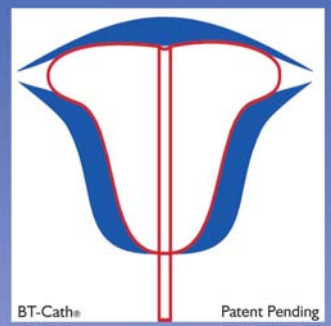
BT-Cath®

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.**

UTAH MEDICAL PRODUCTS INC.

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

PN: 58304 REV: 020812

STERILE EO

℞ ONLY

DEHP LATEX

PN: 58322 REV: 102213

PN: 58322 REV: 102213

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: 58322 REV: 100210

"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: 58322 REV: 102213

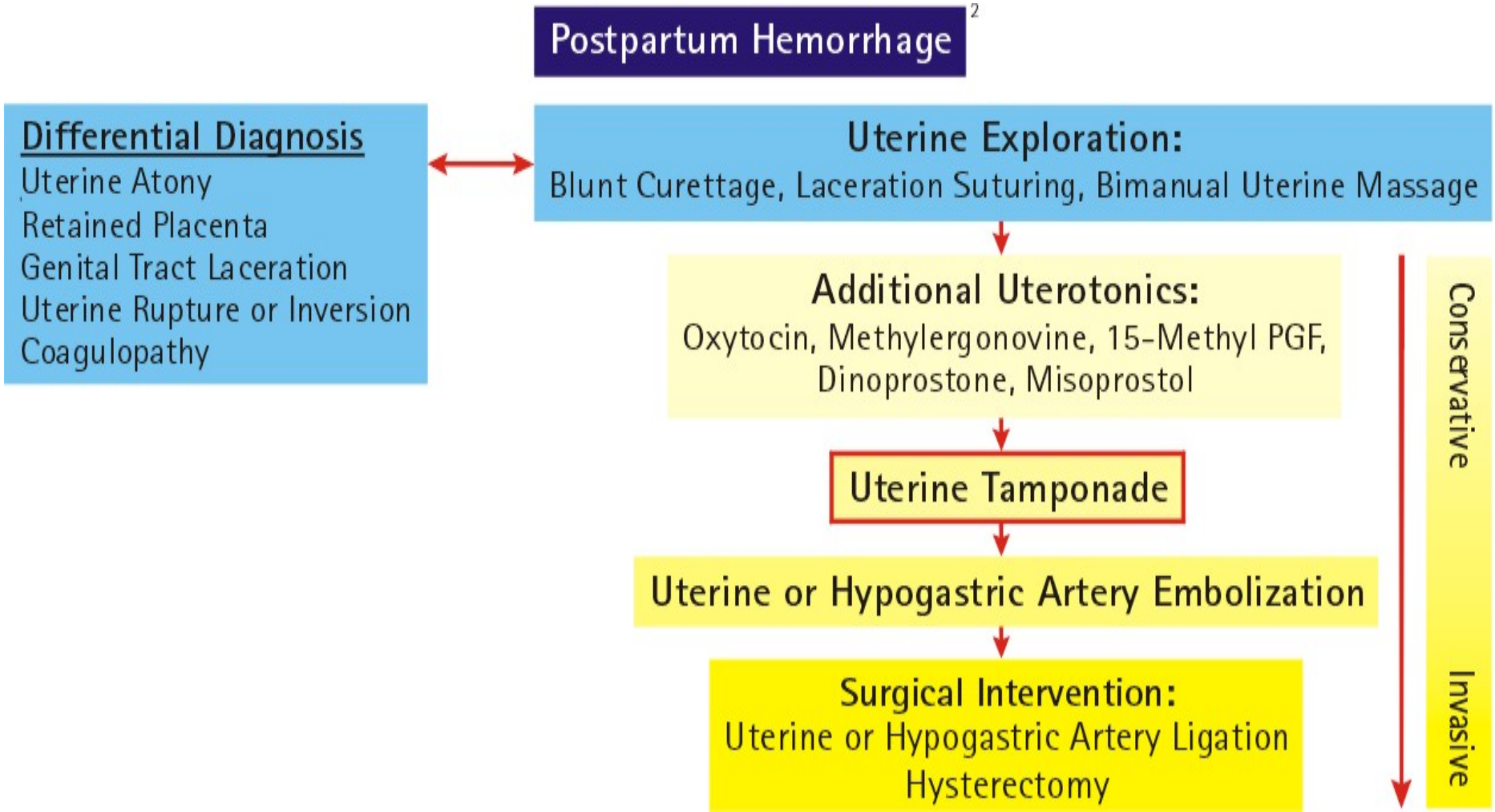
Common Primary Management Steps

- 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: 58322 REV: 102213

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



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

BT-Cath®

Uterine Balloon Tamponade Catheter for Postpartum Hemorrhage

"The advantages of using balloon tamponade include its ease of use, rapid replacement, immediate results, and ablility to measure further bleeding after the catheter is placed."[3]

Patent Pending

Unique Balloon Design is easy to insert, contours to uterine shape, provides drainage at the fundus, and does not require an invasive surgical procedure to remove.

Intrauterine Drainage Port is flush with the catheter balloon.

Dual Lumen Catheter allows infusion of saline to expand the balloon while providing uterine drainage to monitor the progression of hemostasis.

Two Syringes are provided with each BT-Cath for uninterrupted infusion of saline for controlled tamponade expansion.

