



BT-Cath[®]

Balloon Tamponade Catheter with EasyFill™ Inflation System

Instructions For Use

REF **BTC-ESY**

Pouch Contents: (Two Pouches per Box)

- 1 ea. Balloon Tamponade Catheter with Stopcock
- 1 ea. 60 ml Syringe
- 1 ea. EasyFill™ Bag Spike/Tubing Set with Bonded Dual Check-Valve

Cautions:

- Federal (USA) law restricts this device to sale by or on the order of a clinician.
- Sterile unless package damaged or opened. Examine the package prior to opening. Do not use the device if the package is open or damaged.
- Carefully read and follow all instructions prior to use.
- Close patient monitoring is required at all times during and after balloon tamponade use.

Precautions:

- Prophylactic antibiotics should be considered when this device is placed.
- Avoid contact with device by sharp instruments or clamps, since these might damage the soft balloon or catheter material and result in device failure.
- Avoid excessive force when inserting balloon into vagina and uterus.
- Urine output should be monitored while the device is in use.
- Perform a vaginal exam after balloon inflation to ensure the balloon is not below the cervix.
- Be aware of the possibility of a concealed hemorrhage.

Warnings:

- This device is intended as a temporary means of establishing hemostasis in cases indicating conservative management of postpartum uterine bleeding.
- Device should not be left indwelling for more than twenty-four (24) hours.
- Maximum inflation volume is 500 mL.
- Clinical data to support the safety and effectiveness of balloon tamponade in the setting of uterine atony are limited.
- 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 per hospital protocol should be followed.
- There are no clinical data to support the use of this device in DIC.
- Patient monitoring is an integral part of managing postpartum hemorrhage. Signs of deteriorating or non-improving condition should lead to a more aggressive treatment and management of patient uterine bleeding.













Intended Use:

- BT-Cath is intended to provide temporary control or reduction of uterine bleeding during postpartum hemorrhage that is unresponsive to standard therapy including massage and oxytocin administration, when conservative management is warranted.

Contraindications:

- cervical cancer
- purulent infections in the vagina, cervix or uterus
- postpartum vaginal bleeding unaccompanied by uterine bleeding
- disseminated intravascular coagulation (DIC)
- untreated uterine anomaly
- bleeding requiring surgical exploration (including hysterectomy) or angiographic embolization
- cases indicating hysterectomy
- pregnancy
- a surgical site that would prohibit the device from effectively controlling bleeding

Symbology:

	Medical Device
	Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner
	Refer to Instructions for Use
	Do not use if packaging is opened or damaged
	Single use, do not reuse
	Do not resterilize
	Sterilized using ethylene oxide
	Product code
	Manufacturer
	Representative in the European Union
	Device is not manufactured with natural rubber latex
	Device is not manufactured with phthalates

Catheter Placement:

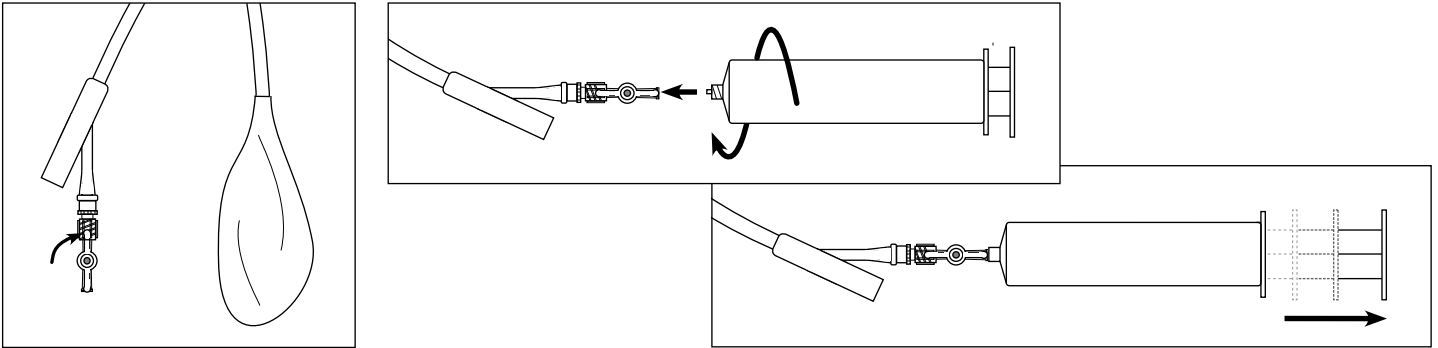
Note: A urinary drainage catheter should be placed in the patient's bladder prior to the insertion of BT-Cath to monitor urinary output.

