(revakinagene taroretcel-lwey)
implant, for intravitreal use
ENCELTO™

Instructions for Use

℞ Only

ENCELTO procedures should be performed by an ophthalmologist experienced in vitreoretinal surgery and trained in ENCELTO procedures.

Neurotech Pharmaceuticals, Inc.
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U.S. License No. 2321

This IFU has been approved by the U.S. Food and Drug Administration.
Approved: 2025/03

F11002A Rev: 03

ENCELTO Patient Card

Following the procedure, provide the patient with a completed ENCELTO Patient Card and advise the patient to keep the card in a safe place for future reference.

The patient should be advised that this card contains important information related to ENCELTO and that the card should be shown to their current and future eye care providers.

ENCELTO™ Patient Card

Patient name .....

Physician name .....

Clinic name .....

.....

Clinic phone number .....

Date of insertion .....

LOT number .....

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MR Conditional

This person is implanted with ENCELTO and can be safely scanned with magnetic resonance imaging (MRI) only under very specific conditions.

Scanning under different conditions may result in severe patient injury or implant malfunction.

Full MRI safety information is available in the 'Magnetic Resonance Imaging (MRI)' section of the ENCELTO Instructions for Use which can be obtained at:

www.ENCELTO.com/ecp/instructions-for-use

Or telephone: 1-833-963-9275

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Contents

Introduction

These instructions include the procedures for using ENCELTO™. For more information on dosage, administration, warnings, and precautions, refer to the ENCELTO Prescribing Information.

Intended Use/Indications for Use

ENCELTO is indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

Recommended Dose

For intravitreal implantation only.

- ENCELTO is administered by a single surgical intravitreal procedure performed by a qualified ophthalmologist.
- The recommended dose of ENCELTO is one implant per affected eye. Each ENCELTO implant contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line), a neurotrophic factor.

ENCELTO Description

ENCELTO (revakinagene taroretcel-lwey) is single-dose, sterile, nonpyrogenic and retrievable.

ENCELTO is an allogeneic encapsulated cell-based gene therapy product that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line) for surgical intravitreal placement.

ENCELTO consists of an opaque, semi-permeable white to off-white capsule surrounding a scaffold of polyethylene terephthalate (PET) yarn, loaded with rhCNTF secreting allogeneic retinal pigment epithelial cells (NTC-201-6A cell line). Each end of the semi-permeable capsule is sealed with medical grade methacrylate adhesive, and to one end a titanium fixation loop is attached. ENCELTO width is 1.2 ± 0.1 mm, its length is 6.1 ± 0.4 mm, and its internal diameter is 0.88 ± 0.02 mm.

ENCELTO is packaged in a protective inner container within an orange to pink liquid hold medium referred to as Endothelial Serum Free Media (Endo-SFM), which is maintained sterile by a sealed outer container. ENCELTO is provided attached to a gripper that both suspends ENCELTO in the Endo-SFM and facilitates intraocular

insertion. The Endo-SFM within the packaging inner container may contain visible particles generally described as fiber, solid, white, or metallic in appearance.

Components

Components in the Corepack

On the day of surgery, before bringing the patient to the operating room, in a proper clean environment, remove the ENCELTO container from the corepack.

Perform the inspection as instructed within the Inspection Checklist and IFU. Verify that all conditions meet the inspection criteria before ENCELTO is cleared for surgical use. Do not open the outer container until the surgeon is ready to accept ENCELTO onto the surgical field.

A corepack contains one ENCELTO sealed within a sterile inner container.

The inner container is sealed within an outer container to facilitate sterile transfer to the surgical technician or surgeon for preparation.

The outer container is held in support foam within the corepack and provided alongside the Instructions for Use, ENCELTO Medium pH Color Guide, Inspection Checklist, a disposable temperature recording device, and the United States Prescribing Information (USPI).

Components in the Corepack

1. Corepack
2. Outer container holding the sterile inner container
3. Disposable temperature recording device
4. ENCELTO Medium pH Color Guide
5. ENCELTO Instructions for Use
6. ENCELTO Inspection Checklist
7. United States Prescribing Information

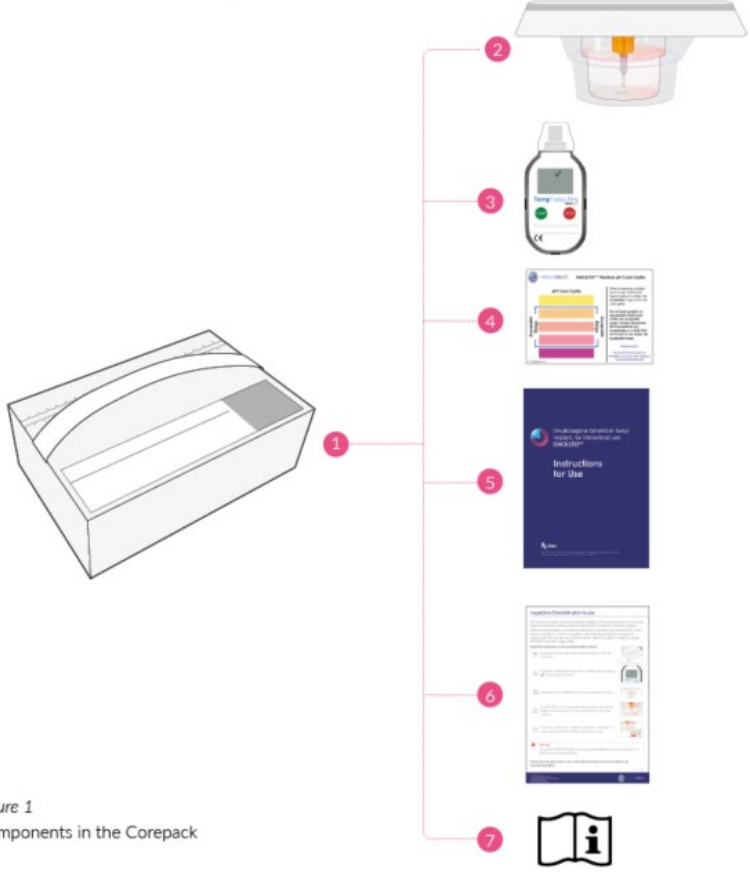

Figure 1
Components in the Corepack

Table 1 Description of Corepack components

Components	Description
Inner container	This is provided sterile. It is a cylindrical plastic container with a lower compartment filled with liquid medium. It has an upper compartment connected to it via a narrow channel that is secured shut with a luer lock cap.
Outer container	This is a plastic container with a Tyvek lid. It maintains the sterility of the inner container until ready to use.
Disposable temperature recording device	A disposable device that measures and records the temperature in the corepack. If ENCELTO has been stored within the acceptable range, a ✓ will be shown at the top of the screen. If an ✗ is displayed, ENCELTO has been exposed to temperatures outside of the acceptable range and must not be used.
ENCELTO Medium pH Color Guide	A card that provides a color scale to indicate the acceptable pH range for the liquid medium.
ENCELTO Instructions for Use	A booklet that contains the full instructions and includes the ENCELTO patient card.
ENCELTO Inspection Checklist	An information sheet that contains instructions for inspection prior to use.
USPI	United States Prescribing Information.

