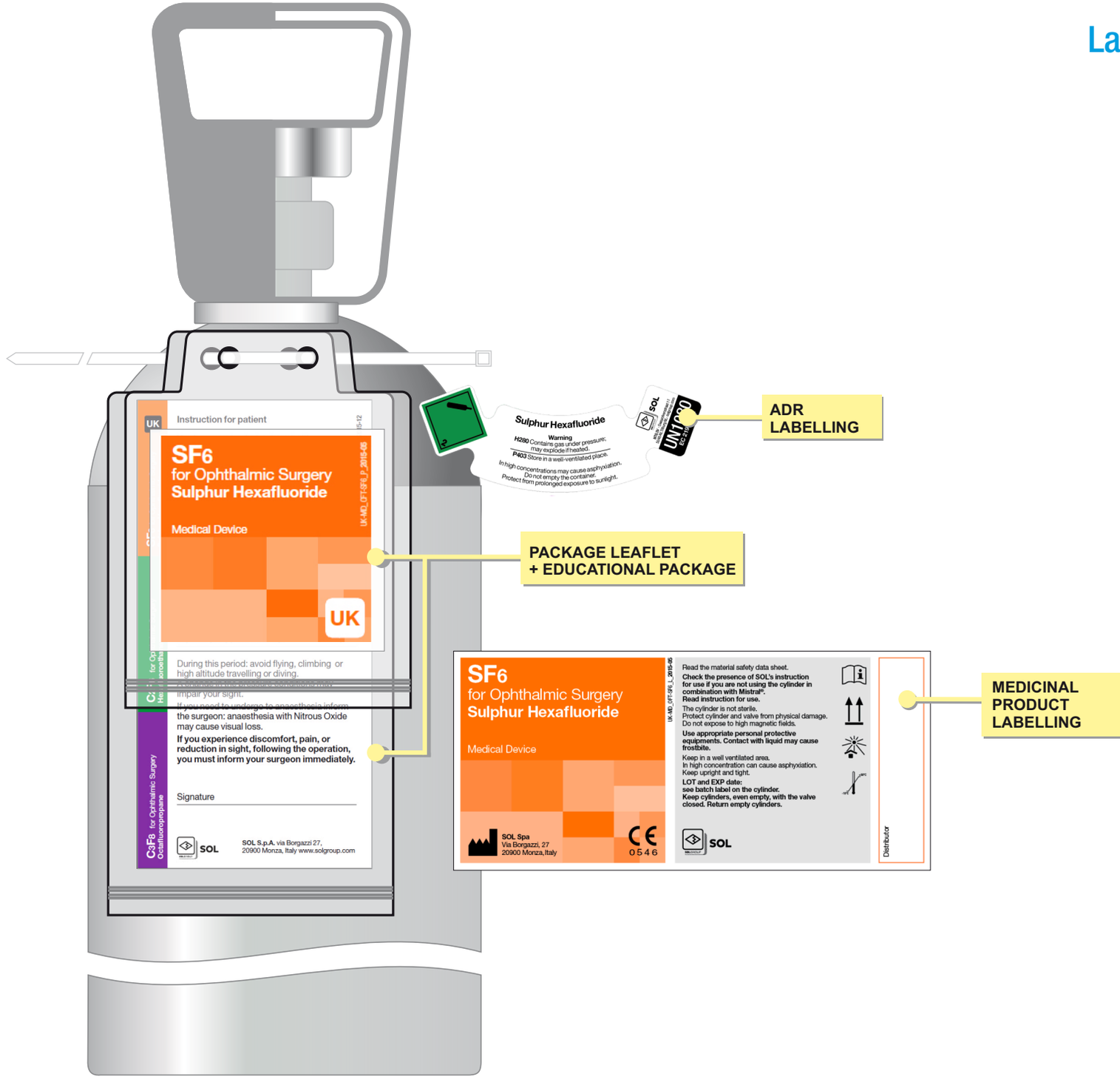
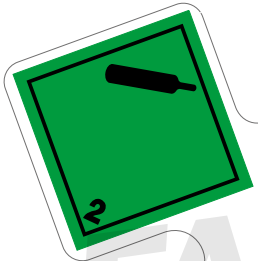
Labels on cylinders
MD oftalmici

English



UK_SULPHUR-HEXAFLUORIDE_A_ **2015-01**

IT_ESAFLUORURO-DI-ZOLFO



Sulphur Hexafluoride

Warning

H280 Contains gas under pressure; may explode if heated.

