mL. Hypersensitivity reactions may manifest as severe intraocular inflammation.

Warnings

- **Do not** use if the sterility has been compromised or the contents have been dropped, damaged or tampered with.
- Minimize air bubbles within the implant reservoir as they may cause slower drug release. If an air bubble is present, it must be no larger than 1/3 of the widest diameter of the implant.

  If excess air is observed after initial fill, **do not** use the implant.
- Perpendicular entry of the implant is important to avoid contact between the implant and intraocular structures such as the lens, as contact between the implant and the intraocular structures may cause adverse events such as traumatic cataract.
- Avoid excessive force on the globe by first ensuring that the tip of the implant has passed through the sclero-pars plana incision before slowly pushing the implant into place.

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 the Susvimo components and materials as specified in these instructions to perform the implant insertion procedure including initial fill.
- Avoid contact between sharp surgical instruments and the implant as the material of the septum and silicone encasing are soft and susceptible to damage.
- The implant is MR Conditional. The Patient Implant card is provided with instructions and must be completed and given to the patient after implant insertion. For further information please refer to the 'Post-insertion patient instructions' section.

Use with Standard Procedures

Susvimo implant is compatible for use with the following standard procedures: A-scan ophthalmic ultrasound, slit lamp examination, indirect ophthalmoscopy, tonometry, optical coherence tomography (OCT), visual field (perimetry), standard lasers for ophthalmic treatments, radiography (x-ray), computed tomography (CT) scan, fluorescein/ indocyanine angiography, and fundus autofluorescence.

Use caution when performing ophthalmic procedures that may cause deflection of the implant and subsequent injury. For example, B-scan ophthalmic ultrasound, scleral depression, or gonioscopy.

Magnetic Resonance Imaging (MRI) Safety Information

MR Conditional.

Non-clinical testing has demonstrated that the Susvimo implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T)
- Maximum spatial field gradient of 3,000 G/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the Susvimo implant is expected to produce a maximum temperature rise of less than 1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 4 mm from the Susvimo implant when imaged with a gradient echo pulse sequence in a 3 T MRI system.

How Supplied, Handling, and Storage

- All Susvimo components are supplied sterile.
  Do not reprocess or resterilize.
- All Susvimo components are for single use only.
  Do not reuse Susvimo components.
- **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 ocular implant and insertion tool assembly

- The sealed tray has been sterilized with ethylene oxide gas.
- Store the Susvimo implant and insertion tool assembly at room temperature 15°C to 25°C (59°F to 77°F).

Susvimo (ranibizumab injection) and initial fill needle kit

- Susvimo initial fill kit should be stored at 2°C to 8°C (36°F to 46°F). **Do not** freeze. Protect from light. **Do not** shake. Prior to use, the unopened vial may be kept at 9°C to 30°C (48°F to 86°F) for up to 24 hours.
- Susvimo initial fill needle has been sterilized with electron beam processing.

See Susvimo (ranibizumab injection) prescribing information for additional information.

Instructions for Use

Introduction and Materials

Implant insertion is a surgical procedure that is performed in an operating room. The implant is filled with Susvimo (ranibizumab injection) immediately prior to insertion.

Materials List

The materials that are required in the operating room on the day of the procedure are listed in Tables 4 and 5.

Table 4 Susvimo components provided for initial fill and implant procedure

Item Description
Susvimo ocular implant with insertion tool assembly
Susvimo initial fill needle, 34 G, with blue cap
Susvimo (ranibizumab injection) 100 mg/mL
Susvimo explant tool (Refer to Susvimo implant removal Instructions for Use for information on implant removal.)

Table 5 Additional materials required but not provided for initial fill and implant procedure

Item Description
One sterile 1 mL Luer Lock syringe **(not included)**
One sterile 5-micron filter needle (19-gauge x 1½ inch) **(not included)**
Surgical microscope
Vitrectomy surgical control system
Standard 25 G or 27 G vitrectomy set up
23 G or 25 G 532 nm Endolaser probe and associated source
Standard vitrectomy tray *(including adjustable caliper, 0.12 straight toothed forceps, blunt wescott scissors)*
Cauterization equipment *(including standard fine tip diathermy and eraser tip wet-field cautery)*
Ophthalmic broad-spectrum microbicide solution
Marking pad
3.5 mm and 4.0 mm fixed caliper *or equivalent fixed tool*
3.5 mm fixed width gauge *or equivalent fixed tool*
19 G or 20 G MVR Straight Knife
Slit Knife, 3.2 mm Straight
Gut or Vicryl sutures for conjunctival tissues *(suggested 7-0 to 9-0: monofilament recommended)*
Indirect ophthalmoscope and lens
Drapes

Preparatory Procedures

1. Inspect packaging and components

- Prior to use in the operating room, inspect the packaging of the components for damage.
- Check the expiration date printed on the label.
- Remove the vial from the carton.
  NOTE: the outside of the vial is not sterile.
- Open sterile packaging and using aseptic technique, remove the components from their tray.
- Inspect components and place onto sterile field (Figure 8).

Warning

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

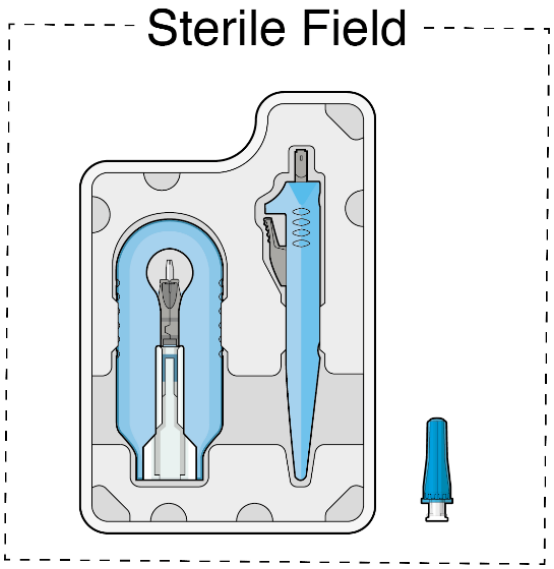


Figure 8
Susvimo components on sterile field

2. Inspect Susvimo (ranibizumab injection)

- Visually inspect the contents of the ranibizumab vial for particulate matter and discoloration.
- The drug solution should be colorless to pale brown.