ENCELTO Overview

ENCELTO is packaged in a protective inner container within an Endothelial Serum Free Media (Endo-SFM), which is maintained sterile by a sealed outer container. ENCELTO is provided attached to a gripper that both suspends ENCELTO in the Endo-SFM and facilitates intraocular insertion. ENCELTO contains no preservatives.

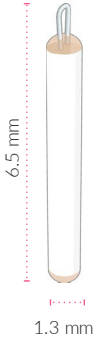

Figure 2
ENCELTO in detail
Not to scale

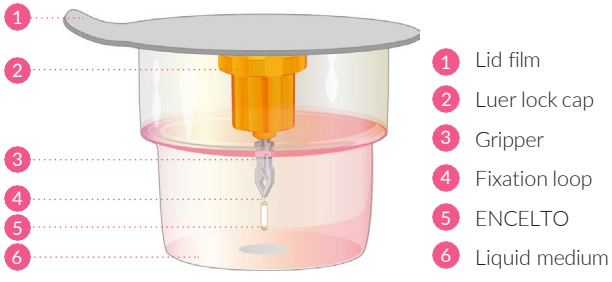

Figure 3
ENCELTO within sterile inner container

Table 2 ENCELTO component description

Components	Description
Lid film	The lid film provides a seal to maintain the sterile environment within the inner container. It should be peeled back to reveal the luer lock cap when the surgeon is ready to implant ENCELTO.
Luer lock cap	A luer lock fitting is attached to the gripper and is used to suspend ENCELTO in liquid medium within the inner packaging. It is also used to handle and manipulate ENCELTO during preparation and insertion.
Gripper	The gripper holds ENCELTO by the fixation loop. Squeezing the gripper releases ENCELTO.
Fixation loop	A titanium loop that is attached to one end of ENCELTO. It is used to suture ENCELTO to the sclera.
ENCELTO	ENCELTO is a sealed semi-permeable capsule that has a width of 1.2 ± 0.1 mm, length of 6.1 ± 0.4 mm, and internal diameter of 0.88 ± 0.02 mm.
Liquid medium	The liquid medium provides a nutrient rich environment to sustain ENCELTO during storage and transport.

Storage and Handling

Using the handle, remove the corepack from the larger shipping box.

Store ENCELTO in the corepack at 16° to 37°C (61° to 99°F) until ready for use.

Inspect the disposable temperature recording device. If a check mark is displayed, ENCELTO has remained within the acceptable temperature range and may be used. If a "X" is displayed, the ENCELTO was exposed to temperatures outside the acceptable range and must not be used. Contact Neurotech immediately at (833)-963-9275.

Protect ENCELTO from light.

Handle inner container (Figure 3) using sterile technique.

Prior to disposal of an ENCELTO implant per local institutional protocols, call 1-833-963-9275 for assessment of ENCELTO return or replacement.

Caution

- Do not use beyond the "use by" date identified on the corepack label.
- Do not freeze, refrigerate, or expose to temperatures >38°C (101°F).

ENCELTO Medium pH Color Guide

When inspecting the inner container prior to use, ensure the liquid medium is within the acceptable pH range on the ENCELTO Medium pH Color Guide.

Orange to pink liquid hold medium referred to as Endothelial Serum Free Media (Endo-SFM) within packaging inner container may contain visible particles. Particle general description fiber, solid, white, or metallic in appearance.

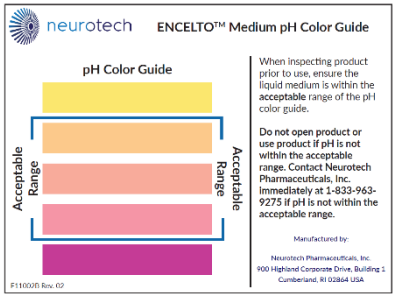

Figure 4
ENCELTO Medium pH Color Guide

Caution

- Do not use ENCELTO if the pH is not within the acceptable range. Contact Neurotech immediately at 1-833-963-9275.

Warnings

Read and follow all instructions, warnings, and cautions prior to use.

The ENCELTO Prescribing Information contains a complete list of indications, contraindications, warnings, precautions, and adverse events.

ENCELTO Insertion Procedure

1 Preparatory Procedures

- Do not use ENCELTO if there are any signs of leakage or damage to the corepack, as sterility may have been compromised. Contact Neurotech immediately at 1-833-963-9275.
- Do not use ENCELTO if there are signs of damage to the outer container and lid films. Contact Neurotech immediately at 1-833-963-9275.
- Do not use ENCELTO if there is medium in the upper portion of the inner container, as sterility may have been compromised. Contact Neurotech immediately at 1-833-963-9275.
- Do not use ENCELTO if the pH of the medium is not within the acceptable range. Contact Neurotech immediately at 1-833-963-9275.
- Do not use ENCELTO if there are any concerns following the visual inspection or if sterility has been compromised. Contact Neurotech immediately at 1-833-963-9275.

2 Surgical Site Preparation

- Do not use the superior quadrants. When ENCELTO is inserted in a superior quadrant, it may enter the patient's visual axis.
- Do not insert ENCELTO outside of the pars plana.
- Ensure the sclerotomy incision is 3.0 mm in length, parallel to the limbus, and full-thickness throughout with square corners.

3 ENCELTO Preparation

- Do not use ENCELTO if it is damaged or if sterility has been compromised. Contact Neurotech immediately at 1-833-963-9275.

4 Insertion and Closure

- Using an alternative knot to the anchor knot and not placing it at the apex of the fixation loop increases the risk of migration and extrusion of ENCELTO.
- Ensure the second and third throws of the polypropylene anchor suture are tight locking throws at the very apex of the fixation loop.
- When suturing ENCELTO to the sclera, avoid shallow placement of the polypropylene suture as this increases the risk of migration and extrusion of ENCELTO.
- Passing the polypropylene suture too wide from the incision increases the risk of hitting other ocular structures.
- Placing the polypropylene suture off-center makes wound closure more difficult and increases the risk of wound leak, ENCELTO migration, and/or endophthalmitis.
- Ensure the fixation loop is at 90-99% depth for correct wound closure to minimize the risk of migration and extrusion of ENCELTO.
- Do not tie or pull the polypropylene suture too tight when securing with the 3-1-1 knot as this could lead to migration and extrusion of the ENCELTO. This is an anchor suture and is not used for closure.
- Do not cut off the needles from the polypropylene suture as they will be needed to bury the ends of the suture. Not burying the suture ends will increase the risk of postoperative complications.
- Do not pass the polypropylene suture more anterior or posterior to the incision to avoid other structures of the eye.
- Failure to perform indirect ophthalmoscopy can lead to unidentified malpositioning of ENCELTO and intraocular complications.

5 End of Surgery

- None specified

Warnings (cont'd)

6 Postoperative Wound Care

- Failure to follow postoperative antibiotic and steroid application can lead to increased risk of injury, inflammation, or infection.

