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CooperSurgical®

Bakri® Postpartum Balloon

Instructions for Use

CE 2797 UKCA 0086

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

DEVICE DESCRIPTION

The Bakri 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.

RPN	Description	GPN
J-SOS-100500	Bakri® Postpartum Balloon	G30673
J-SOSR-100500	Bakri® Postpartum Balloon with Rapid Instillation components	G24237

OPERATING PRINCIPLE

The balloon catheter can be placed either transvaginally or transabdominally (during a cesarean section) when there is postpartum uterine bleeding. The silicone balloon catheter is inflated to a maximum of 500mL within the lower uterine segment using the provided syringe and stopcock or the rapid instillation components with syringe and stopcock to fill the balloon directly from a saline bag. The inflated balloon provides tamponade to the lower uterine segment which can control or reduce postpartum uterine bleeding. The balloon catheter has a drainage lumen to allow for drainage of blood through the side ports at the distal tip. Blood drains to the drainage funnel, which may be connected to a fluid collection bag.

PERFORMANCE CHARACTERISTICS

- The balloon catheter inflates to up to 500 mL and may remain inflated for up to 24 hours.
- The provided stopcock and syringe allow for device inflation.
- The Rapid Instillation Components, part number J-SOSR-100500, facilitate inflation without the need to refill and reattach the syringe multiple times.
- The drainage lumen and the two side ports at the distal tip allow for drainage of fluid.

DEVICE COMPATIBILITY

The balloon catheter has a drainage port that is compatible with standard tapered connectors on fluid collection bags. The rapid instillation component has a bag spike that is compatible with standard saline bags. The balloon catheter is compatible with sterile saline and sterile water.

CLINICAL BENEFITS

The clinical benefits and expected clinical outcomes of Bakri Postpartum Balloon is for the temporary control and reduction of postpartum uterine bleeding.

INTENDED USE

This device is intended for conservative management of postpartum uterine bleeding.

INDICATIONS FOR USE

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

INTENDED USER

This device is intended for licensed health care professionals experienced in management of postpartum uterine bleeding.

INTENDED PATIENT POPULATION

Women experiencing 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

- The device should not be left indwelling for more than 24 hours.
- Balloon inflation and flushing of the lumen should only use sterile liquid such as sterile water or sterile saline. Air, carbon dioxide, or any other gas should never be used to inflate the balloon or flush the lumen.
- 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 uterine bleeding. 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 Bakri Postpartum Balloon is in use.

PRECAUTIONS

- 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.

REPORTING OF SERIOUS INCIDENTS

PLEASE NOTE: If a serious incident is suspected from using the Bakri Postpartum Balloon, report the details of the incident to CooperSurgical via the online complaint form https://www.coopersurgical.com/support/customer-complaint-form/, by email at ProductSurveillance@coopersurgical.com, or by phone number +1 203-601-5200 Ext. 3100 and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

INSTRUCTIONS FOR USE

IMPORTANT: Prior to transvaginal or transabdominal placement of the Bakri Postpartum Balloon, the uterus should be free of all placental fragments, and the patient should be evaluated to ensure that there are no lacerations or trauma to the genital tract and that the source of the bleeding is not arterial.

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.
3. Place an indwelling urinary bladder Foley catheter at this time, if not already in place, to collect and monitor urine output.

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.

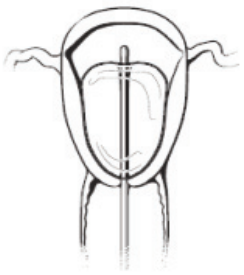
   Note: Ensure that all product components are intact and the hysterotomy is securely sutured prior to inflating the balloon. If clinically relevant, the abdomen may remain open upon inflation of the balloon to closely monitor uterine distention and confirm the hysterotomy closure.

   Note: If clinically relevant, a B-Lynch compression suture may be used in conjunction with the Bakri Postpartum Balloon.

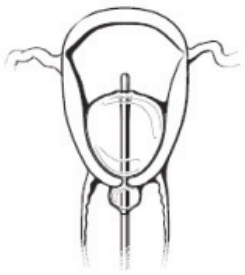
Balloon Inflation - With Syringe

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.

1. Place an indwelling urinary bladder Foley catheter at this time, if not already in place, to collect and monitor urine output.
2. Using the enclosed syringe, begin filling the balloon to the predetermined volume through the stopcock.
3. Once the balloon has been inflated to the predetermined volume, confirm placement via ultrasound.



Proper Placement



Improper Placement

4. 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.

5. Connect the drainage port to a fluid collection bag to monitor hemostasis.

   Note: Do not over-insert the drainage bag adapter onto the catheter adapter. Over-insertion of the drainage port may cause blockage of inflation lumen and the balloon may be difficult to deflate.

   Note: To adequately monitor hemostasis, the balloon drainage port and tubing may be flushed clear of clots with sterile isotonic saline.
6. Monitor the patient continuously for signs of increased bleeding and uterine cramping.

Balloon Inflation - With Rapid Instillation Components

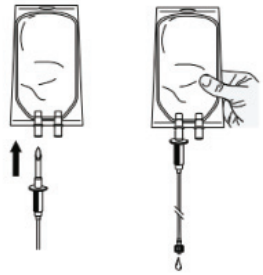


Figure 1

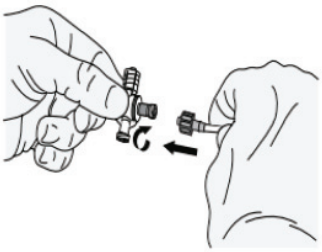


Figure 2

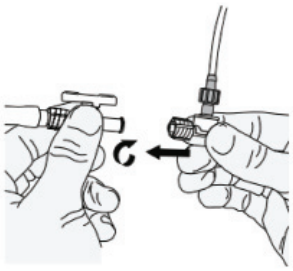


Figure 3

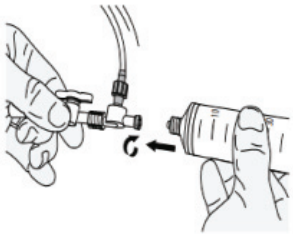


Figure 4

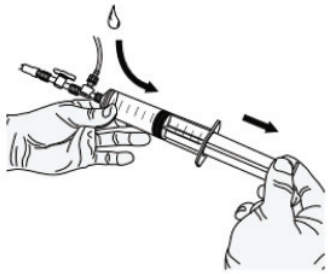


Figure 5

Figure 6

Figure 7

Note: Ultrasound should be used to confirm proper placement of the balloon once the balloon is inflated to the predetermined volume.

Balloon 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 OF DEVICE

Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

STORAGE CONDITIONS

Store in a dry and cool place. Avoid extended exposure to light. Upon the removal from the package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local CooperSurgical, Inc (CSI) sales representative for information on available literature.

GLOSSARY OF SYMBOLS

Source: ISO 15223-1 and ISO 7000

Symbol	Title
	Packaging unit
	Catalogue number
	Batch code
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)
	Date of manufacture
	Manufacturer
	Use-by date
	Medical Device
	Do not re-use
	Do not resterilize
	Sterilized using ethylene oxide

Symbol	Title
	Single sterile barrier system
	Caution
	Consult instructions for use or consult electronic instructions for use
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations
	The product conforms to the UK Device Medical Regulation 2002, as amended. The product can be freely marketed in Great Britain (England, Wales and Scotland)
	Importer
	Authorized representative in the European Community

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