Caution

Do not use if particulate, cloudiness or discoloration are visible.

3. Patient Preparation

- Dilate the pupil of the eye.
- Place the patient in a supine position on the operating table.
- Implant insertion is a surgical procedure and therefore requires sterile controls (i.e. use of 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.

Infusion Line Placement Procedure

1. Place infusion line

- Place an infusion cannula in the inferotemporal quadrant via an angled entry wound.
  - Alternate placement is acceptable based on patient anatomy per physician discretion (superotemporal placement should be avoided).
  - Alternatively, the line may be placed after the peritomy but prior to the scleral dissection.
- Attach the infusion line. Keep the infusion line off (Figure 9).

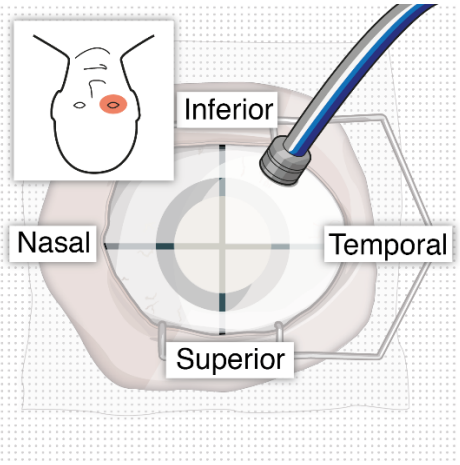


Figure 9

Place infusion cannula in inferotemporal quadrant

Conjunctival Dissection Procedure

1. Identify the site of insertion

- Identify the site in the superotemporal quadrant 4 mm posterior to the limbus where the implant will be inserted (Figure 10 and Figure 11).
- Placing a traction suture is strongly recommended for better visualization of the superotemporal quadrant throughout the entire implant insertion procedure.

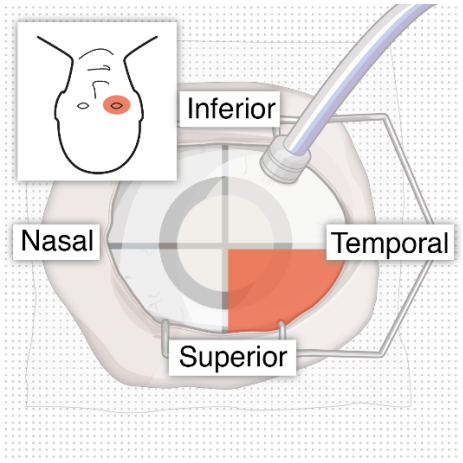


Figure 10
Superotemporal quadrant

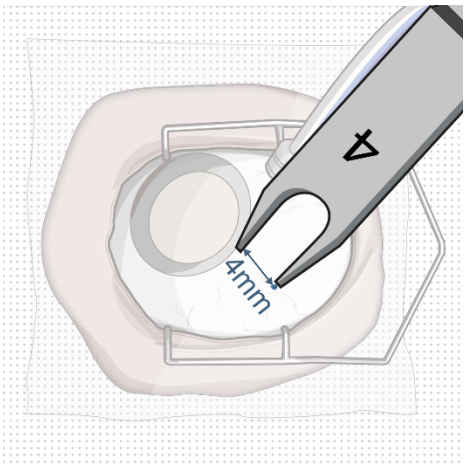


Figure 11
4 mm posterior to the limbus

2. Create conjunctival peritomy

Caution

The peritomy size should be at least 6 mm by 6 mm centered around the selected implant location to ensure the proper clearance of the conjunctiva and Tenon's capsule from the implant flange once the implant is inserted into the eye.

- Measure with adjustable caliper and create at least a 6mm by 6mm peritomy of the conjunctiva and Tenon's capsule around the selected implant location, using wet field cautery (eraser tip) to achieve hemostasis of the underlying episcleral tissues (Figure 12).
  - A peritomy size of at least 6 mm by 6 mm centered around the selected implant location provides proper clearance of the conjunctiva and Tenon's capsule for the implant flange (long axis of implant flange = 4.6 mm).
  - A peritomy size of at least 6 mm by 6 mm facilitates implant placement away from radial relaxing incision.
  - Appropriate peritomy size is vital for ease of subsequent surgery.

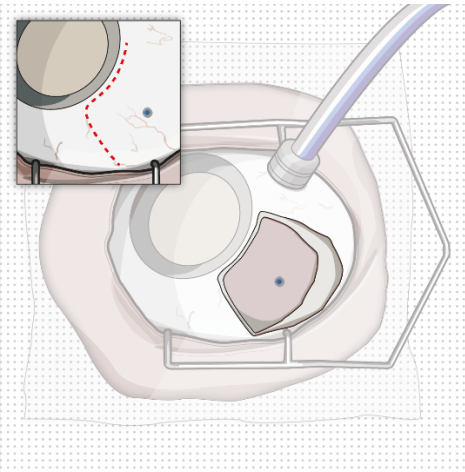


Figure 12

Conjunctival peritomy with blue dot representing selected implant location

  - Only one radial incision is recommended, to avoid excessive conjunctival suturing and longer healing process.
  - Careful incision creation is key to maintain integrity of conjunctiva and Tenon's capsule. Careful and generous undermining is key to minimize mechanical tension and adequate coverage of the implant while closing the conjunctiva and Tenon's capsule.

- Maintain hemostasis around the scleral incision throughout the surgery to facilitate the identification and management of incisional bleeding, to avoid post-operative vitreous hemorrhage.

Syringe Preparation and Initial Implant Fill

Using aseptic technique, the implant will be filled with 0.02 mL of ranibizumab prior to insertion of the implant into the patient's eye.

1. Transfer dose from vial to syringe

Caution

Use the filter needle to withdraw ranibizumab from the vial.

Do not use the initial fill needle for this step.

