Bakri® Postpartum Balloon | by CooperSurgical®

Tamponade Technique for Postpartum Hemorrhage

Refer to the **Instructions for Use** for complete information on product usage, precautions, warnings, and contraindications.

1 Confirm before placement.

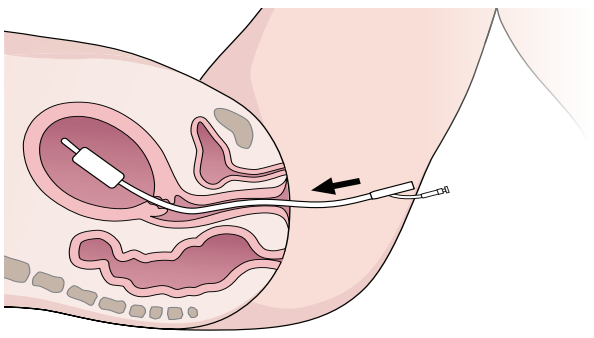
Confirm that these statements are true:

- ✓ The uterus is free of placental fragments.
- ✓ The genital tract has no trauma or lacerations.
- ✓ The source of the bleeding is not arterial.
- ✓ Patient does not present with any contraindications for use of this device.

2 Determine the uterine cavity's volume.

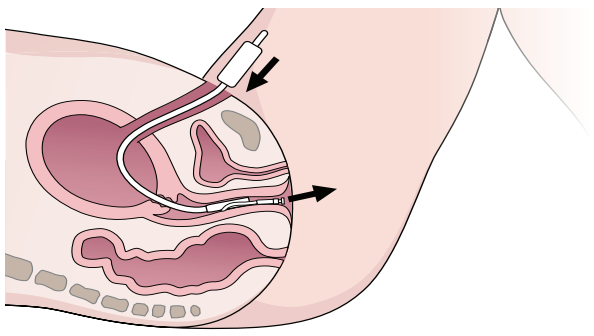
- **For transvaginal placement, determine uterine volume by direct examination or ultrasound examination. For transabdominal placement, determine uterine volume by direct examination.**
- **Place the predetermined volume of sterile fluid in a separate container.**
- **If you will use the rapid instillation components, note the redetermined volume for rapid instillation.**
- **The maximum balloon volume is 500 mL.**

3 Place the balloon.



Transvaginal placement, postvaginal delivery

- 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.



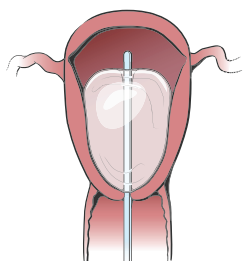
Transabdominal placement, postcesarean delivery

- Pass the uninflated balloon, inflation port first, through the cesarean incision and into the uterus and cervix. Remove the stopcock to aid in placement and reattach prior to filling the balloon.
- Have an assistant pull the balloon shaft through the vaginal canal until the base of the balloon contacts the internal cervical ostium.
- Close the incision, being careful not to puncture the uninflated balloon while suturing.

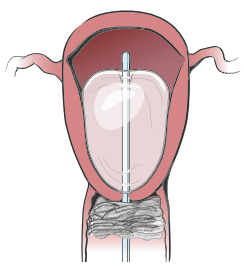
4 Fill the balloon with sterile liquid.

- ✓ **Never inflate with air, carbon dioxide, or any other gas.**
- ✓ **Do not fill with more than 500 mL. Overinflation may result in the balloon being displaced into the vagina.**
- ✓ **Ensure that all product components are intact and that the hysterotomy is securely sutured prior to balloon inflation.**
- Place a Foley catheter in the patient's bladder to collect urine and monitor urine output.
- Use the enclosed syringe or rapid instillation components to fill the balloon to the predetermined volume through the stopcock.
- If desired, apply traction to the balloon's 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 gauze.
- **Use ultrasound to confirm that the balloon is properly placed.**

Proper Placement



- Make sure that the entire balloon is inserted past the cervical canal and internal ostium.
- After the balloon is inflated to the predetermined volume, use ultrasound to confirm that it is properly placed.



- If necessary, pack the vagina with iodine- or antibiotic-soaked gauze.
- Do not extend the packing into the uterus.

5 Flush the lumen and monitor hemostasis.

- Connect the drainage port to a fluid collection bag to monitor hemostasis.
- The balloon drainage port and tubing may be flushed clear of clots with sterile isotonic saline to facilitate monitoring.
- Monitor the patient for signs of increased bleeding and uterine cramping.

