INSTRUCTIONS FOR USE

RADA Postpartum Balloon

Device Description

The RADA Postpartum Balloon is a sterile, single-use medical device intended for the temporary control and management of postpartum uterine bleeding.

The device consists of a flexible catheter with a soft, atraumatic distal tip and an inflatable balloon with a maximum filling capacity of **500 mL**. The system incorporates a separate drainage lumen to allow continuous drainage and monitoring of blood and fluid from the uterine cavity.

The balloon inflation system includes a filling tube with an integrated spike for connection to a bag of **sterile water for irrigation**, a **three-way connector**, and an integrated **on/off valve**. This design allows repeated aspiration and injection of sterile water without disconnecting the syringe during balloon inflation. After inflation, the filling assembly can be disconnected while the integrated on/off valve maintains balloon inflation and allows simple balloon deflation when required.

The device is manufactured from biocompatible medical-grade materials and is supplied sterile.

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Intended Use

The RADA Postpartum Balloon is intended for the temporary control and reduction of postpartum uterine bleeding by providing intrauterine tamponade following vaginal delivery or cesarean section.

Indications for Use

The device is indicated for:

- Management of postpartum hemorrhage (PPH);
- Temporary control of uterine bleeding following vaginal delivery;
- Temporary control of uterine bleeding following cesarean section;
- Situations in which conservative management of postpartum hemorrhage is clinically indicated.

Contraindications

Do not use the device in patients with:

- Untreated uterine infection;
- Known or suspected uterine rupture;
- Retained placental tissue or retained products of conception requiring surgical management;
- Cervical or uterine abnormalities that prevent proper placement of the balloon;
- Any condition in which intrauterine balloon tamponade is contraindicated according to the physician's clinical judgment.

Warnings

- This device must be used only by qualified healthcare professionals experienced in obstetric procedures.
- Strict aseptic technique must be maintained throughout the procedure.
- Do not use the product if the package is opened, damaged, or beyond the expiration date.
- Reuse, reprocessing, or resterilization is prohibited.
- Do not exceed the maximum balloon filling volume of **500 mL**.
- Inflate the balloon only with **sterile water for irrigation**.
- Overinflation may result in uterine injury.

Precautions

- Confirm correct intrauterine placement before balloon inflation.
- Determine the balloon filling volume according to the patient's clinical condition.
- Continuously monitor the patient's clinical status throughout treatment.
- Ensure that the drainage lumen remains unobstructed to allow continuous drainage and monitoring.
- Remove the device gradually in accordance with institutional protocols and the patient's clinical condition.

Instructions for Use

1. Prepare the patient according to standard obstetric practice.
2. Using aseptic technique, introduce the distal tip of the catheter into the uterine cavity and confirm correct placement of the balloon.
3. Connect the spike of the filling tube to a bag of **sterile water for irrigation**.
4. Connect the filling tube to the side port of the three-way connector and securely attach a syringe to the proximal port of the connector.

5. Aspirate sterile water into the syringe by retracting the plunger, then slowly depress the plunger to inject the sterile water through the three-way connector into the balloon.
6. Repeat the aspiration and injection process without disconnecting the syringe until the desired balloon volume is achieved. Do not exceed the maximum filling volume of **500 mL**.
7. After the desired balloon volume has been achieved, close the integrated on/off valve on the inflation line.
8. Disconnect the filling assembly, including the three-way connector and filling tube, from the balloon.
9. Ensure that the drainage lumen remains patent to allow continuous drainage and monitoring of uterine bleeding.
10. Continuously monitor the patient's clinical condition and bleeding according to institutional protocols.
11. When balloon removal is indicated, open the integrated on/off valve to allow complete drainage of the sterile water from the balloon.
12. After complete balloon deflation, gently withdraw the catheter from the uterus.
13. Discard the device after single use.

Potential Adverse Events

Potential adverse events associated with postpartum balloon tamponade may include:

- Pelvic pain or uterine cramping;
- Vaginal bleeding;
- Infection;
- Balloon displacement;
- Uterine injury or perforation (rare);
- Failure to control postpartum hemorrhage.

Sterility

- Sterilized using Ethylene Oxide (EO).
- Do not use the product if the package has been opened or damaged.

Storage Conditions

Store the product in a clean, dry environment away from direct sunlight, heat sources, and excessive humidity.

Disposal

Dispose of the device after use in accordance with applicable local regulations for biohazardous medical waste.