ENCELTO Removal Procedure

1 Surgical Site Preparation

- None specified

2 ENCELTO Removal and Closure

- Do not cut the center polypropylene anchor suture when removing the nylon sutures.
- Do not cut the posterior side of the polypropylene anchor suture before grasping the fixation loop.
- Failure to grasp the fixation loop may release ENCELTO into the vitreous and may require a complete vitrectomy to recover.

3 Post-operative Wound Care

- Failure to follow postoperative antibiotic and steroid application can lead to increased risk of injury, inflammation, or infection.

Precautions

- There is no data on the use of ENCELTO in pregnant women.
- There is no data on the presence of ENCELTO in human milk, the effects of ENCELTO on breastfed infant, and effects of ENCELTO on milk production.
- The safety and effectiveness of ENCELTO has not been established in pediatric patients

Contraindications

ENCELTO is contraindicated in patients with:

- Active or suspected ocular or periocular infections.
- Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)

Use with Standard Procedures

ENCELTO 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
- Fundus autofluorescence

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

Magnetic Resonance Imaging (MRI)

A patient with ENCELTO may be safely scanned under the following conditions. Failure to follow the conditions outlined in Table 3 might result in injury to the patient.

Table 3 MRI Safety Information

Parameter	Condition of Use/Information
Static Magnetic Field Strength (B_o)	1.5T or 3.0T
Static Magnetic Field (B_o) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient	40 T/m (4000 gauss/cm)
RF Polarization	Circularly Polarized (CP) (ie, quadrature drive)
RF Transmit Coil Type	Any Transmit RF coil may be used
RF Receive Coil Type	Any Receive RF coil may be used
RF Operating Mode	Normal Operating Mode
Scan Duration	Scan for 60 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 5 minutes before resuming scanning.
MR Image Artifact	The image artifact can extend approximately 1 mm from the ENCELTO. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

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Insertion Procedure

Preoperative Procedure

Prepare additional items for surgery

Standard ophthalmic instruments will be required for this procedure.

The following surgical instruments are referenced and suggested for use but are not provided.

Table 4 Surgical instruments description

Item description	Further detail
20-gauge microvitreoretinal blade	-
15-degree asymmetric blade	-
Sutures - all on spatulated needles	• 7-0 Vicryl corneal traction suture to rotate eye • 9-0 polypropylene double-armed anchor suture • 9-0 nylon wound closure suture • 6-0 plain gut or chromic suture preferred, but can use 7-Vicryl conjunctival suture
Cautery	18-gauge eraser tip and 25-gauge fine tip

Topical antibiotics and topical steroids are suggested for use but are not provided.

Prepare patient for surgery

Prepare patient for surgery using standard sterile surgical methods and standard operating room practices.

Conduct standard periocular preparation and draping. Place a lid speculum and optional corneal shield. See Figure 5.

Perform the procedure under local anesthesia using either peribulbar, retrobulbar, or subtenon's technique.

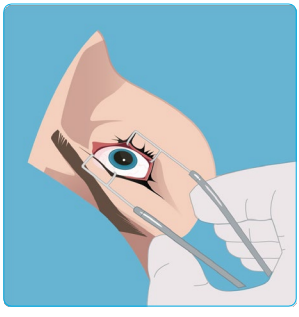

Figure 5 Prepare patient for insertion procedure

1 Preparatory Procedures

On the day of surgery, before bringing the patient to the operating room, in a proper clean environment, carefully remove the ENCELTO container from the corepack.

Perform the inspection as instructed within the Inspection Checklist and IFU. Verify that all conditions meet the inspection criteria before ENCELTO is cleared for surgical use. Do not open the outer container until the surgeon is ready to accept ENCELTO onto the surgical field.

1.1 Inspect ENCELTO prior to use

i. Inspect the corepack for damage and signs of leakage.

Warning

- Do not use ENCELTO if there are any signs of leakage or damage to the corepack, as sterility may have been compromised.

  Contact Neurotech immediately at 1-833-963-9275.

ii. Confirm the use-by date on the corepack label has not passed. See Figure 6.

Caution

- Do not use ENCELTO beyond the use-by date. See corepack label for use-by date.

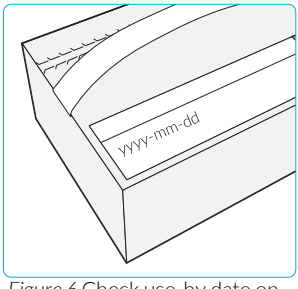

Figure 6 Check use-by date on corepack

iii. Open the corepack and confirm the disposable temperature recording device displays a ✓ at the top of the screen. See Figure 7.

Caution

If the temperature recording device displays an ✗ at the top of the screen, this indicates a temperature exposure outside of the acceptable range occurred. Contact Neurotech immediately at 1-833-963-9275 to report the issue. The appropriate action will be taken to initiate return of ENCELTO and possible replacement. Maintain the original packing material.

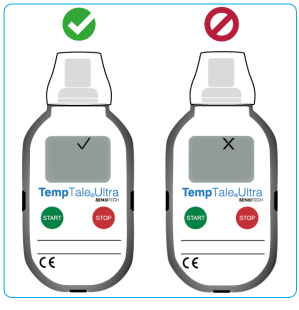

Figure 7 Check disposable temperature recording device

1.1 Inspect ENCELTO prior to use (cont'd)

iv. Remove the outer container from the corepack and perform an inspection of ENCELTO by confirming:

- All seals and lid films are intact.
- The liquid medium is in the lower portion of the inner container.
- ENCELTO is suspended in the liquid medium by the gripper. See Figure 8.

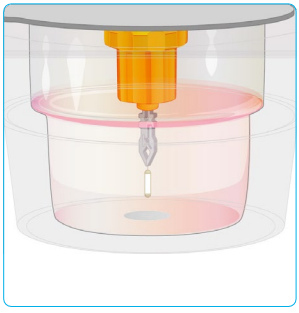

Figure 8 Check ENCELTO is suspended in liquid medium

ⓘ Note

ENCELTO can be visually inspected in the outer container. Do not open the outer container until ready to use.

Warning

- Do not use ENCELTO if there are signs of damage to the outer container and lid films.
- Do not use ENCELTO if there is medium in the upper portion of the inner container, as sterility may have been compromised.

Contact Neurotech immediately at 1-833-963-9275.

v. Using the ENCELTO Medium pH Color Guide, inspect the color of the liquid medium and confirm it is within the acceptable pH range. See Figure 9.

Warning

- Do not use ENCELTO if the pH of the medium is not within the acceptable range.

Contact Neurotech immediately at 1-833-963-9275.

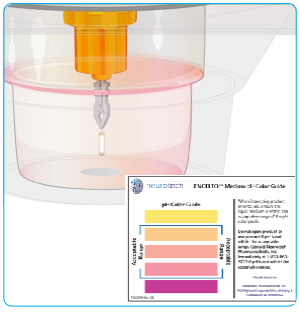

Figure 9 Inspect integrity of medium

1.2 Transfer the inner container to the sterile field

Warning

- Do not use ENCELTO if there are any concerns following the visual inspection or if sterility has been compromised.