P403 Store in a well-ventilated place.

In high concentrations may cause asphyxiation.
Do not empty the container.
Protect from prolonged exposure to sunlight.

SOL

SOL GROUP

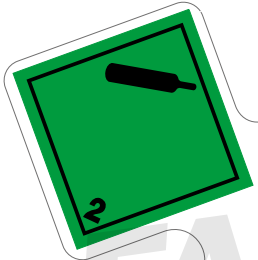
NTG BV - Swaardvenstraat 11
5048 AV Tilburg NL - solgroup.com

UN1080

EC 219-854-2

UK_HEXAFLUOROETHANE-R116_A_**2015-01**

IT_ESAFLUOROETANO (GAS REFRIG. R116)



Hexafluoroethane

Compressed Gas n.o.s.

Warning

H280 Contains gas under pressure; may explode if heated.

P403 Store in a well-ventilated place.

In high concentrations may cause asphyxiation.
Do not empty the container.
Protect from prolonged exposure to sunlight.

SOL

SOL GROUP

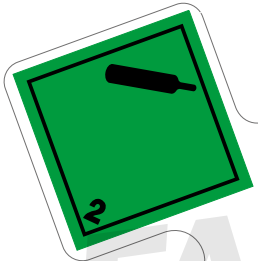
NTG BV - Swaardvenstraat 11
5048 AV Tilburg NL - solgroup.com

UN1956

EC 200-939-8

UK_OCTAFLUOROPROPANE-R218_A_ **2015-01**

IT_OTTAFLUOROPROPANO (GAS REFRIG. R218)



Octafluoropropane

Compressed Gas n.o.s.

Warning

H280 Contains gas under pressure; may explode if heated.

P403 Store in a well-ventilated place.

In high concentrations may cause asphyxiation.
Do not empty the container.
Protect from prolonged exposure to sunlight.

SOL

SOLSHOP

NTG&V - Swaardvenstraat 11
5048 AV Tilburg NL - solgroup.com

UN1956

EC 200-941-9

SF_6

for Ophthalmic Surgery

Sulphur Hexafluoride

Medical Device

SOL Spa
Via Borgazzi, 27
20900 Monza, Italy

CE
0546

UK-MD_OFT-SF6_L_**2015-05**

Read the material safety data sheet.

Check the presence of SOL's instruction for use if you are not using the cylinder in combination with Mistral®.
Read instruction for use.

The cylinder is not sterile.
Protect cylinder and valve from physical damage.
Do not expose to high magnetic fields.

Use appropriate personal protective equipments. Contact with liquid may cause frostbite.

Keep in a well ventilated area.
In high concentration can cause asphyxiation.
Keep upright and tight.

LOT and EXP date:
see batch label on the cylinder.
Keep cylinders, even empty, with the valve closed. Return empty cylinders.

SOL
SOLGROUP

Distributor

C_2F_6

for Ophthalmic Surgery

Hexafluoroethane

Medical Device

SOL Spa
Via Borgazzi, 27
20900 Monza, Italy

CE
0546

UK-MD_OFT-C2F6_L_**2015-05**

Read the material safety data sheet.

Check the presence of SOL's instruction for use if you are not using the cylinder in combination with Mistral®.
Read instruction for use.

The cylinder is not sterile.
Protect cylinder and valve from physical damage.
Do not expose to high magnetic fields.

Use appropriate personal protective equipments. Contact with liquid may cause frostbite.

Keep in a well ventilated area.
In high concentration can cause asphyxiation.
In low concentration can cause narcotic effects.
Keep upright and tight.

