

Alcon PERFLUORON™

ENGLISH

(purified perfluoro-n-octane liquid)

REF 8065900110 PERFLUORON, Kit with 2 mL vial
REF 8065900111 PERFLUORON, Kit with 5 mL vial
REF 8065900112 PERFLUORON, Kit with 7 mL vial

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Package Insert

PERFLUORON™

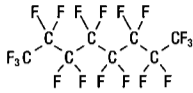
(purified perfluoro-n-octane liquid)

DESCRIPTION

PERFLUORON™

(purified perfluoro-n-octane liquid) is sterile, non-pyrogenic, purified perfluoro-n-octane (≥99.9% PFnO) for temporary use as a mechanical tool during vitreoretinal surgery. Perfluoro-n-octane is a member of the perfluorocarbon chemical family, chemicals composed of carbon and fluorine atoms. Perfluorocarbons exhibit high oxygen solubility and are relatively inert substances with little biological toxicity potential.

The structure of the molecule is:



C₈F₁₈ or CF₃(CF₂)₆CF₃

(CAS No. 307-34-6)

PERFLUORON is a low viscosity, optically clear fluid with a high vapor pressure, a high specific gravity, low surface tension, and much lower refractive index than aqueous solutions. It is chemically and biologically inert and is immiscible in water, ionic solutions and common organic solvents.

The chemical and physical properties of PERFLUORON™ (purified perfluoro-n-octane liquid) are listed below.

Molecular Weight	438
Specific Gravity	1.754
Surface Tension (dynes/cm, 27.2°C)	16.98
Refractive Index	1.27
Vapor Pressure (mmHg @ 37°C)	52
Viscosity (centistoke @ 25°C)	0.69

PERFLUORON is a pure liquid that contains no preservatives or other ingredients.

For intraocular use only.

INDICATIONS FOR USE

PERFLUORON is an intraoperative tool indicated for use during vitreoretinal surgery in patients with primary or recurrent retinal detachment which is complicated by penetrating ocular trauma, giant retinal tear(s) or proliferative vitreoretinopathy (PVR).

CONTRAINDICATIONS

• PERFLUORON™ (purified perfluoro-n-octane liquid) is contraindicated for long-term use in the eye or as a vitreous replacement.

WARNINGS

- PERFLUORON should not be injected directly into the vitreous, or injected simultaneously with aspiration of the vitreous, as severe intraocular damage may occur.
- At the conclusion of the surgical procedure, PERFLUORON must be COMPLETELY removed from the eye, and replaced with an appropriate vitreous substitute.

PRECAUTIONS

- Directions for Use of PERFLUORON should be followed closely.
- Subretinal migration, or placement, of PERFLUORON may occur during the injection of the device. (See Directions for Use)
- The safety and effectiveness of the use of PERFLUORON in patients under 15 months of age has not been established.
- During the clinical trials, posterior retinal slippage occurred at the anterior edge of the giant retinal tear in 18% of patients with giant retinal tears. (See Directions for Use.)
- To avoid inadvertent placement of PERFLUORON behind the retina during injection, the final fill level in the eye should always remain posterior to any large retinal breaks.
- If PERFLUORON™ (purified perfluoro-n-octane liquid) is introduced into a large retinal break, it may slip into the subretinal space. Special care should be taken to examine for and remove any subretinal PERFLUORON through an existing posterior tear or through a posterior retinotomy prior to the completion of surgery. (See Directions for Use.)
- Do not admix PERFLUORON with any other substances prior to use.
- Do not use PERFLUORON after its expiration date.
- Avoid migration of PERFLUORON into the anterior chamber in aphakic patients.
- Avoid formation of small bubbles during injection by keeping cannula tip within the PERFLUORON bubble.

ADVERSE REACTIONS AND COMPLICATIONS

Adverse Events reported during the clinical trial of PERFLUORON include enucleation (3 eyes, 1 day to 1 month following surgery), heart attack (1 patient, 8 days following surgery) and death (1 patient, greater than 3 months after surgery). None were considered to be associated with the use of PERFLUORON.