Durable Silicone Components allow for patient comfort while maintaining optimal biocompatibility and strength.

Bag Spike and **Stopcock** are equipped with **check valves** for efficient saline infusion without the need to repeatedly open and close a stopcock.

UTAH MEDICAL PRODUCTS INC.

USA: 7043 South 300 West • Midvale, UT 84047
Customer Service, Toll Free: 800.533.4984

Ordering Information

Part Number: BTC-100
Packaging: 2 per box

Single Use, Sterile
LATEX and DEHP Free

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

PN: 58322 REV: 102213

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage

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

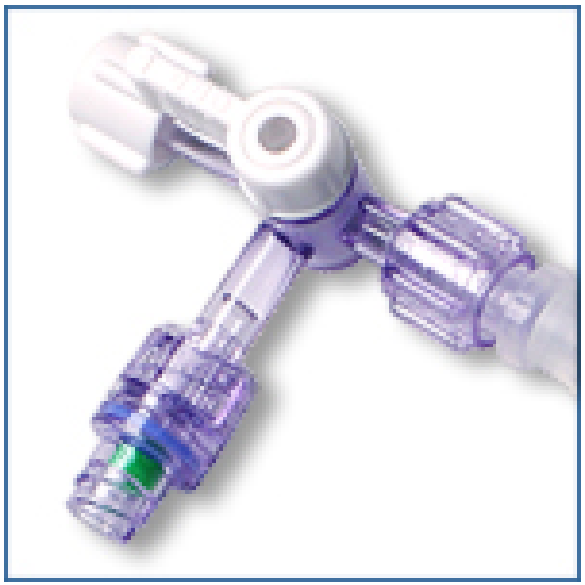
BT-Cath is **LATEX** and **DEHP** free.

UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Sterile Contents:

1 ea. Balloon Tamponade Catheter with 4-Way Stopcock and Check Valve
2 ea. 60 mL Syringes
1 ea. Bag Spike with 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 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 manageing 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 following any intrauterine surgical procedure requiring hemostasis.

Contraindications:

- Cervical cancer
- Purulent infections in the vagina, cervix or uterus.
- Postpartum vaginal bleeding unaccompanied by uterine bleeding.
- Disseminated intravascular coagulation
- 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 this device 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.

