

PATIENT INFORMATION BROCHURE

RETINAL TAMPONADE:

UNIPURE™ SF₆ OPHTHALMIC GAS IN THE UNIFEYE™ AND UNIPEXY™ GAS DELIVERY SYSTEMS

To Accompany Patient Implant Card

GENERAL INFORMATION ABOUT UNIPURE SF₆ OPHTHALMIC GASES IN THE UNIFEYE AND UNIPEXY GAS DELIVERY SYSTEMS USED IN EYE SURGERY

What are retinal detachments and breaks?

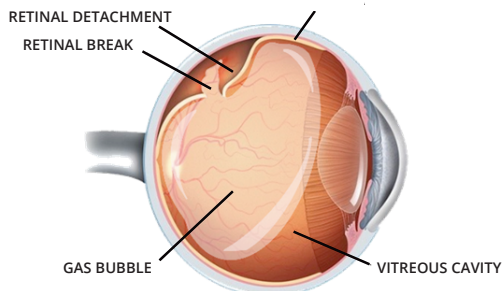
The retina is a thin layer of tissue lining the back of your eye that detects light and enables you to see. A retinal detachment occurs when the retina is pulled from its normal position, away from the nourishing tissues beneath the retina. A retinal break is when a tear or hole forms in the retina, which can lead to retinal detachments. Retinal detachments may lead to a loss of vision if untreated.

Why was gas put into my eye?

UNIPURE SF₆ Ophthalmic Gas is used for injection into the eye for the treatment of certain retinal detachments, retinal breaks, and to reabsorb unwanted fluid in the eye. A gas bubble is formed that pushes the detached retina back in place. While the retinal break heals, the gas holds the retina in place and forms a barrier against fluid entering the space between the detached retina and its supporting structures.

What occurred during my surgery?

During your retinal repair, UNIPURE SF₆ Ophthalmic Gas was injected into your vitreous cavity, the gel-like space that fills the inside of the eyeball. This gas bubble was used to hold your retina in place while it was reattached. This gas bubble holds your retina stable until the gas dissolves, giving your retina time to heal.



Who can receive UNIPURE SF₆ Ophthalmic Gas?

UNIPURE SF₆ Ophthalmic Gas is used to treat retinal detachments or breaks. Your doctor will determine whether this treatment is appropriate for you. Treatment should be avoided in certain serious eye conditions such as diabetic eye disease, severely high eye pressure, or inflammation in the eye. The procedure should be avoided if you require hyperbaric oxygen therapy before the gas dissolves, or if you are unable to avoid high-altitude or airplane travel before the gas dissolves. Safety and effectiveness have not been established in pregnant women.

UNIPURE SF₆ OPHTHALMIC GAS IN THE UNIFEYE AND UNIPEXY GAS DELIVERY SYSTEMS

A UNIPEXY or UNIFEYE Gas Delivery System was used to deliver the UNIPURE SF₆ Ophthalmic Gas during surgery. Your eye doctor used sulfur hexafluoride (SF₆) gas in your surgery. The gas will remain in your eye until it dissolves.

SAFETY INFORMATION FOR UNIPURE SF₆ OPHTHALMIC GAS IN THE UNIFEYE AND UNIPEXY GAS DELIVERY SYSTEMS

As with any surgery, there is risk involved with gas injection during retina surgery. Complications range from minor (usually temporary) side effects to serious complications. Patients with pre-existing diseases or conditions (i.e., previous eye injuries) may be at higher risk of experiencing complications.

- Temporary surgical complications include temporary decrease in vision, irritation, redness, inflammation, visual disturbance, a temporary increase of eye pressure, and physical injury.
- Serious complications include infection, pus inside your eye, toxic reaction, blood vessel blockage in the retina, a serious decrease in eye pressure, a serious increase in eye pressure, cataract formation, glaucoma, physical damage to your eye tissues, inflammation of the back of the eye, retinal tears or holes, retinal detachment, permanently decreased vision, and blindness. However, the frequency of significant serious complications is low.
- There is a risk of needing further surgical treatment to reattach the retina after the initial healing is evaluated.

CONSIDERATIONS AFTER SURGERY

Important Instructions after UNIPURE SF₆ Ophthalmic Gas delivery

Contact your eye doctor immediately if you have any of these symptoms after surgery:

- Significant decrease in vision or vision loss
- Significant eye pain
- Significant eye redness
- Significant eye discharge
- New symptoms of flashes and floaters
- Increased sensitivity to light

Before undergoing any surgical or dental procedure or hyperbaric oxygen therapy, advise all health care providers that you have a gas bubble in your eye. Have them contact the eye doctor listed on your patient information card or your wristband.

Postoperative Care Instructions

Take care to maintain head positioning as advised by your eye doctor. Your eye doctor will tell you when to return for a medical visit(s) to monitor your eye after surgery. Always consult with your eye doctor if you have any questions or concerns as a result of your surgery and the recovery process after surgery.

