GLENVEIGH BELFORT-DILDY OBSTETRIC TAMPONADE SYSTEM
PACKAGE INSERT

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

INSTRUCTIONS FOR USE

Contents:
One Pouch per dispensing carton
Sterile Contents of each Pouch:
1 each Belfort-Dildy Obstetric Tamponade System (OTS)

GLENVEIGH BELFORT-DILDY OTS

Uterine balloon
Vaginal balloon
Irrigation port
Traction triangle
Drainage lumen

Vaginal balloon volume adjustment port
Vaginal balloon distance adjustment

Balloons can be inflated/deflated separately

Saline bag direct infusion port (vaginal)
Uterine balloon volume adjustment port
Saline bag direct infusion port (uterine)
Product Description:
The Belfort-Dildy Obstetric Tamponade System (OTS) is a disposable, multiple lumen catheter attached to an inflatable balloon system designed to provide tamponade for controlling hemorrhage from the uterus and vagina. The device consists of two inflatable balloons: The upper uterine balloon is inflated inside the uterus and the lower vaginal balloon is inflated inside the vagina. Inflation is accomplished with isotonic intravenous fluid such as normal saline or Ringers Lactate. The uterine balloon catheter has separate lumens to enable inflation/deflation, irrigation and drainage. The vaginal balloon catheter has a lumen to enable inflation/deflation. The uterine and vaginal balloons are permanently assembled and are not to be separated. The device may be retained in position for up to 24 hours in the post-operative mode of treatment. The Belfort-Dildy Obstetric Tamponade System (OTS) is supplied sterile in peel open pouches for one time use to a single patient.

Indications for Use:
The Belfort-Dildy Obstetric Tamponade System (OTS) is indicated for use in providing temporary control or reduction of postpartum uterine bleeding. Inflation of the vaginal balloon anchors the uterine balloon and provides vaginal tamponade if vaginal bleeding is present. The OTS should only be used in the setting of post-partum uterine bleeding when conservative management is warranted.

Contraindications:
- Arterial bleeding requiring surgical exploration or angiographic embolization
- A surgical site which would prohibit the device from effectively controlling bleeding
- Purulent infections of the vagina, cervix or uterus
- Cases indicating hysterectomy
- Cervical cancer
- Untreated uterine anomaly
- Disseminated intravascular coagulation
- Post-partum vaginal bleeding unaccompanied by uterine bleeding

Warnings:
- The application of this device should be concomitant with close monitoring for signs of on-going uterine bleeding and/or disseminated intravascular coagulation (DIC).
- Maximum recommended amount of fluid to be used in the upper balloon when it is in place within the uterus is 750ml. NOTE: Fill volume ≤ 500ml is usually sufficient for tamponade.
- To reduce the risk of uterine rupture, do not overfill uterine balloon. Begin fill at 250ml and gradually add fluid in increments ONLY UNTIL TAMPONADE IS ACHIEVED.
- Rapid infusion of fluid into uterine balloon at high pressure may increase the risk of uterine rupture.
- The fill volume of the uterine balloon must be determined clinically on a case-by-case basis. A maximum fill volume of 750ml may not be clinically appropriate or safe for all patients.
- Maximum recommended amount of fluid to be used in the lower vaginal balloon when it is in place in the vagina is 300ml.
- Always inflate the balloons with sterile isotonic liquid such as normal saline or Ringers lactate. Never inflate with air, carbon dioxide or any other gas.
- Device should not be left indwelling for more than 24 hours.
- The safety and effectiveness of the OTS have not been evaluated clinically.
Precautions:
- This device is restricted to use by a physician
- Close patient monitoring is required at all times during balloon use
- Carefully read and follow all instructions prior to use
- One-time use for a single patient
- The safety and performance of the BD-OTS has not been evaluated under reuse conditions. As this is a one-time single use device, Glenveigh does not recommend reuse of this device as it may cause harm to the patient.
- Sterile unless package damaged or opened. Sterilized by ethylene oxide. Examine the package prior to opening. Do not use the device if the package is open or damaged.
- Prophylactic antibiotics should be considered when this device is placed
- Do not use sharp instruments or clamps on the catheters or balloons since these could damage the device and result in failure.
- Avoid excessive force when inserting balloon into vagina and uterus. Using the Placement Method described below, guide it manually with one hand into the vagina and into the uterus through the cervix.
- Urine output should be monitored while the OTS is in use

Instructions for Use:

Catheter Placement:
Only physicians trained to perform vaginal/cervical examination and who have experience in the placement of an intrauterine catheter should perform the following procedure. The Belfort-Dildy Obstetric Tamponade System (OTS) may be used in cases of vaginal delivery and cesarean section.

