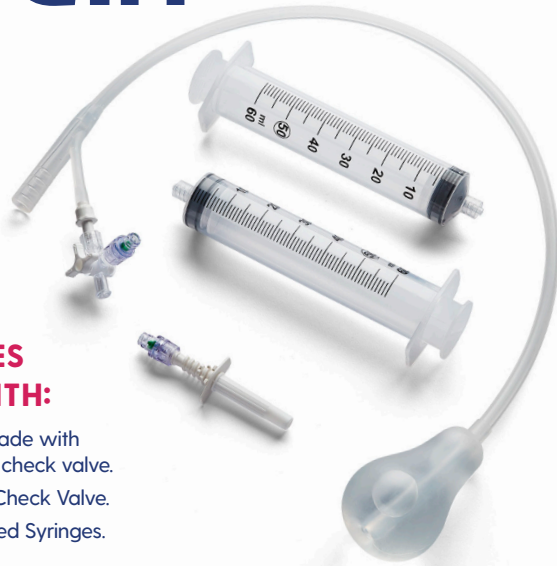


Toffeln[®]



THE STERILE SYSTEM COMES COMPLETE WITH:

- 1 ea. Balloon Tamponade with 3-way stopcock and check valve.
- 1 ea. Bag Spike with Check Valve.
- 2 ea. 50ml Luer-Locked Syringes.

EVALUATING AND MONITORING PATIENT

1. Assess the patient's postpartum haemorrhage and its causes.
2. Determine possible contraindications to the use of the Postpartum Balloon.
3. Confirm that the uterus is free of all placental fragments and attachments, that there are no lacerations or trauma to the genital tract and that the source of the bleeding is not arterial.
4. Evaluate the patient for:
 - Vital signs
 - Pallor
 - Blood pressure
 - Uterine output
 - Uterine tone
 - Active and total blood loss
 - Pulmonary function
 - Hematocrit level
 - General patient condition
5. Continue to monitor the patient carefully throughout the process.

DETERMINING UTERINE VOLUME

2. Determine uterine volume by direct inspection or ultrasound examination.
3. Place the predetermined volume into the syringe provided.
4. **Maximum inflation volume is 500ml.**

BALLOON INSERTION

Transvaginal placement (post-vaginal delivery)

- Using ultrasound guidance, introduce the balloon component of the catheter into the uterine cavity. Please note that manual insertion or Sponge Forceps are viable methods for proper placement.
- Ensure the balloon is placed through the cervical canal and the internal ostium. (Figure 1)

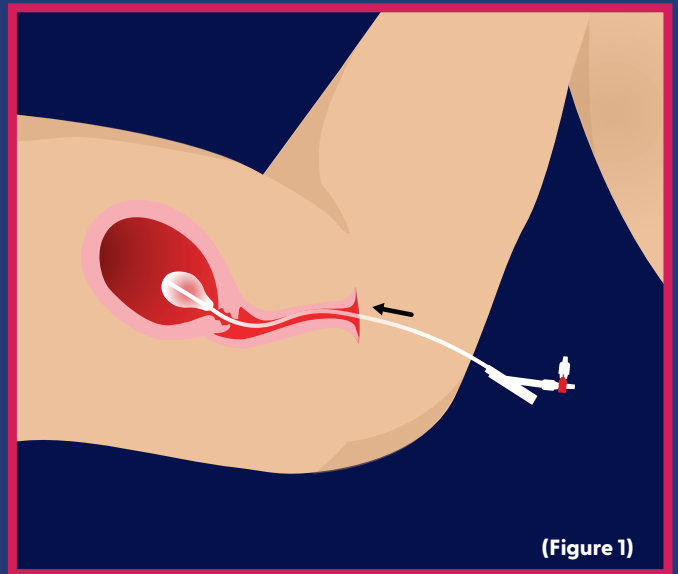
Transabdominal placement (post caesarean section)

3. From above, through access to the surgical incision, pass the tamponade balloon inflation port first through the uterus and cervix. **NOTE:** Three-way stopcock may be removed to aid placement and reconnected before filling the balloon.
4. Pull the balloon shaft out of the vaginal canal until it touches the inner cervical ostium.
5. Close caesarean incision by following normal procedure; take care not to puncture the balloon while suturing. **NOTE:** Before inflating the balloon, ensure all product components are intact, and the hysterotomy is securely sutured. (Figure 2)

