# INSTRUCTIONS FOR USE:

## INTENDED USE

Postpartum Balloon is a disposable, dual lumen catheter attached to an inflatable balloon system designed to provide tamponade for controlling hemorrhage after a vaginal or cesarean delivery. The device consists of a silicone balloon connected to a catheter of the same material

## CONTENTS OF A POSTPARTUM BALLOON CATHETHER

- 1 ea. Balloon Tamponade Catheter with 3-way
- Stopcock and Check Valve
- 1 ea. Bag Spike with Check Valve
- 2 ea. 50 mL Luer-locked Syringes

## PACKAGING INFORMATION

- Sterilized with ethylene oxide gas.
- Carefully inspect the sterile package before opening. Do not use if the package has been opened or damaged
- Use the device before the 'Use By' date as specified on the product label.
- Disposable

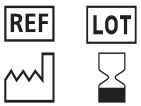
## INDICATIONS

The device is indicated to ensure temporary control or reduction of postpartum uterine bleeding when conservative management is warranted

## CONTRAINDICATIONS

- A surgical site that would prohibit any treatment, therapy or effective uterine tamponade
- Cases indicating hysterectomy
- Pregnancy
- Cervical cancer
- Arterial bleeding
- Untreated uterine anomaly

SEE PRODUCT LABEL FOR:




MedGyn Postpartum Balloon
Catheter IFU-English

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# MEDGYN POSTPARTUM BALLOON CATHETER

## TRANSVAGINAL PLACEMENT:

1-Determine uterine volume by direct inspection or ultrasound examination.
2-Place the balloon section of the catheter into the uterus, make sure that the entire balloon is placed through the cervical canal and the internal ostium. (Figure 1)

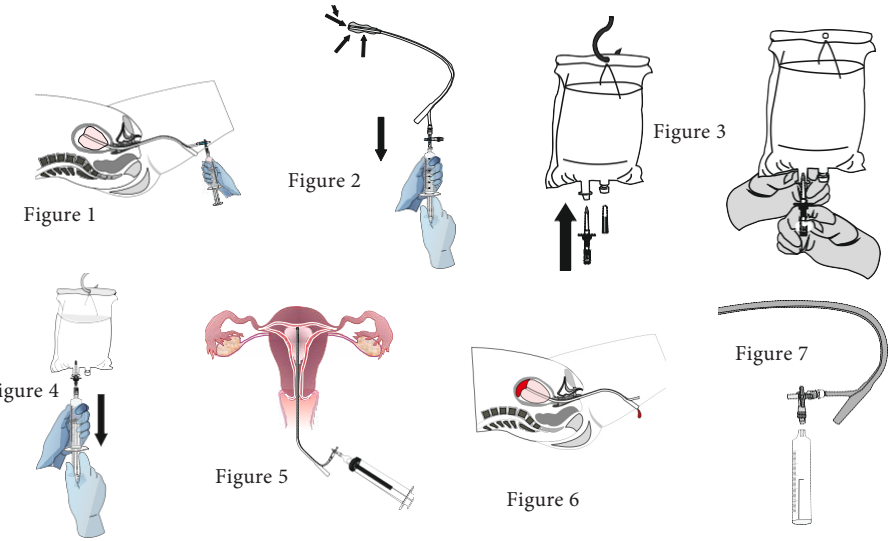
### BALLOON INFLATION ATTENTION:

The balloon should be inflated with a sterile liquid such as sterile water, sterile saline or lactated ringer's solution. The balloon should never be inflated with air, carbon dioxide or any other gas.
The maximum inflation volume is 500 mL. Do not overinflate the balloon. Over inflation of the balloon may cause undesirable results.
1-Insert the injector tip into the check valve and then rotate as required to secure the connection. Make sure that the three-way stopcock is open in the direction of the injector and balloon. If not, rotate it to correct position. The arms of the stopcock indicate connection channel. Aspirate the air inside the balloon.Remove the injector. (See Fig. 2)
2-Spike the serum bag using the bag spike provided (See Fig. 3).
3-Fill the injectors by connecting to the bag spike (See Fig. 4).
4-Make sure three-way stopcock is closed as shown. Before injecting the liquid solution into the catheter, remove the air bubbles from the injector and then inject the liquid into the balloon. (See Fig.7)
5-Repeat step 3 and 4 until the balloon reaches the desired volume.
6-Once the balloon has been inflated to the desired volume check the position of the balloon and confirm placement via ultrasound.
NOTE: The proper placement is shown in (Figure 5).
7-Attach the drainage port to a fluid collection container to monitor hemostasis.
(Fig. 6).
8-Monitor the patient perpetually for indications of increasing bleeding and uterine cramping.

### BALLOON REMOVAL

NOTE: The timing of balloon removal should be specified by the attending physician upon assessment of the patient once bleeding has been controlled and the patient has been stabilized. The maximum indwell time is 24 hours The balloon may be removed sooner upon the attending physician's determination of hemostasis.
1-Remove any vaginal packing.
2-Using a luer lock injector, aspirate the contents of the balloon until wholly deflated. Attach the injector to the catheter and set the three-way stopcock to the direction of the injector and then pull the liquid into the injector (See Fig. 7).
3-Evacuate the injector into a wash basin.
4-Repeat step 2 and 3 until the balloon is fully deflated.
NOTE: In an emergency the catheter shaft may be cut to quicken deflation.
5-Gently withdraw the balloon respectively from the uterus and vaginal canal.
The balloon should be disposed of according to the hospital or facility disposal procedures.
6-Monitor patient for signs of bleeding.






## ATTENTION:

- The postpartum balloon is indicated for use in the event of primary postpartum hemorrhage within 24 hours of postvaginal or postcesarean delivery.
- The device should not be left residing permanently or for more than 24 hours.
- The balloon should be inflated with a sterile liquid such as sterile water, sterile saline or lactated ringer's solution.
- The balloon should never be inflated with air, carbon dioxide or any other gas.
- The maximum inflation volume is 500 mL. Do not overinflate the balloon. Over inflation of the balloon may cause undesirable results.
- Do not apply excessive force when placing the balloon into the uterus.
- Patients in whom this device is being used should be closely monitored and in case of emergency, the emergency response protocol of the hospital or facility should be followed
- Patient monitoring is an integral part of managing postpartum hemorrhage treatment from the beginning to the end.
- A patient who does not respond to treatment in a positive way must be immediately intervened.

## STORAGE CONDITIONS:

Store in a dry, cool and dark environment.
Do not perform any actions other than those specified in this IFU's. It can only be used as instructed and as specified by specialist clinicians.Strictly do not use it except instructions. It is the responsibility of each medical facility to ensure that trained, competent and knowledgeable personnel about the processes and the hospital infection control protocol are involved in the use of these medical devices. MedGyn cannot be held responsible if the product is used diferently than described in these instructions. Using products whose integrity is not ensured is dangerous and forbidden. Use the device before the 'Use By' date as specified on the product label.