  Contact Neurotech immediately at 1-833-963-9275.

i. Peel back the lid film of the non-sterile outer container and hold it open for the sterile surgical technician or nurse. See Figure 10.

Figure 10 Open outer container

Maintain the sterility of the inner container while handling.

ii. Using sterile technique, remove the inner container and place it in an upright position into the sterile field. See Figure 11.

Discard the outer container after the inner container is removed.

Figure 11 Transfer inner container into sterile field

iii. Perform a second inspection of ENCELTO by confirming:

- All seals and lid films are intact.
- ENCELTO is suspended in the liquid medium by the gripper.
- The medium is in the lower portion of the inner container.
- The color is within the acceptable pH range using the ENCELTO Medium pH Color Guide. See Figure 12.

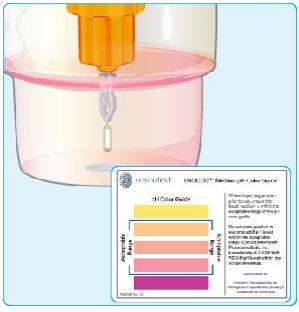

Figure 12 Perform inspection of ENCELTO

2 Surgical Site Preparation

2.1 Conduct conjunctival peritomy

i. Identify the inferior quadrant for planned ENCELTO insertion.

Warning

- Do not use the superior quadrants. When ENCELTO is inserted in a superior quadrant, it may enter the patient's visual axis.

ii. Expose the planned insertion site by creating a 7.0 mm conjunctival limbal peritomy and a 7.0mm conjunctival radial incision, or similar. See Figure 13.

ⓘ Note

Avoid creating buttonholes in the conjunctiva during this procedure.

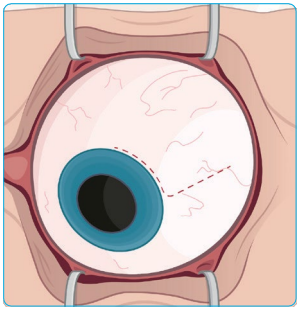

Figure 13 Create insertion site

iii. Carefully dissect the conjunctiva and Tenon's capsule from the bare sclera. See Figure 14.

iv. Maintain hemostasis using wet-field cautery.

ⓘ Note

Avoid blood entering the scleral wound.

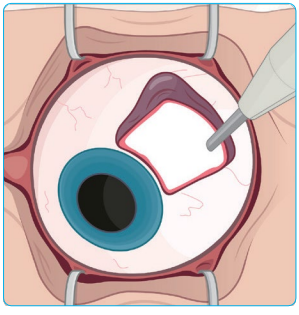

Figure 14 Dissect from sclera

v. Under microscopic visualization, place a corneal-limbal traction suture using a 7-0 Vicryl suture on a spatulated needle or similar, in the identified inferotemporal or inferonasal quadrant. See Figure 15.

ⓘ Note

Take care to avoid penetrating the anterior chamber, as this could lead to procedural complications and visual impairment.

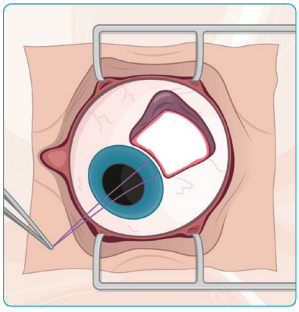

Figure 15 Place corneal-limbal traction suture in inferior quadrant

2.2 Perform a 3.0 mm sclerotomy

Warning

- Do not insert ENCELTO outside of the pars plana.

i. While keeping the sclera dry, measure and mark 3.75 mm from the limbus using an inked adjustable caliper at the selected location.

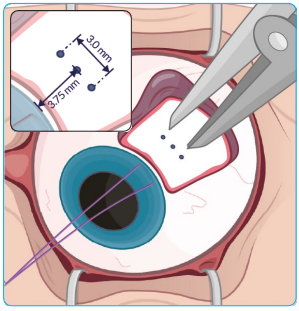

Figure 16 Measure and mark 3.0 mm incision

ii. Mark a 3.0 mm length for the scleral incision, parallel to and 3.75 mm posterior to the limbus using an inked adjustable caliper. See Figure 16.

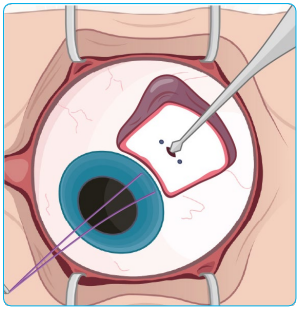

Figure 17 Enter sclera 3.75 mm posterior to limbus

iii. Use a 20 gauge microvitreoretinal blade or similar to enter the sclera 3.75 mm posterior to the limbus, creating a full-thickness incision of the sclera and choroid. See Figure 17.

iv. Enlarge the full-thickness incision of the sclera and choroid to 3.0 mm using a 15 degree asymmetric blade, or similar. See Figure 18.

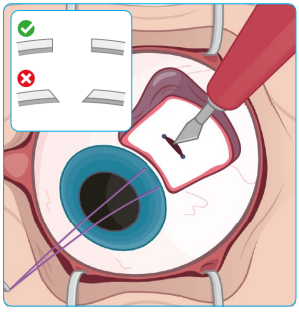

Figure 18 Enlarge the full-thickness incision to 3.0mm

Warning

- Ensure the sclerotomy incision is 3.0mm in length, parallel to the limbus, and full-thickness throughout with square corners.

v. Gently open the sclerotomy incision.

Confirm the incision is full-thickness and that hemostasis has been achieved. If there is any spanning uveal tissue, incise the wound again. If there is any active bleeding, apply further wet-field cautery. See Figure 19.

ⓘ Note

Take care to ensure the incision is full thickness to avoid potential complications such as vitreous hemorrhage, cyclodialysis or retinal detachment.

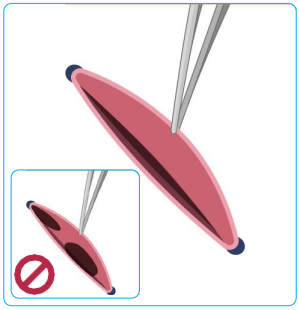

Figure 19 Confirm no spanning uveal tissue

vi. Excise any significant prolapsed vitreous with minimal traction 'Weck-Cel vitrectomy' or a standard vitrectomy cutter prior to insertion. See Figure 20.

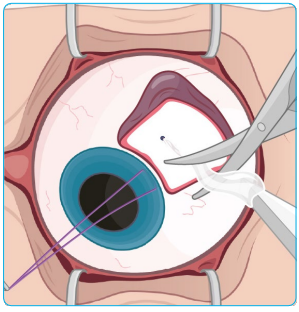

Figure 20 Excise prolapsed vitreous

3 ENCELTO Preparation

3.1 Prepare ENCELTO for insertion

Warning

- Do not use ENCELTO if it is damaged or if sterility has been compromised.

  Contact Neurotech immediately at 1-833-963-9275.

i. Peel back the lid film of the inner container exposing the upper compartment of the container and the luer lock cap. See Figure 21.

ⓘ Note

Keep the inner container in the sterile field as ENCELTO can be returned to the liquid medium if necessary.

