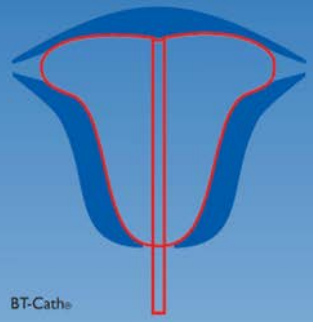
BT-Cath®

Balloon Tamponade Catheter for Postpartum Hemorrhage

Simple & Timely When it's Needed Most.



Catalog No. BTC-100

BT-Cath's soft silicone balloon material contours to the internal uterine shape.

The intrauterine drainage port is flush with the top of the balloon allowing **placement near the fundus.**

Several design components facilitate **timely balloon inflation.**

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Call customer service at 800-533-4984 or access www.utahmed.com for more information.

U.S. Patent 8,123,773

PN: 58304 REV: 111523

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STERILE EO

℞ ONLY

PHT

LATEX

PN: 58343 REV: 041024

BT-Cath®

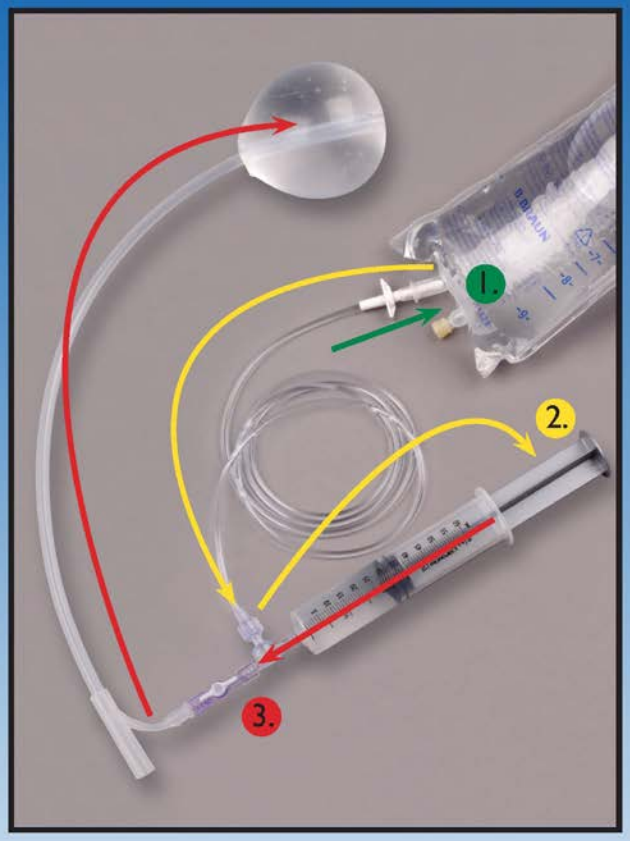
with **EasyFill™** Inflation System (Catalog No. BTC-ESY)

- Single-person, simplified operation.
- Allows inflation directly from the fluid bag.
- Creates a closed system.

1. **Spike** a 500 mL bag of fluid.

2. **Prime the tubing** by attaching the syringe and drawing fluid through the tubing.

3. **Inflate** by connecting EasyFill™ to BT-Cath and pushing fluid into the balloon.



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Catalog Numbers	Description	Packaging
BTC-100	BT-Cath with bag spike and 2 syringes	2/box
BTC-ESY	BT-Cath with EasyFill inflation system	2/box

Customer Service
US: 1-800-533-4984
UK: (01794) 525100

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BT-Cath with **EasyFill** Inflation System.

Part No. BTC-ESY

ACOG Clinical Management Guidelines:

"When treating postpartum hemorrhage, it is necessary to balance the use of conservative management techniques with the need to [timely] control the bleeding and achieve hemostasis."

ACOG Practice Bulletin Number 76, October 2006

PN: 58343 REV: 041024

"The advantages of using balloon tamponade include its ease of use, rapid replacement, immediate results, and ability to measure further bleeding after the catheter is placed."

Intrauterine balloon tamponade in the management of postpartum hemorrhage. American Journal of Perinatology, 24:6 2007 p. 363

PN: 58343 REV: 041024

Common Primary Management Steps

- Uterine Exploration
  - Bimanual Uterine Massage
  - Blunt Curettage
  - Laceration Suturing
- Additional Uterotonics
  - Oxytocin, Methylergonovine, 15-Methyl PGF, Dinoprostone, Misoprostol

Journal of Reproductive Medicine, Feb. 1999 p. 124

PN: 58343 REV: 041024

A systematic, stepwise approach to managing uterine hemorrhage includes the use of a Balloon Tamponade Catheter.