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

Catheter Placement

Step 2:

While maintaining sterile technique, turn the stopcock off to the white capped standard locking port. Attach one of the provided sterile syringes to the check valve, and remove any excess air from the catheter balloon. Remove the syringe and expel air from the syringe.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage

UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

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 blue stopcock from the catheter's silicone "Y" connector.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage

UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

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.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage

UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Catheter placement after cesarean delivery:

Step 3b (cont.):

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.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage

UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Catheter Placement

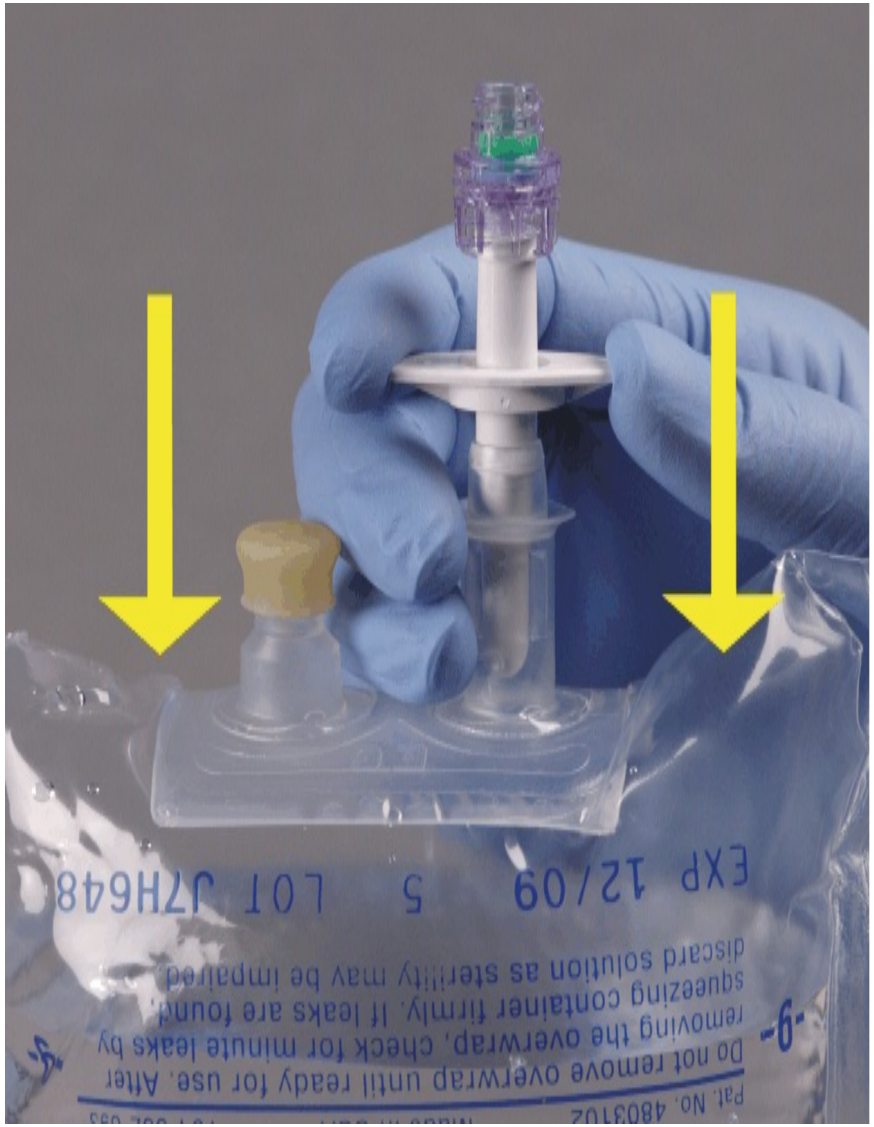
Step 4:

Spike a bag of sterile saline solution with the spike provided in the sterile kit. Fill the 60 mL syringes from the bag.

