

Endoscopic Spray Device for Glubran® 2 Surgical Glue

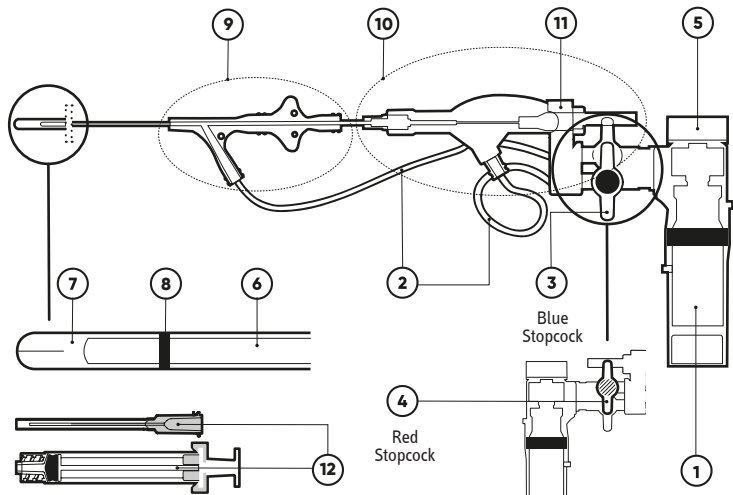


Figure 1

Features (Description of device)

The ENDONEB class IIa medical device allows the application of Glubran® 2 Surgical Glue in spray form in digestive endoscopy procedures. It is suitable for use with both gastroscopes and colonoscopes with a working channel of not less than 2.6 mm. For Glubran® 2 applications, refer to the Intended Use in the Technical Data Sheet. The system consists of:

- **A steel canister** (Fig. 1, No. 1) housed in two polycarbonate half-shells.
 - Two hoses (figure/point 2) with blue and red stopcocks (figure/points 3 and 4) for non-toxic, non-flammable gas flow out of the canister valve through the upper half-shell. The two valves are in the closed position (OFF) as shown in the figure.
 - Above the upper half of the shell and integral with it there is the syringe connection housing (figure/point 5).
- **A flexible catheter with a functional length of 2 m, composed as follows:**
 - **internal catheter** (figure/point 6) through which the propellant gas and Glubran® 2 flow in spray mode.
 - **outer sheath**, diameter 2.4 mm, with protective function for the catheter that runs inside it. The gas for cleaning the final section passes through this outer section. The outer sheath ends with a notch (figure/point 8) which allows the identification of the 2 cm working exit length from the endoscope.
- **A connection base**, located at the proximal end of the catheter (figure/point 9), to which the gas tube with red stopcock is connected.
- **A unit** at the rear end (figure/point 10), to which the gas tube with blue stopcock is connected, and to which, via a female luer connector, the syringe into which Glubran® 2 is withdrawn is connected. This unit, thanks to a hinge anchorage (figure/point 11) is kept integral with the two underneath gas tubes.
- **Two truncated tip needles and two syringes** (figure/point 12), both with luer connector, intended to withdraw Glubran® 2 from the single-dose vials, supplied separately.

Intended use

Application of Glubran® 2 as a spray in digestive endoscopy procedures for the treatment and prevention of post-resorptive bleeding of the gastrointestinal mucosa and sub-mucosa.

Indications

Indicated for an adult population subject to digestive endoscopy procedures for the treatment and prevention of post-resorptive bleeding of the gastrointestinal mucosa and sub-mucosa.

Warnings

- ⚠ The spray device must only be used by physicians experienced in the use of the system.
- ⚠ Do not use the product if the package has been damaged or tampered with.
- ⚠ The product is single-use. (X)
- ⚠ The device can be used a maximum of two times during the same operation on the same patient.
- ⚠ The device cannot be reconditioned or re-used or re-sterilised after it has been opened for the first time. Reuse poses a risk of infection to the patient due to loss of sterility of the contents.
- ⚠ To aim Glubran® 2 correctly and safely, please read point 9 of the 'Instructions for Use' carefully. (X)
- ⚠ 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. **Once activated, the canister must always be kept in a vertical position.**
- ⚠ Before using the spray always check that the system is functioning correctly by performing a spray test on a surgical drape.
- ⚠ To minimise the risk of unwanted obstruction of the spray device, keep the tip of the catheter approximately 2 cm away from the bleeding site.
- ⚠ After using Glubran® 2, to avoid possible damage to the endoscope, the internal catheter should be retracted into the protective sheath before removing the spray device from the working channel.
- ⚠ At the end of surgery, empty the gas canister completely before disposing of the spray device, leaving the red and blue stopcocks open to prevent any residual gas from interfering with the disposal procedure.
- ⚠ **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 may not be used to spray liquids other than Glubran® 2. Read the instructions for use of the Glubran® 2 medical device before use.
- ⚠ The manufacturer will not accept any responsibility for damage caused by improper use or use other than as indicated in this Instruction Sheet.
- ⚠ Failure to adhere to the times indicated in this instruction sheet for opening and closing the gas may result in failure to complete the procedure.

Disposal

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

Storage

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

Expiry date

The expiry date is shown on the package.