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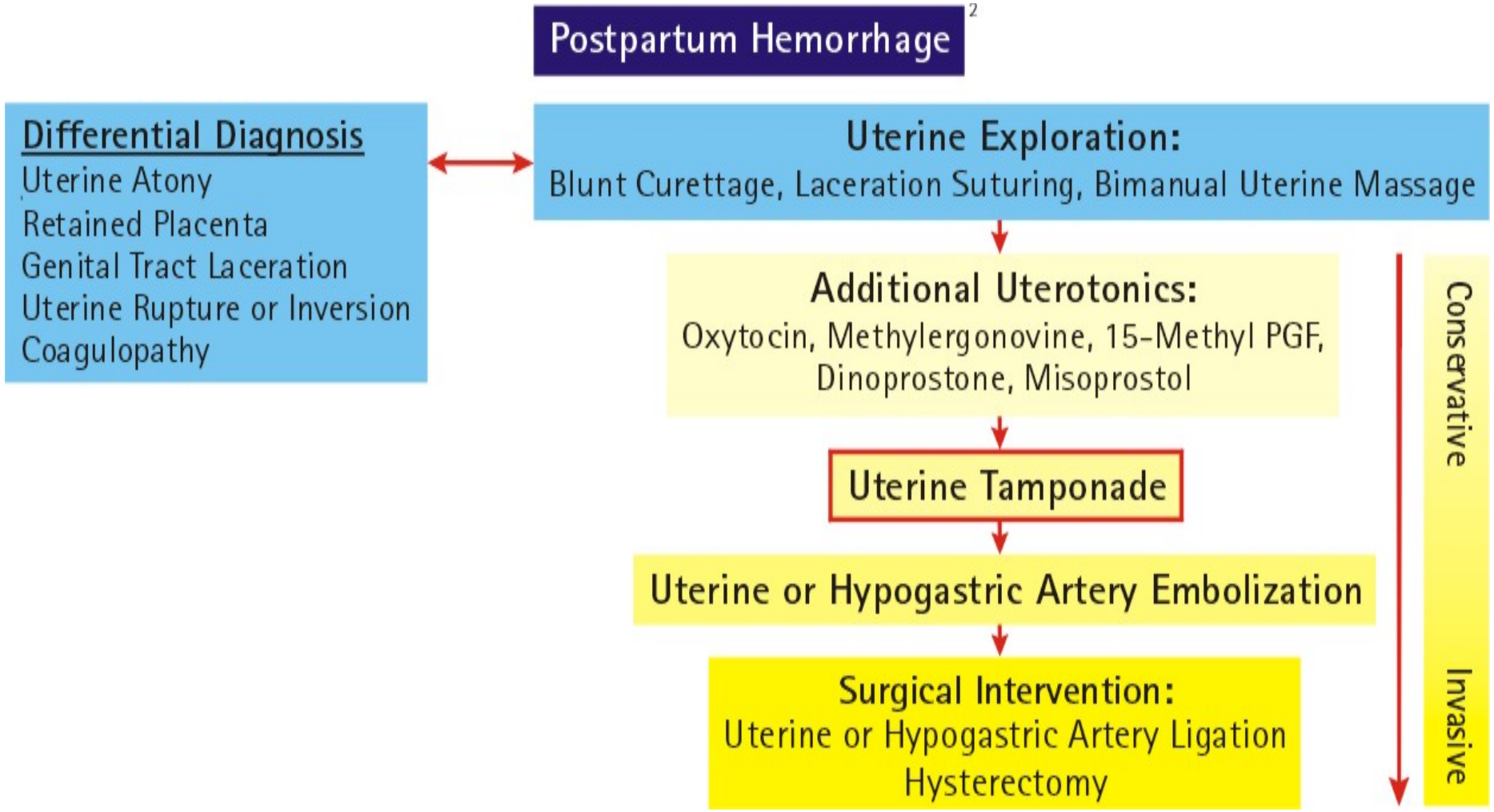
Balloon Tamponade Catheter for Uterine Hemorrhage



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Algorithm for treatment of postpartum hemorrhage. Journal of Reproductive Medicine, Feb. 1999 p. 124

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Balloon Tamponade Catheter for Uterine Hemorrhage

BT-Cath is a single-use, disposable, silicone, dual lumen catheter and balloon tamponade for managing uterine hemorrhage.

BT-Cath is **LATEX** and **DEHP** free.

