UNIFEYE™
GAS DELIVERY SYSTEM

Directions for Use

℞ only

DESCRIPTION AND CHARACTERISTICS

The integrated UNIPURE™ SF_6 Ophthalmic Gas pico-cylinder in the UNIFEYE Gas Delivery System contains undiluted, non-sterile, liquefied sulfur hexafluoride (SF_6) gas under pressure. The gas is non-toxic, inert, non-flammable, odorless, and colorless. The UNIFEYE Gas Delivery System is used to mix filtered UNIPURE SF_6 Ophthalmic Gas with filtered air and inject the gas/air mix into the vitreous cavity of the eye. The prepared gas/air mixture for injection is sterile via the 0.2-micron filtration of the gas and air.

UNIPURE SF6 Ophthalmic Gas Properties		
Expansion Rate[β]	**Vapor Pressure 35 ± 2°C**	**Boiling Point**
24-48 hrs	2,843,000 – 3,109,000 Pa	-64°C -83°F

β Expansion Rate is dependent upon atmospheric pressure.

As-Delivered Gas Purity Ranges		
Selected Mix Ratio	**Mix Ratio Accuracy**	**As-Delivered SF6% Molar Purity**
14%	± 1.5%	12.5 - 15.5%
16%		14.5 - 17.5%
18%		16.5 - 19.5%
20%		18.5 - 21.5%
23%		21.5 - 24.5%
26%		24.5 - 27.5%

MODE OF ACTION

During the healing phase, surface tension of the gas plugs the retinal break, preventing further accumulation of fluid under the retina, while the retinal pigment epithelial pump removes subretinal fluid. UNIPURE SF_6 Ophthalmic Gas bubble may minimally expand within 24 to 48 hours depending on the atmospheric pressure and the gas/air mix ratio. The UNIFEYE Gas Delivery System mix ratios of 14% to 20% are nonexpansile concentrations while 23% to 26% are minimally expansile concentrations[15, 16]. The UNIPURE SF_6 Ophthalmic Gas substantially diffuses from the eye in approximately 12 to 14 days.

INDICATION(S) FOR USE

The UNIPURE SF_6 Ophthalmic Gas in the UNIFEYE Gas Delivery System is indicated for intraocular injection into the eye for the treatment of uncomplicated retinal detachments. Associated measures used include vitrectomy, fluid/air exchange, transconjunctival and transscleral cryotherapy, laser photocoagulation, and air/gas exchange.

TARGET PATIENT POPULATION

The target patient population is adult patients with an uncomplicated retinal detachment with the mental capacity to maintain proper positioning.

INTENDED USERS

The UNIPURE SF_6 Ophthalmic Gas in the UNIFEYE Gas Delivery System is intended to be used by ophthalmic surgeons and their surgical teams.

CLINICAL BENEFITS

The clinical benefits specific to the UNIPURE SF_6 Ophthalmic Gas in the UNIFEYE Gas Delivery System used during ophthalmic surgery are to create a barrier against vitreous fluid entering the space between the retina and supporting structures by forming a gas bubble to tamponade the retina. The UNIPURE SF_6 Ophthalmic Gas is a short-acting gas, having an effect for 12 to 14 days, which offers an alternative to the longer-acting gas tamponades. The surface tension of the gas can prevent further progression of the retinal detachment to preserve vision.

CONTRAINDICATIONS

Proliferative vitreoretinopathy (PVR) greater than Stage C, the mental or physical inability to maintain the therapeutic position for 5 postoperative days, severe glaucoma with more than a minimum of vision field loss and a cup to disc ratio equal to or greater than 0.6; uveitis; severe peripheral retinal degeneration; congenital malformations (such as coloboma), and any other condition that may facilitate the migration of the gas bubble out of the vitreous chamber; and high-altitude travel, including but not limited to airline travel.

- Air travel is contraindicated until the gas/air bubble has completely dissipated. Normal cabin pressure changes will cause a severe enlargement of the gas/air bubble with a resultant potential blinding, due to an increase in intraocular pressure (IOP)[1-7].
- Patients should not travel through high elevations and over mountain ranges until the mixed gas/air bubble has dissipated[8].

WARNINGS

A Use of Nitrous Oxide (N_2O) must be stopped at least 15 minutes before injection of UNIPURE SF_6 Ophthalmic Gas to ensure an adequate postoperative bubble is achieved. **Do not administer N_2O if a gas bubble is present.** N_2O rapidly partitions into the gas/air bubble causing expansion and a pressure increase in the eye that has been known to result in vision decrease and blindness.

B Postoperative acute rises in IOP, which can threaten ocular blood flow, lasting more than 10 minutes, may be controlled with pharmacologic methods, and/or paracentesis of aqueous fluid, and/or removal of some of the gas/air bubble. Patients with compromised ocular blood flow such as those with severe diabetic retinopathy or ocular ischemia are at greater risk of vascular occlusion following the use of a gas/air bubble. IOP should be checked by an experienced surgeon with either tactile touch or applanation tonometry when the gas/air bubble is in place. Schiotz tonometry will give false low values compared to the true IOP.