- Prepare ranibizumab vial by removing the flip-off cap and disinfecting the rubber vial septum with alcohol.
- Attach a filter needle to the syringe by screwing it tightly onto the Luer lock (Figure 13).
- Carefully remove the needle cap by pulling it straight off.
- Using aseptic technique, withdraw all of the contents of the ranibizumab vial through the filter needle into the syringe.
-

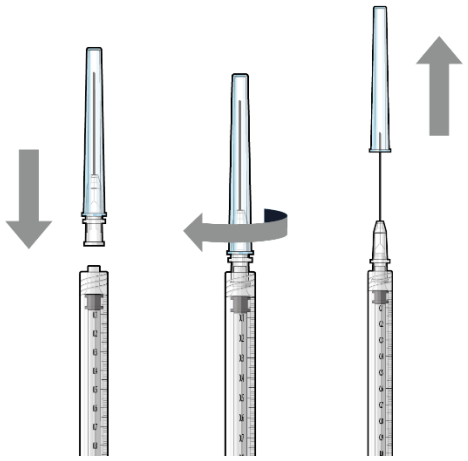


Figure 13

Filter needle attached to syringe and cap removal

2. Remove air from syringe

- With the filter needle attached, hold the syringe with the needle pointing up.
- If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (Figure 14).
- Slowly push the plunger rod just until all air is expelled from the syringe and needle.
  - It is important to preserve as much drug as possible in order to completely fill the implant.
- Remove and properly dispose of the filter needle after air is removed from syringe.

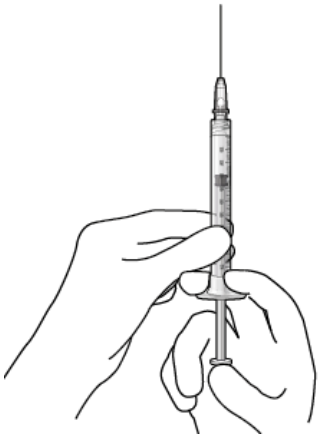


Figure 14

No air bubbles in syringe

3. Attach initial fill needle

- Attach the initial fill needle firmly onto the syringe by screwing it tightly onto the Luer lock (Figure 15).
- Carefully remove the needle cap by pulling straight off.
- **Do not** wipe the needle at any time.

Caution

Ensure that the initial fill needle is attached to the syringe.

Do not use the filter needle to fill the implant.

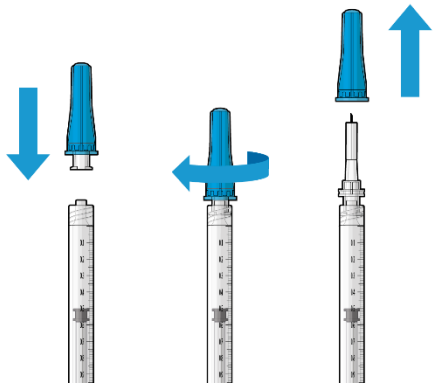


Figure 15

Initial fill needle attached to syringe and cap removal

4. Remove any remaining air from syringe

- With the initial fill needle attached, hold the syringe with the needle pointing up.
- If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (Figure 16).
- Slowly push the plunger rod just until all air is expelled from the syringe and needle, and a drop of drug solution is seen at the needle tip (Figure 17).
  - It is important to preserve as much drug as possible in order to completely fill the implant.

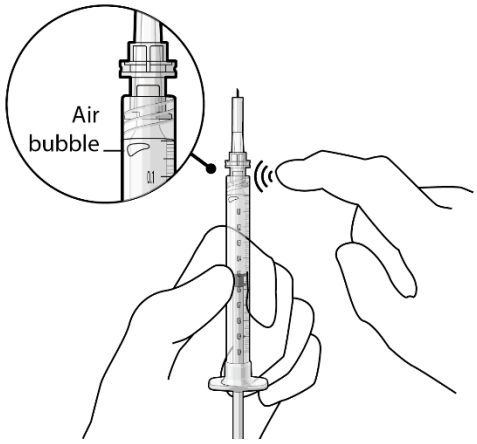


Figure 16
Gently tap the syringe to dislodge bubbles

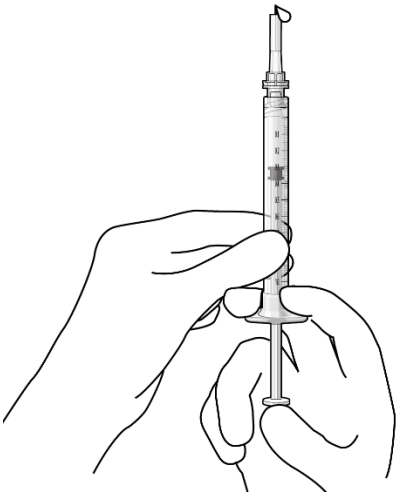


Figure 17
No air bubbles and a drop of drug at the needle tip

5. Inspect the syringe for air bubbles

- Inspect the syringe and the needle hub to ensure that no air bubbles are present (Figure 18).
- If air bubbles are present, continue to remove air from the syringe and reinspect.

Caution

Use the syringe within **15 minutes** of removing all air to avoid ranibizumab drying in the needle and impeding fluid flow.

Do not use the initial fill needle if the needle is clogged.

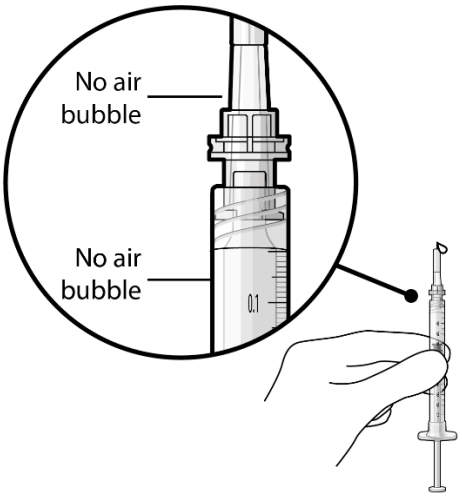


Figure 18

No air bubbles in the syringe and needle hub

6. Load syringe into the carrier

Caution

Do not hold or push on the plunger rod of the syringe while inserting the needle into the implant septum.

