

**PACKAGING SPECIFICATION**

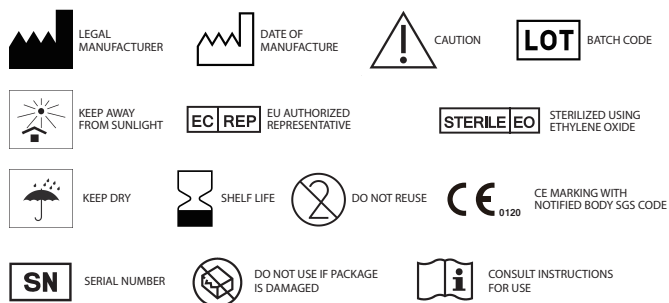
1 Piece/Box

STORAGE

1. Keep the package complete and avoid damaging by pressure.
2. This product is stored at room temperature and used in medical facilities.

VALIDITY

2 years

IDENTIFICATION INSTRUCTIONS**LEGAL MANUFACTURER**

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DISPOSABLE CIRCUMCISION SUTURE DEVICE II INSTRUCTION

**LANGHE MEDICAL**

DISPOSABLE CIRCUMCISION SUTURE DEVICE II

DEVICE NAME

Disposable Circumcision Suture Device II

MODEL/TYPE

12 mm, 15mm, 18 mm, 21 mm, 26 mm, 30 mm, 36 mm

CODE

WHQ12, WHQ15, WHQ18, WHQ21, WHQ26, WHQ30, WHQ36

INTENDED USE

This product intends to use for male circumcision operation.

APPLICATION

Male patients with redundant prepuce or phimosis patients.

MAIN STRUCTURES

This product is composed of Glans Bell, Suturing Staple, Staple Cabin Cap, Circular Scalpel Blade, Shell Body, Handle, Adjusting Knob, Safty Clasp and Strapping Tape.

CONTRAINDICATIONS

1. Patients with foreskin, and glans deformity (including severe prepuce adhesion), and occult penis.
2. Foreskin and glans with infection and edema.
3. Patients with penile cancer.
4. Patients with systemic diseases (such as bleeding tendency, hypoproteinemia, severe cardiovascular disease, etc.).
5. Diabetic patients are disabled to control within the normal blood glucose range.
6. Patients used the anticoagulant drugs recently.

WARNINGS AND PRECAUTIONS

1. Prohibit the use of the product when the package is opened, damaged or expiration of the sterilization validity.
2. It is a disposable product, which is strictly prohibited to reuse and should be placed and disposed strictly in accordance with medical waste handling method to avoid the health risk to people.
3. Measure glans size by measuring scale, select the appropriate model, select bigger one if glans size between two sizes. The foreskin adhesion must be peeled off. If the phimosis, cut dorsal frenulum to inset the glans bell.
4. Operating scissors can be used to trim if the prepuce has not been cut off completely, as for significant hemorrhage, suture hemostasis can be used when press hemostasis is ineffective. It is a normal phenomenon that the palace of local anesthesia and operative incision are within light swell, which will be diminished gradually.
5. Sensitive constitution with light inflammation in prepuce may have local edema, which can be controlled by anti-inflammatory and anti-allergic agent.

6. Alcohol and spicy food are forbidden before wound healing.

7. In the case of a few amount of staples without completely sutured, please suture them properly. When the frenulum is too short and the severe foreskin adhesion including the other congenital abnormalities should be treated first and hemostasis, etc., afterwards go ahead to use this device.

8. If the suturing staple can not drop completely after 30 days, it is recommended to remove the suturing staple by forcep.

POSTOPERATIVE CARING

1. Avoid heavy activities after surgery, pay attention to local hygiene and anti-inflammatory treatment. When contaminated by urine, it should be quickly disinfected with iodophor. In case of severe hematoma and hemorrhage, please return to hospital for treatment.
2. All dressings are removed 48 hours after surgery and then disinfected daily with iodophor.
3. In case of postoperative bleeding in individual patients, it should be considered whether the patient has bleeding tendency, whether there is the postoperative erection, or whether the postoperative dressing is loose, and finally symptomatic treatment.
4. Suturing staples are dropping automatically from 7 days, and usually complete dropping within 30 days.
5. No sexual life within 50 days.

OPERATIONAL INSTRUCTIONS



1. Loosen and turn out the adjusting knob, take out the glans bell.
2. Insert the glans bell into foreskin and cover the glans, keep the glans bell parallel to the coronary sulcus and make sure the foreskin fixed on the glans bell shaft.
3. Link the device, clockwise screw the adjusting knob, don't screw it too tightly. It is enough when the screw rod is parallel or a little up to the adjusting knob.
4. Loosen the safety clasp and trigger the device.
5. Release the trigger and secure the safety clasp.
6. Loosen the adjusting knob and gently remove the glans bell. Observe whether all foreskin be cut completely, if not, scissor it.