The following adverse reactions related to the use of PERFLUORON™ (purified perfluoro-n-octane liquid) were observed during the clinical trials (These rates of complications may be influenced by the duration of follow-up in the clinical trials):

• Intraoperative Subretinal PERFLUORON Migration	8.1%
• Post-operative Residual PERFLUORON	6.3%

Other complications reported by the investigators are general complications resulting from vitreoretinal surgery, and were not associated specifically to the use of PERFLUORON:

• Corneal Abnormalities	46%
• Anterior Chamber Abnormalities	34%
• Elevated IOP	18%
• Hypotony	15%
• Iris Abnormalities	15%
• Cataract Formation in Phakic Eyes	13.8%
• Intraoperative Retinal Slippage	8.4%
• Progression to "No Light Perception" (NLP)	4.4%

Do Not Resterilize PERFLUORON™ or any of the components supplied with it.

DIRECTIONS FOR USE

PERFLUORON is supplied in 2 mL, 5 mL and 7 mL vial sizes. The 5 mL volume is adequate for an average eye, but highly myopic eyes may require the larger 7 mL vial. The 2 mL may be used as a supplemental volume whenever 5 mL or 7 mL volumes are insufficient.

Assembly Instructions

The PERFLUORON vial and components are packaged sterile and ready to use.

Caution: Do not use if sterile barrier is breached.

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

Sterile Transfer

1. Open each of the following sterile, single-use components, and pass them into the sterile field, using routine procedure for sterile transfer:
 - PERFLUORON 2 mL, 5 mL or 7 mL vial
 - 23 gauge blunt cannula
 - 0.2 µm microbial filter unit (MILLEX™ FG MILLIPORE™ 0.2 micron microbial filter 025LS or equivalent)
 - 10 mL LUER-LOK™ syringe
 - 20 gauge x 1 ½" beveled needle
2. Perform assembly of components in the sterile field.

Assembly

1. Connect the 0.2 µm filter unit to the 10 mL disposable syringe.
2. Place the 20 gauge beveled needle securely on the end of the filter unit. The syringe is ready to fill with PERFLUORON™ (purified perfluoro-n-octane liquid).
3. Hold the PERFLUORON vial firmly, and introduce the 20 gauge beveled needle into the vial to withdraw the PERFLUORON.
4. After the PERFLUORON has been completely transferred to the syringe, withdraw the needle from the vial.
5. Remove the 20 gauge needle and filter unit from the syringe and dispose of properly.
6. Securely place the 23 gauge blunt cannula on the syringe. The PERFLUORON is now ready to be used. The syringe may be stored temporarily with the cannula pointed upward to avoid loss of material.
7. Discard the syringe and any unused PERFLUORON remaining in it at the conclusion of the procedure.

The Use of PERFLUORON™

(purified perfluoro-n-octane liquid)

Properties

PERFLUORON, by virtue of its high specific gravity, functions as a mechanical tool during vitreoretinal surgery, providing hydrokinetic manipulation of the detached retina. This high specific gravity allows PERFLUORON to be infused over the posterior portion of the retina to facilitate retinal flattening and anterior displacement of subretinal fluid. PERFLUORON has a significantly different refractive index than Aqueous (1.27 vs 1.33) which assists intraocular visualization and control of the device. It is optically clear and does not interfere with visualization of the retina.

PERFLUORON is immiscible with water, ionic solutions, and common organic solvents. It tends to form into droplets rather than dispersing. These physical properties make it easy to both observe during surgery and remove by aspiration at the conclusion of the intraoperative procedure.

PERFLUORON has a high vapor pressure, which facilitates removal of residual material remaining after aspiration. At room temperature, during the fluid-gas exchange at the conclusion of surgery, any remaining portion of the device will usually evaporate and exit through the sclerotomy sites.

TOXICITY AND METABOLISM

PERFLUORON™ (purified perfluoro-n-octane liquid) is a biologically inert substance. There are no known *in vivo* biological enzymes which metabolize the carbon-fluoride bonds.

In a series of *in vitro* and *in vivo* tests, PERFLUORON has been shown to be non-toxic, non-hemolytic, non-pyrogenic, non-mutagenic, and non-irritating. In a retinal and intraocular tolerance study, it was shown to be well-tolerated following short term exposure, but poorly-tolerated following extended term exposures.

GENERAL USE

PERFLUORON should be slowly injected over the optic disc to flatten the retina posteriorly. As the retina is flattened, examine it for areas of residual membranes, for traction remaining on the retina and for the presence of previously undetected posterior breaks. Such membranes should be removed or peeled to the extent possible. If large posterior breaks are detected, additional application of PERFLUORON should be discontinued. If no large posterior breaks are present, PERFLUORON should be infused up to the level of the most posterior retinal break, forming a "bubble" in the posterior portion of the retina.