- Retrieve insertion tool carrier with pre-positioned implant from the inner tray.
- Align the syringe Luer lock above the Luer lock slot in the carrier to protect the needle from being damaged.
- Lower the syringe into the carrier (Figure 19).
- Push the syringe forward until it stops, taking care to avoid touching the plunger rod (Figure 20).
- With the syringe loaded, (Figure 21) the initial fill needle should now be penetrating the implant septum.

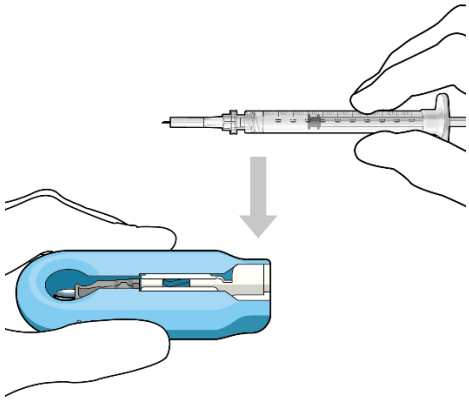


Figure 19
Align and lower the syringe into the carrier

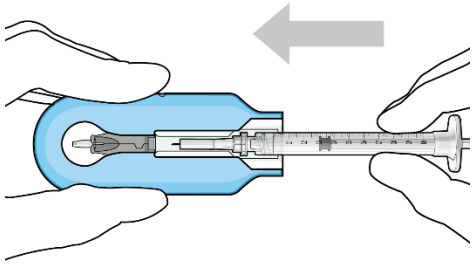


Figure 20
Push the syringe into the carrier

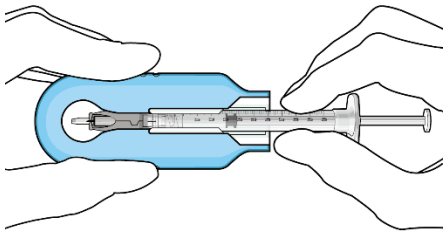


Figure 21
Syringe with initial fill needle inserted through the implant septum

7. Fill implant with ranibizumab under microscope

- Under the microscope, **slowly** administer ranibizumab into the implant by slightly tilting the carrier upwards (Figure 22).
- The implant should be filled over approximately **5 to 10 seconds**, to help avoid air entrapment in the implant reservoir.
- Continue filling the implant until the implant is completely full of drug solution and all air has been expelled as evidenced by a dome of drug solution formed at the tip of the implant on the release control element (Figure 23).

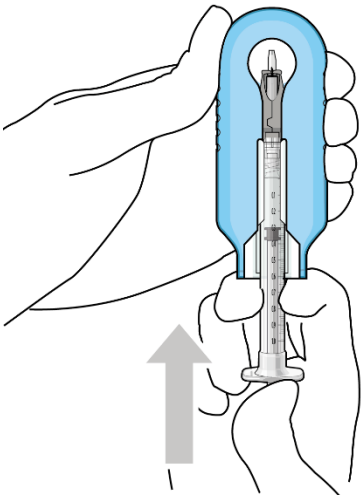


Figure 22
Administer ranibizumab into the implant

Caution

When filling the implant, fluid should only exit the implant from the release control element. If fluid is leaking from the implant at a different location, such as the side of the implant, **do not** use the implant.

If fluid is leaking from the septum at the needle insertion site, the needle may not be fully penetrating the implant septum. Fully push the syringe forward before continuing to fill the implant.

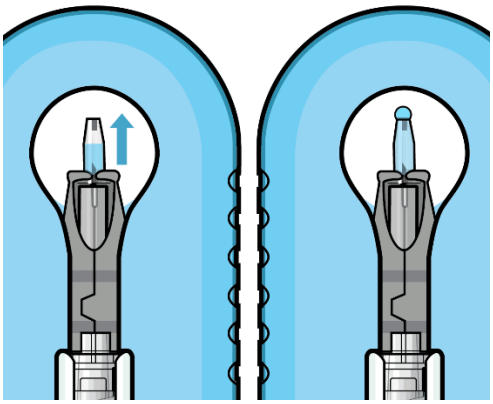


Figure 23
Dome of drug solution forms at tip of implant as viewed under magnification

8. Inspect the filled implant under the microscope

- Inspect the implant under the microscope to ensure that the implant is completely full of drug solution (Figure 24).

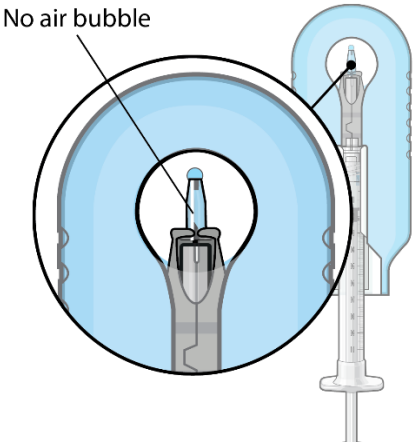


Figure 24

Proper appearance of implant after initial filling with ranibizumab

Warning

Minimize air bubbles within the implant reservoir as they may cause slower drug release. If an air bubble is present, it must be no larger than 1/3 of the widest diameter of the implant.

If excess air is observed, **do not** use the implant.

Caution

No more than **30 minutes** should pass between the initial fill of the implant and the insertion into the patient's eye to ensure that the release control element remains saturated with ranibizumab. If ranibizumab dries in the release control element, the implant may not release the drug properly into the vitreous after insertion.

9. Remove the syringe and guide sleeve from the carrier

- Remove the syringe and guide sleeve from the carrier by pulling back on the syringe (Figure 25). The syringe will be locked into the guide sleeve.
- Properly dispose of the used syringe together with the needle and guide sleeve in a sharps disposal container or in accordance with local requirements.

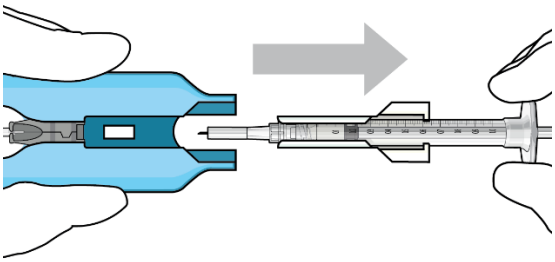


Figure 25
Remove the syringe and guide sleeve from the insertion tool carrier

10. Slide the insertion tool handle into the carrier

- Slide the insertion tool handle into the guide channel of the carrier, ensuring that both components are facing upwards (Figure 26).
- Push the handle forward as far as it will go into the gripper tips (Figure 27).