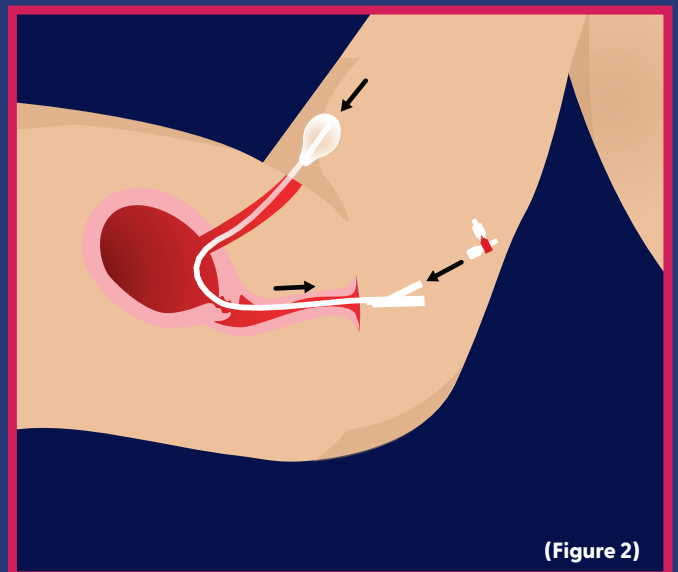
For steps 4-6 please see overleaf >>

ObCare Postpartum Balloon

Tomponade technique for Postpartum Haemorrhage



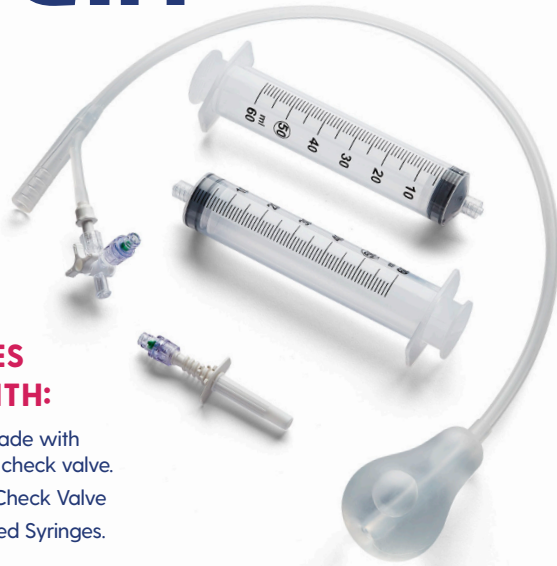
(Figure 1) Transvaginal placement (postvaginal delivery)



(Figure 2) Transabdominal placement (post caesarean section)

Refer to **Pergo Instructions for Use** for complete information on product usage, proper indications & contraindications.

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THE STERILE SYSTEM COMES COMPLETE WITH:

- 1 ea. Balloon Tamponade with 3-way stopcock and check valve.
- 1 ea. Bag Spike with Check Valve
- 2 ea. 50ml Luer-Locked Syringes.

BALLOON INFLATION ATTENTION:

- The balloon should be inflated with a sterile liquid such as sterile water, sterile saline or lactated ringer's solution. **The balloon should never be inflated with air, carbon dioxide, or other gas.**
- Maximum inflation volume is 500ml.
- Place a Foley catheter in patients bladder to collect and monitor urine output.
- Fill the balloon to a predetermined volume using the enclosed syringe through the stopcock.
- Attach a drainage port to a fluid collection container to monitor haemostasis.
- Once the balloon has been inflated to the desired volume, check the balloon's position and confirm placement via ultrasound. **NOTE: See figure 3 for proper placement.**

4

FLUSH LUMEN & MONITORING HEMOSTASIS

- Flush balloon drainage port and tubing with sterile isotonic saline to clear clots. **(Appropriate volume and frequency should be determined by attending medical staff)**
- Attach the drainage port to a fluid collection bag to monitor haemostasis.
- Maximum inflation volume is 500ml.
- Continue to monitor the patient as of step one.

5

REMOVING THE BALLOON

- Maximum indwell time: 24 hours
- The balloon may be removed sooner upon haemostasis or if more aggressive treatment is required.
- Remove any vaginal packing.
- Aspirate balloon contents until empty.
- Gently retract the balloon and discard it.
- Monitor the patient for signs of bleeding.

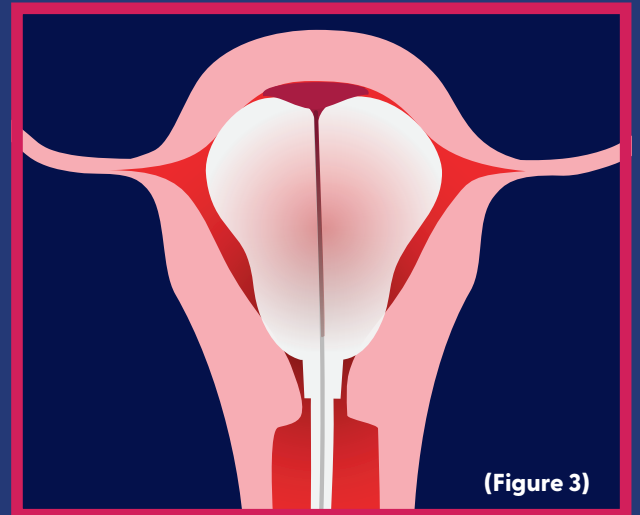
6

IN THE EVENT OF AN EMERGENCY:

Cut the catheter shaft to quicken deflation.

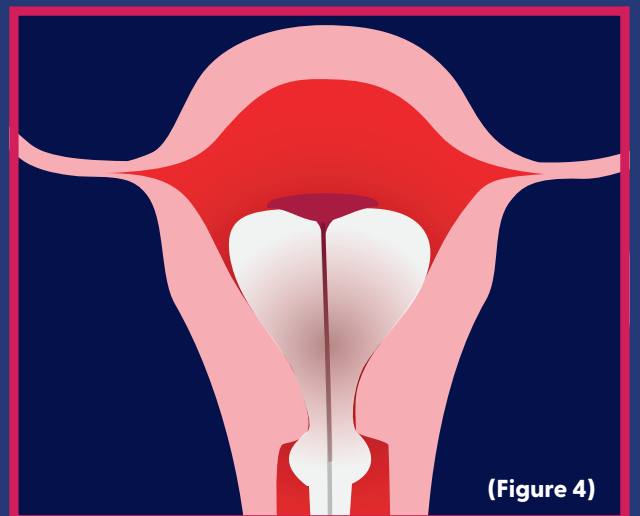
ObCare Postpartum Balloon

Tomponade technique for Postpartum Haemorrhage



Proper placement

Ensure the entire balloon is inserted past the cervical canal and internal ostium.



If balloon becomes displaced:

- Deflate the balloon
- Reposition the balloon in the uterus **(see Fig 3 for proper placement)**
- Refill as indicated in step 4.

Refer to **Pergo Instructions for Use** for complete information on product usage, proper indications & contraindications.