C Patient positioning following gas/air injection is of great importance. The gas/air bubble must be properly situated with proper positioning to allow contact of the bubble against the targeted area of the retina. Prone or face down positioning can prevent protracted contact between the bubble and the lens to avert a posterior subcapsular cataract. It can also prevent pressure on the ciliary body and iris, and pupillary block in aphakic patients, which might increase IOP. The central retinal artery should be monitored during and after air-gas exchange. Administration of systemic carbonic anhydrase inhibitors or topical glaucoma medications may be given for less severe elevations of IOP.

D Patients should not receive hyperbaric oxygen therapy until the gas/air bubble has dissipated[9]. Receiving hyperbaric oxygen therapy may lead to potential patient harms, including retinal ischemia or blindness.

E Treatment to manage possible postoperative ocular hypertension should be established with daily IOP monitoring. Failure to monitor and treat elevated IOP may lead to potential patient harms, including retinal ischemia.

F Sterile surgical techniques should be used for the injection of UNIPURE SF_6 Ophthalmic Gas since compromised sterility could lead to inflammation and infection.

G Do not remove any part of the attached External 0.2-micron Filter prior to releasing and mixing gas and do not use if a high-pitched squealing noise is present, as this may result in inaccurate gas/air mix ratios, which may lead to potential patient harms, including serious microbial infection.

H Never inject unmixed gas into the patient's eye. Injecting unmixed gas into the patient's eye may lead to blindness.

I The gas delivery system is intended for one gas injection procedure only. Potential risk from reuse/resterilization/reprocessing of a single-use medical device may result in: physical damage to the medical device; failure of the medical device to perform as intended; patient illness or injury due to infection; inflammation and/or illness due to product contamination; transmission of infection; and lack of product sterility.

J Do not use the UNIFEYE Gas Delivery System beyond the expiration date.

K Do not use if the Plunger Ring is not centered on the desired Mix Ratio Mark after releasing the gas and do not use if the Syringe Handle is difficult to retract or the Plunger Ring does not stay at the Fill Line / 0 mL Mark after gas mixing as this may lead to potential patient harms, including decreased vision and retinal ischemia.

L Inject the gas/air mixture within 15 minutes of mixing to prevent a reduction in the duration of the endotamponade, which may lead to potential patient harms, including hypotony and retinal detachment.

M Failure to properly complete each step as specified in the mixing procedure or interfering with gas delivery system activation may result in inaccurate gas/air mix ratios (higher or lower mix ratio than gas delivery system indicates), which may lead to potential patient harms, including hypotony and retinal ischemia.

PRECAUTIONS

A Caution should be used in eyes with angle recession, pigment dispersion syndrome, significant anterior synechiae, traumatized eyes, and eyes with significant vitreous hemorrhage obscuring an adequate view of the peripheral retina.

B Safety and effectiveness in pregnant women have not been established.

C Contents of gas pico-cylinder under pressure. Do not puncture.

D Do not use and immediately notify Alcon if the UNIFEYE Gas Delivery System and/or the packaging are received in a defective condition.
- Do not use if the Syringe Handle is extended from the Syringe Barrel and it is not possible to rotate the mix ratio Selector Pointer.
- Do not use the device if the External 0.2-micron Filter is loose or disconnected from the UNIFEYE Gas Delivery System.

E After surgery, provide the items below to the patient:
- Wristband with insert
- Patient Implant Card
- Information brochure (located at www.ifu.alcon.com)

These take-home patient materials contain important information about the surgery and postoperative instructions.

ADVERSE REACTIONS

Operative complications associated with the use of gas/air ocular endotamponades in eyes with or without vitrectomy may include:

- Central retinal artery occlusion
- Subconjunctival gas
- Subretinal hemorrhage
- Small subretinal gas bubble
- Hypotony
- Choroidal hemorrhage
- Choroidal detachment
- Crystalline lens touch by needle
- Hyphema
- Escape of mixed gas/air through the surgical incisions
- Vitreous or iris incarceration at the wound
- Elevated IOP, which may require additional medical or surgical intervention to reduce pressure

Postoperative complications associated with surgical procedures using gas/air ocular endotamponades in eyes with or without vitrectomy may include:

- Elevated IOP, which may require additional medical or surgical intervention to reduce pressure
- Severe elevated IOP that has been known to result in vision decrease or blindness if N_2O is administered during a subsequent surgical or dental procedure with a gas bubble present in the eye
- Central retinal artery occlusion
- Malignant glaucoma
- Changes to the crystalline lens
- Cataract