Caution

Do not withdraw the handle and implant until the eye is ready for insertion. Contact between the implant and any surface or object – even within the sterile field – may result in the introduction of a foreign body into the vitreous.

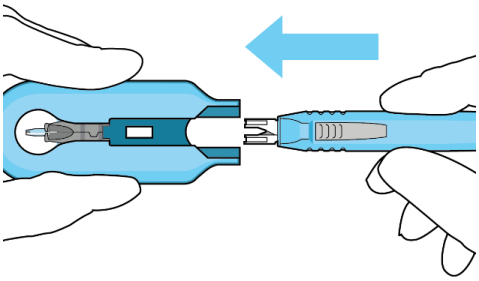


Figure 26
Insert the handle into the insertion tool carrier

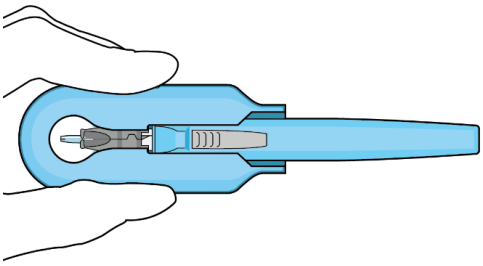


Figure 27
Fully inserted handle

Implant Insertion

1. Verify hemostasis of the scleral surface

- Clear any excess blood from the scleral surface.
- Perform careful scleral wet field cauterization as needed, particularly in the area of the sclero-pars plana incision.

2. Mark incision site

- Keep sclera dry and create discrete ink marks using a light touch.
- Mark a location **4 mm** from the limbus using an inked fixed width caliper (or equivalent) at the selected implant location (Figure 28).
- Mark a **3.5 mm** length for scleral dissection parallel to and 4 mm posterior to the limbus using an inked fixed width caliper (or equivalent) (Figure 29).

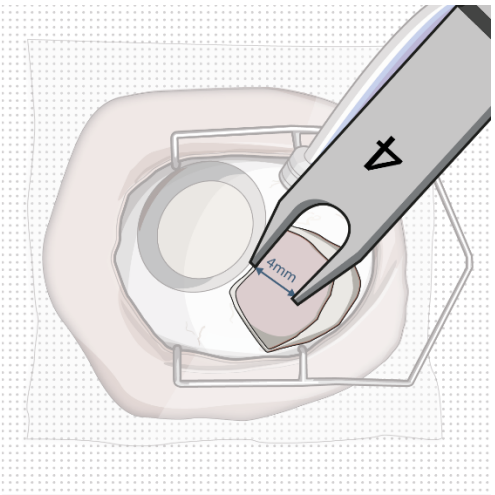


Figure 28
4 mm posterior to the limbus

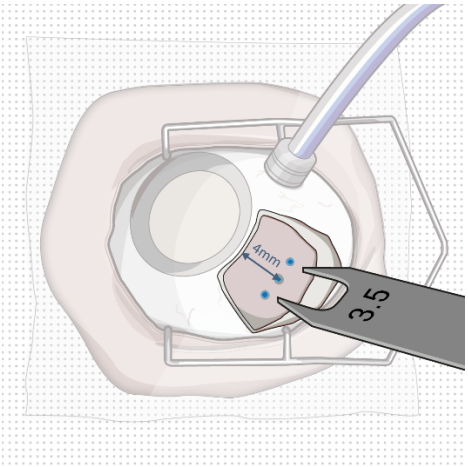


Figure 29
Fixed width caliper measurement

3. Perform scleral incision

- Using an MVR blade, create a full thickness dissection of the sclera until the pars plana is fully visible (Figure 30).
  - Ensure scleral dissection location is away from the radial conjunctival incision.

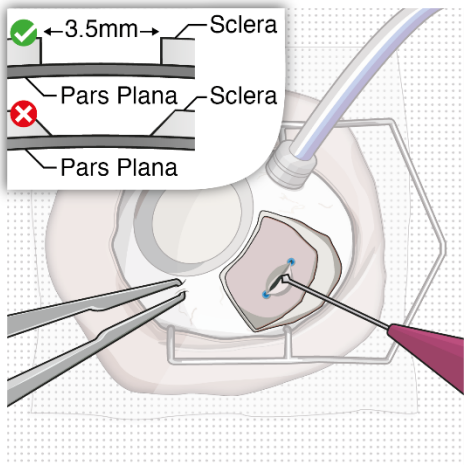


Figure 30

Stabilize the globe and perform full thickness scleral incision

Caution

The final target length for the scleral incision is 3.5 mm. Keep in mind that laser may further result in enlargement of incision and limit the secureness of the fit of the implant.

- Confirm the length of the incision by using the largest width of the 3.5 mm incision gauge (Figure 31).
- If the incision is over 3.5 mm, as indicated by a loose fit/side to side motion of 3.5 mm gauge, place a suture through the wound opposite the relaxing incision to reduce the incision down to 3.5 mm, and bury the knot. After suturing, confirm the incision length is 3.5 mm (Figure 31).
- If there are any areas of visible bleeding from the wound, carefully perform diathermy.

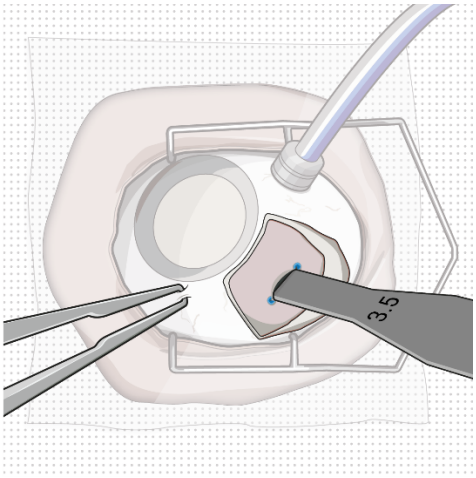


Figure 31

Confirm correct length of scleral incision

4. Perform laser treatment of the pars plana

Caution

Laser treatment may result in enlargement of the incision. Laser treatment should not be used to intentionally enlarge the length of scleral incision.

