CE 0197

Brun Medical Co., Ltd.

GRA-416002,Rev.02

# Postpartum Balloon [INSTRUCTION FOR USE]

1. INTENDED PURPOSE

The product is used for uterine tamponade for postpartum hemorrhage treatment 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, 3-Way stopcock,1-Way stopcock,protective cap and 50ml syringe(BR-PPB-24F-Π).

Specifications: BR-PPB-24F，BR-PPB-24F-Π (50ml syringe)

7. PRODUCT PERFORMANCE

There are wide compression area.It is easy to monitor hemostatic effect.It includes rapid instillation components to facilitate inflation of the balloon.The material has good biocompatibility.

8. INSTRUCTION FOR USE

Confirm before placement

1. The uterus is free of placental fragments.
2. The genital tract has no trauma or lacerations.
3. The source of the bleeding is not arterial.
4. The patient does not present with any contraindications for use of this device.

Device Placement

Transvaginal Placement

1. Determine uterine volume by direct examination or ultrasound examination.
2. Insert the balloon portion of the catheter into the uterus, making certain that the entire balloon is inserted past the cervical canal and internal ostium.

Transabdominal Placement, Post-Cesarean Section

1. Determine uterine volume by direct examination.
2. From above, via access of the cesarean incision, pass the tamponade balloon, inflation port first, through the uterus and cervix.

NOTE: Remove the stopcock to aid in placement and reattach prior to filling balloon.

3. Have an assistant pull the shaft of the balloon through the vaginal canal until the deflated balloon base comes into

contact with the internal cervical ostium.
4. Close the incision per normal procedure, taking care to avoid puncturing the balloon while suturing.
NOTE: Ensure that all product components are intact and the hysterotomy is securely sutured prior to inflating the balloon.If clinically relevant, the abdomen may remain open upon inflation of the balloon to closely monitor uterine distention and confirm the hysterotomy closure.
NOTE: If clinically relevant, a B-Lynch compression suture may be used in conjunction with the Postpartum Balloon.
Balloon Inflation With Syringe
1.Using the enclosed syringe, begin filling the balloon to the predetermined volume through the stopcock.
NOTE: To ensure that the balloon is filled to the desired volume, it is recommended that the predetermined volume of fluid be placed in a separate container, rather than relying on a syringe count to verify the amount of fluid that has been instilled into the balloon.
2. Once the balloon has been inflated to the predetermined volume, confirm placement via ultrasound.
NOTE: See Fig. 1 for proper placement.

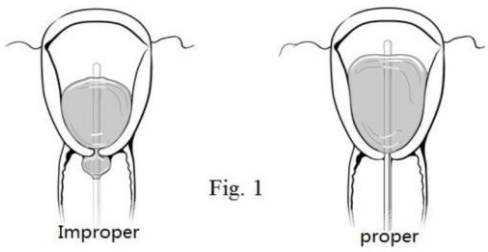
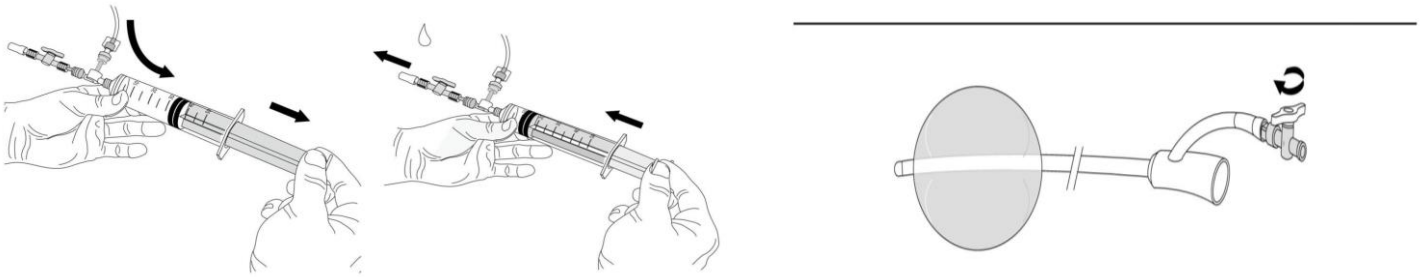


Fig. 1

3.If desired ,traction can be applied to the balloon shaft .In order to maintain tension,secure the balloon shaft to the patient's leg or attach to a weight, not to exceed 500 grams.
NOTE: To prevent displacement of the balloon into the vagina, counterpressure can be applied by packing the vaginal canal with iodine- or antibiotic-soaked vaginal gauze.
4. Connect the drainage port to a fluid collection bag to monitor hemostasis.
NOTE: To adequately monitor hemostasis, the balloon drainage port and tubing may be flushed clear of clots with sterile isotonic saline.

5.Monitor the patient continuously for signs of increased bleeding and uterine cramping. With Rapid Instillation Components See Figs. 2-8, at the front of this booklet.



NOTE: Ultrasound should be used to confirm proper placement of the balloon once the balloon is inflated to the predetermined volume.
Device Removal
NOTE: The timing of balloon removal should be determined by the attending clinician upon evaluation of the patient once bleeding has been controlled and the patient has been stabilized. The balloon may be removed sooner upon the clinician's determination of hemostasis. The maximum indwell time is 24 hours.
1. Remove tension from the balloon shaft.
2. Remove any vaginal packing.
3. Using an appropriate syringe, aspirate the contents of the balloon until fully deflated. The fluid may be removed incrementally to allow periodic observation of the patient.
NOTE: In an emergent situation, the catheter shaft may be cut to facilitate more rapid deflation.
4. Gently retract the balloon from the uterus and vaginal canal and discard.

5. Monitor patient for signs of bleeding.

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
●This device is intended as a temporary means of establishing hemostasis in cases indicating conservative management of postpartum uterine bleeding.
●The Postpartum Balloon is indicated for use in the event of primary postpartum hemorrhage within 24 hours of delivery.
●The device should not be left indwelling for more than 24 hours.
●The balloon should be inflated with a sterile liquid such as sterile water, sterile saline, or lactated ringers solution. The balloon should never be inflated with air, carbon dioxide or any other gas.
●The maximum inflation is 500 mL. Do not overinflate the balloon. Overinflation of the balloon may result in the balloon being displaced into the vagina.
●Patients in whom this device is being used should be closely monitored for signs of worsening bleeding and/or disseminated intravascular coagulation (DIC). In such cases, emergency intervention per hospital protocol should be followed.
●There are no clinical data to support use of this device in the setting of DIC.
●Patient monitoring is an integral part of managing postpartum hemorrhage. Signs of deteriorating or non-improving condition should lead to a more aggressive treatment and management of patient uterine bleeding.
●Patient urine output should be monitored while the Postpartum Balloon is in use.


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

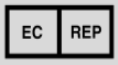
Authorized representative in the European Commutity/ European Union


Consult instructions for use or consult electronic instructions for use

Do not resterilize

Medical device


Single sterile barrier system

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