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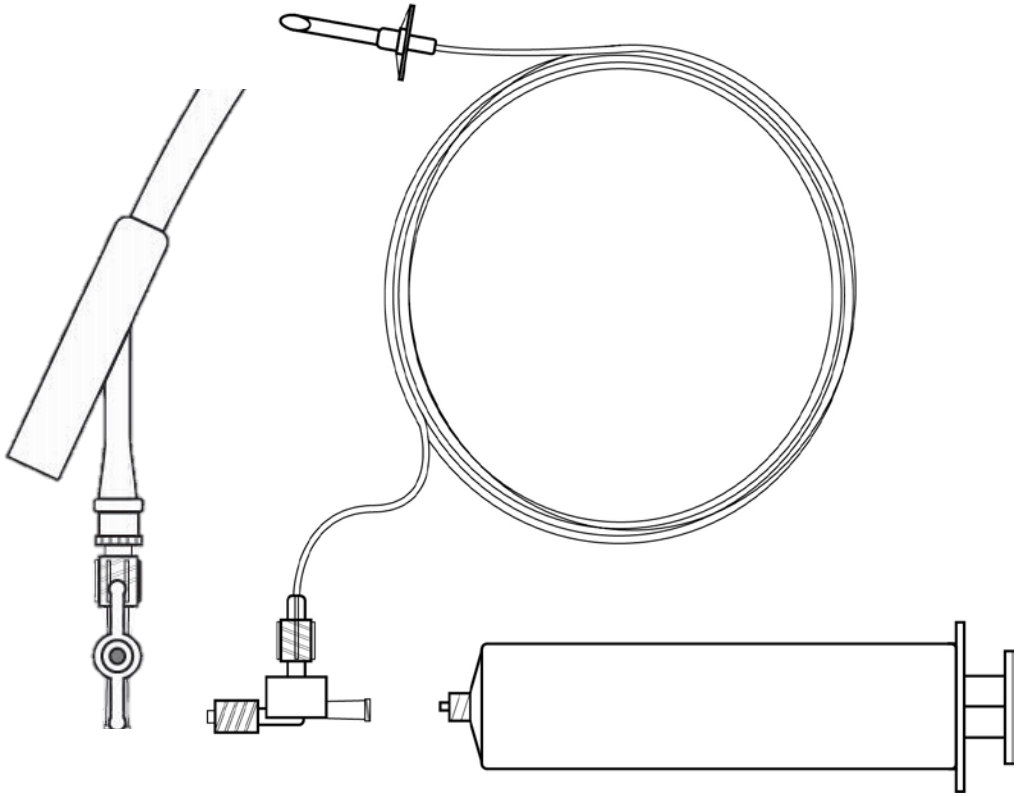
Sterile Contents:

1 ea. Balloon Tamponade Catheter with 1-Way Stopcock
1 ea. 60 mL Syringe
1 ea. EasyFill Tubing Set



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 with this device is placed.
- Avoid contact with device by sharp instruments or clamps, since these might damage the soft catheter 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:

- 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.
- 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.

Warnings (cont.):

- 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.

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.

Catheter Placement

Step 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.

Catheter Placement

Step 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.

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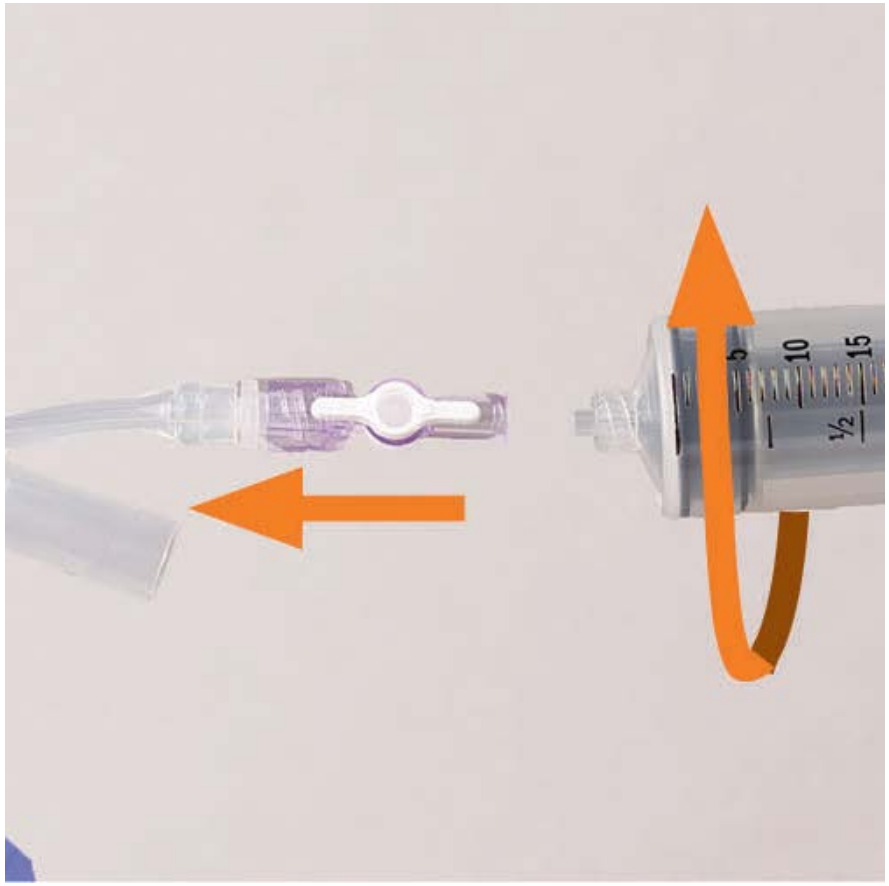
Balloon Tamponade Catheter for Uterine Hemorrhage