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

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage



UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Catheter Placement

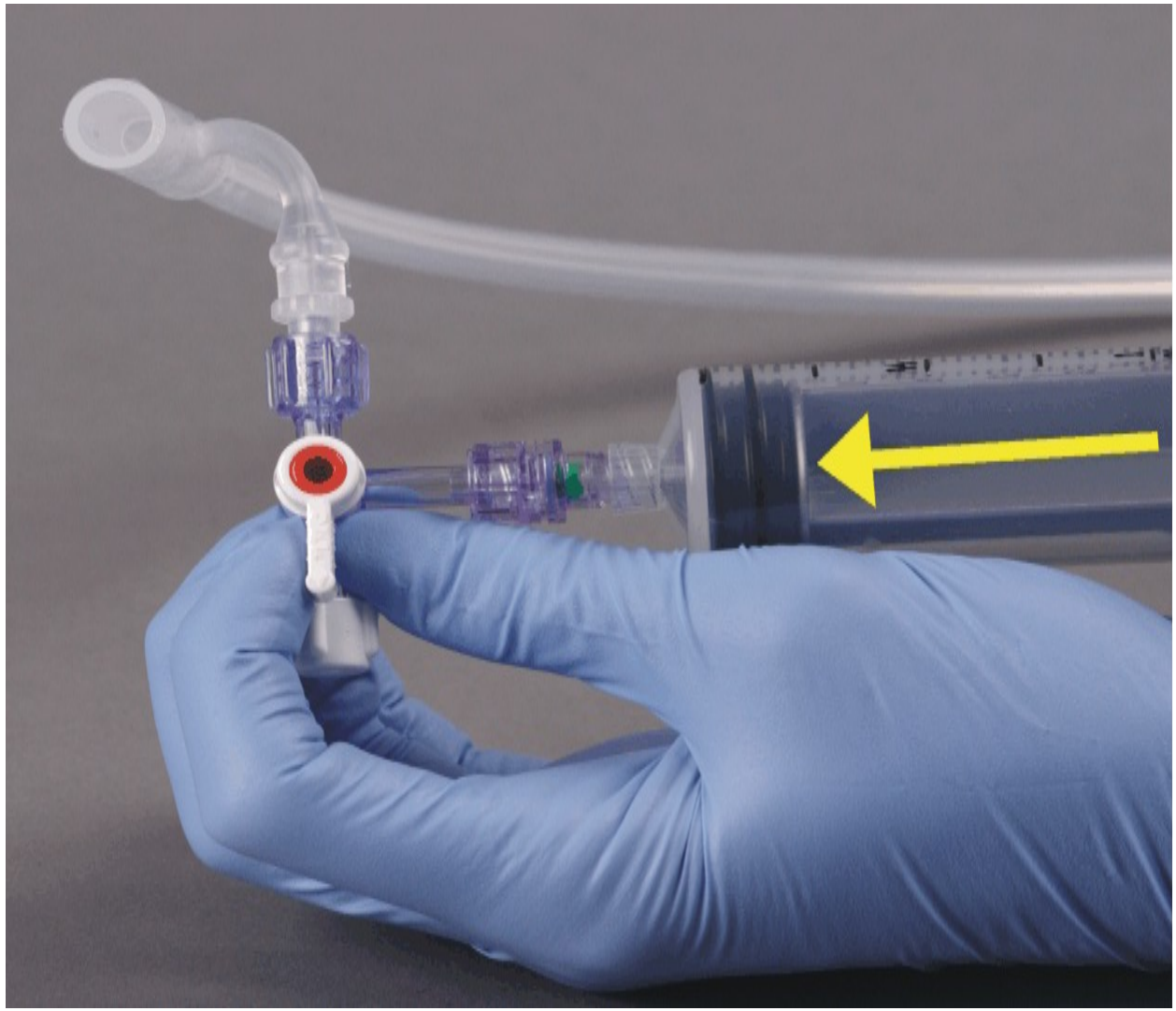
Step 5:

Connect a saline-filled 60 mL syringe to the proximal luer connection which contains a check valve

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

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage



UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Catheter Placement

Step 5 (cont.):

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.

Catheter Placement

Step 5 (cont.):

The second 60 mL syringe provided in the kit may be filled by an assistant during infusion of saline from the first syringe in order to minimize elapsed time to reach tamponade. The check valve eliminates the need to operate a stopcock when changing syringes.

