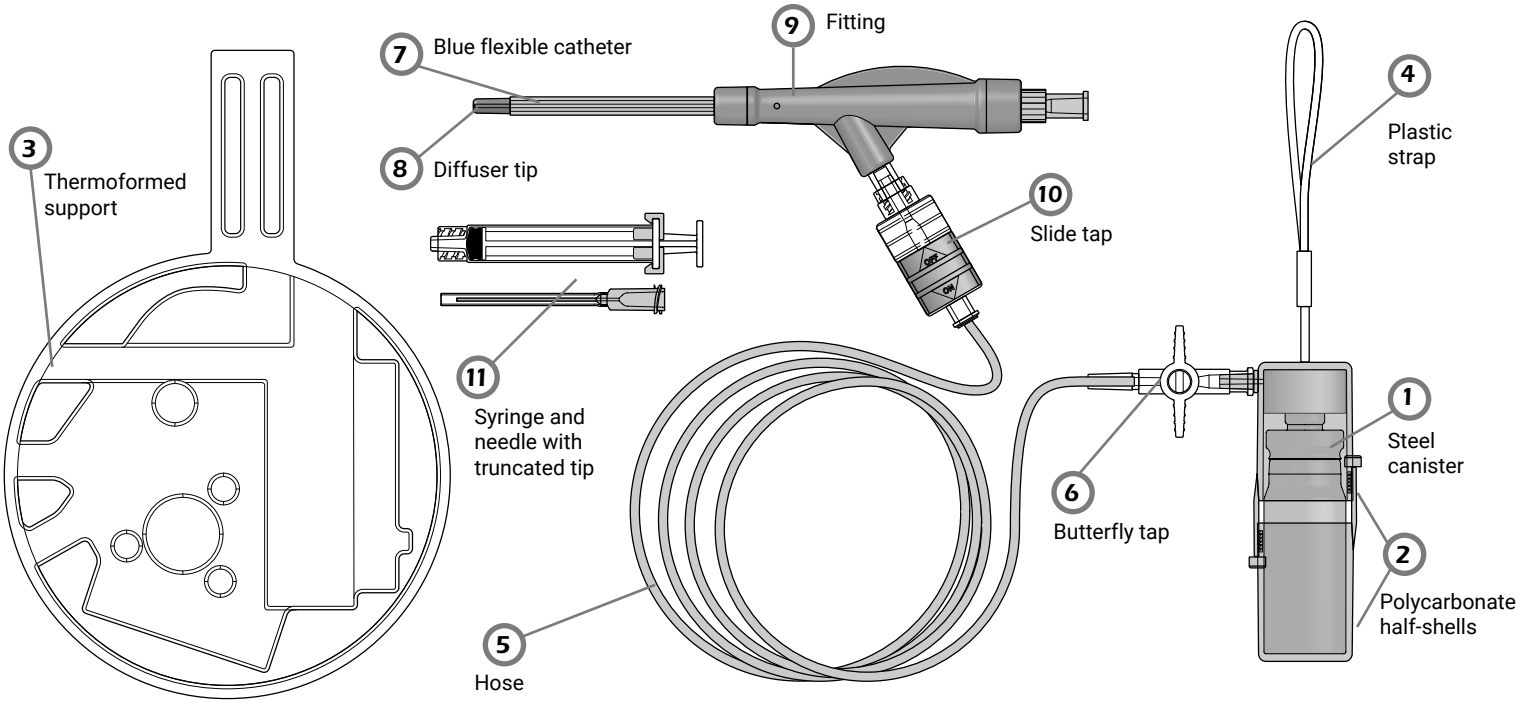
EN

CE 1936

Short Spray device for surgical glue Glubran® 2

Ref. G2-NBT-SHORT



Features

The medical Spray device is used to apply Glubran® 2 Surgical Glue in spray form in laparotomic and thoracoscopic surgical procedures. With regard to the applications of Glubran® 2 Surgical Glue, refer to the Intended Use indicated on the Technical Data Sheet of Glubran® 2.

The system consists of:

- **a steel canister** (item 1 in the figure) housed in two polycarbonate half-shells (item 2 in the figure) supplied in a thermoformed support (item 3 in the figure) and in hanging mode (item 4 in the figure).

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

A **hose** for gas flow (item 5 in the figure) 193 cm long **fitted with butterfly valve** (item 6 in the figure) comes out from the canister valve, through the upper half-shell.

- **a blue flexible catheter** , 6.5 cm long, external diameter Ø 5 mm (item 7 in the figure).

Two tubes are inserted inside the catheter, one of which is for gas and the other for Glubran® 2 Surgical Glue. Gas and Glubran® 2 flow into **a diffuser tip** (item 8 in the figure) placed inside the catheter at its distal end, which sprays the product.

- **a fitting**, placed at the proximal end of the catheter (item 9 in the figure), which connects to the gas tube via a second **slide tap** (item 10 in the figure), and via a female luer connection connects to the syringe where the Glubran® 2 Surgical Glue has been withdrawn.
- **two truncated tip needles and two syringes** (item 11 in the figure), intended to withdraw Glubran® 2 from the single-dose vials, supplied separately.

Method of use

Withdraw Glubran® 2 Surgical Glue into one or both of the supplied syringes by means of a truncated tip needle with luer connection.

Remove the device from its packaging under sterile conditions, and unwind the entire hose.

Check that the butterfly tap at the outlet of the gas valve is closed.