LOT and EXP date:
see batch label on the cylinder.
Keep cylinders, even empty, with the valve closed. Return empty cylinders.

SOL
SOLGROUP

Distributor

C_3F_8

for Ophthalmic Surgery

Octafluoropropane

Medical Device

SOL Spa
Via Borgazzi, 27
20900 Monza, Italy

CE
0546

UK-MD_OFT-C3F8_L_**2015-05**

Read the material safety data sheet.

Check the presence of SOL's instruction for use if you are not using the cylinder in combination with Mistral®.
Read instruction for use.

The cylinder is not sterile.
Protect cylinder and valve from physical damage.
Do not expose to high magnetic fields.

Use appropriate personal protective equipments. Contact with liquid may cause frostbite.

Keep in a well ventilated area.
In high concentration can cause asphyxiation.
In low concentration can cause narcotic effects.
Keep upright and tight.

LOT and EXP date:
see batch label on the cylinder.
Keep cylinders, even empty, with the valve closed. Return empty cylinders.

SOL
SOLGROUP

Distributor

SF6
for Ophthalmic Surgery
Sulphur Hexafluoride

Medical Device

UK-MD_0FT-SF6_P_2015-05

UK

Instruction for professional user of SF6 MD

Composition

Medical Sulfur hexafluoride for ophtalmic surgery is a liquefied gas at its vapour tension (23.08 bar at 21.1°C) with the following specification:

Assay SF6 ≥ 99,9%

Destination of use

SF6 is a vitreous tamponade used in vitreo-retinal surgery, in particular for the treatment of isolated retinal tears, or whenever the desired permanence in the eye is of about 10-15 days.

Available configuration

Cylinders' capacity (l)	1
Valve connection	ISO 5145 No. 33

CE
0546

SOL
SOLGROUP
SOL S.p.A.
via Borgazzi 27
20900 Monza, Italy

Recommendations for installation

This cylinder shall never be carried in an environment with a high magnetic field (like N.M.R.) or nearby.

Keep the cylinder in upright position and tight.

Keep the cylinder at environmental temperature before and during its use.

The device is supplied with a protective seal that when removed cannot be replaced.

The cylinder and the gas are not sterile and not designed to be sterilized.

If cleaning of external surface is necessary, use only soapy water and cotton fabrics which don't left residues.

Check the cleaning condition of the valve connections before every use.

Connect the cylinder to equipments with standardized connections before opening the valve.

Do not use any intermediate connection that can allow the connection of two devices not designed to be connected together.

Connect the valve to a pressure reducer and the latter to the flexible hose.

Do not stay in front of the valve outlet but always at the opposite side of the pressure reducer, behind the cylinder and well back.

Open the valve slowly and progressively.

Purge the hose before suck the gas.

Use an antibacterical filter (0,22 µm) between the syringe and the needle.

The syringe, the filter and the flexible plastic hose used shall be single use and sterile.

Connect the antibacterial filter to the syringe before suck the gas.

The product is a liquefied gas at its vapour pressure. Thus the information supplied by a manometer connected to this device cannot indicate the amount of gas still available in the cylinder (pressure is constant). To define the residual content weighing is necessary. The net content for the new device is stamped on the cylinder.

Check the valve closure after every use and re-screw the cap, for all the cylinders provided with it.

Precautions for surgical use

This device is designed to be used by surgeon fully familiar with the use of tamponading agent in surgical procedures.. It can be used by medical assistants only for the preparation for use.

The selection of the gas and required expansion rate is responsibility of the surgeon only, according with the required effect, the treated pathology and the patient conditions.

Particular caution should be employed in patients whose eyes have the following pre-existing conditions:
Narrow angle glaucoma;
Implanted glaucoma drainage devices;
Aphakia.

To obtain a not-expansive mixture with air the percentage of gas to be used is about: SF6 20%.

