Postpartum Balloon

DESCRIPTION

The Postpartum Balloon is a silicone balloon catheter with a maximum inflation volume of 500 mL.
The Rapid Instillation Components include polymer tubing with an IV bag spike and three-way valve.

CONTENT

PPB-24F:
Postpartum Balloon (1)

PPB-24F-II:
Postpartum Balloon (1)
150cm extension tube with puncture device (1)
Three-way cock with one-way valve (1)
60ml plastic syringe (1)

INTENDED USE

This device is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

CONTRAINDICATIONS

- Arterial bleeding requiring surgical exploration or angiographic embolization
- Cases indicating hysterectomy
- Pregnancy
- Cervical cancer
- Purulent infections in the vagina, cervix, or uterus
- Untreated uterine anomaly
- Disseminated intravascular coagulation
- A surgical site that would prohibit the device from effectively controlling bleeding

WARNINGS

- 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.

PERCAUTIONS

READ INSTRUCTIONS PRIOR TO USE.
DO NOT USE IF THE UNIT PACKAGING OR THE PRODUCT HAVE BEEN DAMAGED OR SOILED.
FOR SINGLE USE ONLY, DO NOT REUSE.
If fetal membranes rupture spontaneously while this device is in place, it is recommended that both balloons be deflated and the device removed in preparation for spontaneous active labor contractions.

POTENTIAL ADVERSE EVENTS

- This product is intended for use by physicians trained and experienced in obstetrics and gynecological techniques.
- Avoid excessive force when inserting the balloon into the uterus.

INDICATION 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.

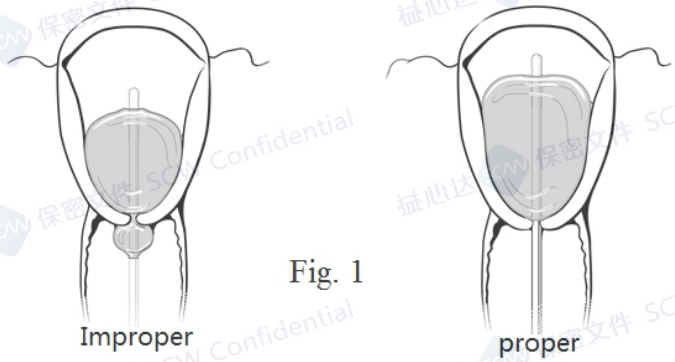

Fig. 1

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.

