INSTRUCTIONS FOR USE

STERIMED HAEMOLOCK CATHETER (UTERINE BALLOON TAMPONADE)

*Please Read All Instructions Carefully (Sterile, for single use only)

SMDPL/IFU/HMK/01, Rev. No.:00, Dt.26.12.2023

PRODUCT DESCRIPTION:

A latex uterine balloon tamponade is a simple device that can stop postpartum Haemorrhage due to a relaxed uterus. It is inserted inside the uterus, filled with fluid and works by compressing the bleeding vessels. It is intended for short term use.

INTENDED USE:

The Uterine Balloon Tamponade (UBT) is inserted inside the uterus by a trained health care provider and inflated to compress blood vessels to stop the hemorrhaging and stabilize the woman for short term use.

INDICATIONS:

Haemolock (Uterine Balloon Tamponade) is used for temporary control or reduction of Primary postpartum Haemorrhage within 24 hours after delivery.

CONTRAINDICATIONS

- Cervical cancer
- Arterial bleeding requiring surgical exploration or angiographic embolization.
- A surgical site that would prohibit the device from effectively controlling bleeding.
- Pregnancy
- Cases indicating hysterectomy
- Purulent infections in the vagina, cervix, or uterus
- Untreated uterine anomaly
- Disseminated intravascular coagulation

LIMITATIONS:

Do not use the Haemolock (Uterine Balloon Tamponade) more than 24 hours for temporary control or reduction of Primary postpartum Haemorrhage.

INTENDED USERS:

This device should be used by Gynaecologist or healthcare professional only.

INTENDED PATIENT POPULATION:

Haemolock (Uterine Balloon Tamponade) is used for woman after delivery.

PERFORMANCE:

After performing uterine massage and evacuating the uterine cavity, the deflated balloon is inserted through the cervix into the uterine cavity. Once positioned, the medical provider inflates the balloon, typically using saline, through the syringe, until the bleeding slows or stops.

WARNINGS:

- Avoid contact with the device by sharp instruments or clamps which might damage the soft balloons or catheter material and result in device failure.
- Avoid excessive force when inserting the catheter through the vagina and into the uterus.
- Aggressive insertion may cause injury of the uterus.
- The balloon should not be kept in the uterus for more than 24 hours.
- If bleeding has not considerably decreased within 15 minutes of insertion, surgical intervention or rapid referral should be considered.
- Connect the drainage port to a fluid collecting bag to monitor haemostasis.
- The balloon drainage port and tubing may be flushed clear of clots with sterile isotonic to facilitate monitoring.
- Closely monitor the patient and determine the sign of bleeding.
- If there is no sign of bleeding than prepare to remove the device.
- Patient in whom this device is being used should be closely monitored for sign of worsening bleeding and/or disseminated intravascular coagulation (DIC). In such cases, emergency intervention per hospital protocol should be followed.
- Sign of deteriorating or non-improving condition should lead to a more aggressive treatment and management of patient uterine bleeding.
- Patient's bleeding volume and urine output should be monitored while Haemolock is in use.
- These products contain natural rubber latex which may cause allergic reactions. Allergic patients use Silicone products.
- Visually inspect the product package prior to use. Do not use the device.
- The maximum volume of inflation of Balloon is 500 ml. Do not overinflate the balloon overinflating may cause the balloon to move into the vagina.
- Inflate the balloon appropriately with sterile water only.
- Do not use the device after expiry Date mentioned on the Label.

DIRECTIONS FOR USE:

Note: *Before inserting Haemolock (Uterine Balloon Tamponade) through the canal, the uterus should be free of any placental residue, and the patient should be evaluated. Make sure there are no lacerations or trauma to the birth canal so that it bleeds rather than irritates. Determine the uterine cavity by direct examination or ultrasound.*

- Consider washing the patient's genital area before the procedure if visibly soiled. Use sterile gloves and wash the patient's genital area thoroughly with foam body cleanser or ready-cleanse wipes. Remove gloves and wash hands.
- Remove the device from its unit packing using an aseptic technique.
- Visually inspect the catheter for any mechanical damage.
- Perform inflation and deflation test of the Balloon with air, prior to use to check for any balloon leaks.
- Maintain aseptic condition and ensure tap close.
- Holding the balloon portion of catheter between two fingers and insert through vagina in to the uterus.
- Make sure that the entire balloon is inserted past the cervical canal and internal ostium.