The weight of PERFLUORON™ (purified perfluoro-n-octane liquid) on the posterior retina displaces subretinal fluids anteriorly, resulting in a flattened retina up to the edge of the most posterior break. Membrane removal, if necessary, is performed in the aqueous phase with PERFLUORON providing mechanical stabilization of the posterior retina. Areas of residual traction which cannot be freed by dissection may be subject to retinotomy anterior to the bubble. Thermal adhesive treatment can be applied to the edges of the flattened retina through the bubble. If the edge of the tear is too peripheral for endophotocoagulation, transcleral cryotherapy can be applied.

Air-fluid exchange is then performed. With the use of a flute needle, infusion fluid above the bubble should be removed as completely as possible by using air to flatten the anterior retina and displace all anterior subretinal fluid before removal of the PERFLUORON. Endophotocoagulation to the anterior retina should be applied, as indicated.

If PERFLUORON™ (purified perfluoro-n-octane liquid) is introduced into a large retinal break, it may slip behind the retinal detachment. This event can be handled by the complete aspiration of the device with either a 20 or 23 gauge cannula, utilizing the break through which it originally migrated.

If aspiration at the primary break site does not provide complete removal, a retinotomy should be performed to remove all PERFLUORON.

Occasionally, PERFLUORON may be inadvertently dispersed during injection, resulting in small bubbles (droplets) that are not identified and completely aspirated at the conclusion of surgery. Dispersion of the PERFLUORON can be best controlled by keeping the 23 gauge blunt cannula recommended for injection in the middle of the PERFLUORON bubble as more of the device is injected, and away from the tip of any active infusion cannula.

During the clinical trials, residual droplets of PERFLUORON were occasionally observed in either the anterior or posterior chamber post-operatively. These droplets were not associated with any adverse reactions or complications, but if the situation does arise, it may be necessary to remove the residual PERFLUORON by surgery.

In GIANT RETINAL TEARS¹

PERFLUORON™ (purified perfluoro-n-octane liquid) should be injected with the patient in the supine position to gently unfold the flap of the tear, and to flatten the retina against the choroidal surface.

If epiretinal membranes are present, they should be removed from both surfaces of the retina, as completely as possible, by conventional means. A small amount of PERFLUORON (0.8 to 1.0 mL) should then be injected over the optic disc. As any additional epiretinal membranes are exposed and removed, more PERFLUORON can be slowly injected up to the edge of the tear.

Once the retina is unfolded and the tear is positioned, an appropriate thermal adhesive modality should be applied, through the PERFLUORON, along the edge of the tear. A scleral buckle may be placed before the PERFLUORON is removed.

Remove the PERFLUORON at the conclusion of the procedure by aspiration through either a 23 gauge or flute needle during the air-fluid exchange.

During the clinical trials, posterior retinal slippage occurred at the equator of the giant retinal tear in 18% of patients with giant retinal tears. To reduce the potential for the edge of the flap to move posteriorly, carefully remove all saline at the edge of the break before proceeding with the aspiration of PERFLUORON™ (purified perfluoro-n-octane liquid) posteriorly. This maneuver reduces the chance of slippage by removing subretinal fluids that might otherwise tend to flow posteriorly. Retinal slippage, if it occurs during the fluid-air exchange, can be corrected by replacing some of the air with saline solution and by using an expanding gas concentration after turning the patient into the appropriate position post-operatively.

When gas tamponade is chosen, an automated air infusion system should be used during fluid-air exchange. A flute or extrusion needle with a soft silicone tip may be used, being placed first near the margin of the tear. As the air bubble descends, it flattens the anterior retina, expressing the subretinal fluid through the break. All saline at the edge of the break should be carefully removed before proceeding to aspirate the PERFLUORON posteriorly. This maneuver reduces the chance of slippage of the posterior flap.

The intrinsic elasticity of the detached retina may result in extensive slipping and retinal folding under air. When this occurs, the air should be replaced by balanced saline, and the PERFLUORON™ (purified perfluoro-n-octane liquid) re-injected to reposition the retinal detachment.

When the tear is repositioned, direct exchange of PERFLUORON for silicone oil, which engages the edge of the tear as it descends, will prevent slippage and folding of the retina.