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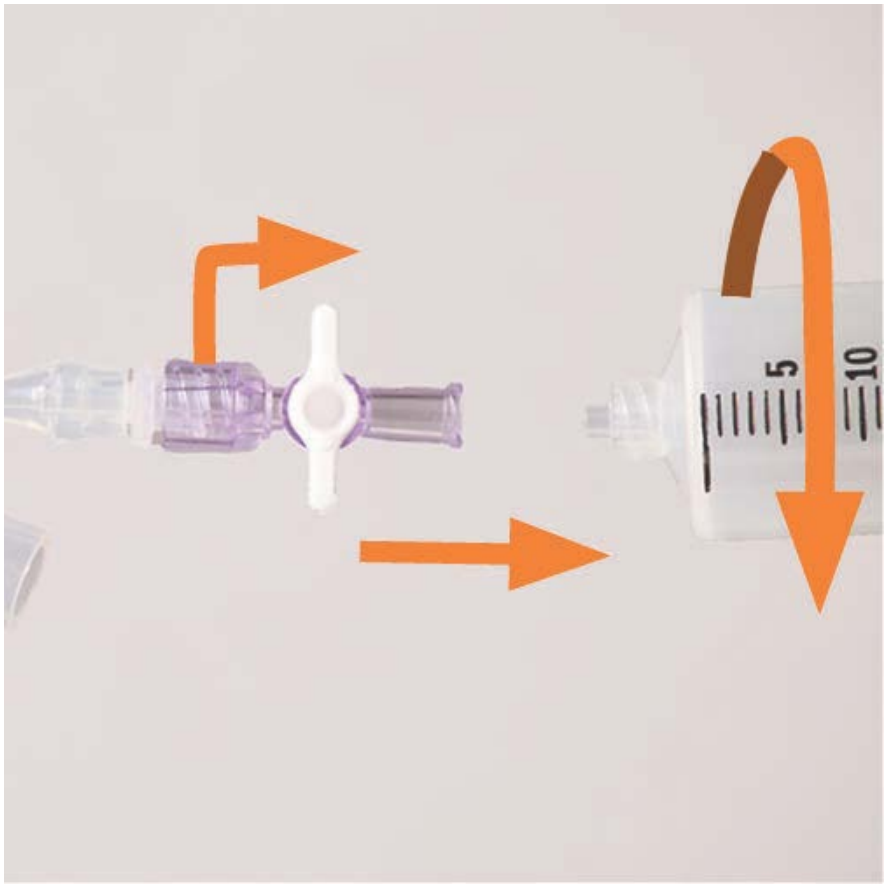
Balloon Tamponade Catheter for Uterine Hemorrhage



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Catheter placement after vaginal delivery:

Step 3a:

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.

Catheter placement after cesarean delivery:

Step 3b:

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.

Catheter placement after cesarean delivery:

Step 3b (cont.):

Unscrew and remove the stopcock from the catheter's silicone "Y" connector.

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Catheter placement after cesarean delivery:

Step 3b (cont.):

Leading with the catheter's silicone "Y" connector, insert catheter tubing through the abdominal/uterine wall incision and thread the drainage/inflation lumen though the cervix and vagina until the entire balloon is within the uterine cavity.

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Catheter placement after cesarean delivery:

Step 3b (cont.):

Reattach the 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. Follow step 2 instructions for removing air from balloon.

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Inflation with EasyFill

Step 4, Prime the EasyFill Tubing:

4a. Attach the syringe to the available luer port of the EasyFill Tubing Set.