6 Remove the balloon.

- ✓ **Maximum indwelling time: 24 hours.**
- ✓ **The attending clinician determines when the balloon is removed after bleeding is controlled and the patient is stable.**
- Release the tension on the shaft and remove any vaginal packing.
- Aspirate balloon contents until the balloon is completely empty. The fluid may be removed incrementally to allow for periodic observation of the patient. In an emergency, the shaft may be cut to rapidly deflate the balloon.
- Gently retract the balloon and discard it.
- Monitor the patient for signs of bleeding.

Please contact your CooperSurgical sales representative for additional information:

800.243.2974 | 203.601.5200 | www.coopersurgical.com

IMPORTANT SAFETY INFORMATION

The Bakri® Postpartum Balloon is a single use device, intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

CONTRAINDICATIONS: Do not use, If there is arterial bleeding requiring surgical exploration or angiographic embolization; hysterectomy is indicated; pregnancy; cervical cancer; purulent infections in vagina, cervix or uterus; untreated uterine anomaly; disseminated intravascular coagulation (DIC); or bleeding is at a site that would prohibit the device from effectively controlling bleeding.

WARNINGS: The Bakri Postpartum Balloon is indicated for use in the event of primary postpartum hemorrhage within 24 hours of delivery and should not be left indwelling for more than 24 hours; inflate with a sterile liquid to a maximum inflation of 500 mL; Do Not overinflate the balloon or use air, carbon dioxide or any other gas. Patients should be monitored closely for signs of deteriorating or non-improving condition. Patients urine output should be monitored while the balloon is in use.

IMPORTANT: Prior to placement of the balloon, the uterus should be free of all placental fragments and ensured there are no lacerations or trauma to the genital tract and source of bleeding is not arterial.

Consult the IFU prior to use of the Bakri Postpartum Balloon, for detailed instructions and potential risks. https://coopersurgical.com/bakri-ifu

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How to Use the Rapid Instillation Components

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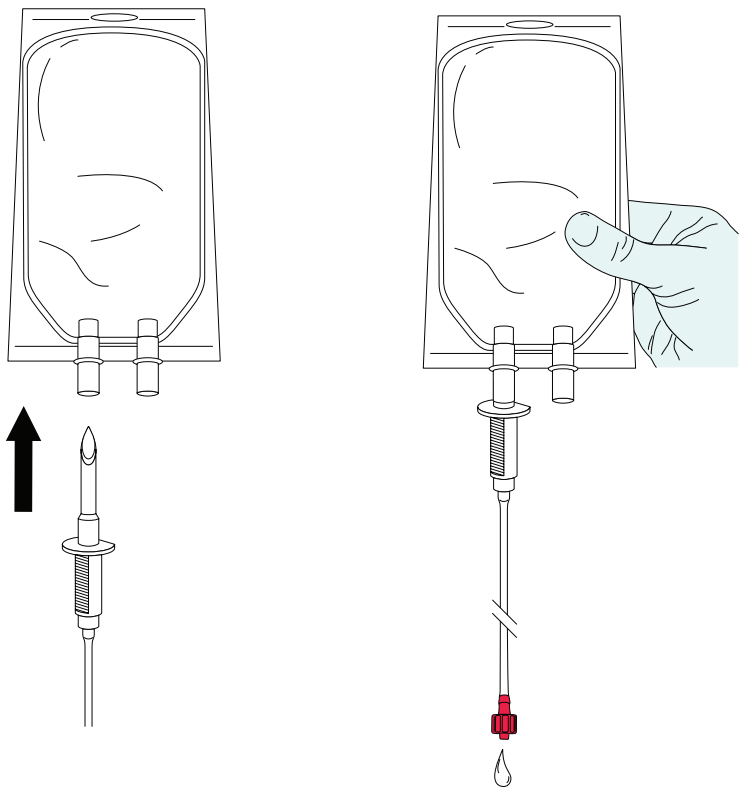

