

Tamponade Technique for Postpartum Hemorrhage

Refer to the Instructions for Use for complete information on product usage and proper indications and contraindications.

1 Evaluating and Monitoring the Patient

- Assess the patient's postpartum hemorrhage and its causes.
- Determine possible contraindications to the use of the Bakri Postpartum Balloon.
- Confirm that the uterus is free of placental attachments or fragments and that there are no lacerations.
- Evaluate the patient for:

- Vital signs	- Active and total blood loss
- Pallor	- Pulmonary function
- Blood pressure	- Hematocrit level
- Urine output	- General patient condition (shock)
- Uterine tone	
- Continue monitoring the patient carefully throughout the process.

2 Determining Uterine Volume

- Estimate the uterine cavity's volume by direct or ultrasound examination.
- Place the predetermined volume of sterile fluid in a separate container. Do not rely on a syringe count to verify the volume.
- If using SOS-R, note the predetermined volume for rapid instillation.
- The maximum balloon volume is 500 mL.

3 Inserting the Balloon

Transvaginal Placement, Postvaginal Delivery (See Fig. 1)

- Insert the balloon portion of the catheter into the uterus, making certain that the entire balloon is inserted past the cervical canal and internal osium.

Transabdominal Placement, Postcesarean Delivery (See Fig. 2)

- Pass the uninflated balloon, inflation port first, through the incision into the uterus and cervix. Remove the stopcock to facilitate placement, if desired.
- Have an assistant pull the balloon shaft through the vaginal canal until the base contacts the internal cervical osium.
- Close the incision, being careful not to puncture the uninflated balloon with the suture.

4 Filling the Balloon with Sterile Liquid

- Never inflate with air, carbon dioxide or any other gas.
- Do not fill with more than 500 mL. Over-inflation 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 inflating the balloon.

- Place a Foley catheter in the patient's bladder to collect urine and monitor urine output.
- Using the enclosed syringe, or rapid instillation components, fill the balloon to the predetermined volume through the stopcock.
- Traction may be applied to the balloon shaft to ensure proper contact between the balloon and the tissue surface by securing the balloon shaft to the patient's leg or attaching it to a weight (not to exceed 500 g).
- Use ultrasound to confirm proper placement of the balloon once the balloon is inflated to the predetermined volume.

5 Flushing the Lumen and Monitoring Hemostasis

- Flush the balloon drainage port and tubing with sterile isotonic saline to clear clots. (The appropriate volume of saline and frequency of flushing should be determined by attending medical staff.)
- Connect the drainage port to a fluid collection bag to monitor hemostasis.
- Monitor the patient for signs of increased bleeding and uterine cramping.
- Continue evaluating the patient for the signs listed in Step 1.

6 Removing the Balloon

- Maximum indwelling time: 24 hours.
- 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 is stable.

- Release the tension on the shaft and remove any vaginal packing.
- Aspirate balloon contents until the balloon is completely empty.
- Gently retract the balloon and discard it.
- Monitor the patient for signs of bleeding.

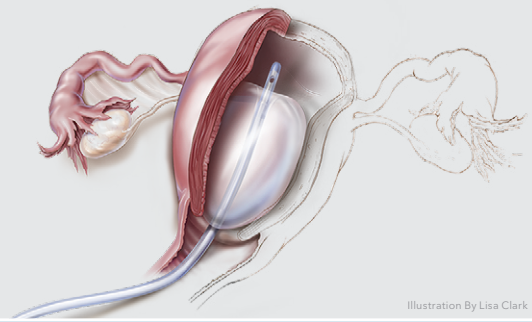


Illustration By Lisa Clark

Bakri®

POSTPARTUM BALLOON WITH RAPID INSTILLATION COMPONENTS

Illustrations for Inserting the Bakri Balloon (Step 3)

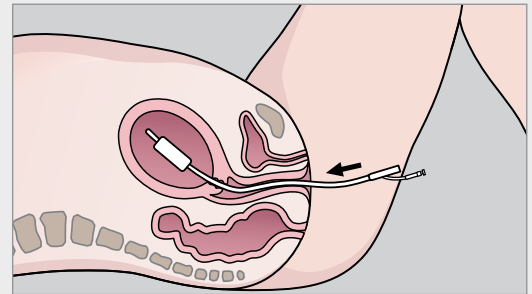


Fig. 1: Transvaginal Placement, Postvaginal Delivery

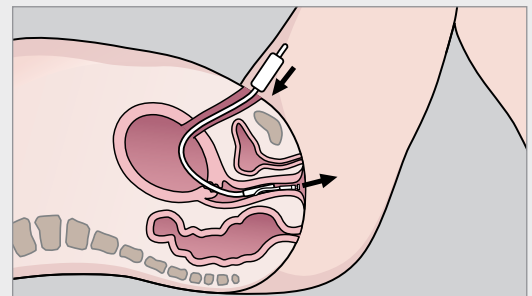
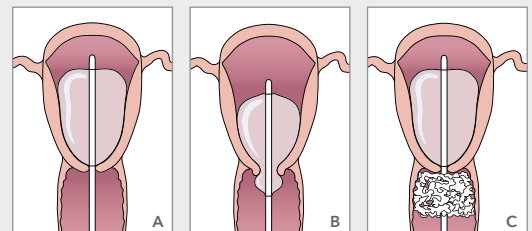


Fig. 2: Transabdominal Placement, Postcesarean Delivery

Explanation of Proper Placement



Proper Placement:

- Make sure that the entire balloon is inserted past the cervical canal and internal osium.
- Use ultrasound to confirm proper placement of the balloon once the balloon is inflated to the predetermined volume.

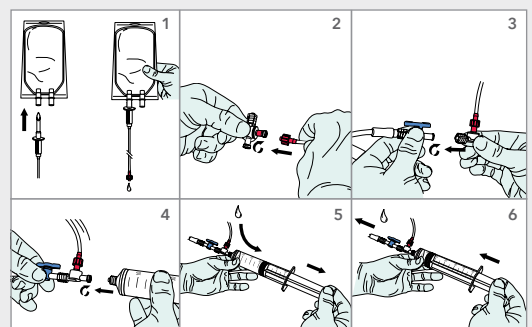
If the Balloon Becomes Displaced:

- Empty and deflate the balloon.
- Reposition the balloon in the uterus. (Reference illustration A for details.)
- Refill as indicated in Step 4.

To Prevent Displacement:

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

Steps for the Use of Rapid Instillation Components



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