Warning: The application of BT-Cath should be concomitant with close monitoring for signs of on-going uterine bleeding and/or disseminated intravascular coagulation.

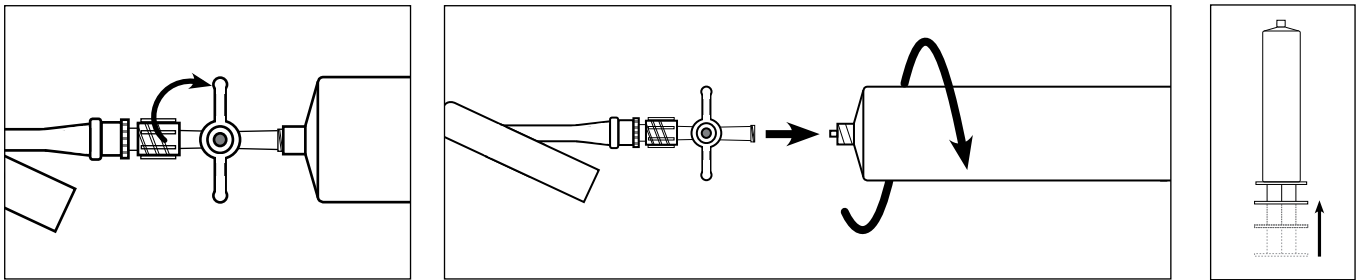
1. Determine uterine volume by direct examination or ultrasound.

Warning: Ensure that the uterus is clear of any placental fragments, arterial bleeding, lacerations or trauma before beginning deployment of the tamponade catheter.

2. While maintaining sterile technique, OPEN the stopcock. Attach the syringe to the available female luer port and remove air from the catheter balloon.



CLOSE the stopcock. Remove and expel air from the syringe.



3a. Catheter placement after vaginal delivery:

Insert the catheter by cupping the balloon end and directly inserting it through the dilated cervix to the fundus through the clinician's finger tips. Ultrasound may be used for guidance.

3b. Catheter placement after Cesarean delivery:

Warning: Careful insertion procedure should be followed to minimize hysterotomy repair disruption. Catheter placement at time of laparotomy under direct visualization and palpation is recommended.

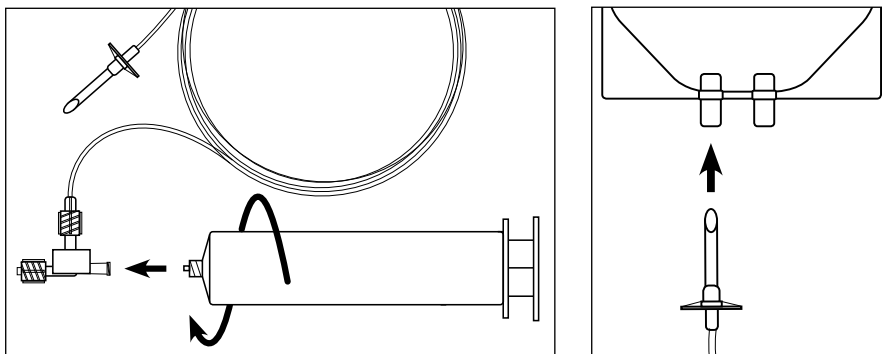
Unscrew and remove the stopcock from the catheter's silicone "Y" connector. Leading with the catheter's silicone "Y" connector, insert catheter tubing through the abdominal/uterine wall incision and thread the drainage/inflation lumen through the cervix and vagina until the entire balloon is within the uterine cavity. Reattach the blue stopcock to the catheter's silicone "Y" connector after catheter placement. Close the incision per normal procedure, taking care to avoid puncturing the balloon while suturing. Ensure that the hysterotomy is securely sutured prior to balloon inflation. Follow step 2 instructions for removing air from balloon.