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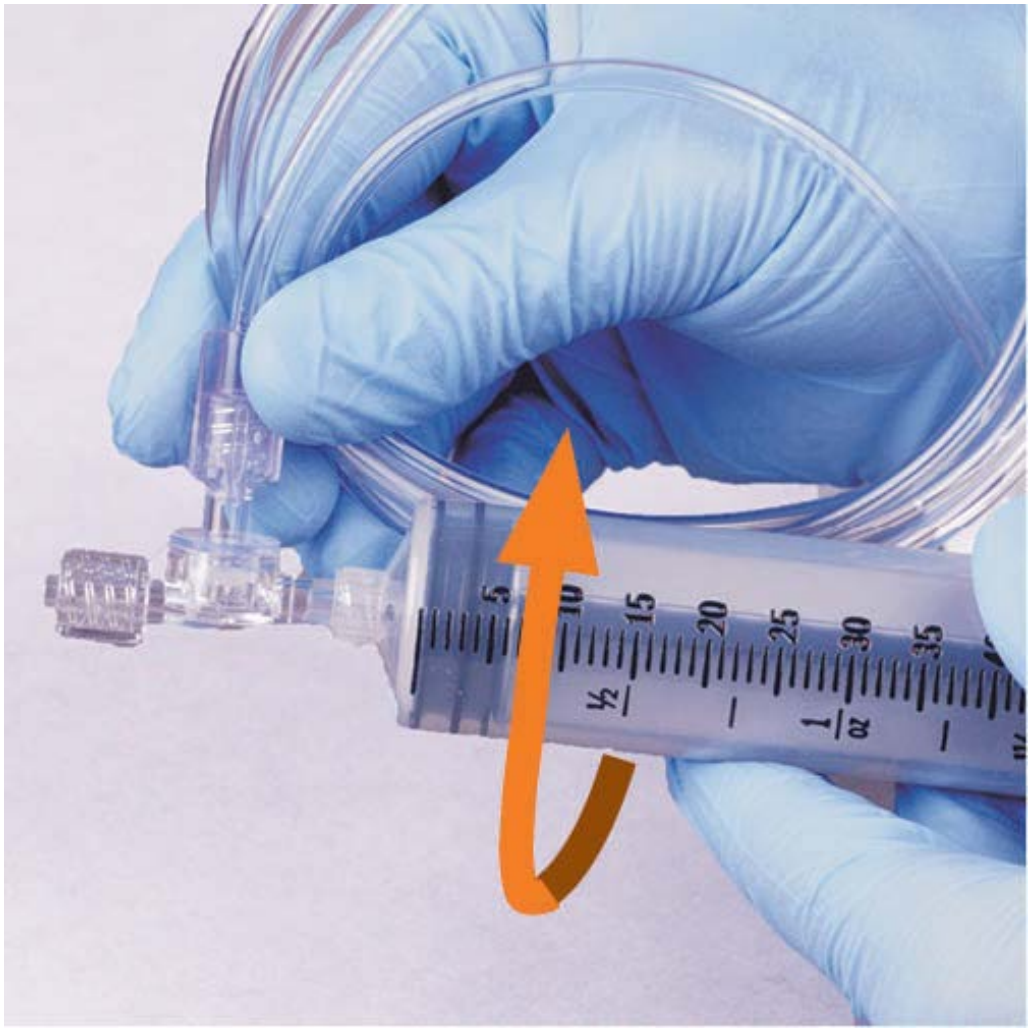
Balloon Tamponade Catheter for Uterine Hemorrhage



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Inflation with EasyFill

Step 4, Prime the EasyFill Tubing:

4b. 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.

