

INSTRUCTIONS FOR USE (continued from page 3)

F. CONTRA-INDICATIONS FOR UTERINE BALLOON TAMPONADE

- Bleeding as a result of a perineal, vaginal or cervical tears.
- When a congenital uterine anomaly is the cause of a mid-trimester miscarriage.
- Uterine rupture.
- Cases of retained placenta: *without operating theater facilities* - place UBT, transfer patient and ensure that referral hospital is aware of retained placenta. *with operating theater facilities* - first evacuate uterus, then, if bleeding continues, place UBT.

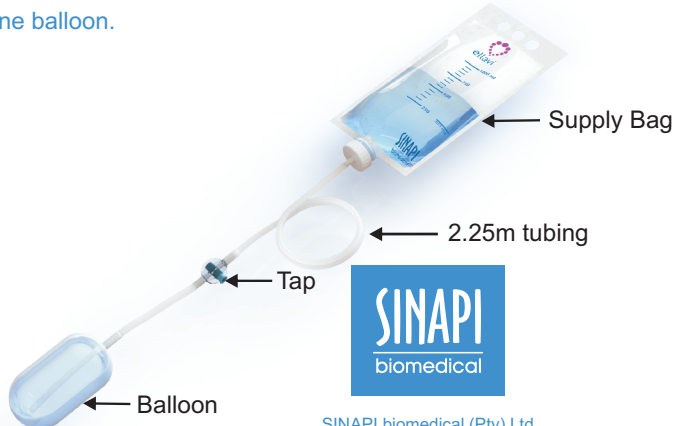
CAUTIONS and WARNINGS

- Only appropriately trained personnel should use this device.
- The balloon can be kept in the uterus for a maximum of 24 hours.
- If bleeding has not considerably decreased within 15 minutes of insertion, surgical intervention or rapid referral should be considered.
- Any patient who has a UBT inserted, should receive a 5 day course of broad spectrum antibiotics.

POST-CAESARIAN SECTION

If the uterus fails to contract after delivery of the placenta with the abdomen open:

- Redrape the patient in the modified Lloyd-Davis position
- Bimanually compress the uterus. If the bleeding decreases, insert compression sutures.
- If the bleeding continues following insertion of compression sutures, insert an Ellavi UBT via the vagina.
- If bleeding still continues, systematic devascularisation or subtotal hysterectomy is required.
- In the case of elective caesarean section, the cervix may need dilatation prior to inserting the uterine balloon.



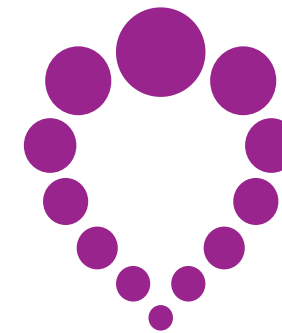
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Evaluation form

REF UBT

CONTENTS: 1 x Uterine balloon tamponade device

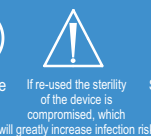
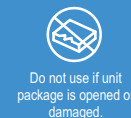


ellavi

uterine balloon tamponade

For the management of post-partum hemorrhage

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



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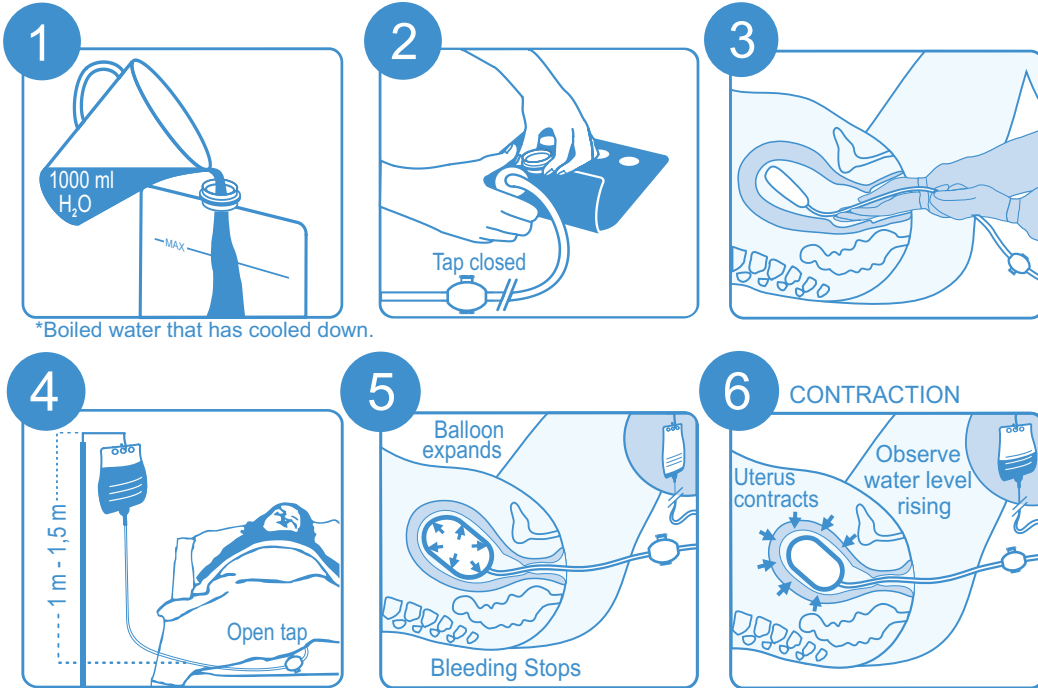
MANUFACTURED IN SOUTH AFRICA
Int. Pat. Appl. No: PCT/IB2017/054458