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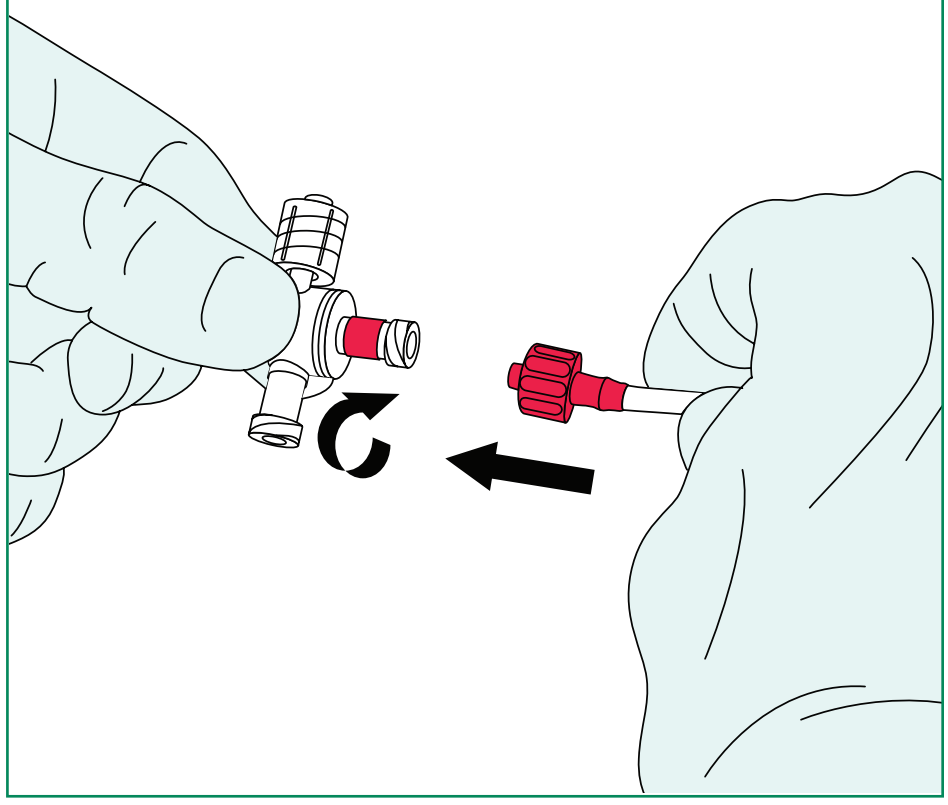

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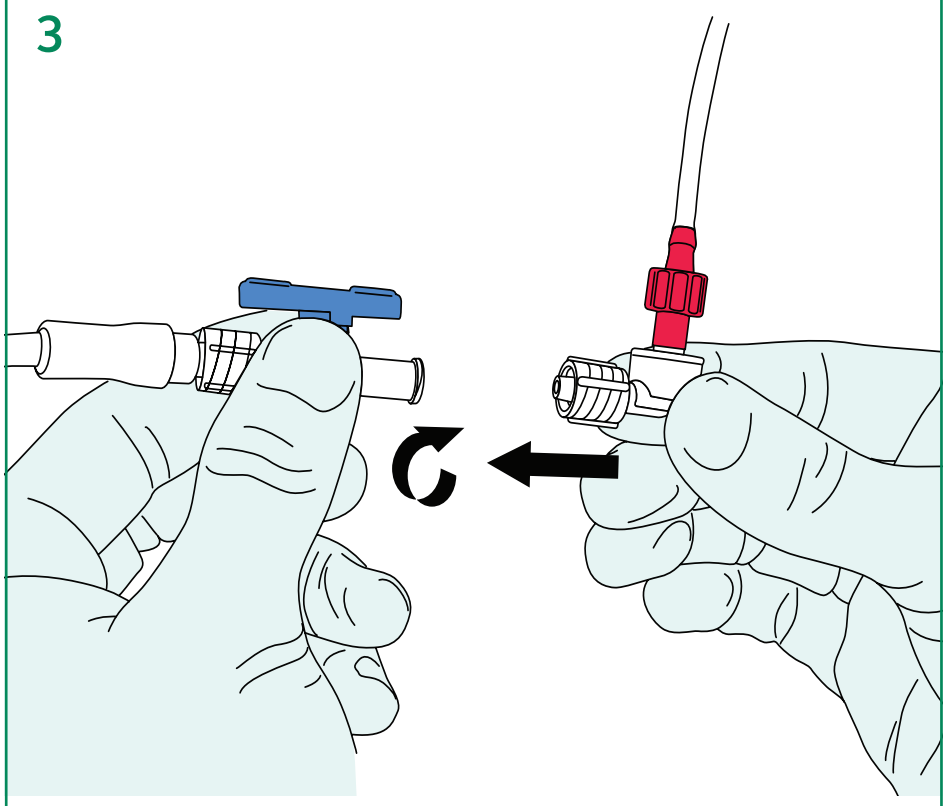

