CE 0197

Brun®

Brun Medical Co., Ltd.

GRA-415002,Rev.02

Balloon Uterine Stent [INSTRUCTION FOR USE]

1. INTENDED PURPOSE

The product is intended to be used for intrauterine operation and curettage operation to reduce intrauterine bleeding and prevent adhesion by professional physician.

2. INTENDED USER

Intended users are the competent physician who have the training in postpartum hemorrhage treatment.

3. INTENDED PATIENT POPULATION

Patients needing postpartum hemorrhage treatment.

4. CONTRAINDICATION

1) Pregnancy
2) Systemic coagulation dysfunction disease
3) Fever
4) Invasive cervical cancer and genital tuberculosis have not been treated for tuberculosis
5) Acute or subacute genital tract or pelvic inflammation
6) Uterine perforation occurred recently
7) Other contraindications related to various uterine cavity surgeries and operation

5. HANDING AND STORAGE

Stored in the relative humidity of not more than 80%, non-corrosive gases, a common, dry, well-ventilated and clean environment.

6. STRUCTURE AND SPECIFICATIONS

The device is consist of the catheter, balloon, tip, filling valve and 5ml /8ml syringe.

Specifications:

Model	Volume(ml)	Length(cm)	Balloon width(cm)	Syringe(ml)
BR-BUS-5	5	3	2.8	/
BR-BUS-5Ⅱ	5	3	2.8	5
BR-BUS-8	8	4	4.0	/
BR-BUS-8Ⅱ	8	4	4.0	10

7. PRODUCT PERFORMANCE

Balloon uterine stent was designed to fit into the uterine cavity and tamponade the uterus to prevent post-operative uterine bleeding There are wide compression area big enough to prevent intrauterine adhesions (IUAs).The material has good biocompatibility.

8. INSTRUCTION FOR USE

1）Open the outer packing and take out the contents of the package.
2) The procedure should be under strict aseptic surgical technique.
3) Roll the balloon to the smallest diameter,then grab the top of the roll balloon with toothless forceps.
4) The forceps head with a balloon is inserted into the uterine cavity above the cervix.

5) Filling part of the balloon.

Warning: Always inflate the balloon with a sterile saline. Never inflate with air, carbon dioxide or any other gas.

6) Gently pull back the sterile forceps and leave the balloon in place.

7) Fill the balloon to the maximum filling volume indicated on the product label.

Warning: Do not exceed the maximum filling volume indicated on the label.

8) Balloon indwelling should be decided by the physician until the endometrial cavity is completely hemostatic.

9)Open the filling valve, draw out the liquid in the balloon with a syringe, withdraw the liquid and observe the hemostasis.

10) The balloon is gently removed from the vagina through the cervix.Dispose the waste products according to hospital regulations

9. PRODUCT LABEL AND PACKAGING (See the label or packaging)

1.Product name, model and specification.
2.Production date, batch lot.
3.Sterilization expiry date.

10. CAUTION

1. Procedure must be performed by trained medical personnel.
2. Sterilization is valid for three years, please confirm date of sterilization before use,do not use if expiry.
3. Do not use if luer taper leakage.
4. The device is designed and intended for SINGLE USE ONLY.
5. Do not resterilize and/or reuse, otherwise patients could get the risk of infection.
6. Sterilized by ethylene oxide. Do not use if the package damaged.


Caution


Use-by date


Keep dry


Keep away from sunlight

Catalogue number


Date of manufacture


Manufacturer


Do not re-use

Sterilized Using ethylene oxide


Do not use if package is damaged and consult instrction for use

Batch code

Unique device identifier

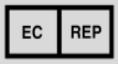
Authorized representative in the European Commutity/ European Union


Consult instructions for use or consult electronic instructions for use

Do not resterilize

Medical device


Single sterile barrier system



Cnovate Medical B.V.

ADDRESS：Terminalweg 15, 3821AJ Amersfoort, The Netherlands

TEL：+31 850140404 E-mail：cs@cnovate.eu


Brun Medical Co., Ltd.

ADDRESS: Building B8, Entrepreneurship and Innovation Park.88 Changtang Road, Yunlong Demonstration Zone,Zhuzhou, 412000 Hunan ,P.R.China

TEL：+0731-22029666 WEB：www.brunmd.com

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