Figure 21 Open inner container

ii. Unlock the luer lock cap with one complete counter-clockwise turn.

Lift the luer lock cap vertically to remove ENCELTO, which should be attached to the gripper. See Figure 22.

ⓘ Notes

Avoid dislodging ENCELTO from the gripper when withdrawing it from the inner container.

Ensure ENCELTO does not come into contact with anything.

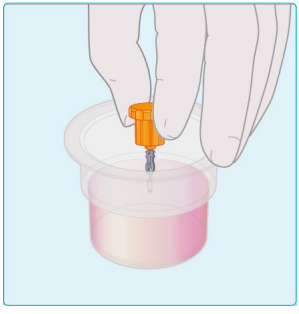

Figure 22 Unlock and remove ENCELTO from inner container

iii. Rinse ENCELTO with at least 5 mL of sterile Balanced Salt Solution (BSS) prior to insertion, until no excess liquid medium is left on the surface.

BSS rinse should be applied every 10 minutes to keep ENCELTO moist and prevent dehydration. See Figure 23.

Figure 23 Rinse with at least 5 mL of BSS

ⓘ Note

Avoid touching ENCELTO while rinsing.

⚠ Caution

- Rinse all liquid medium from the surface of ENCELTO prior to insertion, to reduce the patient's exposure to excipients.
- Avoid resting ENCELTO on an absorbent surface.
- Avoid exposing ENCELTO to air for more than 10 minutes, as this could reduce the efficacy of the therapy.
- Only use BSS or other salt solutions to rinse ENCELTO.

3.1 Prepare ENCELTO for insertion (cont'd)

iv. While holding the luer lock cap, visualize the fixation loop at the end of ENCELTO under the microscope.

Pass a double-armed 9-0 polypropylene suture needle through the fixation loop and pull one fourth of the suture length through. See Figure 24.

ⓘ Notes

There is a 0.5 mm distance between the fixation loop and end of ENCELTO.

Pulling one fourth of suture length makes it easier to create a 3-1-1 knot than if pulled halfway.

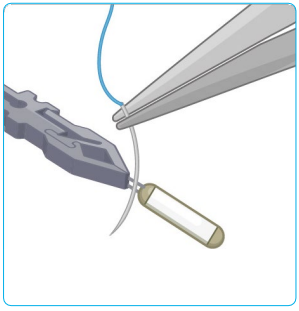

Figure 24 Pass 9-0 polypropylene suture through fixation loop

⚠ Caution

- Using alternative sutures may cause post-operative complications.

4 ENCELTO Insertion and Closure

4.1 ENCELTO insertion

Warning

- Do not use ENCELTO if it is damaged or if sterility has been compromised.

  Contact Neurotech immediately at 1-833-963-9275.

i. Gently open the sclerotomy incision using toothed forceps.

ⓘ Note

Confirm complete hemostasis and that there is no blood over or around the sclerotomy site.

ii. Holding the luer lock cap, insert ENCELTO perpendicularly to the globe through the scleral incision until only the fixation loop is exposed. See Figure 25 and 26.

ⓘ Note

While inserting ENCELTO, aim towards the optic nerve and away from the lens and out of the visual axis.

Caution

- Avoid inserting ENCELTO towards the lens or deeply into the eye. Do not insert ENCELTO beyond the fixation loop.

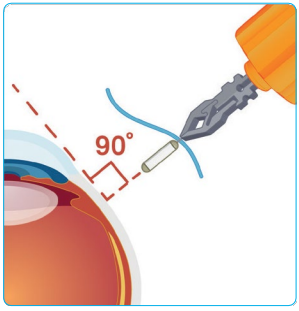

Figure 25 Perpendicular entry of ENCELTO

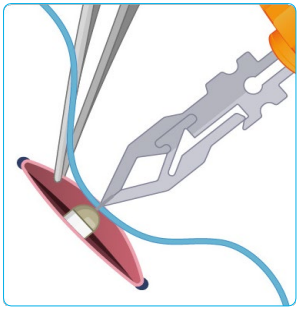

Figure 26 Insert ENCELTO

4.1 ENCELTO insertion (cont'd)

iii. Using forceps or needle holders, squeeze the gripper in the indicated region to release ENCELTO. See Figure 27.

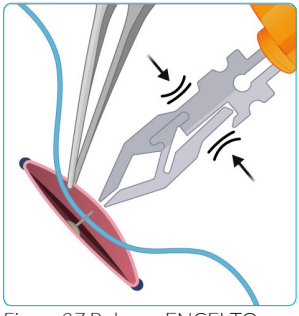

Figure 27 Release ENCELTO

ⓘ Notes

The traction suture might need to be released to allow visualization of the gripper release site.

Squeezing below the indicated region or using other methods to release ENCELTO may crush the gripper, making it difficult or impossible to release. If the release fails or is damaged in any way, ENCELTO cannot be used, and procedure must be rescheduled. Contact Neurotech immediately at 1-833-963-9275 to report the issues. The appropriate action will be taken to initiate return of ENCELTO and possible replacement.

iv. Create an anchor knot by tying the polypropylene suture in a 3-1-1 knot using large tying loops. See Figure 28.

ⓘ Note

The polypropylene suture has memory and requires careful handling. It is best to keep large tying loops and grasp the needle rather than the suture for the pull through.

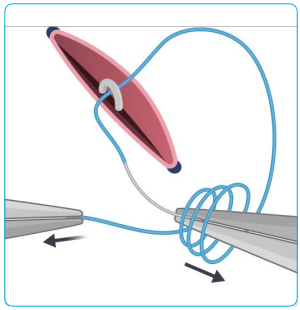

Figure 28 Create anchor knot by tying a 3-1-1 knot

Warning

- Using an alternative knot to the anchor knot and not placing it at the apex of the fixation loop increases the risk of migration and extrusion of ENCELTO.

v. Place the anchor knot at the apex of the fixation loop. See Figure 29.

Warning

- Ensure the second and third throws of the polypropylene anchor suture are tight locking throws at the very apex of the fixation loop.

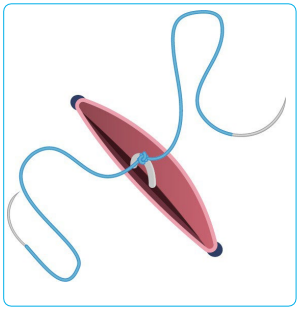

Figure 29 Place anchor knot at apex of fixation loop

4.2 Anchoring ENCELTO to the sclera

i. Gently grasp the edge of the sclerotomy with toothed forceps to open the wound.

With ENCELTO centered in the incision, pass each arm of the polypropylene suture centrally through either side of the wound at a scleral depth of 90 - 99%. See Figure 30.

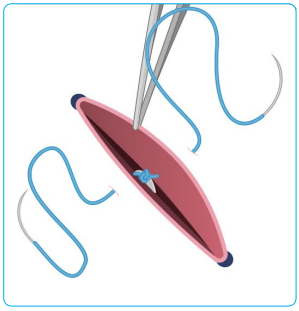

Figure 30 Pass polypropylene suture at 90-99% depth

ⓘ Note

Adjust the fixation loop as needed if it is in the way of the passing sutures.