Catheter Placement

Step 6:

Using additional syringes of saline, incrementally inflate the balloon only until tamponade is achieved.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage

UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Catheter Placement

Step 6:

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.

Catheter Placement

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.

Catheter Placement

Step 8:

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.

Catheter Placement

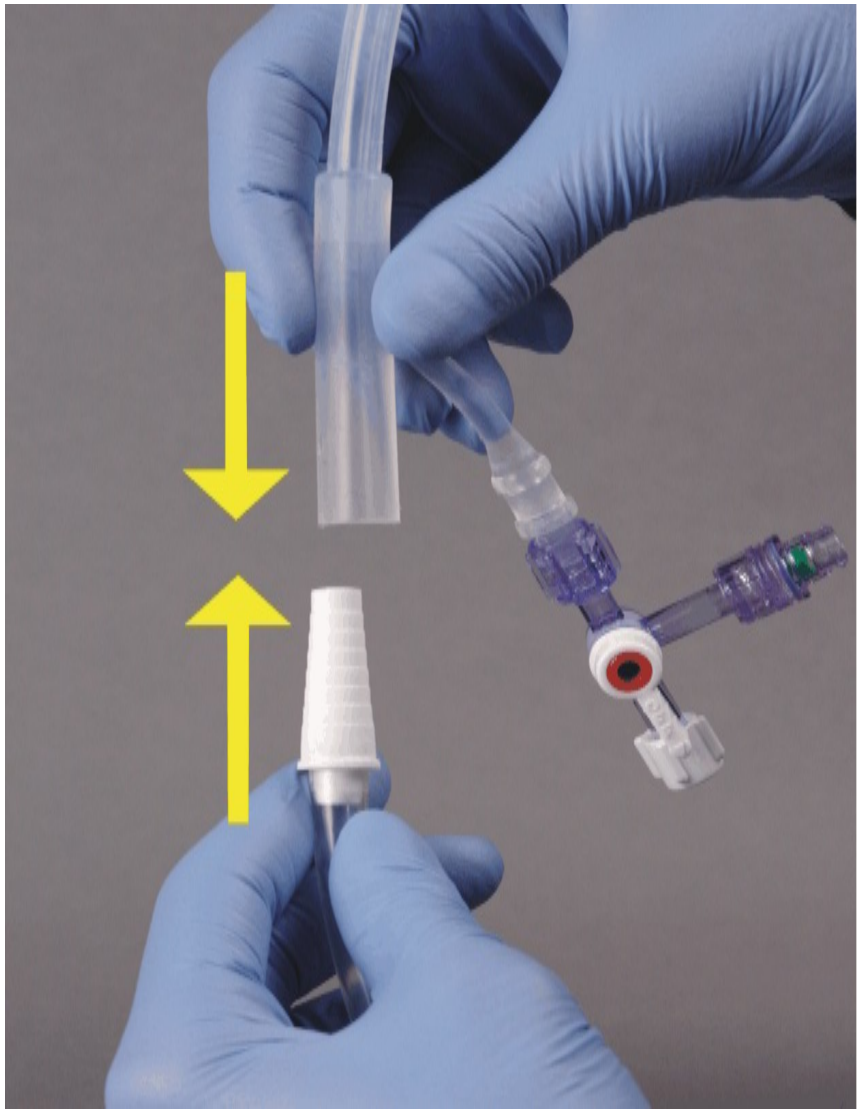
Step 8 (cont.):

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.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage



UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Catheter Placement

Step 9:

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 an vaginal packing if applicable.