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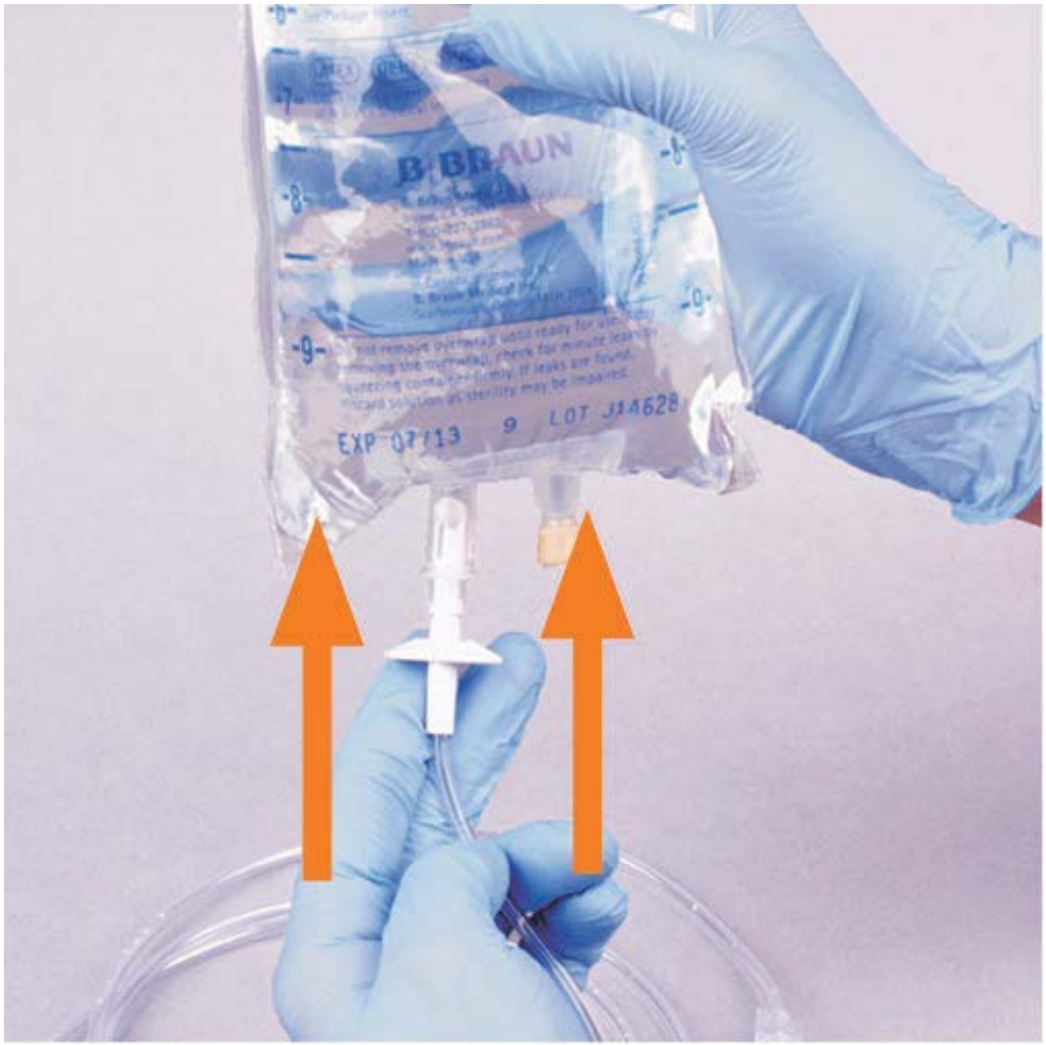
Balloon Tamponade Catheter for Uterine Hemorrhage



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Inflation with EasyFill

Step 4, Prime the EasyFill Tubing:

4c. Draw 10 – 20 mL's of saline from the bag through the tubing into the syringe.

4d. Depress the syringe plunger until fluid flows from the tubing set.

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Balloon Tamponade Catheter for Uterine Hemorrhage

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Inflation with EasyFill

Step 4, Prime the EasyFill Tubing:

4e. Connect the EasyFill system to the available female luer connector of the BT-Cath. Open the BT-Cath stopcock.