- New, missed, or recurrent retinal detachment or retinal breaks
- Subconjuctival gas
- Subconjunctival hemorrhage
- Vitreous hemorrhage
- Subretinal fluid
- Subretinal hemorrhage
- Subretinal gas
- Macular hole
- Macular pucker/epiretinal membrane
- Proliferative vitreoretinopathy
- Choroidal hemorrhage
- Choroidal detachment
- Uveitis
- Cystoid macular edema/ macular edema
- Hyphema
- Extrafoveal subretinal pigment migration
- Vitreal opacification (known as "floaters" or "tobacco dust")
- Endophthalmitis
- Refractive changes
- Escape of mixed gas/air through the surgical incisions
- Vitreous or iris incarceration at the wound

CONTENTS

Each pre-assembled single-use UNIFEYE™ Gas Delivery System is provided with an integrated 1 mL UNIPURE™ SF_6 Ophthalmic Gas pico-cylinder with a 0.2-micron internal filter to filter the gas as it enters the syringe, a 50 mL syringe, a pre-attached 0.2-micron external filter to filter ambient air drawn into the syringe, and a mix ratio selector with six selectable gas/air mix ratios.

A patient implant card and wristband with insert are provided with this product to be given to the patient prior to discharge from their eye surgery with a patient information brochure. The patient information brochure is a convenient way to remind the patient about the important restrictions noted above, including limitations on the use of N_2O in subsequent surgical or dental procedures, travel in an airplane or through high elevations, hyperbaric oxygen therapy, and proper head positioning. A copy of the patient information brochure is available at www.ifu.alcon.com. Print a copy of the patient information brochure. The take-home patient materials contain important information about the surgery and postoperative instructions.

The patient implant card and wristband insert included in the package are to be completed and given to the patient, together with instructions to keep the card as a record to be shown to any healthcare professional that the patient consults in the future.

1 Remove patient chart label from accessory bag and adhere sticker to back of the patient implant card where indicated.

2 Fill out the following information on the card:
- Date of surgery,
- Eye implanted [mark left (L) or right (R)],
- Patient name,
- Surgeon name, and
- Hospital or health institution name and address.

The wristband with insert is to be worn by the patient at all times while the gas/air mixture is in their eye to alert subsequent health professionals that the patient may have a gas/air bubble in their eye and that they should confer with the patient's ophthalmologist prior to treating the patient.

Ensure both sides of the wristband insert and patient implant card are completed and reviewed with the patient.

DIRECTIONS FOR USE

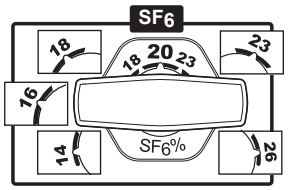
WARNING: Failure to properly complete <u>each</u> step as specified in the mixing procedure or interfering with gas delivery system activation may result in inaccurate gas/air mix ratios (higher or lower mix ratio than gas delivery system indicates).

Gas Delivery System Set Up Procedure

Prior to use, inspect the product packaging. Open tray lid and aseptically transfer internal contents to sterile field. Do not use and immediately notify Alcon if the UNIFEYE Gas Delivery System and/or the packaging are received in a defective condition.
- Do not use if the Syringe Handle is extended from the Syringe Barrel and it is not possible to rotate the mix ratio Selector Pointer.
- Do not use the device if the External 0.2-micron Filter is loose or disconnected from the UNIFEYE Gas Delivery System.
- **Do not remove or loosen the External 0.2-micron Filter prior to the completion of Step 5 as this may lead to potential patient harms including serious microbial infection.**

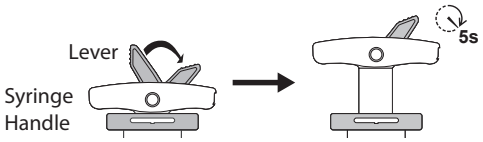
1. Select the desired mix ratio ensuring the Selector Pointer is centered on the Mix Ratio Number.

   Never intentionally pull on the Syringe Handle prior to Step 5.



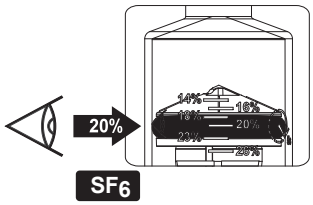
2. In one continuous motion, push the Lever to the opposite side of the Syringe Handle to the full stop position. The Syringe Handle will move outward as gas is released and passes through an internal 0.2-micron filter into the Syringe. Wait at least 5 seconds after the Syringe Handle stops moving before proceeding to Step 3.

   Do not use if a high-pitched squealing noise is present during gas release as this may lead to potential patient harms, including serious microbial infection.

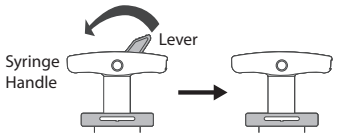


3. Confirm that the Plunger Ring is centered on the desired Mix Ratio Mark.

   Do not use if the Plunger Ring is not centered on the desired Mix Ratio Mark as this may lead to potential patient harms, including decreased vision and retinal ischemia.