If used pure the gas undergoes to expansion in the eye. The expansion rate is gas-specific and may occur within few days from the intervention.
In the following table are reported the indicative rates and delays:

Rate	SF6	x2
Delay	SF6	36 hours (1.5 days)

Anaesthesia with nitrous oxide shall be stopped at least 20 minutes before or avoided if possible.

Post operative Recommendations

After gas injection the patency of the retinal and optic disc circulation should be checked.

Appropriate postoperative monitoring of intraocular pressure should be arranged following introduction of a gas bubble.

Inform the patient about the risks connected to pressure changes while the gas bubble is in the eye.

Inform the patient about the risks connected to the use of nitrous oxide while the gas bubble is in the eye.

Fill in the patient's information material with the indicative date until the gas bubble will be present.

The gas retention time is, on average:
SF6 10-14 days, inform the patient if positioning time is required and fill in the patient's information material with the dates.

Provide the patient with the filled copy of the patient information material.

Precautions for the storage

Keep the cylinder in a well ventilated area, with temperatures between – 15 °C and + 50° C.
The prolonged exposition to temperatures higher than 50°C can cause the rupture of the breaking disk and the expulsion of the gas.

To avoid damages due to shocks and falls:
Keep the cylinder in upright position and tight.

To avoid contamination leave a residual pressure in the empty cylinder.

Keep cylinders, even empty, with the valve closed and the protection cap installed (when expected).

The empty cylinder has to be returned to the manufacturer for disposal.

Safety information

Not flammable gas.

For all gas properties read the material safety data sheet.

Protect hands and eyes when handling the cylinder.

In case of eyes and skin contact: rinse eyes immediately with plenty of water for at least 15 minutes.

In case of frostbite: rinse with water for at 15 minutes.

In any case contact a physician.

Specific risks and potential side effects

In case of spillage in a confined atmosphere: in high concentration can cause asphyxiation. Symptoms can include loss of mobility and/or consciousness.

Victims cannot realize asphyxiation.

Retinal ischemia and visual loss for prolonged and increased intraocular pressure due to the use of Nitrous oxide anaesthesia while the gas bubble is in the eye, since nitrous oxide diffuses in the gas bubble expanding it:

- new or missed retinal breaks that induce
- reaccumulation of subretinal fluid;
- subconjuntival gas presence;
- subretinal gas migration;
- gas entrapement in pre-hyaloid or sub-pars plana space;
- anterior chamber gas entrapment;
- incarceration of iris and vitreous at the paracentesis wound;
- suprachoroidal gas injection;
- endophthalmitis;
- macular hole development;
- cataract;
- uveitis;
- intaocular Hemorrhage;
- macular folds;
- malignant glaucoma;
- corneal wound dehiscence.

Muscoskeletal and neurological complication due to the requirement of head-tilting positioning for a prolonged period.

Additional information

For any additional information or communications, please contact the manufacturer at the address herein reported or your local distributor.

C_2F_6
for Ophthalmic Surgery
Hexafluoroethane

Medical Device

UK-MD_OFT-C2F6_P_2015-05

UK

Instruction for professional user of C2F6 MD

Composition

Medical Hexafluoroethane for ophtalmic surgery is a liquefied gas at its vapour tension (30.7 bar at 21.1°C) with the following specification:

Assay C2F6 ≥ 99,9%

Destination of use

C2F6 is a vitreous tamponade used in vitreo-retinal surgery, in particular for the treatment of extended retinal tears or whenever the desired permanence in the eye is of about 30-40 days.
It is indicated for patients with keratoglobe, keratocone, high risk of retinal edema, serious miopy.

Available configuration

Cylinders' capacity (l)	1
Valve connection	ISO 5145 No. 33

CE
0546

SOL
SOLGROUP
SOL S.p.A.
via Borgazzi 27
20900 Monza, Italy

Recommendations for installation

This cylinder shall never be carried in an environment with a high magnetic field (like N.M.R.) or nearby.

Keep the cylinder in upright position and tight.

Keep the cylinder at environmental temperature before and during its use.

The device is supplied with a protective seal that when removed cannot be replaced.