BALLOON INFLATION

- For rapid instillation fill both the syringe with 50 ml sterile water. (A helper is needed to fill the alternate syringe while a syringe is in use.)
- Connect the syringe with stopcock to facilitate the inflation.
- Inflate the Balloon with sterile water by properly holding the stopcock with the thumb and index finger with the help of syringe as per the desired volume between 300-500 ml.
- To ensure that the balloon is filled to the desired volume, it is recommended that the predetermined volume of sterile water be placed in a separate container rather than relying on a syringe count to verify the amount of fluid that has been instilled into the balloon.
- Use stopcock to lock and open the passage of inflation.
- Once the balloon has been inflated to the pre-determined volume confirm placement via ultrasound.

NOTE: -*To prevent displacement of the balloon into the vagina, counterpressure can be applied by packing the vaginal canal with iodine or antibiotic-soaked vaginal gauze.*

BALLOON REMOVAL

- Remove the tension on the shaft and remove any vaginal packing.
- Aspiration of the balloon may be done in small increments whilst monitoring the vital signs of the patient.
- Gently retract the balloon and discard balloon directly into a medical waste container as per infection control protocol.

PRECAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- This is a single-use device and discards after single-use appropriately.
- ***STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE***.
- Do not reuse. Reuse of this device (or portions of this device) may create a risk of product degradation , which may result in device failure and/or cross-contamination , which may lead to infection or transmission of blood-borne pathogens to patients and users.
- Do not re-sterile.
- Store in a Cool and dry place.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packing.

SIDE EFFECTS:

- Isolated cases of allergic reactions to latex products ranging from mild symptoms (rash; hives; flushing; itching, nasal eye, and sinus irritation; asthma) to anaphylaxis have been reported.
- It can lead to genital skin lesions, ulceration, rashes, damage, irritation, or infection.
- Difficulty in the removal of the catheter in case of excessive aspiration of fluid from the balloon and/or failure to deflate.

CLINICAL BENEFITS:

- Less maternal morbidity
- Reduce the risk of this complication
- Low risk of harm
- Reduce bleeding
- Minimal adverse effects
- Easy to insert

RESIDUAL RISKS:

- Type 1 Allergy, Uterine rupture
- Uterus perforation, Infection

MATERIAL USED :

HAEMOLOCK (UTERINE BALLOON TAMPONADE)

Component	Material
Haemolock (Uterine Balloon Tamponade)	Natural Rubber Latex
PVC Sleeve	Polyvinyl Chloride
Female Connector	Poly Carbonate (PC)

STERILITY:

This device is sterilized by ethylene oxide gas. Device is sterile unless packing is damaged or opened. Do not use it if the package is opened or damaged. Discard opened, unused catheters.

SUPPLY:

Sterimed Haemolock Catheter (Uterine Balloon Temponade) SMD 812

STORAGE:

These products should be stored in their original box in a dry place between 5 °C - 45° C, preferably away from the direct and indirect source of light and heat. Do not use after expiry.

DEVICE DISPOSAL:

Used catheters may be contaminated with infectious and/or other hazardous materials. Discard used catheters in the container meant for infectious waste. Unused expired catheters should be disposed of as per local regulations.

NOTE: *Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

SYMBOLS:

REF Catalogue No.

See instructions for Use

Do not use it if the packaging is damaged.

Single-Use

LOT Batch / Lot No.

Manufacturer

STERILE EO Sterilized using Ethylene Oxide

Date of Mfg.

Avoid Direct Sunlight

EC REP Authorized Representative in the European Union

Importer

Rx ONLY Medical Prescription

Cautions

Keep Dry

Keep in a dry place between 5°c to 45 °C

Do not Re-sterilize

IN Country of Manufacture

LATEX Contains or presence of natural rubber latex

Date of Exp.

Sterile Barrier System

UDI Unique Device Identifier

Distributor

MD Medical Device

STERIMED®

Sterimed Group, 501 Ring Road Mall,
21, Manglam Place, Rohini Sec-3 Delhi-85
Manufactured by:
Sterimed Medical Devices Pvt. Ltd.
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