4. Pull the Lever in the opposite direction to return the Lever into the Syringe Handle.

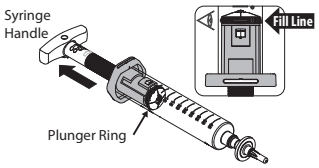


5. Slowly pull the Syringe Handle to draw ambient air through the External 0.2-micron Filter into the Syringe until the Plunger Ring stops at the Fill Line. Visually confirm the Plunger Ring remains on the Fill Line / 0 mL Mark.

   Do not use if the Syringe Handle is difficult to retract or the Plunger Ring does not stay at the Fill Line / 0 mL Mark when released as this may lead to potential patient harms, including decreased vision and retinal ischemia.

   Do not remove or loosen the External 0.2-micron Filter prior to the completion of Step 5. Removal or loosening of the External 0.2-micron Filter may lead to potential patient harms, including serious microbial infection.

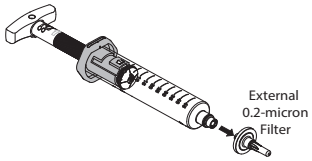
   Never intentionally push on the Syringe Handle until user is ready to express mixed gas.



6. Remove and discard the External 0.2-micron Filter to seal the gas in the Syringe.

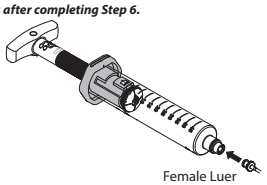
   The gas/air mixture should be expressed within 15 minutes of mixing to ensure gas/air mix ratio accuracy and avoid a possible reduction in duration of the endotamponade, which may lead to potential patient harms, including hypotony and retinal detachment.

   Do not reuse the External 0.2-micron Filter.



7. Firmly attach the Infusion Cannula female luer to the UNIFEYE™ Gas Delivery System male luer and prepare an exit path to enable the lavage of the gas/air mix through the air-filled posterior segment[10-14] as instructed in Steps 7 through 9. The posterior segment must be filled with air prior to use of the UNIFEYE Gas Delivery System.

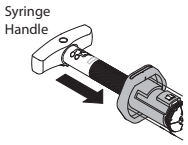
   Mixed gas should be used within 15 minutes after completing Step 6.



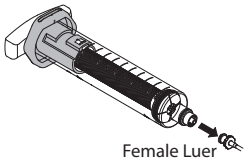
8. Push the Syringe Handle into the Syringe until the desired amount of mixed gas has been expressed.

   If the Syringe Handle cannot be depressed to express the mixed gas after connection of the Infusion Cannula, ensure the Infusion Cannula is tightly attached and depress the Syringe Handle again. Do not use if firm attachment of the Infusion Cannula does not allow the expression of mixed gas.

   Never intentionally pull on the Syringe Handle when expressing mixed gas.



9. At the completion of the air-gas exchange, disconnect the UNIFEYE Gas Delivery System from the Infusion Cannula. At the end of the vitreoretinal procedure, dispose of the gas delivery system as medical waste in accordance with local laws and regulations.



UNIPURE™ SF_6 Ophthalmic Gas is a fluorinated greenhouse gas covered by the Kyoto Protocol and has a Global Warming Potential (GWP) of 22,200.

STORAGE CONDITIONS

Store at 15-30°C (59-86°F).

CONTACT INFORMATION

Do not use and immediately notify Alcon if the UNIFEYE™ Gas Delivery System and/or the packaging are received in a defective condition. In these cases, please contact:

By Phone:
In USA: (800) 757-9780
In EU/ International: Contact your local Alcon Representative.

By Website:
https://www.alcon.com/contact-us/

Each UNIFEYE Gas Delivery System is identified by a lot number which provides traceability and should be given to your local Alcon representative when discussing the product.

PACKAGING AND STERILIZATION

The UNIPURE SF_6 Ophthalmic Gas in the UNIFEYE Gas Delivery System is packaged in a sealed plastic tray with Tyvek lid. The patient implant card, patient chart labels, and wristband with insert are provided within the package.

The UNIFEYE Gas Delivery System and the packaged product are sterilized using ethylene oxide.

The integrated UNIPURE SF_6 Ophthalmic Gas pico-cylinder in the UNIFEYE Gas Delivery System is provided non-sterile. The gas passes through the sterile 0.2-micron internal filter within the sterile UNIFEYE Gas Delivery System prior to filling the syringe with gas and before intraocular injection. (Step 2) Ambient air passes through the sterile 0.2-micron external filter prior to filling the syringe with air and before intraocular injection. (Step 5) The prepared gas/air mixture for injection is sterile via the 0.2-micron filtration of the gas and air.

SERIOUS INCIDENT REPORTING

Any serious incident related to the use of this medical device should be reported to Alcon Laboratories Inc.:

By Phone:
In USA: (800) 757-9780
In EU/International: Contact the local country office or your Alcon distributor.

By E-mail (EU-only):
qa.complaints@alcon.com

By Website:
https://www.alcon.com/contact-us/

These serious incidents should also be reported to the competent authority for medical devices of your State.