The cylinder and the gas are not sterile and not designed to be sterilized.

If cleaning of external surface is necessary, use only soapy water and cotton fabrics which don't left residues.

Check the cleaning condition of the valve connections before every use.

Connect the cylinder to equipments with standardized connections before opening the valve.

Do not use any intermediate connection that can allow the connection of two devices not designed to be connected together.

Connect the valve to a pressure reducer and the latter to the flexible hose.

Do not stay in front of the valve outlet but always at the opposite side of the pressure reducer, behind the cylinder and well back.

Open the valve slowly and progressively.

Purge the hose before suck the gas.

Use an antibacterical filter (0,22 µm) between the syringe and the needle.

The syringe, the filter and the flexible plastic hose used shall be single use and sterile.

Connect the antibacterial filter to the syringe before suck the gas.

The product is a liquefied gas at its vapour pressure. Thus the information supplied by a manometer connected to this device cannot indicate the amount of gas still available in the cylinder (pressure is constant). To define the residual content weighing is necessary. The net content for the new device is stamped on the cylinder.

Check the valve closure after every use and re-screw the cap, for all the cylinders provided with it.

Precautions for surgical use

This device is designed to be used by surgeon fully familiar with the use of tamponading agent in surgical procedures. It can be used by medical assistants only for the preparation for use.

The selection of the gas and required expansion rate is responsibility of the surgeon only, according with the required effect, the treated pathology and the patient conditions.

Particular caution should be employed in patients whose eyes have the following pre-existing conditions:
Narrow angle glaucoma;
Implanted glaucoma drainage devices;
Aphakia.

To obtain a not-expansive mixture with air the percentage of gas to be used is about: C2F6 16%.

If used pure the gas undergoes to expansion in the eye. The expansion rate is gas-specific and may occur within few days from the intervention. In the following table are reported the indicative rates and delays:

Rate	C2F6 x3.3
Delay	C2F6 48 hours (2 days)

Anaesthesia with nitrous oxide shall be stopped at least 20 minutes before or avoided if possible.

Post operative Recommendations

After gas injection the patency of the retinal and optic disc circulation should be checked.

Appropriate postoperative monitoring of intraocular pressure should be arranged following introduction of a gas bubble.

Inform the patient about the risks connected to pressure changes while the gas bubble is in the eye.

Inform the patient about the risks connected to the use of nitrous oxide while the gas bubble is in the eye.

Fill in the patient's information material with the indicative date until the gas bubble will be present.

The gas retention time is, on average:
C2F6 30-40 days, inform the patient if positioning time is required and fill in the patient's information material with the dates.

Provide the patient with the filled copy of the patient information material.

Precautions for the storage

Keep the cylinder in a well ventilated area, with temperatures between – 15 °C and + 50° C.
The prolonged exposition to temperatures higher than 50°C can cause the rupture of the breaking disk and the expulsion of the gas.

To avoid damages due to shocks and falls:
Keep the cylinder in upright position and tight.

To avoid contamination leave a residual pressure in the empty cylinder.

Keep cylinders, even empty, with the valve closed and the protection cap installed (when expected).

The empty cylinder has to be returned to the manufacturer for disposal.

Safety information

Not flammable gas.

For all gas properties read the material safety data sheet.

Protect hands and eyes when handling the cylinder.

In case of eyes and skin contact: Rinse eyes immediately with plenty of water for at least 15 minutes.

In case of frostbite: rinse with water for at 15 minutes.

In any case contact a physician.

Specific risks and potential side effects

In case of spillage in a confined atmosphere: in high concentration can cause asphyxiation. Symptoms can include loss of mobility and/or consciousness.

Victims cannot realize asphyxiation.

In low concentration can cause narcotic effects. Symptoms may include dizziness, headache, nausea, and loss of coordination.