Important:
- The position of the vaginal balloon with respect to the uterine balloon can be adjusted for patient anatomy by increasing or decreasing the distance between the two balloons.
- External traction may be applied at the physician’s discretion for cases that require individualization of care to increase tamponade effect by securing a 500 gram weight up to a maximum of 1000 grams (a 1/2 liter or liter IV bag) to the traction bar feature below the vaginal balloon.
- Catheter placement should be performed with concomitant ultrasound guidance to ensure complete insertion safety and reduce risk of iatrogenic injury with the device.

Placement Method:

1. The stopcock on the fill catheters may be used to remove excess fluid or residual air prior to placement or after placement as needed.
2. The “spikes” on the fill catheters allow use of standard IV bags for inflation. If a catheter is attached to an IV fluid bag prior to insertion, make sure to leave the fluid bag at or below the level of the balloon to prevent premature filling.
3. Insert the Belfort-Dildy Obstetric Tamponade System (OTS) by cupping the uterine balloon end of the catheter and directly inserting it through the dilated cervix to the
fundus through the clinician's finger tips under ultrasound guidance to ensure correct placement.

4. Advance the OTS until the entire upper balloon is within the uterine cavity and the vaginal balloon is arranged neatly within the vaginal cavity. The cervical cuff between the uterine and vaginal balloons should be within the cervical os. Ultrasound should be used to verify placement.

5. Once the balloons are properly placed, begin transferring the fluid from the IV bag into the uterine balloon – **always fill the uterine balloon first**.

6. The fill 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. The uterine balloon should be filled beginning with 250ml and increasing incrementally until bleeding is stopped or it is determined by the clinician that further fill may result in unsafe over-distension of the uterus. During and after each incremental fill, using ultrasound, the clinician should determine whether additional fill is warranted and safe, based on repeated/continued evaluations of bleeding, volume dispensed, resistance to fill and patient characteristics such as uterine wall thickness and surgical history. Most patients require less than 500ml to achieve tamponade.

7. Once tamponade is achieved, using ultrasound, identify the top of the balloon in the uterus. Evaluate the amount of blood and clots between the balloon and the fundus. It is advisable to periodically assess whether the space between the balloon and fundus is continuing to expand with blood despite apparent tamponade. Alternatively to ultrasound, when tamponade is achieved, mark the height of the fundus on the abdomen to allow for continued detection of increasing uterine size post-procedurally.

8. Unless clinically indicated, it is recommended that filling of the uterine balloon not exceed a maximum of 750ml.

9. A vaginal exam should be done to ensure that the intrauterine balloon has not been overinflated, which could cause the balloon to prolapse into the vagina. If this is seen, placement or inflation is improper. The balloon should be deflated and repositioned, then re-inflated to assure proper tamponade.

0. The vaginal balloon may be left un-inflated or may be inflated as required. A maximum of 300ml can be infused into the vaginal balloon.

1. An irrigation lumen is provided which allows for irrigation of the uterus distal to the uterine balloon should the physician determine there is a need to ensure drainage lumen patency. **Irrigation should not be initiated for the purpose of dislodging or removing clots.** To irrigate, connect a suitable syringe to the one-way luer connector on the irrigation lumen and flushing with a small amount of sterile fluid until drainage is visualized.

2. The drainage lumen of the Belfort-Dildy Obstetric Tamponade System (OTS) should be connected to a graduated collection container and monitored for signs of persistent significant bleeding. If this occurs the balloon must be deflated and either repositioned or removed.