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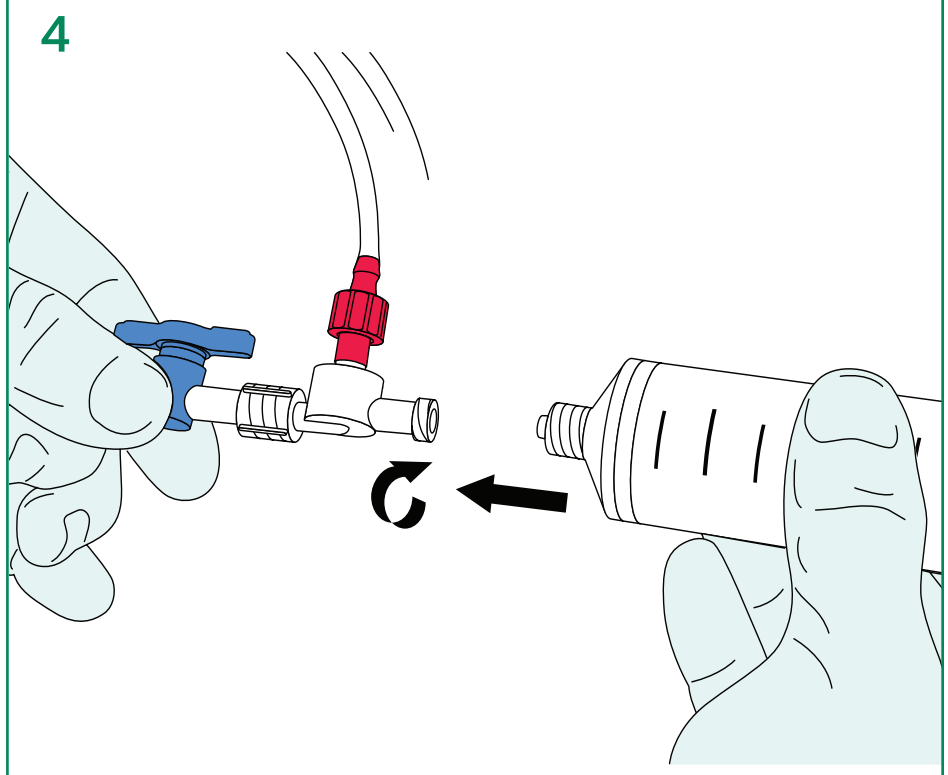

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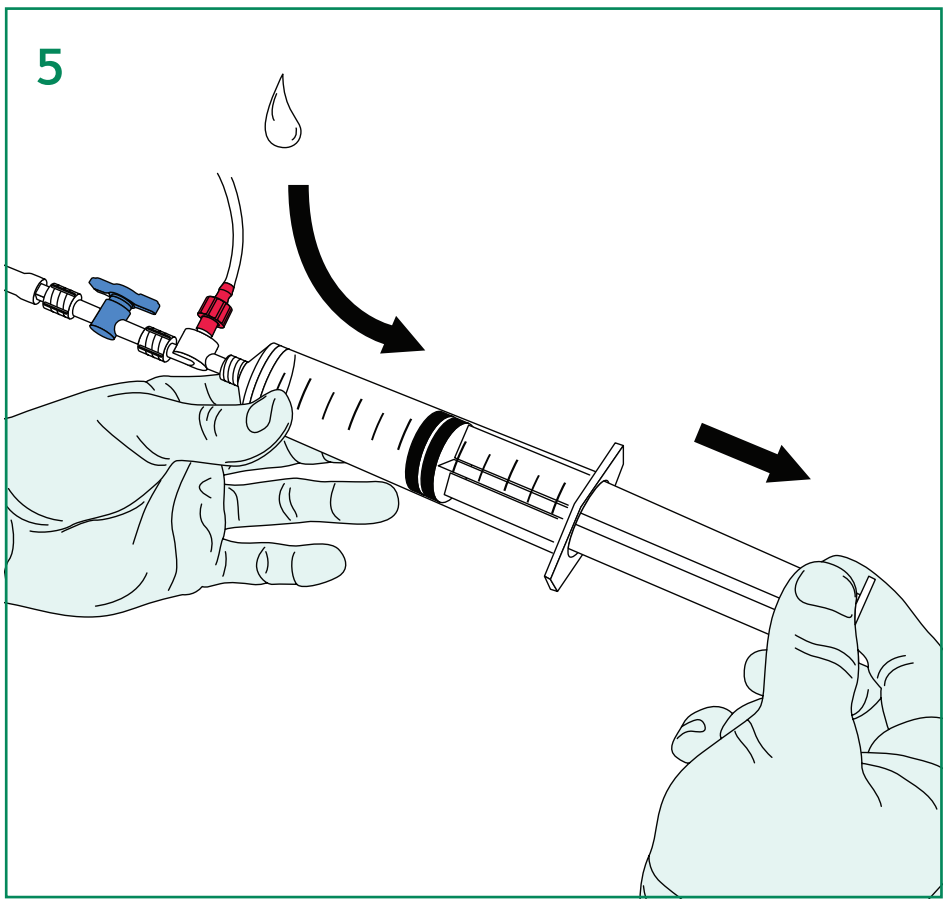

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