4. Prime the EasyFill™ Tubing:

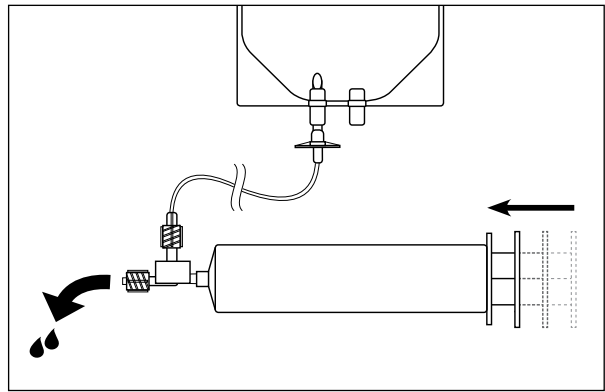
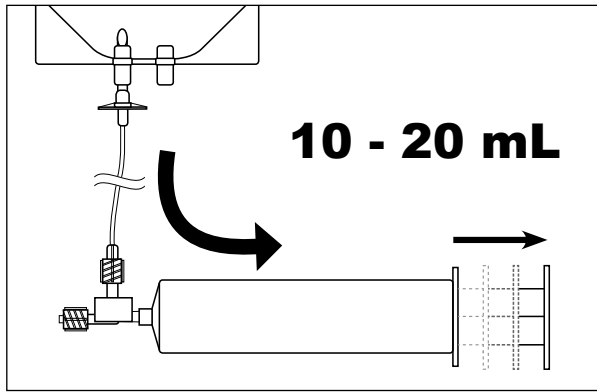
a. Attach the syringe to the available female luer port of the EasyFill™ tubing set.

b. Spike a 500 mL bag of sterile saline solution with the bag spike bonded to the other end of the EasyFill tubing.

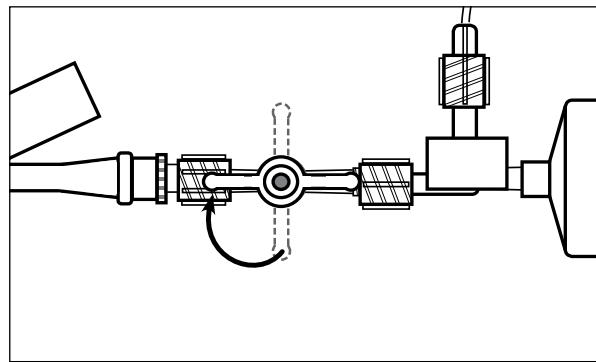
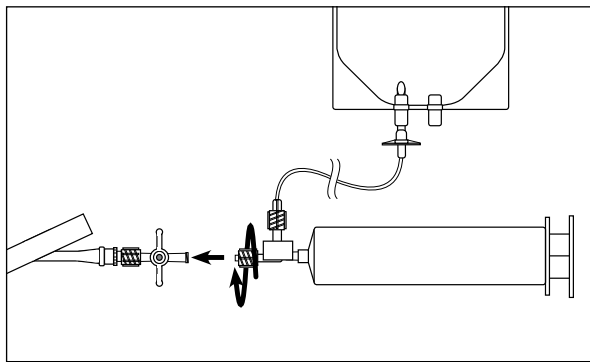
Precaution: A prefilled 500 mL bag of saline may be used to help avoid the possibility of overfilling the balloon.



- c. Draw 10-20 mL of saline from the bag through the tubing into syringe.
- d. Depress the syringe plunger until fluid flows from the tubing set.



- e. Connect the EasyFill™ system to the available female luer connector of the BT-Cath.
- f. OPEN the BT-Cath stopcock.



Caution: Do not infuse anything other than sterile saline into the balloon.

The infusion procedure begins with one hand in the vagina and an abdominal hand on the uterine fundus to confirm correct position of the balloon against the uterine wall and uterine expansion as the balloon is filled.

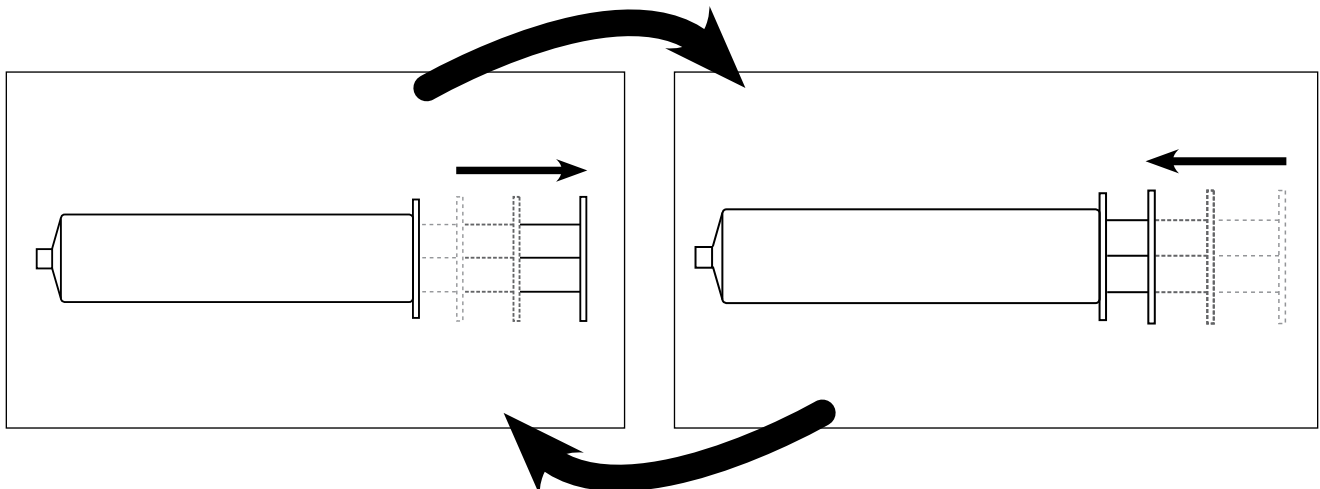
Warning: Rapid infusion of saline into the balloon at high pressure may increase the risk of uterine rupture.