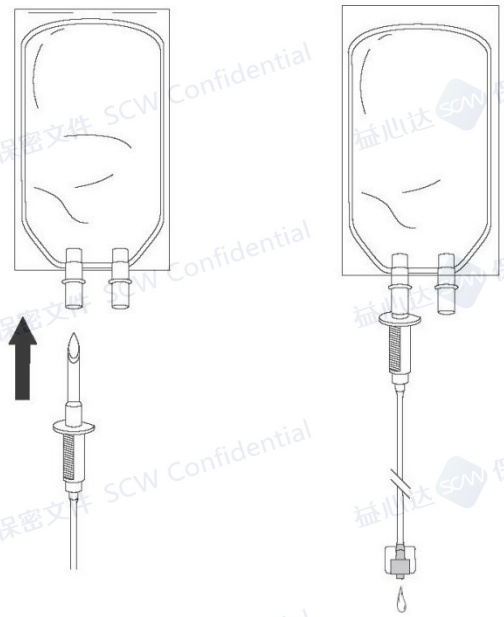

Fig. 2

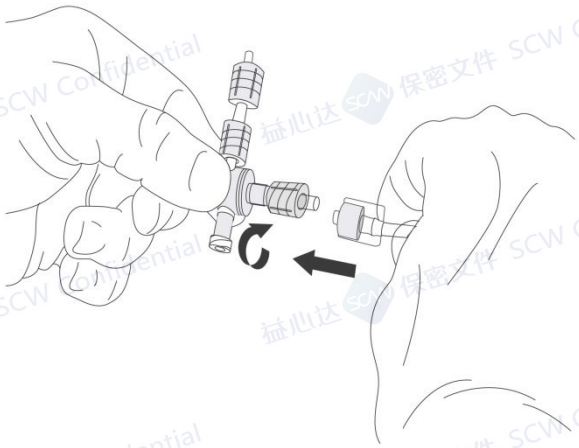

Fig. 3

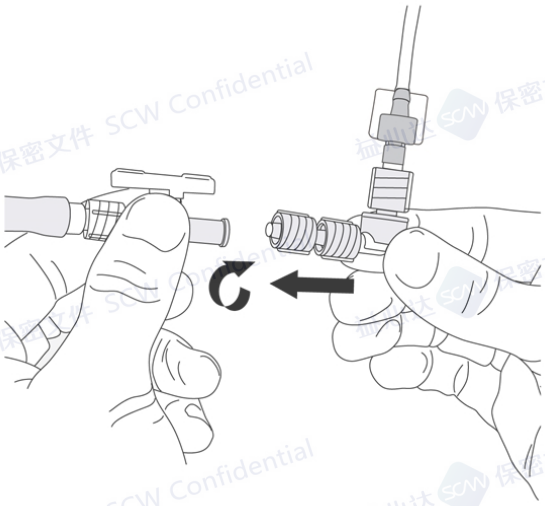

Fig. 4

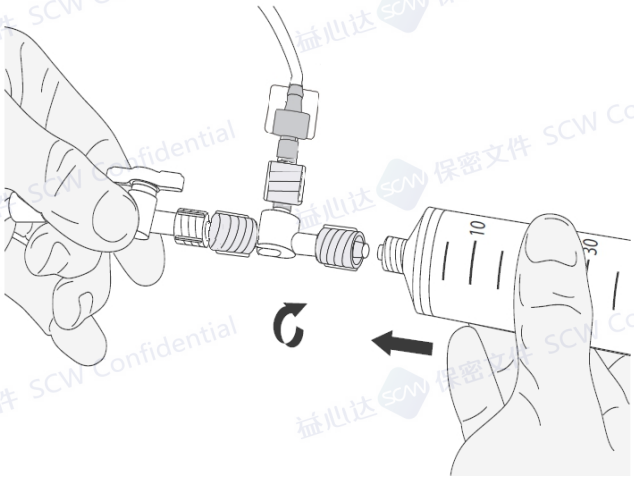

Fig. 5

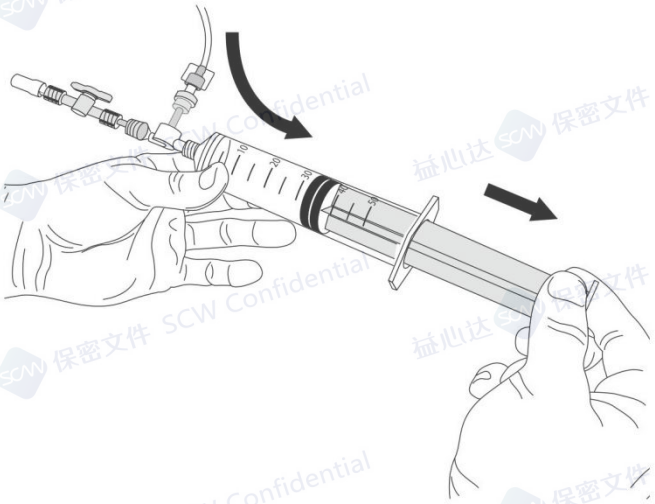

Fig. 6

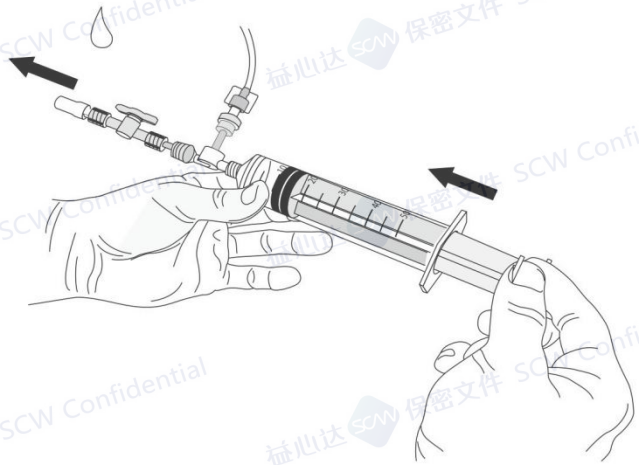

Fig. 7

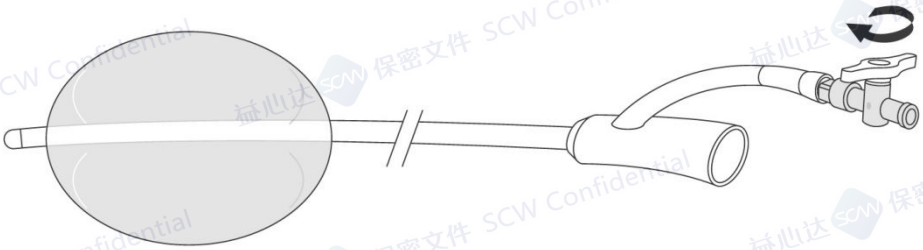

Fig. 8

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.

DISPOSAL

The product should not be reprocessed and used again. It should be considered as healthcare waste and be treated or disposed of in facilities with the appropriate authorisations.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING


Keep dry


Do not use if package is damaged


Consult operating instructions


Keep away from sunlight


Date of Manufacture

Sterilized using ethylene oxide

Lot number


Do not reuse


Do not resterilize


Attention, see instructions for use

Catalog number


Use by

CE Mark

SCW Medicath Ltd.
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