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 intravitreous 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.
10. Mendrinos E, Dang-Burgener NP, Stangos AN, Sommerhalder J, Pournaras CJ. Primary vitrectomy without scleral buckling for pseudophakic rhegmatogenous retinal detachment. Am J Ophthalmol. 2008 Jun;145(6):1063-1070.
11. Lambrou FH, Devenyi RG, Han DP. Fluid-gas exchange after vitrectomy using long-acting gases in an outpatient setting. Arch ophthalmol 1988;106:1344.
12. Mittra RA, Pollack JS, Dev S, Han DP, Mieler WF, Pulido JS, Connor TB. The use of topical aqueous suppressants in the prevention of postoperative intraocular pressure elevation after pars plana vitrectomy with long-acting gas tamponade. Ophthalmology. 2000 Mar;107(3):588-92.
13. Williams DF, Peters MA, Abrams GW, Han DP, Mieler WF. A two stage technique for intraoperative fluid gas exchange following pars plana vitrectomy. Arch Ophthalmol. 1990 Oct;108(10):1484-6. Shunmugam
14. M, Shunmugam S, Williamson TH, Laidlaw DA. Air-gas exchange reevaluated: clinically important results of a computer simulation. Invest Ophthalmol Vis Sci. 2011 Oct 21;52(11):8262-5.
15. Cekic O, Ohji M.; Intraocular Gas Tamponades, Seminars in Ophthalmology. 2000 Mar; 15:1, 3-14.
16. Mohamed S and Lai TYY; Intraocular gas in vitreoretinal surgery. HK J Ophthalmol. 2010;14(1):8-13.

DEFINITION OF SYMBOLS

Shown below are symbols that appear on product labels:

LOT	BATCH CODE		USE-BY: YYYY-MM-DD
	CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE		DO NOT USE IF PACKAGE IS DAMAGED
REF	CATALOG NUMBER		DO NOT RE-USE
	EYE	2 STERILIZE	DO NOT RESTERILIZE
	MANUFACTURER		DATE OF MANUFACTURE: YYYY-MM-DD
CC	COUNTRY OF MANUFACTURE		CAUTION
	VISUAL CONFIRMATION	MD	MEDICAL DEVICE
	PATIENT IDENTIFICATION	31	DATE
	HEALTH CARE CENTRE OR DOCTOR		INFORMATION WEBSITE FOR PATIENTS
L	LEFT	R	RIGHT
5s	WAIT 5 SECONDS MINIMUM	LATEX	DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER
	OPEN HERE		MEDICAL ALERT
Rx only			CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
NON STERILE	SF_6		NON-STERILE
30°C (86°F) / 15°C (59°F)			STORAGE TEMPERATURE LIMITATION
STERILE EO			PACKAGING AND UNIFEYE GAS DELIVERY SYSTEM: SINGLE STERILE BARRIER SYSTEM STERILIZED USING ETHYLENE OXIDE

MD

www.ifu.alcon.com

Alcon

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099 USA

MADE IN USA WITH GLOBAL MATERIALS

U.S. Pat.: www.alconpatents.com

UNIPEXY™
GAS DELIVERY SYSTEM

Directions for Use

Rx only

DESCRIPTION AND CHARACTERISTICS

The integrated UNIPURE™ SF_6 Ophthalmic Gas pico-cylinder in the UNIPEXY Gas Delivery System contains undiluted, non-sterile, liquefied sulfur hexafluoride (SF_6) gas under pressure. The gas is non-toxic, inert, non-flammable, odorless, and colorless. The UNIPEXY Gas Delivery System is used to inject filtered UNIPURE SF_6 Ophthalmic Gas directly into the vitreous cavity to form a gas/air bubble. The prepared gas for injection is sterile via the 0.2-micron filtration of the gas.

UNIPURE SF_6 Ophthalmic Gas Properties		
Expansion Rate[β]	**Vapor Pressure (35 ± 2°C)**	**Boiling Point**
24-48 hrs	2,843,000 – 3,109,000 Pa	-64°C -83°F

β Expansion Rate is dependent upon atmospheric pressure.

As-Delivered Gas Purity	
As-Delivered SF_6 % Purity	97%

MODE OF ACTION

During the healing phase, surface tension of the gas plugs the retinal break, preventing further accumulation of fluid under the retina, while the retinal pigment epithelial pump removes subretinal fluid. UNIPURE SF_6 Ophthalmic Gas bubble expands to about twice the volume injected within 24 to 48 hours and substantially diffuses from the eye in approximately 12-14 days.

INDICATION(S) FOR USE

The UNIPURE SF_6 Ophthalmic Gas in the UNIPEXY Gas Delivery System is indicated for intraocular injection into the eye for the treatment of uncomplicated retinal detachments. Associated measures used include vitrectomy, fluid/air exchange, transconjunctival and transscleral cryotherapy, and laser photocoagulation.