5. Use the EasyFill system to inflate BT-Cath. Pull back on the syringe to draw fluid from the bag and depress the syringe to push fluid into the BT-Cath balloon.

6. Incrementally inflate the BT-Cath balloon only until tamponade is achieved, taking into account the predetermined uterine volume.

Warning: Maximum fill volume is 500 mL, but patients often require less than 500 mL to achieve tamponade.

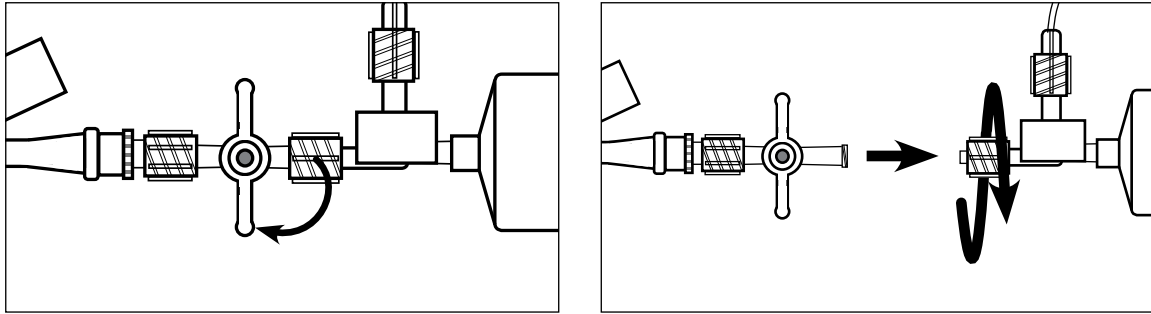
Precaution: Although rapidly reaching effective tamponade of the uterus is desired for stopping bleeding, the clinician should conduct repeated/continued evaluations of bleeding, volume infused and resistance to fill considering patient characteristics such as uterine wall thickness and surgical history in order to determine whether each incremental syringe infusion is warranted and safe, particularly in regard to possible risk of uterine rupture.



7. Should the balloon become dislodged from the uterus, deflate balloon, reposition and reinflate. Vaginal packing may be considered to augment catheter placement.

Precaution: Perform a vaginal exam after balloon inflation to ensure the balloon is not below the cervix.

8. Once balloon has been inflated to desired volume or tamponade has been achieved, CLOSE the stopcock and remove the EasyFill™ system.



9. Connect the catheter drainage port to a fluid collection bag to monitor lost blood volume.

Caution: Catheter drainage port and tubing should be free of clots or occlusions to properly monitor the progression of hemostasis.

Sterile isotonic saline may be used to flush the drainage lumen.

Warning: Irrigation should not be initiated for the purpose of dislodging or removing clots from the uterus.

10. Once tamponade is achieved, 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 and/or management of uterine bleeding.

Catheter Removal:

Warning: To reduce the risk of infection, catheter indwell time should not exceed twenty-four (24) hours. The balloon should be deflated and removed when it is no longer needed to control bleeding, if less than 24 hours.

1. Remove any vaginal packing, if applicable.

2. Use the 60 mL syringe to aspirate the sterile solution from the balloon and discard per hospital protocol. Continue incremental aspiration until balloon is deflated and can be safely removed from the patient. If faster balloon deflation is indicated, the saline may also be drained from the balloon by opening the stopcock, or the catheter shaft may be cut.

3. Remove catheter from patient by carefully sliding it out of the uterus, through the cervix and vagina.

4. Continue careful observation of the patient after removal for signs of continued bleeding or hemodynamic instability.

Disposal

Discard BT-Cath and aspirated fluids per hospital protocol for products contaminated with bodily fluids and tissue.

Reuse:

- One time use for a single patient.
- Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process.
- This device is not structurally designed or validated for reuse.

EU Notice:

Any serious incident (as defined in EU MDR Ch. I, Article 2 (65)) that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State where the incident occurs.



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US Patent No. 8,123,773
PN: 58325 REV: 050721