Retinal ischemia and visual loss for prolonged and increased intraocular pressure due to the use of Nitrous oxide anaesthesia while the gas bubble is in the eye, since nitrous oxide diffuses in the gas bubble expanding it:

- new or missed retinal breaks that induce reaccumulation of subretinal fluid;
- subconjuntival gas presence;
- subretinal gas migration;
- gas entrapement in pre-hyaloid or sub-pars plana space;
- anterior chamber gas entrapment;
- incarceration of iris and vitreous at the paracentesis wound;
- suprachoroidal gas injection;
- endophthalmitis;
- macular hole development;
- cataract;
- uveitis;
- intaocular Hemorrhage;
- macular folds;
- malignant glaucoma;
- corneal wound dehiscence;

Muscoskeletal and neurological complication due to the requirement of head-tilting positioning for a prolonged period.

Additional information

For any additional information or communications, please contact the manufacturer at the address herein reported or your local distributor.

C3F8
for Ophthalmic Surgery
Octafluoropropane

Medical Device

UK-MD_OFT-C3F8_P_2015-05

UK

Instruction for professional user of C3F8 MD

Composition

Medical Octafluoropropane for ophtalmic surgery is a liquefied gas at its vapour tension (7.92bar at 21.1°C) with the following specification:

Assay C3F8 ≥ 99,9%

Destination of use

C3F8 is a vitreous tamponade used in vitreo-retinal surgery, in particular for the treatment of giant retinal tears or whenever the desired permanence in the eye is of about 42-65 days.
It is indicated for patients with keratocone, for the treatment of acute corneal hydrope. It is used also for the treatment of Vitreomacular traction.

Available configuration

Cylinders' capacity (l)	1
Valve connection	ISO 5145 No. 33

CE
0546

SOL
SOLGROUP
SOL S.p.A.
via Borgazzi 27
20900 Monza, Italy

Recommendations for installation

This cylinder shall never be carried in an environment with a high magnetic field (like N.M.R.) or nearby.

Keep the cylinder in upright position and tight.

Keep the cylinder at environmental temperature before and during its use.

The device is supplied with a protective seal that when removed cannot be replaced.

The cylinder and the gas are not sterile and not designed to be sterilized.

If cleaning of external surface is necessary, use only soapy water and cotton fabrics which don't left residues.

Check the cleaning condition of the valve connections before every use.

Connect the cylinder to equipments with standardized connections before opening the valve.

Do not use any intermediate connection that can allow the connection of two devices not designed to be connected together.

Connect the valve to a pressure reducer and the latter to the flexible hose.

Do not stay in front of the valve outlet but always at the opposite side of the pressure reducer, behind the cylinder and well back.

Open the valve slowly and progressively.

Purge the hose before suck the gas.

Use an antibacterical filter (0,22 µm) between the syringe and the needle.

The syringe, the filter and the flexible plastic hose used shall be single use and sterile.

Connect the antibacterial filter to the syringe before suck the gas.

The product is a liquefied gas at its vapour pressure. Thus the information supplied by a manometer connected to this device cannot indicate the amount of gas still available in the cylinder (pressure is constant). To define the residual content weighing is necessary. The net content for the new device is stamped on the cylinder.

Check the valve closure after every use and re-screw the cap, for all the cylinders provided with it.

Precautions for surgical use

This device is designed to be used by surgeon fully familiar with the use of tamponading agent in surgical procedures. It can be used by medical assistants only for the preparation for use.

The selection of the gas and required expansion rate is responsibility of the surgeon only, according with the required effect, the treated pathology and the patient conditions.

Particular caution should be employed in patients whose eyes have the following pre-existing conditions:
Narrow angle glaucoma;
Implanted glaucoma drainage devices;
Aphakia.

To obtain a not-expansive mixture with air the percentage of gas to be used is about: C3F8 12%.

If used pure the gas undergoes to expansion in the eye. The expansion rate is gas-specific and may occur within few days from the intervention. In the following table are reported the indicative rates and delays:

Rate	C3F8	x4
Delay	C3F8	72hours (3 days).

Anaesthesia with nitrous oxide shall be stopped at least 20 minutes before or avoided if possible.