3. The stopcocks on each of the two inflation lumens can be used to reduce or increase the volume of fluid in each balloon as required for effective tamponade.
Post-Cesarean Delivery Catheter Placement:

Note:
- In postpartum uterine bleeding cases following completed cesarean section delivery, surgical wound disruption may occur with use of any device. Catheter placement under ultrasound guidance per the Placement Method instructions above is recommended. In these patients, it is imperative that proper insertion procedures are followed to maximize clinical benefit and minimize hysterotomy repair disruption.

Intraoperative Cesarean Catheter Placement

- In postpartum uterine bleeding cases during cesarean section delivery, surgical wound disruption may occur with use of any device. Catheter placement at time of laparotomy under direct visualization and palpation is recommended.
- In these patients, it is imperative that proper insertion procedures are followed to maximize clinical benefit and minimize risk of hysterotomy repair disruption.

1. Determine that the uterus is clear of any retained placental fragments, arterial bleeding, or lacerations before beginning.

2. Insert the Belfort-Dildy Obstetric Tamponade System (OTS) into the vagina and manually guide it until the entire upper balloon is within the uterine cavity and the vaginal balloon is arranged neatly within the vaginal cavity. The cervical cuff between the uterine and vaginal balloons should be within the cervical os.

3. In patients who have undergone cesarean delivery and experience postpartum hemorrhage before closure, the uterus should be closed prior to insertion of the BD-OTS. Insertion should follow the Placement Method suggested techniques but should be performed under direct observation (abdomen to remain open) and palpation as necessary. Particular attention should be paid to uterine distension and suture integrity. The fill process should be incremental with assessment of volume during and after each incremental fill. The patient must also be assessed following each incremental fill to determine if bleeding has been arrested.

4. Follow the Placement Method instructions above, steps 5-13, for inflation and stabilization, irrigation and drainage.

Belfort-Dildy Obstetric Tamponade System Removal:

The Belfort-Dildy Obstetric Tamponade System (OTS) should be deflated once it is no longer required. The timing of this decision is left to the clinician managing the patient. In general, once bleeding has been controlled, the patient’s hemodynamic status stabilized and any coagulopathy / acidosis / hypothermia / hypoperfusion has been reversed, the catheter should be deflated until it can be atraumatically removed and the area observed for signs of persistent or recurring bleeding. This will usually be within a period of 24 hours, and efforts should be made to remove or deflate the balloon within 24 hours because of the risk of infection.

Deflation of the balloon may be achieved by an incremental reduction of uterine volume followed by a period of observation until the uterine balloon is empty. This is facilitated by opening the relevant stopcock and draining the fluid out of the balloon(s) into a container under gravity.
drainage. Once the initial drainage has stopped, a syringe may be attached to the stopcock and the remaining fluid can be aspirated until there is none left in the balloon(s).

Alternatively, if quicker deflation is desired, the inflation lumen above the spike may be cut. Once bleeding has been stopped, the catheter may be gently removed at the discretion of the clinician by reversing the insertion process.

The patient should be carefully monitored after catheter removal for any signs of re-bleeding or hemodynamic instability.

**Symbols Used in Glenveigh Surgical Labeling**

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<thead>
<tr>
<th>Standard Symbol</th>
<th>Definition</th>
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<tr>
<td><img src="image" alt="Safety Symbol" /></td>
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<tr>
<td><img src="image" alt="Sterile Symbol" /></td>
<td>Sterile using ethylene oxide</td>
</tr>
<tr>
<td><img src="image" alt="Do Not Use Symbol" /></td>
<td>Do not reuse or resterilize</td>
</tr>
<tr>
<td><img src="image" alt="R, Only Symbol" /></td>
<td>Federal (USA) law restricts this device to sale by or on the order of a physician</td>
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<td><img src="image" alt="Lot Symbol" /></td>
<td>Lot or batch information</td>
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<tr>
<td><img src="image" alt="Use By Date Symbol" /></td>
<td>Use by Date: Do not use this product past the indicated expiration as sterility cannot be assured beyond this date</td>
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<tr>
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<td>CONTAINS or PRESENCE of PHTHALATES: Bis(2-ethylhexyl)phthalate (DEHP)</td>
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