Caution

Carefully apply the laser only to the choroidal tissue in the exposed pars plana. Minimize any laser application to the surrounding scleral tissue to avoid damaging tissue integrity.

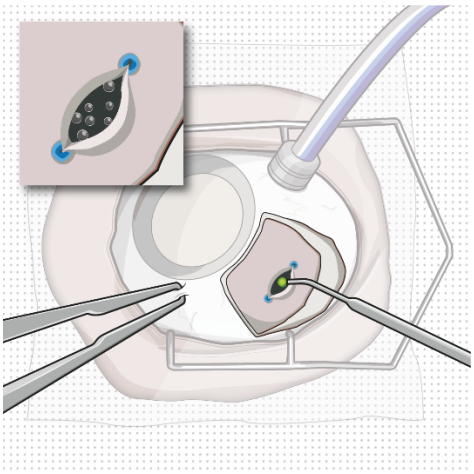


Figure 32

Laser treatment of the pars plana

- Confirm pars plana is dry before laser treatment and keep dry throughout the procedure (with surgical sponge).
  - Consider placing a surgical sponge as a wick at one end of the incision.
- Using a 532 nm laser endoprobe, apply contiguous, overlapping laser spots starting at 300 mW 1000 ms along the full length of the exposed pars plana (Figure 32). Repeat until complete ablation is achieved.
  - Maintain focus of laser on exposed pars plana.
  - Keep foot pedal depressed to achieve full 1000 ms spots (expect smoke).
  - Ensure the pars plana at the corners of scleral incision is adequately treated.
  - **Do not** use painting strokes with the laser.
  - **Do not** contact the pars plana directly with laser probe.
- Repeat application of laser along the full length of the pars plana until full or partial split of the pars plana, or other visual endpoints are achieved, as indicated by:
  - Gray color change.
  - Uniform perforated appearance.
  - Domes of vitreous fluid percolating through pars plana.
- If visual endpoint is not achieved after several passes with the laser, increase laser power in 100 mW increments.
- Once laser ablation of pars plana is completed, remeasure the entire length (including corners) of the scleral incision with 3.5 mm gauge to confirm the final post-laser incision is 3.5 mm. If final incision is greater than 3.5 mm, as indicated by a loose fit/side to side motion of 3.5 mm gauge, place a suture through the wound opposite the relaxing incision to reduce incision down to 3.5 mm.

Caution

A final post-laser incision length of 3.5 mm provides a secure fit for the implant.

Do not enlarge the scleral dissection beyond 3.5 mm as a final incision length greater than 3.5 mm may result in an improperly seated implant and will require additional suturing.

5. Perform pars plana incision

- Pass a 3.2 mm slit knife perpendicularly through the center of the scleral incision to open the underlying pars plana (Figure 33 and Figure 34).
- Ensure widest part of the blade passes through the incision.
- Ensure adequate hemostasis.
- Carefully check for any active bleeding from the pars plana incision; if active bleeding is present, address it with fine tip diathermy within the incision before proceeding.

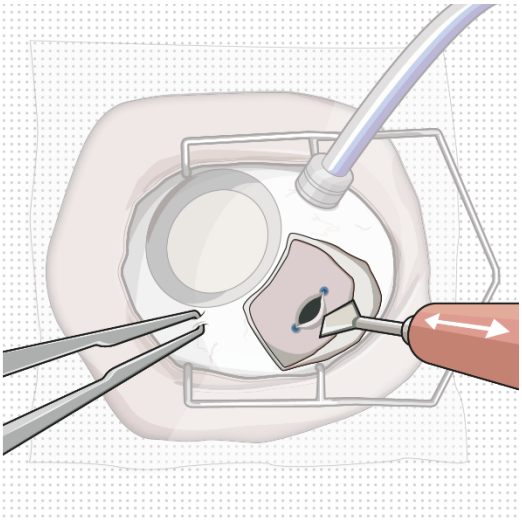


Figure 33
Pars plana incision

Caution

Do not enlarge the pars plana incision with lateral movements. The incision width of 3.2 mm ensures that the pars plana incision is within the laser-treated area of the pars plana and reduces the risk of vitreous hemorrhage.

- Aim to the center of the globe.
- Insert blade straight in and straight out.
- Avoid sideways motion.
- Avoid enlargement of the incision.
- Avoid the edges of the wound.

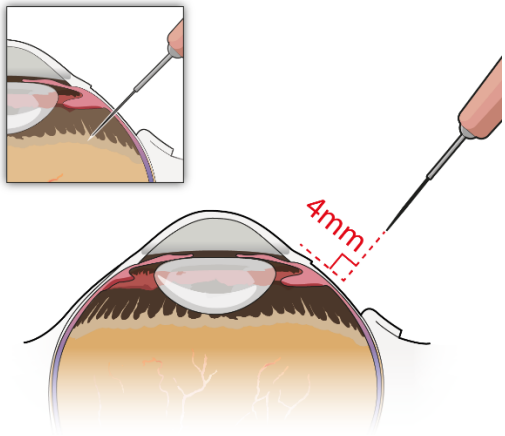


Figure 34
Perpendicular entry of slit knife

6. Withdraw the insertion tool handle with filled implant

- Withdraw the insertion tool handle, which is now attached to the gripper tips and implant, by slowly pulling the carrier and handle apart (Figure 35).
- Take care not to touch implant to any surface other than incision.

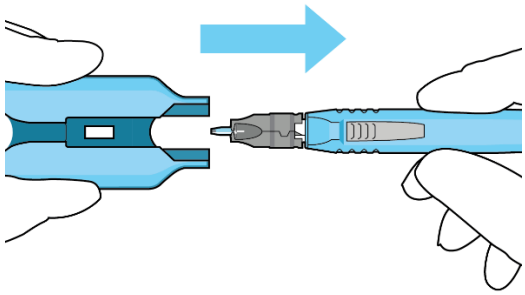


Figure 35

Withdraw the insertion tool handle with filled implant

Caution

When holding the insertion tool handle, take care not to touch the implant to any surface other than the sclero-pars plana incision during the insertion procedure.