The following restrictions apply until you have been advised accordingly by your eye doctor:

- Until the gas bubble has dissolved, do not receive nitrous oxide (N₂O, nitrous, "laughing gas"), as it may cause an increase in pressure in your eye, which can result in blindness.
- Until the gas bubble has dissolved, do not travel in an airplane. Changes in elevation may cause an increase in pressure in the eye which can result in blindness.¹⁻⁷
- Until the gas bubble has dissolved, do not travel to a higher elevation or mountain range from a lower altitude.⁸ Changes in elevation may cause an increase in pressure in the eye which can result in blindness. If you have eye pain while traveling, immediately contact your eye care provider or a medical professional.
- Until the gas bubble has dissolved, do not receive hyperbaric oxygen therapy, as it may alter the blood supply to your eye, which can result in blindness.⁹
- Take care to maintain the proper head positioning as advised by your eye doctor. Incorrect head positioning may cause your surgery to be unsuccessful or lead to further complications.
- The wristband you are wearing will alert health care providers about your surgery in case of an emergency where you are unable to inform them of the gas bubble. Until the gas bubble has dissolved, do not remove the wristband.

Long Term Considerations

Keep the patient implant card provided by your eye doctor as it has important information about the gas implanted in your eye. This patient information brochure, including any recent updates to this brochure, is available electronically at www.ifu.alcon.com.

The wristband with insert is to be worn at all times while the gas is in your eye to alert other health care providers that you have a gas bubble in your eye and that they should confer with your eye doctor prior to your next treatment. Your eye doctor will complete and review the wristband and implant card with you after your surgery.

If you experience a serious health issue related to your surgery, have your patient implant card available (if possible) and take the following steps:

- Consult your eye doctor.
- Report this health issue by (1) calling the local Alcon representative in your Member State or (2) emailing Alcon at <http://www.alcon.com/contact-us/>.
- Contact the competent authority of your Member State about this serious health issue related to the UNIPURE SF₆ Ophthalmic Gas in the UNIFEYE or UNIPEXY Gas Delivery Systems.

DEVICE LIFETIME








The UNIPURE SF₆ Ophthalmic Gas is made of sulfur hexafluoride (SF₆) gas. The gas will remain in your eye until it dissolves in approximately 12 to 14 days.

SUMMARY

The UNIPURE SF₆ Ophthalmic Gas forms a gas bubble in your eye to hold your retina in place while your retina is reattached and healing. Always consult with your eye doctor if you have any questions or concerns.

1. J. P. Dieckert, P. S. O'Connor, D. E. Schacklett et al., "Air travel and intraocular gas," *Ophthalmology*, vol. 93, no. 5, pp. 642-645, 1986.
2. Fuller D: Flying and intraocular gas bubble [letter]. *Am J Ophthalmol* 1981;91:276.
3. Houston S, Graf J, Sharkey J. Commercial air travel after intraocular gas injection. *Aviat Space Environ Med*. 2012 Aug;83(8):809-10.
4. Kokame GT, Ing MR: Intraocular gas and low altitude flight. *Retina* 1994, 14:356-358.
5. Mills MD, Devenyi RG, Lam WC, Berger AR, Beijer CD, Lam SR. An assessment of intraocular pressure rise in patients with gas-filled eyes during simulated air flight. *Ophthalmology*. 2001 Jan;108(1):40-4.
6. Muzychuk AK, Adatia FA, Ford BA, Kherani AM. Commercial air travel with a small intravitreal gas bubble. *Arch Ophthalmol*. 2011 Jun;129(6):811-3.
7. Noble J, Kanchanaranya N, Devenyi RG, Lam WC. Evaluating the safety of air travel for patients with scleral buckles and small volumes of intraocular gas. *Br J Ophthalmol*. 2014 Sep;98(9):1226-9.
8. Hanscom, TA, and Diddle, KR: Mountain travel and intraocular gas bubbles, *AM J Ophthalmology* 104:546, 1987.
9. Jackman, SV, and Thompson, JT: Effects of hyperbaric exposure on eyes with intraocular gas bubbles, *Retina* 15:160-166, 1995.

DEFINITIONS

	MANUFACTURER (A)	L	LEFT
 www.ifu.alcon.com	CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE (B)	R	RIGHT
LOT	BATCH CODE		PATIENT IDENTIFICATION (D)
UDI	UNIQUE DEVICE IDENTIFICATION (NOTE: IN BARCODE FORMAT)		HEALTH CARE CENTRE OR DOCTOR (E)
UDI-DI	UNIQUE DEVICE IDENTIFICATION (NOTE: IN NUMBER FORMAT)		CONSULT INSTRUCTIONS FOR USE (F)
	DATE (C)	MD	MEDICAL DEVICE
	EYE		

- A The person or company that created the device is the manufacturer.
- B This patient brochure is available electronically at the following website: www.ifu.alcon.com. Please read this patient brochure to understand important information regarding the safe use of this device.
- C The date when the surgery was taken place.
- D Name of person receiving medical treatment.
- E This includes the name and address of the implanting healthcare institution/provider.
- F This is for your doctor.