TARGET PATIENT POPULATION

The target patient population is adult patients with an uncomplicated retinal detachment with the mental capacity to maintain proper positioning.

INTENDED USERS

The UNIPURE SF_6 Ophthalmic Gas in the UNIPEXY Gas Delivery System is intended to be used by ophthalmic surgeons and their surgical teams.

CLINICAL BENEFITS

The clinical benefits specific to the UNIPURE SF_6 Ophthalmic Gas in the UNIPEXY Gas Delivery System used during ophthalmic surgery are to create a barrier against vitreous fluid entering the space between the retina and supporting structures by forming a gas bubble to tamponade the retina. The UNIPURE SF_6 Ophthalmic Gas is a short-acting gas, having an effect for 12 to 14 days, which offers an alternative to the longer-acting gas tamponades. The surface tension of the gas can prevent further progression of the retinal detachment to preserve vision.

CONTRAINDICATIONS

Proliferative vitreoretinopathy (PVR) greater than Stage C, the mental or physical inability to maintain the therapeutic position for 5 postoperative days, severe glaucoma with more than a minimum of vision field loss and a cup to disc ratio equal to or greater than 0.6; uveitis; severe peripheral retinal degeneration; congenital malformations (such as coloboma), and any other condition that may facilitate the migration of the gas bubble out of the vitreous chamber; and high altitude travel, including but not limited to airline travel.

- Air travel is contraindicated until the gas/air bubble has completely dissipated. Normal cabin pressure changes will cause a severe enlargement of the gas/air bubble with a resultant potential blinding, due to an increase in intraocular pressure (IOP)[1-7].
- Patients should not travel through high elevations and over mountain ranges until the mixed gas/air bubble has dissipated[8].

WARNINGS

A Use of Nitrous Oxide (N_2O) must be stopped at least 15 minutes before injection of UNIPURE SF_6 Ophthalmic Gas to ensure an adequate postoperative bubble is achieved. **Do not administer N_2O if a gas bubble is present.** N_2O rapidly partitions into the gas/air bubble causing expansion and a pressure increase in the eye that has been known to result in vision decrease and blindness.

B Postoperative acute rises in IOP, which can threaten ocular blood flow, lasting more than 10 minutes, should be controlled with paracentesis of aqueous fluid or removal of some of the gas/air bubble. Patients with compromised ocular blood flow such as those with severe diabetic retinopathy or ocular ischemia are at greater risk of vascular occlusion following the use of a gas injection. IOP should be checked by an experienced surgeon with either tactile touch or applanation tonometry when the gas bubble is in place. Schiotz tonometry will give false low values compared to the true IOP.

C Patient positioning following gas/air injection is of great importance. The gas/air bubble must be properly situated with proper positioning to allow contact of the bubble against the targeted area of the retina. Prone or seated face down positioning can prevent protracted contact between the bubble and the lens to avert a posterior subcapsular cataract, as well as to prevent pressure on the ciliary body and iris, and to prevent pupillary block in aphakic patients, which might increase IOP. The central retinal artery should be monitored during and after gas injection. Administration of systemic carbonic anhydrase inhibitors or topical glaucoma medications may be given for less severe elevations of IOP.

D Patients should not receive hyperbaric oxygen therapy until the gas/air bubble has dissipated[9]. Receiving hyperbaric oxygen therapy may lead to potential patient harms, including retinal ischemia or blindness.

E Treatment to manage possible postoperative ocular hypertension should be established with daily IOP monitoring. Failure to monitor and treat elevated IOP may lead to potential patient harms, including retinal ischemia.

F Sterile surgical techniques should be used for the injection of UNIPURE SF_6 Ophthalmic Gas since compromised sterility could lead to inflammation and infection.

G Never retract the Syringe Plunger after the Syringe has been filled with gas. Retracting the Syringe Plunger may lead to potential patient harms, including hypotony or retinal detachment.

H The gas delivery system is intended for one gas injection procedure only. Potential risk from reuse/resterilization/reprocessing of a single-use medical device may result in: physical damage to the medical device; failure of the medical device to perform as intended; patient illness or injury due to infection; inflammation and/or illness due to product contamination; transmission of infection; and lack of product sterility.

I Do not use the UNIPEXY Gas Delivery System beyond the expiration date.

J Inject the UNIPURE SF_6 Ophthalmic Gas immediately to prevent a reduction in the duration of the endotamponade, which may lead to potential patient harms, including hypotony and retinal detachment.

K Do not use if the sterile needle is contaminated prior to injection. Use of a non-sterile needle may lead to serious microbial infection.

PRECAUTIONS

A Caution should be used in eyes with angle recession, pigment dispersion syndrome, significant anterior synechiae, traumatized eyes and eyes with significant vitreous hemorrhage obscuring an adequate view of the peripheral retina.

B Safety and effectiveness in pregnant women have not been established.

C Contents of gas pico-cylinder under pressure. Do not puncture.