Do not use the implant if it is inadvertently released or is contaminated through contact with any surface other than the exposed sclera, including objects within the surgical field.

7. Stabilize the globe

- Prior to inserting the implant, stabilize the globe with forceps to prevent unwanted eye movement (Figure 36).
- The forceps should remain in place until the insertion procedure is complete.

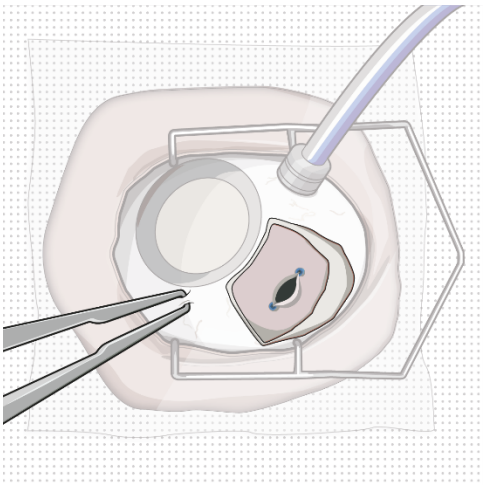


Figure 36

Stabilize the globe with forceps

8. Orient the implant

- Orient the long axis of the implant flange with the length of the sclero-pars plana incision (Figure 37).
- Aligning the implant in this direction enables the intended seating of the implant within the sclero-pars plana incision.

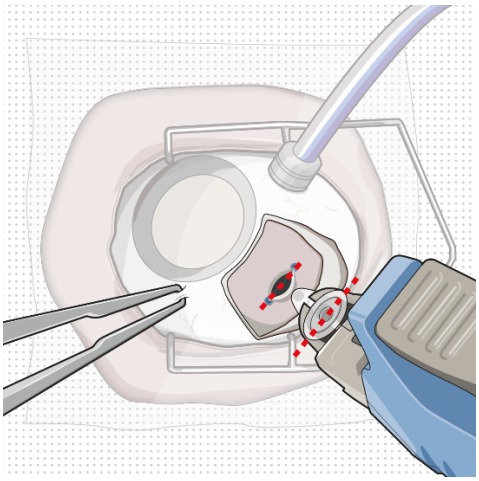


Figure 37

The long axis of the implant aligned with the length of the sclero-pars plana incision

9. Insert the implant

Warning

Perpendicular entry of the implant is important to avoid contact between the implant and intraocular structures such as the lens, as contact between the implant and the intraocular structures may cause adverse events such as traumatic cataract.

Warning

Avoid excessive force on the globe by first ensuring that the tip of the implant has passed through the sclero-pars plana incision before slowly pushing the implant into place.

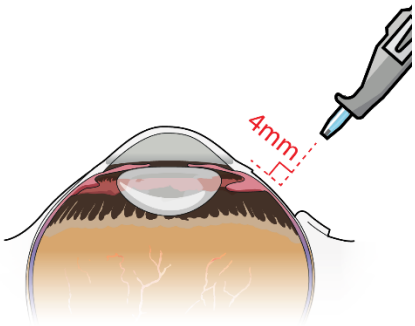


Figure 38
Perpendicular entry of the implant

- Slowly insert the implant through the sclero-pars plana incision perpendicular to the globe (Figure 38 and Figure 39).
- A slight initial twisting motion may be helpful to ease the implant through the sclero-pars plana incision (Figure 40).
- Continue pressing the implant slowly through the incision until the insertion tool handle gripper tips abut the sclera.
- Per the surgeon's discretion, the infusion line may be turned on while inserting the implant.
- If excess vitreous prolapses from the incision, use the vitrector to remove it and then place the implant.
- If a small amount of vitreous prolapse is present, place the implant first and then use the vitrector to remove the excess. Only use the vitrector to remove vitreous prolapse (**do not** use surgical sponge and/or scissors).

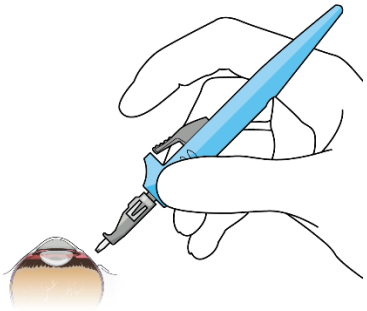


Figure 39
Implant insertion

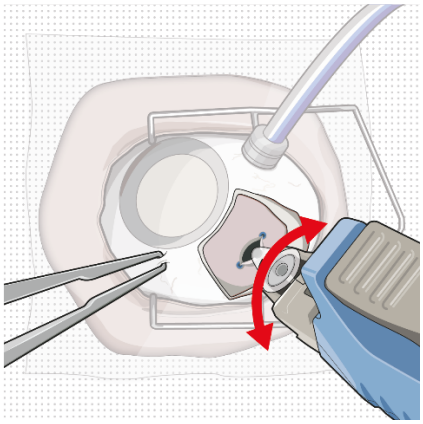


Figure 40
Implant insertion with a slight initial twisting motion

10. Release the implant

- Ensure that the long axis of the implant is properly aligned with the sclero-pars plana incision before releasing the implant from the insertion tool.
- The forceps that are stabilizing the globe should remain in place.
- Release the implant by depressing the release button completely (Figure 41 and Figure 42).

Caution

If the implant flange is not parallel to the limbus after releasing, it needs to be repositioned solely using the gripper tips of the insertion tool handle. Reposition gently to avoid damage to the implant and to avoid contact between the implant and intraocular structures such as the lens. Avoid excessive manipulation of the implant flange.

Do not use any other rigid instruments to reposition.