Warning

- When suturing ENCELTO to the sclera, avoid shallow placement of the polypropylene suture as this increases the risk of migration and extrusion of ENCELTO.
- Passing the polypropylene suture too wide from the incision increases the risk of hitting other ocular structures.
- Placing the polypropylene suture off-center makes wound closure more difficult and increases the risk of wound leak, ENCELTO migration, and/or endophthalmitis.

ii. Pull up the suture ends and confirm that the anchor knot is at the apex of the fixation loop and is visible at 90 - 99% depth. See Figure 31.

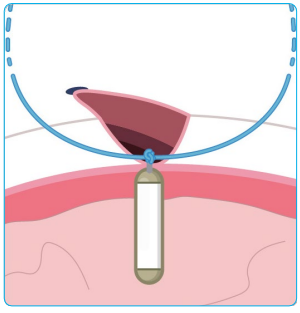

Figure 31 Confirm anchor knot is visible at 90-99% depth

Warning

- Ensure the fixation loop is at 90-99% depth for correct wound closure to minimize the risk of migration and extrusion of ENCELTO.

iii. Tie the polypropylene suture down to the sclera with a 3-1-1 knot. Placing the knot away from the incision will allow for wound healing without the knot in the wound. See Figure 32.

Leave needles attached to the polypropylene suture as they will be used for the final closure.

If a suture breaks, keep the tail as long as possible and lay it flat. Ensure a watertight closure of the sclera.

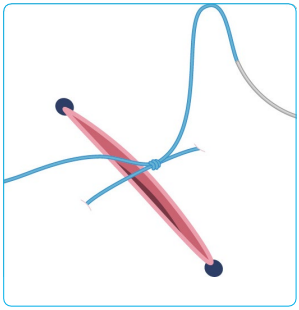

Figure 32 Tie with a 3-1-1 knot

ⓘ Note

The polypropylene suture has memory and requires careful handling. It is best to keep large tying loops and grasp the needle rather than the suture for the pull through.

⚠ Caution

- Tying the polypropylene suture with an alternative knot to a 3-1-1 knot may make wound closure more difficult.

⚠ Warning

- Do not tie or pull the polypropylene suture too tight when securing with the 3-1-1 knot as this could lead to migration and extrusion of ENCELTO. This is an anchor suture and is not used for closure.
- Do not cut off the needles from the polypropylene suture as they will be needed to bury the ends of the suture. Not burying the suture ends will increase the risk of postoperative complications.

4.2 Anchoring ENCELTO to the sclera (cont'd)

iv. With the polypropylene suture, take at least a 2.0 mm long bite of the sclera at 50-75% depth beyond the end of the sclerotomy on each side. See Figure 33.

Warning

- Do not pass the polypropylene suture more anterior or posterior to the incision to avoid other structures of the eye.
- Not burying the suture ends will increase the risk of post-operative complications.

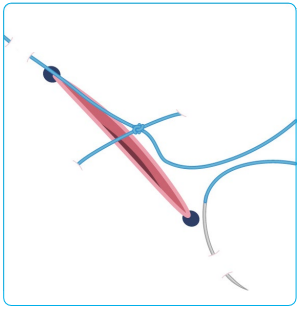

Figure 33 Create 2.0 mm bites of sclera beyond sclerotomy

4.3 Wound closure

i. Using standard surgical techniques for scleral wound closure, close the scleral incision with 9-0 nylon sutures. Recommended best practices follow in section 4.3. The nylon sutures will be used to capture the polypropylene suture to mitigate suture tip irritation and conjunctival erosion.

a. Using 9-0 nylon sutures, divide the sclerotomy into thirds. Pass each needle at a depth of 75 - 80%. See Figure 34.

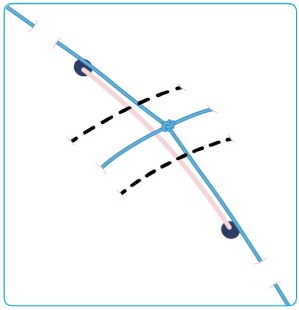

Figure 34 Location of nylon sutures

ⓘ Note

The nylon sutures will be closer to the center polypropylene suture than to the ends of the sclerotomy.

b. Using a 3-1-1 closure, ensure the locking throws are square and tight so the nylon suture knots can be rotated into the sclera. See Figure 35.

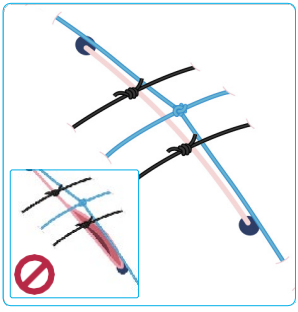

Figure 35 Ensure locking throws are square and tight

ⓘ Note

The nylon sutures must completely close the wound, leaving no wound gape anywhere, to create a watertight closure. If there is any gaping, the sutures should be replaced and closed tighter or another suture placed to close the wound.

c. Rotate the knots and suture tails of the 9-0 nylon sutures into the sclera. See Figure 36.

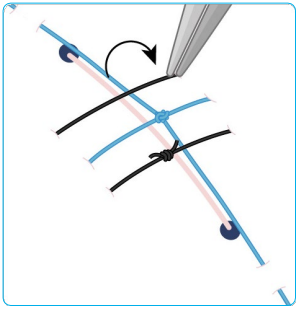

Figure 36 Rotate nylon sutures

ⓘ Note

If you are unable to rotate the nylon knot into the sclera, replace that suture with a new nylon suture and close it with a smaller 1-1-1 “Dangel” style adjustable locking knot.

4.3 Wound closure (cont'd)

ii. Pull the polypropylene suture end taut and cut the polypropylene suture flush to the sclera. See Figure 37.

Caution

- Not pulling the suture taut and not cutting the suture flush to the sclera will increase the risk of post-operative suture exposure and irritation.

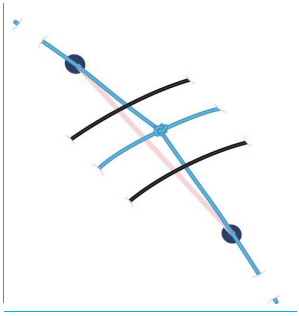

Figure 37 Cut suture flush to sclera

iii. Perform a conjunctival and Tenon's capsule closure using a 6-0 plain gut or chromic suture or a 7-0 Vicryl suture or similar suture. Ensure the Tenon's capsule covers the insertion site. Use a 3-point fixation and scleral bites as indicated in Figure 38.

ⓘ Notes

Make sure conjunctiva and Tenon's capsule are sutured to the limbus and sclera to prevent conjunctival retraction and subsequent exposure of the scleral sutures.

Buried sutures are preferable when possible.

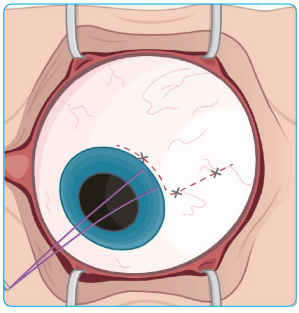

Figure 38 Perform conjunctival and Tenon's capsule closure

iv. Administer sub-conjunctival steroid injection: dexamethasone, 2 mg/0.5 ml (4 mg/ml) or equivalent.

