

Disposable Trocar with Suturing Needle Manual

I. Product Name Disposable Trocar with Suturing Needle.

II. Model Specifications See Appendix A.

III. Product Description The disposable abdominal wall suture kit consists of a **trocar** and an **abdominal wall suturing device**; a **Veress needle** is an optional accessory.

- The **trocar** consists of a cannula (including a sealing component) and an obturator (puncture rod).
- The **Veress needle** consists of a puncture needle, tube, seat, and valve.
- The **abdominal wall suturing device** consists of a suture needle, handle, cap, button, and clamp group.

IV. Product Performance

1. The trocar and obturator should fit well and operate smoothly without jamming.
2. The maximum clearance between the cannula and the obturator should not exceed 0.3mm.
3. When the obturator is fully inserted into the cannula, the conical part of the tip must be fully exposed.
4. The product is sterile (sterilized by Ethylene Oxide) and Ethylene Oxide (EO) residue must not exceed 10 µg/g.

V. Scope of Application Used during laparoscopic examinations and surgeries for abdominal wall tissue puncture, establishing a surgical channel, and for suturing or grasping during laparoscopic surgery to achieve abdominal wall incision or trocar site closure.

VI. Instructions for Use

- **[Veress Needle Method]:**
 1. Align the needle tip with the puncture site and use steady force to puncture the abdominal wall.
 2. Inject gas through the needle to establish pneumoperitoneum.
 3. Once pneumoperitoneum is established, remove the Veress needle.
- **[Trocar Method]:**
 1. Create an appropriately sized skin incision. Ensure the incision is large enough to avoid resistance and maintain control.

2. Insert the trocar at a suitable angle after the abdomen is distended. Do not use excessive force to avoid internal organ injury.
 3. Once the cannula enters the abdominal cavity, remove the obturator and use the cannula as a surgical channel.
- **[Abdominal Wall Suture Device Method]:**
 1. Align the needle with the entry site and puncture slowly.
 2. Hold the handle and push the button to clamp the suture (suggested 2-0 or 0 gauge).
 3. Under laparoscopic supervision, guide the needle and suture through the abdominal wall to perform closure or grasping. Follow standard knotting techniques to close the incision.

VII. Cautions and Warnings

1. Strictly follow aseptic operation standards.
2. Must be operated by a trained physician.
3. Check for defects (rough surfaces, sharp edges) and ensure all connections are secure before use.
4. **Sterilization Indicator: "Red"** means not sterilized (do not use); **"Blue"** means sterilized and ready for use. Do not re-sterilize.
5. Check the expiration date (shelf life is three years).
6. Maintain proper pneumoperitoneum during surgery to ensure operating space and avoid organ injury.
7. Handle sharp instruments carefully to avoid damaging the sealing components.
8. After use, dispose of according to hospital regulations for disposable medical supplies.

VIII. Contraindications

1. Patients unable to undergo anesthesia or laparoscopic surgery.
2. Patients with infections at the puncture site or those unsuitable for suture closure.
3. General contraindications for laparoscopic surgery.

IX. Storage and Transportation Store in a well-ventilated, non-corrosive room with humidity not exceeding 80%. Protect from sunlight, collisions, rain, or heavy pressure during transport.

X. Explanation of Label Symbols

- **Circle with a slash through '2':** Do not reuse.
- **Triangle with Exclamation Mark:** Warning.
- **Book Icon with 'i':** Consult instructions for use.
- **STERILE EO:** Sterilized using Ethylene Oxide.
- **Broken Package Icon:** Do not use if packaging is damaged.

XI. Production and Expiration Date See the specific labels on the qualification certificate.

XII. Registrant and Manufacturer Information

- **Registrant/Manufacturer/After-sales Service:** Bony Medical Technology (Changzhou) Co., Ltd..
- **Address:** Standard Plant, Hutang Science and Technology Industrial Park, Hutang Town, Wujin District, Changzhou City.
- **Production License No.:** Su Yao Jian Xie Sheng Chan Xu No. 20200016.
- **Registration No.:** Su Xie Zhu Zhun 20242020093.
- **Version:** 01 (Compiled: September 2021).

Appendix A: Model Specifications (The sources list a large range of model numbers starting from BCF001 through BCFQ352)