Sterility

The product is gamma-sterilised. [STERILE] R

The product does not contain latex.

Contacts

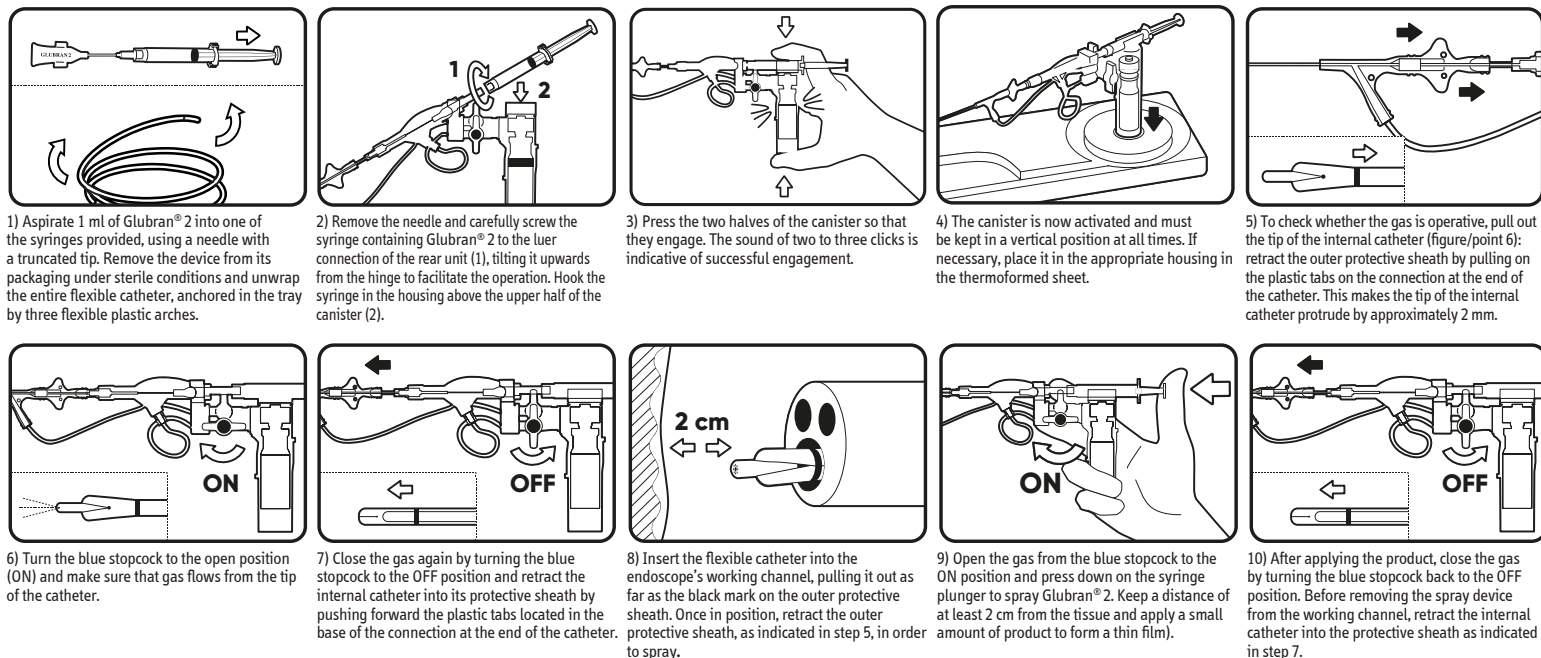
Any serious incident occurring with the device must be reported to the manufacturer GEM srl and to the competent authority of the Member State in which the user and/or patient is established.

Product Code

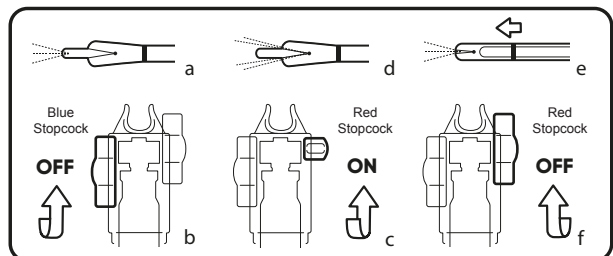
[REF] G2- NBT - ENDO

Methods of use

The device must be adequately prepared and activated to ensure correct functioning.



Cleaning the internal catheter for a possible second spray:



If further spraying of Glubran® 2 for the treatment of a second injury, the internal catheter should be cleansed without removing the device from the endoscope, so as to keep it clear.

At the end of the application of the product, only allow gas to come out from the internal catheter for at least 3-4 sec (a). Then close the blue stopcock (b) and open the red stopcock (c). Release gas from the external catheter for 3-4 sec (d). Keeping the gas open from the red stopcock, retract the internal catheter into the outer protective sheath (e) as indicated in step 7.

Allow the gas to flow for 3-4 seconds to ensure that the tip is perfectly clean and then turn off the gas from the red stopcock to the OFF position (f).

Only at this point may the flexible catheter be removed from the endoscope and the canister placed in the thermoformed housing to keep it upright (point 4). 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.



Rev. 02 dated 25/11/2024
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