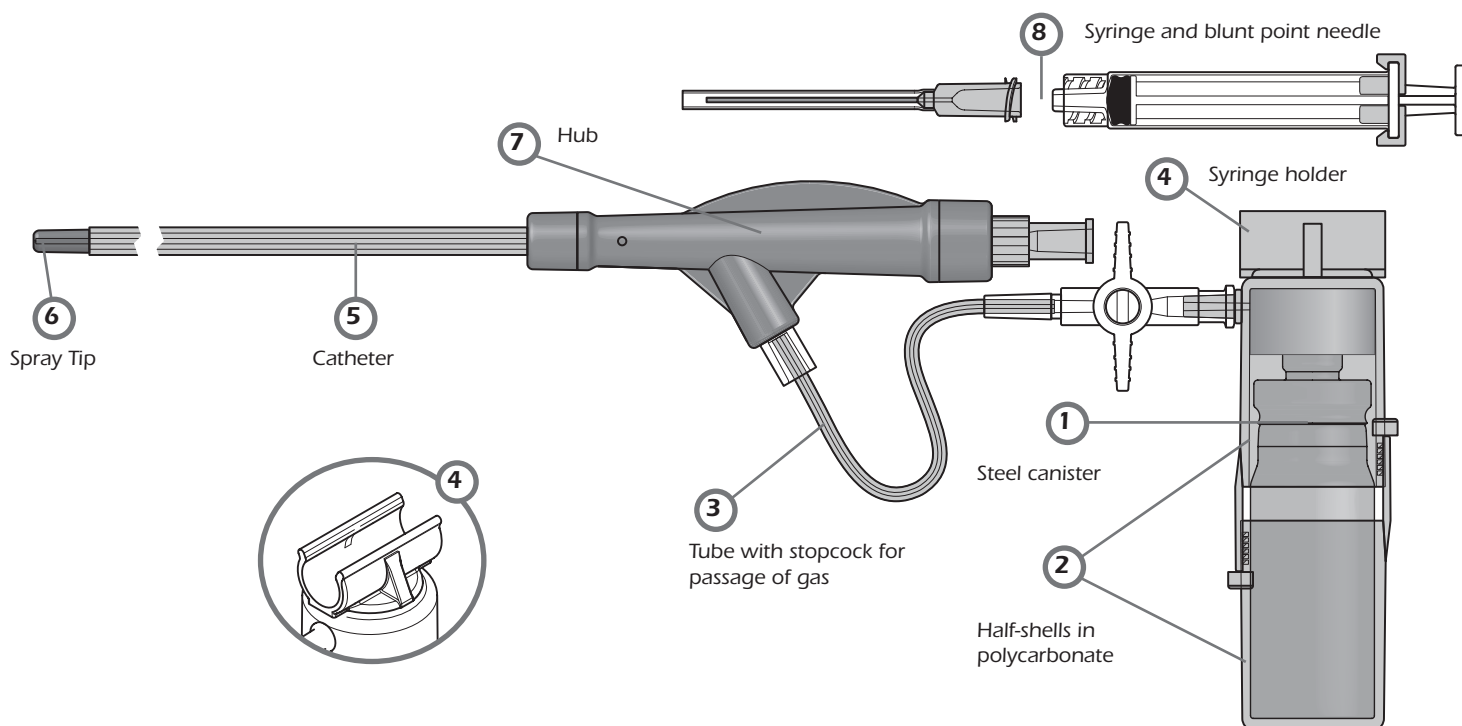


Spray Device for Glubran 2 Surgical Glue

Ref.G2-NBT



Characteristics

The system permits application of Glubran 2 Surgical Glue as a spray in surgical laparotomy, laparoscopy and thoracoscopy procedures.

For applications of Glubran 2 Surgical Glue see Intended Use of its Technical Card.

The system consists of:

- **A steel canister** (figure/point 1) placed in **two half-shells in polycarbonate** (figure/point 2).

The canister is filled with non-toxic, non-flammable HFC134/a (1,1,1,2 tetrafluoroethane) gas, used as the Glubran 2 Surgical Glue propellant.

- **A small tube equipped with a stopcock for passage of gas** (figure/point 3) comes out from the canister valve through the upper half-shell.
- **The holder for the syringe** (figure/point 4 detail), where the Glubran 2 Surgical Glue is withdrawn, is on the upper half-shell.
- **A flexible catheter**, blue colored, 33 cm long, with an external diameter Ø of 5mm (figure/point 5).

There are two small tubes inside the catheter: one for passage of gas and one for passage of Glubran 2 Surgical Glue. Gas and Glubran 2 flow together in a **spray tip** (figure/point 6) which is placed inside the catheter at its distal end and that atomizes the glue.

- **A hub**, at the proximal end of the catheter (figure/point 7 detail), connects to the small tube for gas and, with a female luer lock, to the syringe where the Glubran 2 Surgical Glue was withdrawn.
- **Two blunt point needles and two syringes** (figure/point 8), intended for withdrawing the Glubran 2 Surgical Glue from the single-dose vials, separately provided.