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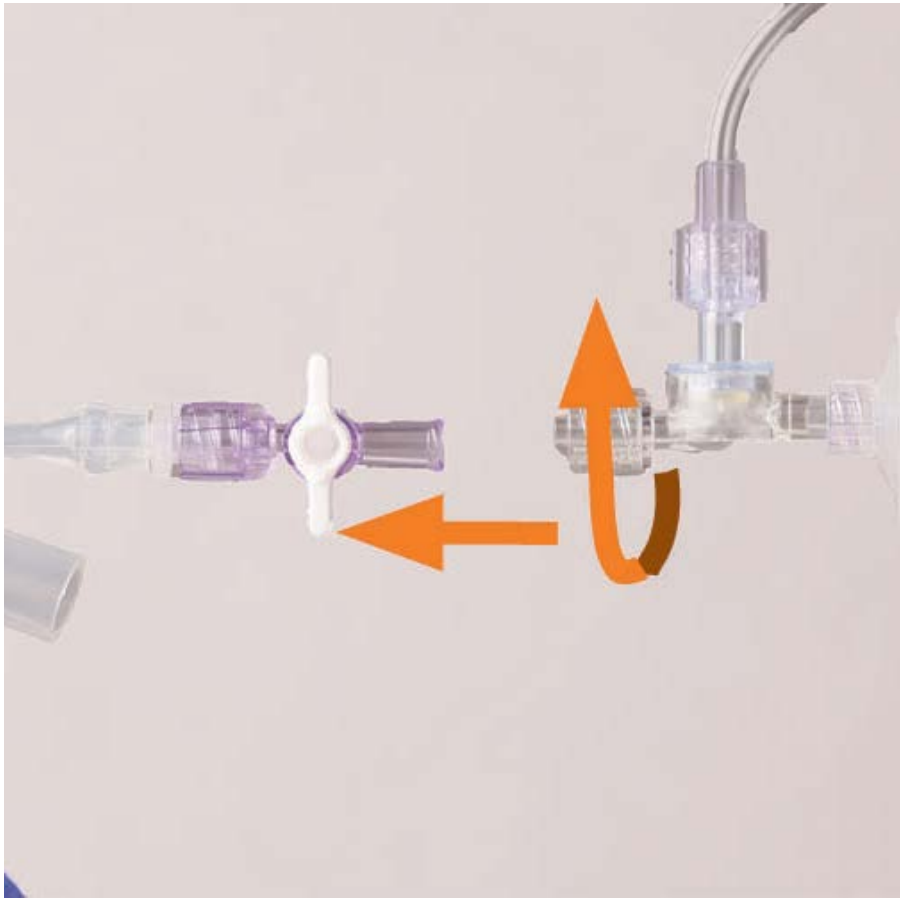
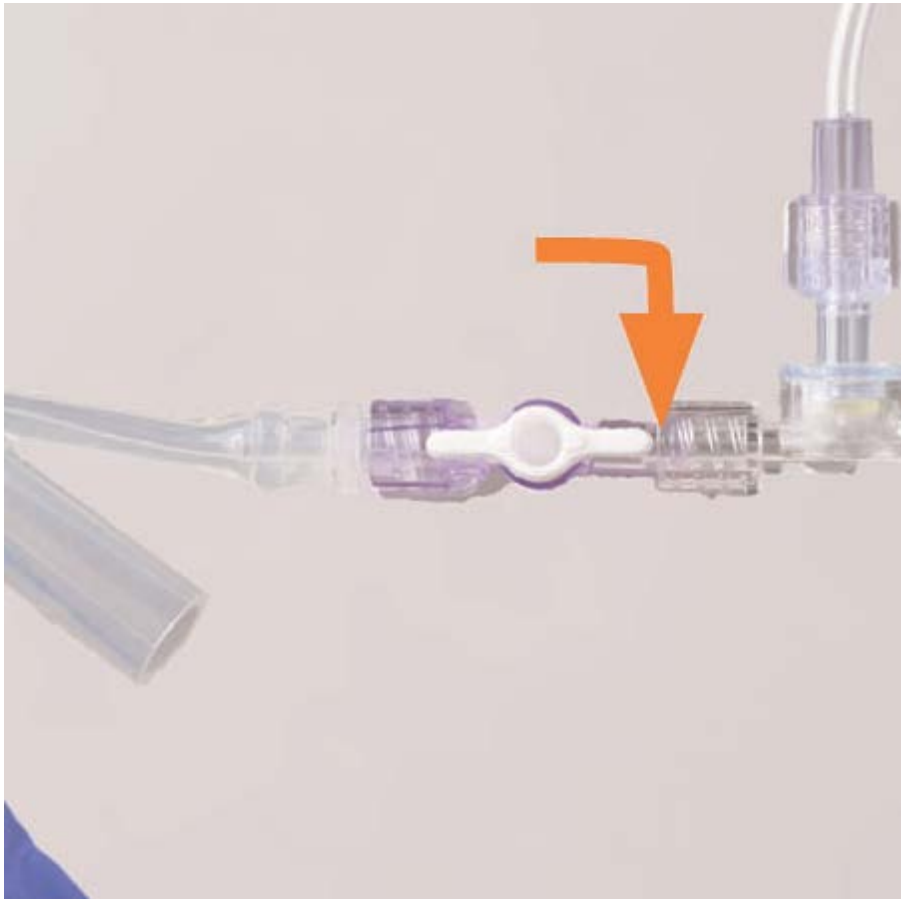
Balloon Tamponade Catheter for Uterine Hemorrhage





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Inflation with EasyFill

Caution:

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

Inflation with EasyFill

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 a high pressure may increase the risk of uterine rupture.

Inflation with EasyFill

Step 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.