When silicone oil is selected for extended tamponade, the PERFLUORON may be directly aspirated as the silicone oil is injected with an automated infusion pump. When the silicone oil is first injected, a soft-tipped flute or extrusion needle is placed anteriorly near the edge of the tear to aspirate all saline anterior to the PERFLUORON. When the silicone bubble contacts the PERFLUORON, the interface is visible and the PERFLUORON is aspirated in an anterior-to-posterior direction.²

When silicone oil is selected for extended retinal tamponade, small droplets of PERFLUORON™ (purified perfluoro-n-octane liquid) may be difficult to distinguish from air bubbles that have become mixed with the silicone oil during its infusion. However, within seconds, air bubbles will float anteriorly in the silicone oil, while the small PERFLUORON droplets will descend onto the surface of the retina, making them easier to identify and aspirate.³

In PROLIFERATIVE VITREORETINOPATHY (PVR)³

PERFLUORON is a useful intraoperative instrument for the hydrokinetic manipulation of the retina during vitrectomy surgery for proliferative vitreoretinopathy. PERFLUORON permits manipulation of the retina with the patient in the supine position. After epiretinal membrane dissection and removal of all visible posterior preretinal membranes, inject the PERFLUORON into the funnel of the retinal detachment, positioned directly above the optic disc. Areas of residual traction and membranes may be exposed as the PERFLUORON fills the vitreous cavity. The PERFLUORON interface should be kept posterior to these areas, and epiretinal membranes removed in a posterior to anterior direction. More PERFLUORON may be injected as needed, up to the level of the most posterior retinal break.

In OCULAR TRAUMA⁴

Penetrating ocular trauma elicits a broad range of ocular responses, including intraocular bleeding, severe inflammation, fibrous proliferation, scarring, and cystic membrane formation. Retinal detachment may result from these processes or from the injury itself.

PERFLUORON™ (purified perfluoro-n-octane liquid) is a useful intraoperative tool during vitreoretinal surgery in the repair of severe ocular trauma, using the techniques described previously for hydrokinetic manipulation of the retina.

POST-PROCEDURE

PERFLUORON must be COMPLETELY removed at the conclusion of the procedure by aspiration through either a 23 gauge or flute needle during the air-fluid exchange, or by direct exchange with an appropriate long term vitreous substitute.

HOW SUPPLIED

PERFLUORON is supplied in a kit containing a sterile vial of PERFLUORON (either 2 mL, 5 mL or 7 mL unit container) and the following sterile, single-use components:

- 23 gauge blunt cannula
- 0.2 µm microbial filter unit
- 10 mL LUER-LOK™ syringe
- 20 gauge beveled needle

The individual components are provided in individual sterile packaging. The PERFLUORON sterile exterior is steam sterilized [STERILE I] the vial is aseptically processed [STERILE IA].

PERFLUORON™ (purified perfluoro-n-octane liquid) is supplied in kits with 2 mL, 5 mL or 7 mL unit vials. Store at room temperature (15°C - 30°C).

REFERENCES

1. Chang S, Lincoff H, Zimmerman NJ, and Fuchs W. Giant Retinal Tears: Surgical Techniques and Results Using Perfluorocarbon Liquids. Arch. Ophthalmol 107: 761-766 (1989).
2. Chang S. Giant Retinal Tears: Surgical Management with Perfluorocarbon Liquids. Medical and Surgical Retina. Lewis and Ryan, editors. Mosby Yearbook, New York (1994).
3. Chang S, Ozmert E, Zimmerman NJ, and Fuchs W. Intraoperative Perfluorocarbon Liquids in the Management of Proliferative Vitreoretinopathy Am. Journal Ophthalmol. 106: 668-674 (1988).
4. Chang S, Reppucci V, Zimmerman NJ, Heinemann MH, Coleman DJ. Perfluorocarbon Liquids in the Management of Traumatic Retinal Detachments. Ophthalmology 96:785-792 (1989).

SYMBOLS USED ON LABELING	
	The following sterilization symbols will apply to components of this package: Sterile - Sterilized by aseptic processing
	Sterile - Sterilized by irradiation
	Sterile - Sterilized by ethylene oxide
	Sterile - Sterilized by steam
	Single use only, do not reuse
	Use by (YYYY-MM: year-month)
	Lot Number
	Attention: Refer to Package Insert
	Catalog Number
	Storage Temperature

Manufacturer:
ALCON LABORATORIES, INC.
6201 South Freeway
Fort Worth, Texas 76134-2099
Made in the U.S.A.

Ordering Information:

REF 8065900110 PERFLUORON, Kit with 2 mL vial
REF 8065900111 PERFLUORON, Kit with 5 mL vial
REF 8065900112 PERFLUORON, Kit with 7 mL vial

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