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OB030000

Paxis™

Post Partum Balloon Rapid Instillation Kit

INSTRUCTION FOR USE

DESCRIPTION

The Paxis™ postpartum balloon is a silicone balloon catheter with a maximum inflation volume of 500 mL. The rapid instillation components include rapid instillation tubing with an IV bag spike, two backcheck valves, a three-way stopcock, and a 60 mL syringe.

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 embolisation, 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.

FOR USE BY A QUALIFIED CLINICIAN. THE BELOW IS ONLY A SUGGESTION AND FACILITY PROTOCOL MUST BE FOLLOWED FOR ALL CLINICAL PROCEDURES WHERE THIS PRODUCT IS USED.

⚠ CAUTION

- This product is intended for use by physicians trained and experienced in obstetrics and gynaecological techniques.
- Avoid excessive force when inserting the balloon into the uterus.
- Single use.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (EO), DO NOT use if the package or product has been damaged or contaminated.
- EU Notice: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and /or patient is established.

STEPS

PRE-PROCEDURE CHECKLIST

Before placing the device, the clinician must confirm the following:

- The uterus is completely free of any remaining placental fragments.
- The genital tract does not have any trauma or lacerations.
- The source of the bleeding is not arterial.
- The patient does not have any clinical contraindications for using this device.

DEVICE PLACEMENT

The uterine volume should be determined prior to placement via direct examination or ultrasound.

TRANS-VAGINAL PLACEMENT (POST VAGINAL DELIVERY)

- Insert the entire balloon portion of the catheter into the uterus, ensuring it is positioned completely past the cervical canal and the internal ostium.

TRANS-ABDOMINAL PLACEMENT (POST-CAESAREAN DELIVERY)

- Pass the uninflated balloon, inflation port first, through the caesarean incision and into the uterus and cervix.
  Note: The stopcock may be removed to assist with placement but must be re-attached before the balloon is filled.
- Have an assistant gently pull the catheter shaft through the vaginal canal until the deflated base of the balloon makes contact with the internal cervical ostium.
- Close the incision according to normal procedure, taking extreme care to avoid puncturing the uninflated balloon with sutures.

BALLOON INFLATION

Important: Never inflate the balloon with air, carbon dioxide, or any other gas.

- Ensure all product components are intact and the hysterotomy is securely sutured before you begin inflation.
- The maximum balloon volume is 500 mL. Over-inflation may cause the balloon to displace into the vagina.
- To prevent displacement into vagina, counter pressure may be applied by packing the vaginal canal with gauze if applicable.

INFLATION USING THE RAPID INSTILLATION KIT

1. Prior to spiking the fluid bag, connect the luer connector of the rapid instillation tubing to the red backcheck valve on the blue stopcock.
2. Once the luer connection is securely attached, insert the spike into the bag of preferred sterile liquid as per institutional protocol.
3. Connect a syringe to the remaining available port of the blue stopcock.
   Note: The blue stopcock tap position remains unchanged during inflation.
4. Draw back the syringe plunger to fill the syringe with fluid. The backcheck valve on the inflation line automatically opens to draw fluid from the IV bag while preventing backflow from the balloon.
5. Depress the syringe plunger to deliver the fluid into the balloon. The backcheck valve on the blue stopcock automatically closes to prevent fluid from travelling back into the IV bag, forcing it directly through the open white stopcock and into the balloon.
   Note: The white stopcock tap remains unchanged in the open position during the inflation procedure.
6. Repeat this process of drawing fluid into the syringe and pushing it into the balloon while monitoring the volume on the fluid bag until the predetermined amount is reached.
   Note: Ultrasound may be used to confirm proper placement once the balloon is inflated to the predetermined volume.

PATIENT MONITORING & BALLOON REMOVAL

- A foley catheter should be placed in the patient's bladder to collect and monitor urine output.
- The device has a maximum indwelling time of 24 hours. The attending clinician determines the timing of balloon removal after the bleeding has been controlled and the patient is stable.

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1. Rotate the white stopcock into the closed position.
2. Detach the red backcheck valve from the white stopcock and attach the syringe ensuring connection is secure.
3. Rotate the white stopcock into the open position and aspirate fluid into the syringe. Fluid may be removed incrementally to allow for periodic patient observation.
4. To empty the fluid from the syringe, rotate the white stopcock into closed position, detach and empty the syringe, then reattach the syringe and rotate the stopcock into the open position. Repeat this cycle until the balloon is fully deflated.
5. In an emergency, the catheter shaft may be cut to facilitate a more rapid deflation.
6. Gently retract the deflated balloon from the uterus and vaginal canal, then discard.
7. Monitor the patient for signs of bleeding.

DISPOSAL

- The product is a single-use device. It should be disposed of as clinical waste in accordance with local and institutional guidelines.

PRECAUTIONS

- This device is intended as a temporary means of establishing haemostasis in cases indicating conservative management of postpartum uterine bleeding.
- NOT for use where clinically contraindicated
- The postpartum balloon is indicated for use in the event of primary postpartum haemorrhage 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, or sterile saline. 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 as per hospital protocol should be followed.
- Patient monitoring is an integral part of managing postpartum haemorrhage. Signs of a deteriorating or non-improving condition should lead to a more aggressive treatment and management of the patient's uterine bleeding.
- The patient's urine output should be monitored while the postpartum balloon is in use.

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