ⓘ Note

If the case is complicated and inflammation is anticipated, a higher dose of dexamethasone (0.5 cc of 10 mg/ml) or equivalent may be used, at the surgeon's discretion.

v. Perform indirect ophthalmoscopy to confirm placement of ENCELTO in the vitreous and that there are no intraocular complications.

Warning

- Failure to perform indirect ophthalmoscopy can lead to unidentified malpositioning of ENCELTO and intraocular complications.

v. Apply topical antibiotic to the surface of the eye.

Caution

- Do not inject antibiotics into the eye.

vi. Patching the eye is optional but encouraged to prevent conjunctival wound dehiscence.

5 End of Surgery

5.1 Complete ENCELTO Patient Card

i. Provide the patient with a completed ENCELTO Patient Card (see page 3) and advise the patient to keep the card in a safe place for future reference. The patient should be advised that this card contains important information related to ENCELTO and that the card should be shown to their current and future health care providers.

5.2 Dispose of all materials

ii. Follow local institutional protocols to dispose of all ENCELTO materials and packaging after the procedure.

6 Postoperative Wound Care

6.1 Antibiotic and steroid application

Warning

- Failure to follow postoperative antibiotic and steroid application can lead to increased risk of injury, inflammation, or infection.

The patient is to use:

- A topical antibiotic solution at a frequency of 1 drop four times a day for 7 days.
- A steroid drop taper of prednisolone acetate 1% (or equivalent) starting the day after surgery with the following taper:
  - 1 drop four times a day for the first 7 days
  - 1 drop three times a day for the next 7 days
  - 1 drop two times a day for the next 7 days
  - 1 drop once a day for the last 7 days.

6.2 Complications

See Adverse Reactions Section of USPI.

(revakinagene taroretcel-lwey)
implant, for intravitreal use
ENCELTO™

Removal Procedure

Preoperative Procedure

Prepare additional items for surgery

Standard ophthalmic instruments will be required for this procedure. The following surgical instruments are referenced and suggested for use but are not provided.

Table 5 Surgical instruments description

Item description	Further details
20-gauge microvitreoretinal blade	-
15-degree asymmetric blade	-
Sutures - all on spatulated needles	• 7-0 Vicryl corneal traction suture to rotate eye and to close the scleral wound • 6-0 plain gut suture for conjunctival closure

Topical antibiotics and topical steroids are suggested for use but are not provided.

Prepare patient for surgery

Prepare patient for surgery using standard sterile surgical methods and standard operating room practices.

Conduct standard periocular preparation and draping. Place a lid speculum and corneal shield (if available). See Figure 39.

Perform the procedure under local anesthesia using either peribulbar, retrobulbar, or sub-tenon's technique.

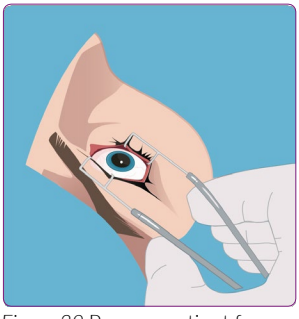

Figure 39 Prepare patient for removal procedure

1 Surgical Site Preparation

1.1 Conduct conjunctival peritomy in the appropriate quadrant

i. Place a partial thickness corneal-limbal traction suture using a 7-0 Vicryl suture on a spatulated needle or similar in the quadrant where ENCELTO is located. See Figure 40.

ⓘ Note

Take care to avoid penetrating the anterior chamber, as this could lead to procedural complications and visual impairment.

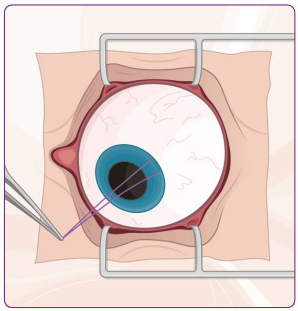

Figure 40 Place corneal-limbal traction suture

ii. Expose ENCELTO insertion site by creating a 7.0 mm conjunctival limbal peritomy and a 7.0 mm conjunctival radial incision. See Figure 41.

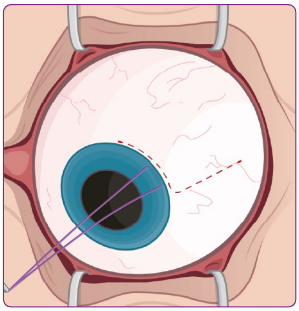

Figure 41 Create limbal peritomy and radial incision

iii. Carefully dissect the conjunctiva and Tenon's capsule to expose the underlying sclera and insertion site. See Figure 42.

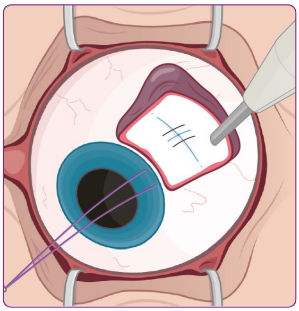

Figure 42 Expose insertion site

iv. Use wet-field cautery to achieve hemostasis.

ⓘ Note

Avoid blood entering the scleral wound.

1.2 Conduct 3-port small gauge vitrectomy

i. Place an infusion cannula and infusion line in the inferior quadrant which is not occupied by ENCELTO. See Figure 43.

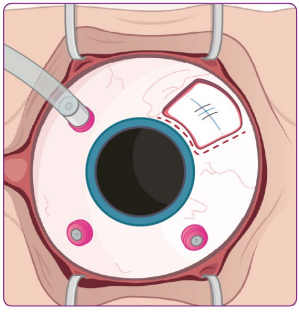

Figure 43 Place infusion cannula

ii. Visually confirm that the infusion line rests within the vitreous cavity prior to opening the infusion. See Figure 44.

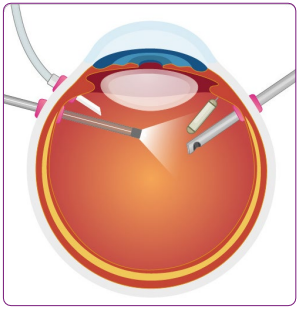

Figure 44 Confirm infusion line position

iii. Insert the other two superior cannulas as per normal routine.

iv. Perform vitrectomy to remove the vitreous surrounding ENCELTO without disrupting the integrity of the white portion of ENCELTO. See Figure 45.

ⓘ Note

Direct the cutter away from ENCELTO. The smooth part of the vitrectomy probe can gently touch the white portion of ENCELTO.

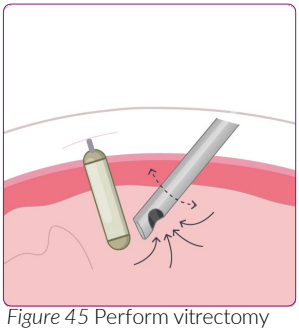

Figure 45 Perform vitrectomy

2 ENCELTO Removal and Closure

2.1 Locate and open incision

ⓘ Notes

This should be located 3.75 mm posterior to limbus.