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D-30855 Hannover-Langenhagen

INSTRUCTIONS FOR USE

QUICK SETUP REFERENCE



A. SETUP

- Use aseptic technique throughout the procedure.
- Ensure that the tap is closed.
- Fill the supply bag with 1000 ml sterile/clean* water (FIG. 1).
- Connect the balloon tubing to the supply bag (FIG. 2).
- Hang the supply bag at a height of between **1 m** and **1,5 m** above the level of the bed. (If bleeding continues increase the height of the supply bag)

B. INSERTING THE BALLOON

- Wearing sterile gloves, apply 2 swab-holding forceps to the anterior lip of the cervix to stabilise the uterus (moderate downward uterine traction facilitates placement.)
- Holding the UBT between the thumb and palm of the hand, place the finger tips between the thick anterior and posterior layers of the upper segment.
- Advance the balloon to a position above the physiologic retraction ring (FIG 3).
- Open tap to fill balloon.(FIG. 4). Keep 2 fingers just below cervix to prevent balloon expulsion.
- Tape the tube to the patient's leg to prevent accidental dislodgement of the balloon.

C. MONITORING OF BLEEDING

- Closely observe the patient for bleeding and signs of shock.
- After 8 hours of insertion, check if the bleeding has stopped:
 - Lower the bag while checking for active bleeding.
 - If actively bleeding, hang the supply bag back at a height of between **1m** and **1,5m** above the level of the bed.
- If the water level in the supply bag rises or the patient complains of abdominal discomfort, it indicates that the atonic uterus is regaining its ability to contract (FIG. 6). Lower the supply bag halfway and gently rub up the uterus. Continue checking for bleeding.

D. TRANSFERRING THE PATIENT

- Close the tap and lower the supply bag to the level of the bed for the duration of the journey.
- To maintain adequate pressure in the balloon, repeat the following every 30 minutes:
 - Lift the supply bag back to a height of between 1 m and 1,5 m above the level of the bed.
 - Open the tap for 30 seconds.
 - Close the tap and place the supply bag back on the bed.
- At the destination, hang the supply bag back at a height of between 1m and 1,5m above the level of the bed and open the tap.

E. REMOVING THE BALLOON

- Check the clinical signs of the patient for improvement.
- Repeat check for bleeding as in C above.
- If bleeding has stopped and removal is indicated, lower the supply bag to allow all the fluid from the balloon to drain back into the supply bag.
- Carefully remove the balloon by pulling on the tubing.
- Discard balloon directly into a medical waste container as per infection control protocol.

USING BLOOD PRESSURE TO DETERMINE SUPPLY BAG HEIGHT

- Determine the patient's systolic blood pressure (SBP) (FIG. 7).
- Multiply the SBP with 1,3 to determine the height (in cm) at which to hang the supply bag, E.g. $120 \text{ mmHg} \times 1,3 = 1,56 \text{ m}$

Systolic Blood Pressure	Height of bag above patient
60 mmHg	0,8 m
80 mmHg	1,1 m
100 mmHg	1,3 m
120 mmHg	1,6 m

- Hang the supply bag at the calculated height, measuring from the level of the bed.
- Black markings on the tube correlate with the SBP. The markings begin at 60 mmHg closest to the supply bag and end at 120 mmHg closest to the balloon with 20mmHg increments between the 4 markings.

E.g. If the SBP = 80mmHg, the 2nd marking from the supply bag must hang at the level of the bed.