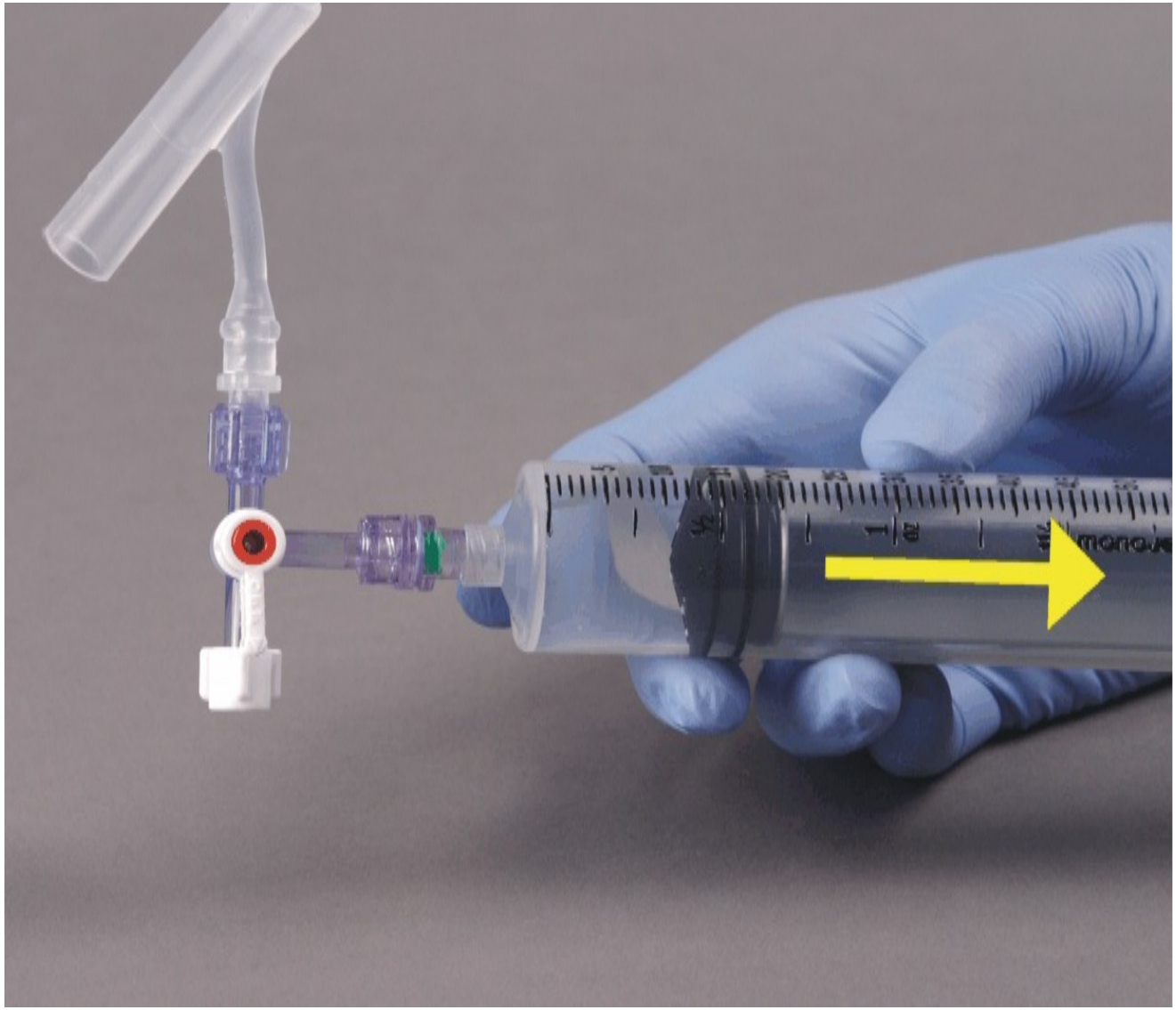
Catheter Removal

Step 2:

Reversing the insertion process, using the syringes provided, aspirate the sterile solution from the balloon and discard per hospital protocol. Continue incremental aspiration until catheter balloon is deflated and can be safely removed from the patient.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage



UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

Catheter Removal

Step 2 (cont.):

If faster balloon deflation is indicated, the saline may also be removed from the balloon by turning the stopcock off to the port with the check valve, removing the white cap from the standard locking hub and allowing fluid to drain.

BT-Cath®

Balloon Tamponade Catheter for Uterine Hemorrhage

UTAH MEDICAL PRODUCTS INC.

PN: 58322 REV: 102213

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

www.utahmed.com