

BT-Cath[®] with EasyFill[™]

Balloon Tamponade Catheter intended to control or reduce postpartum hemorrhage unresponsive to standard therapy including massage and uterotonics.



I. PRELIMINARY CONSIDERATIONS

- Contraindications
- Prophylactic Antibiotics
- A urinary drainage catheter should be placed and urine output should be monitored while BT-Cath is in use.

2. CATHETER PLACEMENT

- Determine uterine volume.
- Ensure uterus is free of placental fragments, arterial bleeding or lacerations.
- Open the stopcock and attach the syringe to the catheter (Figure 1) and remove air from balloon (Figure 2). Close stopcock, remove and expel air from the syringe (Figure 3).

Following Vaginal Delivery:

- Insert catheter by cupping the balloon end and directly inserting through the dilated cervix to the fundus through the fingertips.
- Ultrasound may be used for guidance.

Following Cesarean Delivery:

- Catheter placement at time of laparotomy under direct visualization is recommended.
- Unscrew and remove stopcock (Figure 4)
- Insert catheter through incision and thread through cervix and vagina until balloon is placed in uterine cavity (Figure 5).
- Reconnect Stopcock (Figure 6).

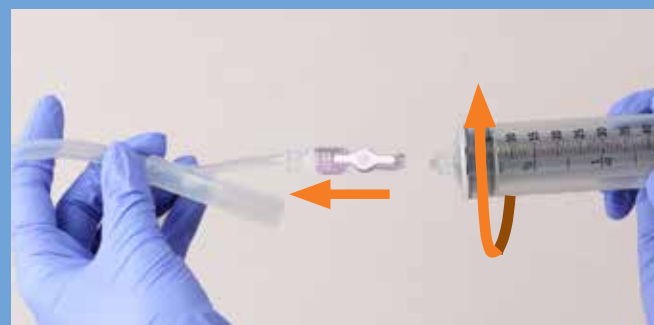


Figure 1



Figure 2



Figure 3



Figure 4

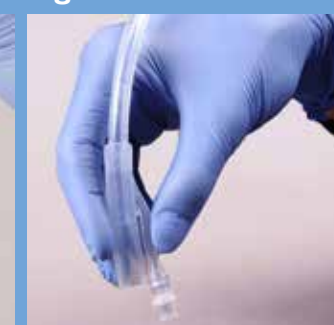


Figure 5



Figure 6

3. INFLATION with EasyFill[™]

- Attach the syringe to EasyFill[™] tubing set (Figure 7) and spike a 500 mL bag of saline (Figure 8). **Do not inflate balloon with anything but sterile saline.**
- Prime tubing by drawing 10-20 mL of saline into syringe and expelling fluid from the set (Figure 9). Connect EasyFill[™] syringe and tubing set to catheter and turn the stopcock off (Figure 10).
- To inflate, pull back on the syringe to draw fluid from the bag. Depress the syringe to push fluid into the balloon (Figure 11).
- Verify that balloon is not below the cervix.
- **Do not exceed maximum balloon fluid volume of 500 mL.**
- When inflation is complete, turn the stopcock off and remove EasyFill[™].
- Connect catheter to a drainage bag (Figure 12) to monitor bleeding (sterile saline may be used to remove clots or occlusions from the tubing).

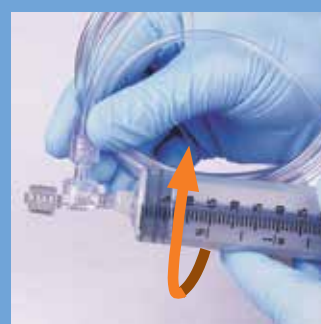


Figure 7

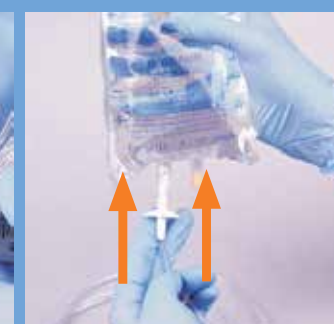


Figure 8

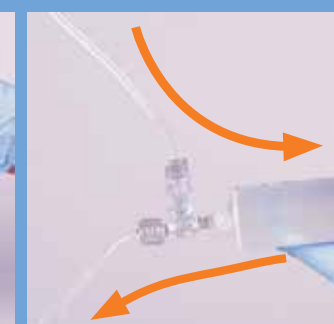


Figure 9

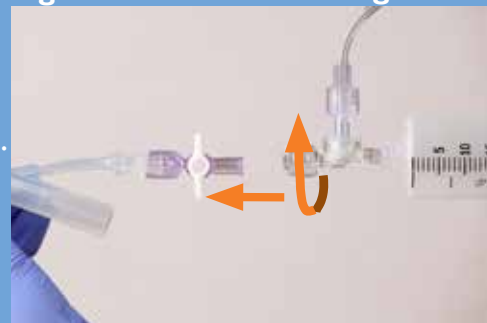


Figure 10

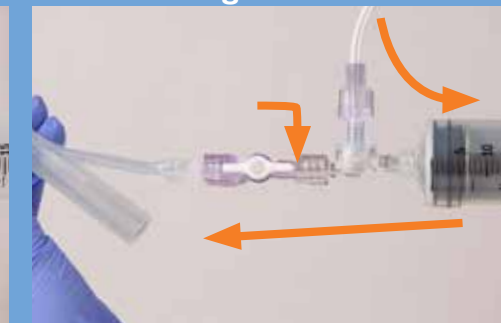


Figure 11



Figure 12

4. CONTINUED MONITORING

- Periodically assess whether the space between the balloon and fundus is continuing to expand. Evaluate the amount of blood and clots between the balloon and fundus. Ultrasound may be used to identify the top of the balloon.
- **CAUTION: Be aware of the possibility of a concealed hemorrhage. Deteriorating or non-improving conditions may indicate more aggressive treatment.**

5. CATHETER REMOVAL

- **Catheter indwell time should not exceed 24 hours.**
- Reversing the inflation process, using the syringe, aspirate fluid from the balloon (Figure 13).
- If faster deflation is indicated open the stopcock and allow fluid to drain (Figure 14).

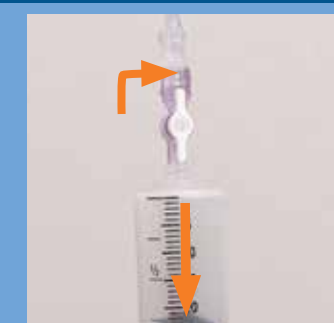


Figure 13

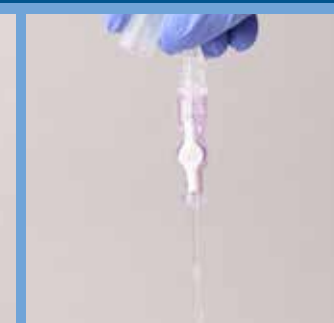


Figure 14