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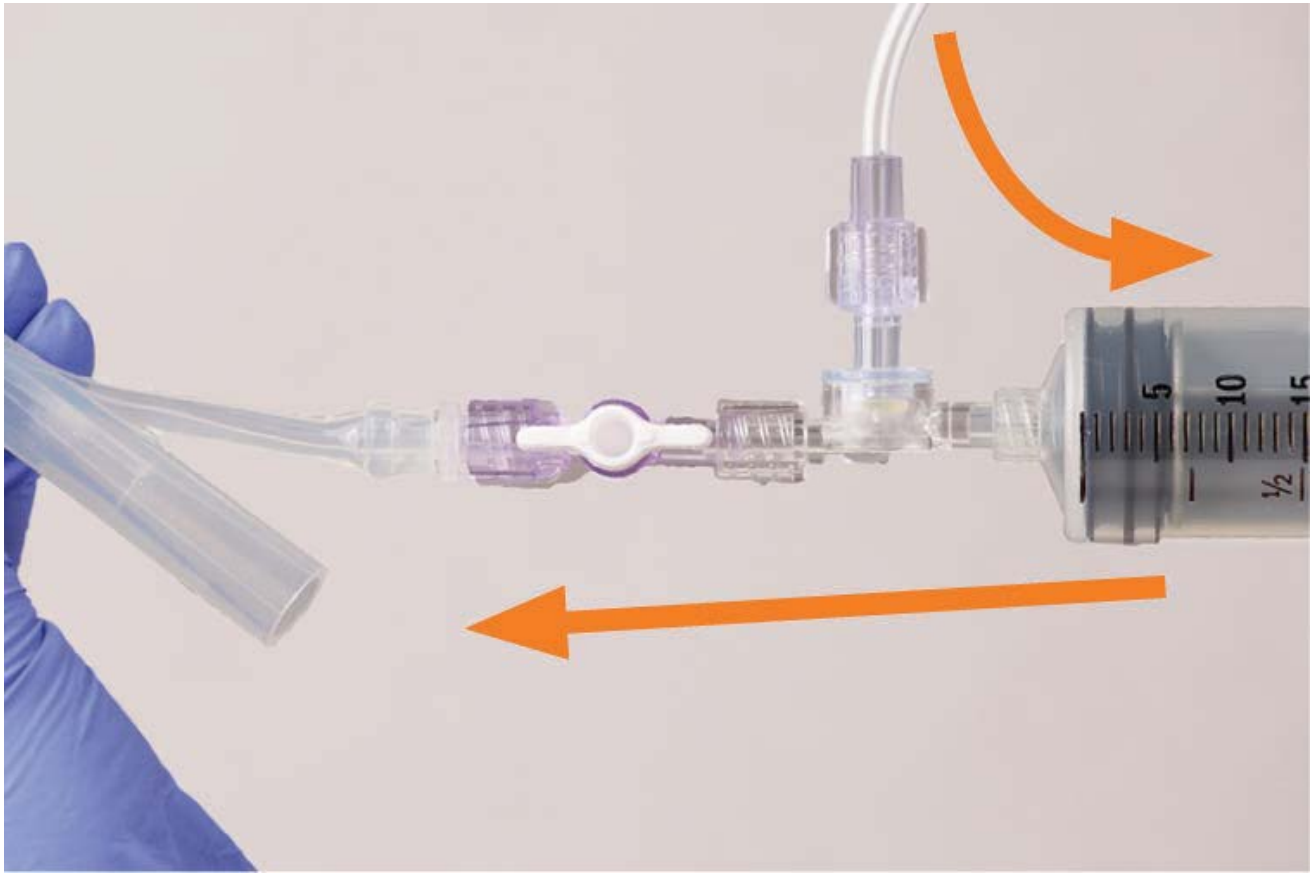
Balloon Tamponade Catheter for Uterine Hemorrhage



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Inflation with EasyFill

Step 6:

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

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Inflation with EasyFill

Step 6 (cont.):

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.

Inflation with EasyFill

Step 7:

Should the balloon become dislodged from the uterus, deflate the 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.

Inflation with EasyFill

Step 8:

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

Continued Monitoring

Step 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.

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Continued Monitoring

Step 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.

Catheter Removal

Step 1:

Remove any vaginal packing, if applicable.

Catheter Removal

Step 2:

Reversing the inflation process, 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.

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Catheter Removal

Step 2 (cont.):

If faster balloon deflation is indicated, the saline may also be freely drained from the balloon by opening the stopcock, or the catheter may be cut.

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Catheter Removal

Step 3:

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

Catheter Removal

Step 4:

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

Customer Service
(800) 533-4984

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