Method of Use

After removing the device from its packaging in sterile conditions, withdraw the Glubran 2 Surgical Glue into one or both the included syringes through a blunt point needle with a luer lock. Check that the stopcock, at the gas valve exit, is closed.

Press the two half-shells of the canister (fig.1) **bringing them together to hook each other.**

The canister is now activated and the gas is at operating pressure.

Never turn upside down the canister during the gas release. Always use the canister with the syringe holder facing upwards.

Open the stopcock to make sure the catheter tip releases the gas, and then close it again.

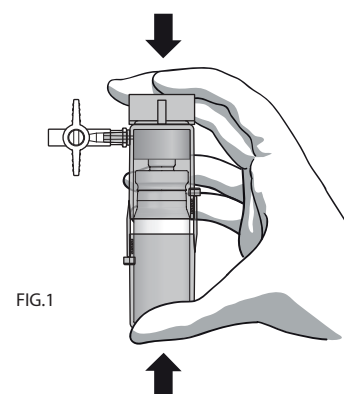


FIG.1

Remove the needle, **screw the syringe containing the Glubran 2 (fig. 2) to the luer lock of the hub** and **place it in the holder on the upper half-shell of the canister**. Click in place (fig. 3). **When you start using it, open the gas by the stopcock, hold the gas canister in one hand and, at the same time, take the distal end of the catheter in the other hand (fig. 4), then push in the syringe plunger to nebulize the product.**

Before using the spray on a patient, test it on a surgical towel to assess beforehand the correct distance between the catheter tip and the area to be treated (2-5cm), and the right pressure to be exerted on the syringe plunger.

During the procedure, **prevent the catheter tip to get into contact with blood or organic fluids**. Should it occur, the glue will polymerize on the catheter tip clogging it.

During the surgical procedure, **at the end of each application of Glubran 2**, before closing the gas stopcock, **make the gas discharging for 5-7 seconds**. This is the thoroughly cleaning of the spray tip prior any further application.

At the end of the surgical procedure, empty the gas canister completely before the spray device disposal.

You can apply 1-4 ml of Glubran 2 Surgical Glue, according to the type of surgical procedure and surface to be treated.

Intended use

Surgical laparotomy, laparoscopy and thoracoscopy.

Warning

- ⚠ Only doctors trained in the use of the system can use the spray device
- ⚠ Do not use the product if the packaging appears to be damaged or there is evidence of tampering
- ⚠ The gas canister is under pressure. Do not expose it to direct sunlight or to temperatures above 30°C. Do not perforate or burn it even after its use.
- ⚠ Before using the spray device, always check the proper functioning of the system by first testing the spray on a surgical towel.
- ⚠ Never turn the canister upside down during the gas release. Always use it with the plastic tie facing upwards.
- ⚠ Completed the surgical procedure, empty the gas canister before the disposal of the spray device.
- ⚠ To obtain a correct application of the glue during the laparoscopic procedure, reduce the CO₂ pressure down to 8-9 mmHg or block the CO₂ flow in order to prevent the creation of vortexes.
- ⚠ **Use protective eyewear during the procedure.**
- ⚠ In case of accidental Glubran 2 Surgical Glue contact with eyes, rinse them immediately with water. If the product has polymerised it will detach spontaneously after about 2-3 days.
- ⚠ Do not use the system to spray any liquids other than Glubran 2 Surgical Glue
- ⚠ The system is disposable. Do not re-use the system as it may cause a risk of infection to the patient, and the impairment of effectiveness and functionality of the device.
- ⚠ The manufacturer declines any responsibility for damage caused by improper use or any use other than those described on this Instruction leaflet.

Storage

Keep product away from direct sunlight and do not store at temperatures above 30°C. ☀️ 🚫

Expiry date

The expiry date is printed on the packaging.

Sterility

The product is sterilised by gamma irradiation. STERILE R

Packaging

Single pack. ☒

Product code

REF G2-NBT.

Compliance directive

MDD 93/42/EEC and subsequent updating

Class

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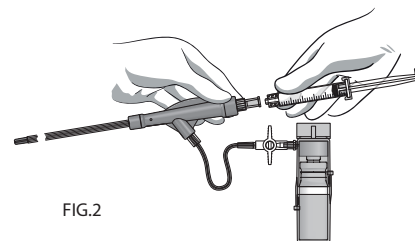


FIG.2

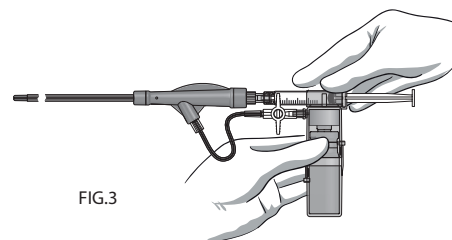


FIG.3

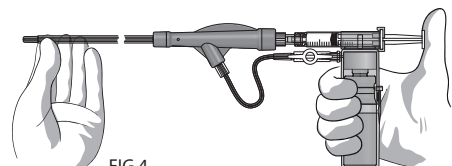


FIG.4