D Do not use and immediately notify Alcon if the UNIPEXY Gas Delivery System and/or the packaging are received in a defective condition.

E After surgery, provide the items below to the patient:
- Wristband with insert
- Patient Implant Card
- Information brochure (located at www.ifu.alcon.com)

These take-home patient materials contain important information about the surgery and postoperative instructions.

ADVERSE REACTIONS

Operative complications associated with the use of gas/air ocular endotamponades in eyes with or without vitrectomy may include:

- Central retinal artery occlusion
- Subconjunctival gas
- Subretinal hemorrhage
- Small subretinal gas bubble
- Hypotony
- Choroidal hemorrhage
- Choroidal detachment
- Crystalline lens touch by needle
- Hyphema
- Escape of gas through the surgical incisions
- Vitreous or iris incarceration at the wound
- Elevated IOP, which may require additional medical or surgical intervention to reduce pressure

Postoperative complications associated with surgical procedures using gas/air ocular endotamponades in eyes with or without vitrectomy may include:

- Elevated IOP, which may require additional medical or surgical intervention to reduce pressure
- Severe elevated IOP that has been known to result in vision decrease or blindness if N_2O is administered during a subsequent surgical or dental procedure with a gas bubble present in the eye
- Central retinal artery occlusion
- Malignant glaucoma
- Changes to the crystalline lens
- Cataract
- New, missed, or recurrent retinal detachment or retinal breaks
- Subconjunctival gas
- Subconjunctival hemorrhage
- Vitreous hemorrhage
- Subretinal fluid
- Subretinal hemorrhage
- Subretinal gas
- Macular hole
- Macular pucker/epiretinal membrane
- Proliferative vitreoretinopathy
- Choroidal hemorrhage
- Choroidal detachment
- Uveitis
- Cystoid macular edema/macular edema
- Hyphema
- Extrafoveal subretinal pigment migration
- Vitreal opacification (known as "floaters" or "tobacco dust")
- Endophthalmitis
- Refractive changes
- Escape of mixed gas/air through the surgical incisions
- Vitreous or iris incarceration at the wound

CONTENTS

Each pre-assembled single-use UNIPEXY™ Gas Delivery System is provided with an integrated 1 mL UNIPURE™ SF_6 Ophthalmic Gas pico-cylinder with a 0.2-micron internal filter to filter the gas as it enters the syringe and a 3-mL syringe with a pre-attached 30-gauge needle.

A patient implant card and wristband with insert are provided with this product to be given to the patient prior to discharge from their eye surgery with a patient information brochure. The patient information brochure is a convenient way to remind the patient about the important restrictions noted above, including limitations on the use of N_2O in subsequent surgical or dental procedures, travel in an airplane or through high elevations, hyperbaric oxygen therapy, and proper head positioning. A copy of the patient information brochure is available at www.ifu.alcon.com. Print a copy of the patient information brochure. The take-home patient materials contain important information about the surgery and postoperative instructions.

The patient implant card and wristband insert included in the package are to be completed and given to the patient, together with instructions to keep the card as a record to be shown to any healthcare professional that the patient consults in the future.

1 Remove patient chart label from accessory bag and adhere sticker to back of the patient implant card where indicated.

2 Fill out the following information on the card:
- Date of surgery,
- Eye implanted [mark left (L) or right (R)],
- Patient name,
- Surgeon name, and
- Hospital or health institution name and address.

The wristband with insert is to be worn by the patient at all times while the gas/air mixture is in their eye to alert subsequent health professionals that the patient may have a gas/air bubble in their eye and that they should confer with the patient's ophthalmologist prior to treating the patient.

Ensure both sides of the wristband insert and patient implant card are completed and reviewed with the patient.

DIRECTIONS FOR USE

WARNING: Failure to properly complete <u>each</u> step as specified in the syringe filling procedure or interfering with gas delivery system activation may result in dilution of gas. Manual retraction of the Syringe Plunger prior to completion of syringe filling or after syringe filling will allow air to enter the syringe.

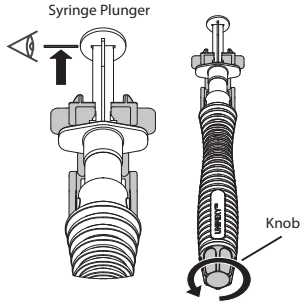
UNIPURE SF_6 Ophthalmic Gas is injected transconjunctivally and transclerally into the vitreous liquid. An average of 0.3 mL to 0.6 mL of gas is injected. Prior to pneumatic retinopexy with UNIPURE SF_6 Ophthalmic Gas, it is common practice to decrease IOP to about 4 mmHg or less. Prepare the injection site with a sterile solution.