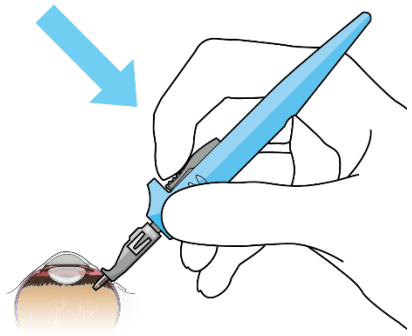


Figure 41

Release implant with the release button

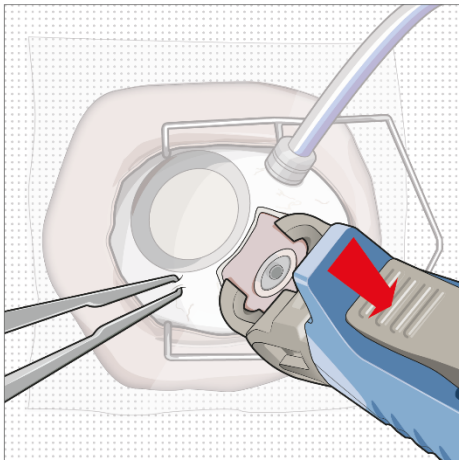


Figure 42

Implant release

11. Seat the implant

Caution

Use the insertion tool gripper tips to seat the implant.

Do not use any other rigid instruments as they may damage the implant.

Caution

Ensure that the long axis of the implant is aligned with the length of the sclero-pars plana incision and that the implant is seated flush against the sclera.

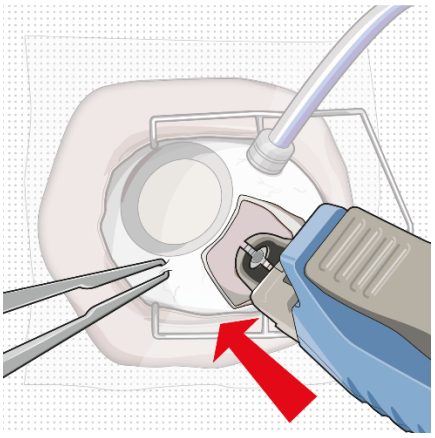


Figure 43

Seat the implant

- Remove finger from the release button to close the insertion tool gripper tips.
- Gently press the closed gripper tips against the **center** of the implant to seat the implant flush against the sclera (Figure 43).
- Clean any residual vitreous around the implant flange using a vitrector.

12. Suture Tenon's capsule and conjunctiva

- Close both Tenon's capsule and conjunctiva, with Vicryl or gut sutures, ensuring complete coverage of the implant flange.
- Use scleral anchoring at the apex of the peritomy.
- Ensure suture placement away from the implant (Figure 44).

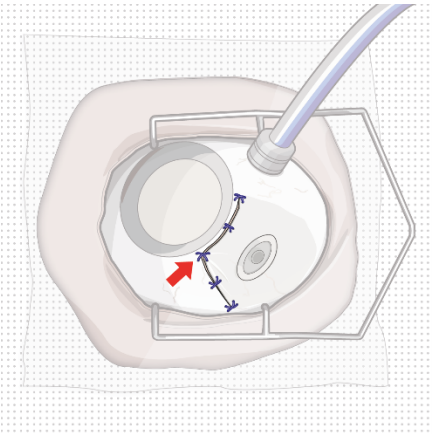


Figure 44
Suture conjunctiva

Caution

Do not place a suture directly over the implant, otherwise adverse events including incomplete healing, infection, and discomfort can occur.

Caution

Complete closure of both Tenon's capsule and conjunctiva across the surgical site is critical to minimize potential complications such as conjunctival retraction over the implant.

13. Remove infusion cannula

- If the infusion was previously turned on, then set the infusion pressure to 20 mmHg before removing the infusion cannula.
- Check for persistent leaks at the infusion cannula site and suture if necessary.

14. Check Intraocular Pressure (IOP)

- Using digital palpation, check the IOP. If necessary, inject additional fluid to restore IOP.

15. Check implant placement

- Perform indirect ophthalmoscopy to confirm implant position and to examine for the presence of any complications.

Disposal and Post-insertion Procedures

1. Dispose of used Susvimo components and tools

- **Do not** recap the needle or detach it from the syringe. Dispose of the used Susvimo components and tools in a sharps disposal container or in accordance with local requirements.

2. Perform post-insertion procedures

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

3. Post-insertion 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 insertion.
- Information on caring for the eye after the procedure, including but not limited to the following:
  - **Do not** remove the eye shield until they are instructed to do so by their physician. At bedtime, continue to wear the eye shield for at least 7 nights following implant insertion.
  - Administer all post-operative eye medications, as directed by their physician.
  - **Do not** push on the eye, rub the eye, or touch the region of the eye where the implant is located (underneath the eyelid in the upper and outer part of the eye) for 30 days following implant insertion. Avoid rubbing the eye or touching the area where the implant is located as much as possible at all other times but if necessary to do so, make sure hands are cleaned prior to touching the eye.
  - **Do not** participate in strenuous activities until 1 month after implant insertion or after discussion with their physician.
- Monitor for symptoms that may require immediate medical attention while the implant is in place.
- MR Conditional information:
  - The surgeon should inform the patient that the implant is MR Conditional (as noted on their Susvimo implant card) and if patient needs to undergo an MRI, they should let their doctor know they have Susvimo implanted in their eye.
  - After implant insertion, the surgeon should give the patient the implant card (enclosed in this IFU on the last page) with the appropriate information filled in, and should advise the patient to keep the card in a safe place, e.g. his or her wallet, for future reference. The surgeon should advise the patient that this implant card contains important information related to the Susvimo implant and that the card should be shown to their current and future health care providers.

Explanation of symbols on product or package labeling

Table 6 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
	Sterilized using ethylene oxide
	Temperature limit
	Expiration date/Use by date
	Lot/Batch number
	MR Conditional

MR Conditional

This person is implanted with a Susvimo™ Ocular Implant and can be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. Full MRI safety information is available in the Precautions section of the Instructions for Use.

Genentech, Inc. A Member of the Roche Group
1 DNA Way, South San Francisco, CA 94080-4990

Susvimo™ Implant Card

Patient Name: _____

Physician Name: _____

Clinic Name: _____

_____

Clinic Phone Number: _____

Date of implantation: _____

Implant LOT Number: _____

Note - The Implant LOT number can be found on the carton and blister tray of the Susvimo™ Insertion Tool Assembly

Manufactured by:

Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990
U.S. License No.: 1048

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Approved: 4/2022