Press the two half-shells of the canister (fig.1) **so that they engage with each other**.

At this point the canister is activated and the gas is under operating pressure.

Open the butterfly tap and ensure that gas flows from the tip of the catheter.

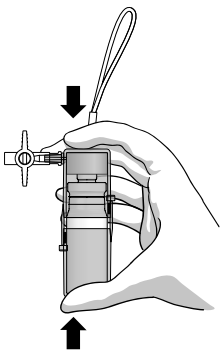


FIG.1

Interrupt the gas supply by closing the slide valve (push upwards, fig. 2a) and place the canister in its housing in the thermoformed mould (fig. 2b), or hang it by means of the plastic strap above it (fig. 2c), so that it is never turned upside down during gas supply.
Remove the needle and screw the syringe containing Glubran® 2 (fig. 3) onto the luer connection of the fitting. When using, open the gas from the slide valve (push down, fig. 4a) and press down on the syringe plunger to release the atomized product (fig. 4b). Before use on a patient, do a spray test on a surgical drape in order to assess in advance the correct distance between the catheter tip and the area to be treated (2-5 cm) and the correct pressure to be exerted on the syringe plunger.
Do not allow **the tip of the catheter to come into contact with blood or body fluids during the procedure**. In this case, the product will polymerize at the tip of the catheter and occlude it.
During surgery, **after each application of Glubran® 2, allow the gas to flow for 5-7 seconds** before turning off the gas tap. The purpose of this is to achieve perfect cleaning of the diffuser tip for any subsequent applications.
At the end of surgery, empty the gas canister completely before disposing of the spray device.
The amount of Glubran® 2 Surgical Glue to be applied can vary from 1 to 4 ml depending on the type of surgery and the surface to be treated.

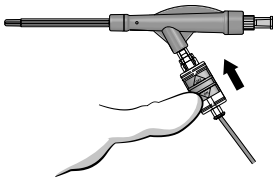


FIG.2a

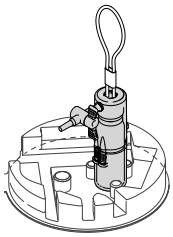


FIG.2b

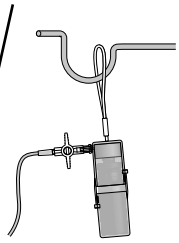


FIG.2c

Intended use and indications
Laparotomic and thoracoscopic surgery.
It is indicated for an adult population awaiting laparotomic and thoracoscopic surgery in combination with the Glubran® 2 medical device.

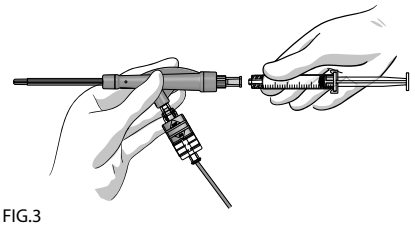


FIG.3

Target population
Adults.

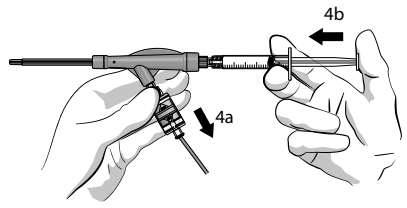
Warnings


FIG.4

- ⚠ The spray device must only be used by physicians experienced in the use of the system.
- ⚠ Read the instructions before use.
- ⚠ Do not use the product if the package has been damaged or tampered with.
- ⚠ The gas canister is a pressure vessel. It must be protected from sunlight, must not be exposed to temperatures above 30 °C and must not be perforated or burnt even after use.
- ⚠ Before using the spray always check that the system is functioning correctly by performing a spray test on a surgical drape.
- ⚠ The canister must never be turned upside down when dispensing gas, but used with the plastic strap always facing upwards.
- ⚠ At the end of surgery, empty the gas canister completely before disposing of the spray device.
- ⚠ During the laparoscopic procedure, in order to achieve a correct application of Glubran® 2 Surgical Glue, it is necessary to reduce the CO_2 pressure to 8-9 mmHg and to block the CO_2 flow in order to avoid the creation of vortices.
- ⚠ **Use protective glasses during the procedure.**
- ⚠ In the event of accidental contact of Glubran® 2 Surgical Glue with the eyes, immediately flush with water. If the product has polymerized, it will detach spontaneously after about 2-3 days.
- ⚠ The system cannot be used to spray liquids other than Glubran® 2 Surgical Glue.
- ⚠ The system is disposable. The system cannot be re-used due to the risk of infection to the patient and the impairment of the functionality and effectiveness of the device.
- ⚠ The manufacturer will not accept any responsibility for damage caused by improper use or use other than what is shown on this Instruction Sheet.

Storage
The product must be protected from sunlight and stored at temperatures not exceeding 30 °C.

Disposal
Once used, dispose of the device according to local procedures and guidelines.

Expiry date
The expiry date is shown on the package.

Sterility
The product is gamma-sterilised. STERILE R

Contact
Any serious incident occurring with the device must be reported to the manufacturer GEM S.r.l. and to the competent authority of the Member State in which the user and/or patient is established.

Packaging
Single package.

Product code
REF G2-NBT-SHORT

Class
IIa

GEM S.r.l. Via dei Campi 2 - PO Box 427 - 55049 Viareggio (LU) Italy
Tel. +39 0584 389784/391388 - Fax +39 0584 397904
www.gemitaly.it - info@gemitaly.it

Rev.00 dated 30/12/2022