Gas Delivery System Set Up Procedure

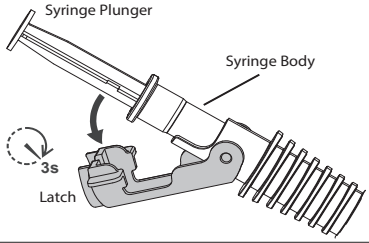
Prior to use, inspect the product packaging. Open tray lid and aseptically transfer internal contents to sterile field. Do not use and immediately notify Alcon if the UNIPEXY Gas Delivery System and/or the packaging are received in a defective condition.

1. Rotate the Knob clockwise to release gas. The Syringe Plunger will move outward as gas is released and passes through an internal 0.2-micron filter into the Syringe.

Immediately after confirming that the Syringe Plunger has stopped moving, rotate the Knob counterclockwise to deactivate the gas release.

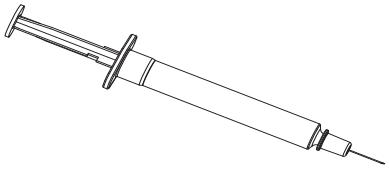


2. Wait at least 3 seconds, then flip the Latch away from the Syringe Body. Grasp the Syringe by the Syringe Body (not the Syringe Plunger) and remove the Syringe from the gas delivery system. The UNIPURE SF_6 Ophthalmic Gas should be injected immediately to avoid gas diffusion causing a possible change in the expansion performance of the gas, resulting in a reduction of the duration of the endotamponade.



3. Express the undesired amount of gas, and then inject the intended amount of gas.

   Use aseptic technique to maintain needle sterility prior to injection. If the sterile needle is contaminated prior to injection, do not use and discard the UNIPEXY Gas Delivery System. Do not attempt to decontaminate the needle.



At the completion of the gas bubble injection, dispose of the gas delivery system as medical waste in accordance with local laws and regulations.

UNIPURE™ SF_6 Ophthalmic Gas is a fluorinated greenhouse gas covered by the Kyoto Protocol and has a Global Warming Potential (GWP) of 22,200.

STORAGE CONDITIONS

Store at 15-30°C (59-86°F).

CONTACT INFORMATION

Do not use and immediately notify Alcon if the UNIPEXY™ Gas Delivery System and/or the packaging are received in a defective condition. In these cases, please contact:

By Phone:
In USA: (800) 757-9780
In EU/ International: Contact your local Alcon Representative.

By Website:
https://www.alcon.com/contact-us/

Each UNIPEXY Gas Delivery System is identified by a lot number which provides traceability and should be given to your local Alcon representative when discussing the product.

PACKAGING AND STERILIZATION

The UNIPURE SF_6 Ophthalmic Gas in the UNIPEXY Gas Delivery System is packaged in a sealed plastic tray with Tyvek lid. The patient implant card, patient chart labels, and wristband with insert are provided within the package.

The UNIPEXY Gas Delivery System and the packaged product are sterilized using ethylene oxide.

The integrated UNIPURE SF_6 Ophthalmic Gas pico-cylinder in the UNIPEXY Gas Delivery System is provided non-sterile. The gas passes through the sterile 0.2-micron internal filter within the sterile UNIPEXY Gas Delivery System prior to filling the syringe with gas and before intraocular injection. (Step 1) The prepared gas for injection is sterile via the 0.2-micron filtration of the gas.

SERIOUS INCIDENT REPORTING

Any serious incident related to the use of this medical device should be reported to Alcon Laboratories Inc.:

By Phone:
In USA: (800) 757-9780
In EU/International: Contact the local country office or your Alcon distributor.

By E-mail (EU-only):
qa.complaints@alcon.com

By Website:
https://www.alcon.com/contact-us/

These serious incidents should also be reported to the competent authority for medical devices of your State.

DEFINITION OF SYMBOLS

Shown below are symbols that appear on product labels:

LOT	BATCH CODE		USE-BY: YYYY-MM-DD
	CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE		DO NOT USE IF PACKAGE IS DAMAGED
REF	CATALOG NUMBER		DO NOT RE-USE
	EYE	2 STERILIZE	DO NOT RESTERILIZE
	MANUFACTURER		DATE OF MANUFACTURE: YYYY-MM-DD
CC	COUNTRY OF MANUFACTURE		CAUTION
	VISUAL CONFIRMATION	MD	MEDICAL DEVICE
?	PATIENT IDENTIFICATION	31	DATE
	HEALTH CARE CENTRE OR DOCTOR		INFORMATION WEBSITE FOR PATIENTS
L	LEFT	R	RIGHT
3s	WAIT 3 SECONDS MINIMUM	LATEX	DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER
	OPEN HERE		MEDICAL ALERT
Rx only			CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
NON STERILE	SF_6		NON-STERILE
30°C (86°F) / 15°C (59°F)			STORAGE TEMPERATURE LIMITATION
STERILE EO			PACKAGING AND UNIPEXY GAS DELIVERY SYSTEM: SINGLE STERILE BARRIER SYSTEM STERILIZED USING ETHYLENE OXIDE

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www.ifu.alcon.com

Alcon

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