Post operative Recommendations

After gas injection the patency of the retinal and optic disc circulation should be checked.

Appropriate postoperative monitoring of intraocular pressure should be arranged following introduction of a gas bubble.

Inform the patient about the risks connected to pressure changes while the gas bubble is in the eye.

Inform the patient about the risks connected to the use of nitrous oxide while the gas bubble is in the eye.

Fill in the patient's information material with the indicative date until the gas bubble will be present.

The gas retention time is, on average:
C3F8 42-65 days, inform the patient if positioning time is required and fill in the patient's information material with the dates.

Provide the patient with the filled copy of the patient information material.

Precautions for the storage

Keep the cylinder in a well ventilated area, with temperatures between – 15 °C and + 50° C.
The prolonged exposition to temperatures higher than 50°C can cause the rupture of the breaking disk and the expulsion of the gas.

To avoid damages due to shocks and falls:
Keep the cylinder in upright position and tight.

To avoid contamination leave a residual pressure in the empty cylinder.

Keep cylinders, even empty, with the valve closed and the protection cap installed (when expected).

The empty cylinder has to be returned to the manufacturer for disposal.

Safety information

Not flammable gas.

For all gas properties read the material safety data sheet.

Protect hands and eyes when handling the cylinder.

In case of eyes and skin contact: Rinse eyes immediately with plenty of water for at least 15 minutes.

In case of frostbite: rinse with water for at 15 minutes.

In any case contact a physician.

Specific risks and potential side effects

In case of spillage in a confined atmosphere: in high concentration can cause asphyxiation. Symptoms can include loss of mobility and/or consciousness.

Victims cannot realize asphyxiation.

In low concentration can cause narcotic effects. Symptoms may include dizziness, headache, nausea, and loss of coordination.

Known complications connected with the use of gas as vitreous tamponade are:
- retinal ischemia and visual loss for prolonged and increased intraocular pressure due to the use of Nitrous oxide anaesthesia while the gas bubble is in the eye, since nitrous oxide diffuses in the gas bubble expanding it;
- new or missed retinal breaks that induce reaccumulation of subretinal fluid;
- subconjuntival gas presence;
- subretinal gas migration;
- gas entrapement in pre-hyaloid or sub-pars plana space;
- anterior chamber gas entrapment;
- incarceration of iris and vitreous at the paracentesis wound;
- suprachoroidal gas injection;
- endophthalmitis;
- macular hole development;
- cataract;
- uveitis;
- intaocular Hemorrhage;
- macular folds;
- malignant glaucoma;
- corneal wound dehiscence;

Muscoskeletal and neurological complication due to the requirement of head-tilting positioning for a prolonged period.

Additional information

For any additional information or communications, please contact the manufacturer at the address herein reported or your local distributor.

UK

SF6 for Ophthalmic Surgery
Sulphur Hexafluoride

C2F6 for Ophthalmic Surgery
Hexafluoroethane

C3F8 for Ophthalmic Surgery
Octafluoropropane

Instruction for patient

You have received a treatment with the gas tamponade:

- ☐ **Sulphur Hexafluoride**
- ☐ **Hexafluoroethane**
- ☐ **Octafluoropropane**

Your surgeon should have already informed you about the possible complications.

If your sight is not clear it is due to the optical effect of the bubble: it is a normal condition.

Strictly follow instruction received by your Surgeon they are important for your safety and a better outcome of the procedure.

Stay in prone position up to _____ hours

The gas bubble will remain in your eye approximatively _____ days

During this period: avoid flying, climbing or high altitude travelling or diving.
A change in the pressure conditions may impair your sight.

If you need to undergo to anaesthesia inform the surgeon: anaesthesia with Nitrous Oxide may cause visual loss.

If you experience discomfort, pain, or reduction in sight, following the operation, you must inform your surgeon immediately.

Signature _____

CE 0546

SOL S.p.A.
via Borgazzi 27
20900 Monza, Italy
www.solgroup.com

SOL

UK-MD_OFT_EP_**2015-12**