Apply bipolar wet-field cautery as needed. Avoid applying cautery to the polypropylene anchor suture or wound lips.

i. Remove the two nylon sutures on either side of the center polypropylene anchor suture, but leave the center anchor suture in place. See Figure 46.

⚠ Warning

- Do not cut the center polypropylene anchor suture when removing the nylon sutures.

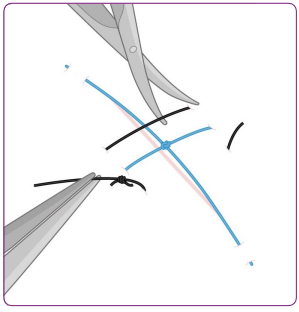

Figure 46 Remove nylon sutures

ii. Using a 20-gauge microvitreoretinal blade or similar, carefully dissect the original scleral incision on either side of polypropylene suture down to the ENCELTO cap at the base of the fixation loop. See Figure 47.

ⓘ Note

Direct blade motion away from ENCELTO to reduce risk of inadvertently cutting ENCELTO.

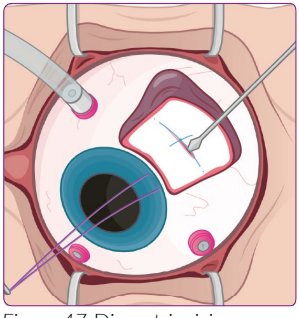

Figure 47 Dissect incision on either side of polypropylene suture to base of the fixation loop

2.1 Locate and open incision (cont'd)

iii. When the original incision is opened to full-thickness along the entire 3.0 mm length, cut the polypropylene anchor suture on the anterior side of the knot. See Figure 48.

ⓘ Note

The remaining polypropylene knot will prevent ENCELTO from dislocating into the vitreous cavity.

Warning

- Do not cut the posterior side of the polypropylene anchor suture before grasping the fixation loop.

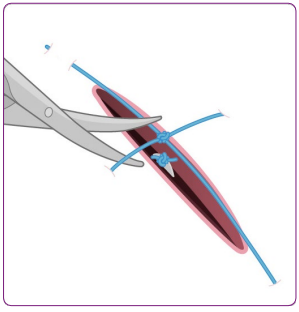

Figure 48 Cut polypropylene suture

iv. Turn off or lower the infusion pressure.

Fully open the pars plana wound, confirm that there is no spanning uveal tissue and identify the fixation loop. See Figure 49.

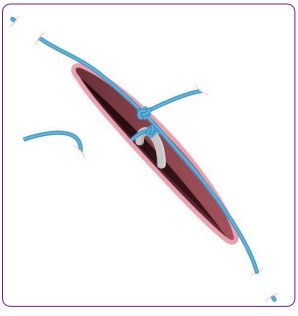

Figure 49 Identify the fixation loop

2.2 ENCELTO removal

i. Grasp the fixation loop with toothed forceps and begin to remove ENCELTO. See Figure 50.

ⓘ Note

Take care not to damage the white portion of ENCELTO during removal.

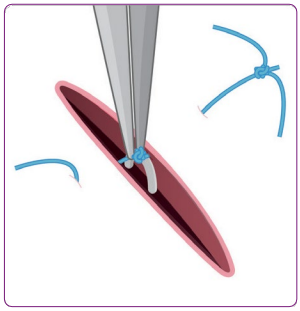

Figure 50 Grasp fixation loop

Warning

- Failure to grasp the fixation loop may release ENCELTO into the vitreous and may require a complete vitrectomy to recover.

ii. Cut off the remaining polypropylene knot and fully remove ENCELTO from the eye. See Figure 51.

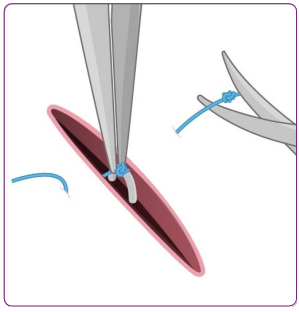

Figure 51 Cut off remaining knot and remove ENCELTO

iii. Carefully inspect ENCELTO capsule for any signs of damage or penetration.

ⓘ Note

If there is suspicion that the white portion of ENCELTO has been penetrated, perform a complete vitrectomy with extra attention to removal of vitreous that had surrounded ENCELTO prior to its removal. The goal is to remove any contents that may have been released into the vitreous when inadvertently penetrated.

Prior to disposal of an ENCELTO implant per local institutional protocols, call 1-833-963-9275 for assessment of ENCELTO return or replacement.

2.3 Removal wound closure

i. Use a vitrector to remove any prolapsed vitreous flush with the sclera. See Figure 52.

ⓘ Note

The vitrector does not need to enter the eye through the sclerotomy.

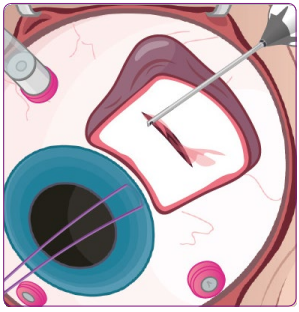

Figure 52 Remove prolapsed vitreous

ii. Close the sclerotomy with interrupted 7-0 Vicryl sutures to create a watertight closure. Remove the infusion line and the additional cannulas. See Figure 53.

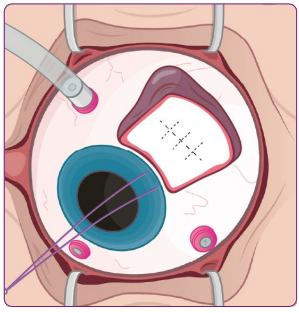

Figure 53 Close sclerotomy

iii. Close the conjunctiva with 6-0 plain gut sutures (or equivalent). See Figure 54.

iv. Administer subconjunctival antibiotic injection per routine.

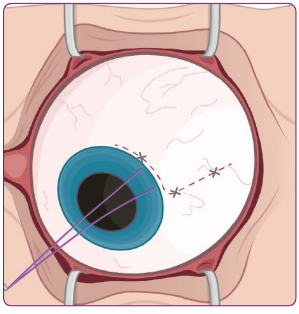

Figure 54 Close incision

3 Postoperative Wound Care

3.1 Antibiotic and steroid application

Warning

- Failure to follow postoperative antibiotic and steroid application can lead to increased risk of injury, inflammation, or infection.

The patient is to use:

- A topical antibiotic solution at a frequency of 1 drop four times a day for 7 days.
- A steroid drop taper of prednisolone acetate 1% (or equivalent) starting the day after surgery with the following taper:
  - 1 drop four times a day for the first 7 days
  - 1 drop three times a day for the next 7 days
  - 1 drop two times a day for the next 7 days
  - 1 drop once a day for the last 7 days.

Explanation of Symbols

Table 6 Symbol description

Symbol	Description
	Prescription only
	Sterile device
	Manufacturer
	Date of Manufacture
	Keep protected from light
	Use By Date
	Do not use if package is damaged
	LOT number
	Global Trade Item Number
	Serial number
	MR Conditional

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This IFU has been approved by the U.S. Food and Drug Administration.
Approved: 2025/03