

Catheter for laparoscopy

Ref. G2-LPC / G2-LPC-RIG

TECHNICAL DATA SHEET

Name

Catheter for laparoscopy Ref. G2-LPC

Rigid catheter for laparoscopy Ref. G2-LPC-RIG

Description and Materials Ref. G2-LPC

Class IIa medical device consisting of:

- Polyethylene hollow catheter with MABS luer terminal for positioning Glubran® 2 surgical glue only;
- Flexible polyester sheath with acrylonitrile-butadiene-styrene luer connector.

It does not contain latex or phthalates.

Description and Materials Ref. G2-LPC-RIG

Class IIa medical device consisting of:

- Polyethylene hollow catheter with MABS luer terminal for positioning Glubran® 2 surgical glue only;
- Rigid stainless steel sheath with MABS luer connector. It does not contain latex or phthalates.

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Method of use

Disposable medical device for use in laparoscopic surgery exclusively for positioning Glubran® 2 surgical glue. The device can only be used with trocars with a diameter of at least 5 mm. Insert the entire device inside the trocar and check for compatibility and tightness.

Then connect the syringe containing Glubran® 2 surgical glue to the luer lock connection of the catheter.

The capillary section of the catheter lumen allows the application of Glubran® 2 Surgical Glue in drops and thin layer. Apply the glue drop by drop to the area to be treated, avoiding touching the tissue with the tip of the catheter so as not to obstruct it. At the end of the procedure, remove the catheter.

Intended use and indications

The device is intended for the application of Glubran® 2 surgical glue in laparoscopic surgery.

It is indicated for an adult population awaiting laparoscopic surgery.

Target population

Adults.

Warnings

- ⚠ The device must only be used by experienced medical practitioners who are suitably trained to use the device.
- ⚠ Read the instructions before use. 
- ⚠ The product is disposable. 
- ⚠ The device is sterile and intended for use on one patient only. Do not reuse, reprocess, clean, disinfect or resterilise the device, as this can lead to a risk of compromising the sterility and performance. 
- ⚠ Do not use the product if the package has been damaged or tampered with. 
- ⚠ The device does not contain user-serviceable parts. Do not try to repair or dismantle the device. If, at any time, the device is found to be damaged or not functioning correctly, discard and replace with another.
- ⚠ The catheter for laparoscopy device must only be used with the Glubran® 2 medical device. Read the instructions of the Glubran® 2 medical device before use.
- ⚠ The manufacturer accepts no liability for damage caused by improper use or use other than as described in this Instruction Sheet.
- ⚠ When applying Glubran® 2 on the tissue, observe the polymerisation times as shown on the product data sheet.

Storage

The product must be protected from sunlight and stored only at a temperature between +5°C and +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. 

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.

Product code

 G2-LPC

 G2-LPC-RIG

Class

IIa