INSTRUCTIONS FOR USE

STERIMED CerviCath® (CERVICAL RIPENING BALLOON CATHETER)

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

SMDPL/IFU/CRBC/01, Rev. No.:00, Dt.10.04.2023

PRODUCT DESCRIPTION:

It is a latex double-balloon catheter. It is a non-pharmaceutical option for dilating the cervical canal prior to labor induction at term when the cervix is unfavorable for induction. It is intended for short term use.

INTENDED USE:

Used for short-term mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

INDICATIONS:

CerviCath is used for ripening the cervix in preparation for labor induction at term when the cervix is unfavorable for the induction process.

Note: *Use of cervical ripening balloon catheters is a medical decision made by healthcare professionals based on the specific circumstances of each patient. The choice of cervical ripening method may vary depending on the patient's medical history, gestational age, and other relevant factors.*

CONTRAINDICATIONS:

- ❖ Patient receiving or planning to undergo exogenous prostaglandin administration.
- ❖ Placenta previa, vasa previa, or placenta percreta.
- ❖ Transverse fetal orientation.
- ❖ Prolapsed umbilical cord.
- ❖ Prior hysterotomy, classic uterine incision, myomectomy or any other full-thickness uterine incision.
- ❖ Pelvic structure abnormality.
- ❖ Invasive cervical cancer.
- ❖ Maternal heart disease.
- ❖ Multiple gestational pregnancy.
- ❖ Polyhydramnios
- ❖ Severe maternal hypertensions.
- ❖ Breech presentation.
- ❖ Abnormal fetal heart rate patterns.
- ❖ Active genital herpes infection
- ❖ Ruptured membranes
- ❖ Any other contraindication to labor induction

LIMITATIONS:

Do not use Cervicath (Cervical ripening balloon Catheter) for more than 12 hours.

INTENDED USERS:

This device should be used by a trained and registered healthcare professional only.

INTENDED PATIENT POPULATION:

Cervicath is intended for short-term use in women who need cervical ripening and preparation for labor induction at term when the cervix is unfavorable for the induction process.

PERFORMANCE:

CerviCath (Cervical Ripening Balloon Catheter) is a double-balloon catheter specifically designed for mechanical cervical ripening prior to labor induction, particularly in cases where the cervix is unfavorable for induction. The catheter is inserted through the vagina into the lower part of the uterus from the catheter tip side, and the balloons are subsequently filled with sterile water. This catheter aids in preparing the cervix for labor by facilitating cervical ripening, resulting in the softening, thinning, and opening of the cervix. This catheter is intended for short-term use only.

WARNINGS:

- ❖ Prior to use, read entire instructions for use. Failure to do so may result in severepatient injury.
- ❖ 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 into the cervix. it may cause injury to the mother or fetus.
- ❖ The tip of the catheter should not be advanced past the internal cervical OS until the stylet is removed. Insertion beyond the internal OS may result in patient injury and/or rupture of membranes.
- ❖ The device should not be used if the amniotic membranes have ruptured and special care should be taken to avoid rupturing the amniotic membranes during insertion. If amniotic membranes rupture after placement, the patient should be examined to ensure the device has not contributed to any emergent condition.
- ❖ Do not inflate the uterine balloon or vaginal balloon with more than 80 ml sterile water.
- ❖ This device should be used by Gynaecologist or healthcare professional only.
- ❖ This is a single-use device and discards after single-use appropriately.
- ❖ Closely monitor the mother and fetus while catheter is in the patient.
- ❖ Do not use the Device CERVICATH (Cervical ripening balloon) for more than 12 hours.
- ❖ The device should be removed if the amniotic membranes rupture.

Note: *Using sterile techniques as per the institutional protocols, the tip is placed through the opening of the vagina to the lower part of the uterus. The balloon is then filled with sterile water only. The balloon catheter helps to get your cervix ready for labor (cervical ripening). It helps to soften, thin, and open the cervix.*

DIRECTIONS FOR USE:

- Perform an abdominal ultrasound to examine BISHOPS SCORE and confirm singleton, vertex presentation and to rule for partial or complete placenta previa.

BISHOPS SCORING SYSTEM

Score	Dilation (cm)	Position of cervix	Effacement (%)	Station (-3 to +3)	Cervical Consistency
0	Closed	Posterior	0-30	-3	Form
1	1-2	Mid Position	40-50	-2	Medium
2	3-4	Anterior	60-70	-1, 0	Soft
3	5-6	-	80	+1, +2	-

Note*: If the score is below 06 than cervix dilation is required. For dilation use the CerviCath* prior to labor induction.

- Place the patient in lithotomy position.
- 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.
- Insert a large vaginal speculum to gain cervical access.
- Remove the device from its unit packing using an aseptic technique.
- Apply sterile gloves and use the strict sterile technique for the CRB catheter insertion.
- Visually inspect the catheter for any mechanical damage.
- Make sure that the balloon is emptied completely before inserting the catheter.

CATHETER PLACEMENT:

- Using your finger, Advance the CRB catheter through the vagina into the uterus until both the balloons have entered the cervical canal.
- Using the 20 mL syringe inflate the uterine balloon labelled as "**U**" with 40 mL of sterile water.
- Gently pull the uterine balloon into the cervical canal, gently pull the catheter so that the uterine balloon abuts the internal cervical OS.The vaginal balloon may be visualized at the external cervical OS.
- Inflate the vaginal balloon labelled as "**V**" with 20 mL of sterile water. *(If a speculum has been used, it may be removed)*
- Continue inflating the uterine & Vaginal balloon in 20 mL increments up to maximum of 80 ml each.

Note: *Optimal balloon inflation volume depends on individual patient anatomy and desired cervical dilation.*

CATHETER REMOVAL:

- Closely monitor the mother and fetus while catheter is in the patient.
- Deflate both the balloons through corresponding valves marked "**U**" and "**V**" simultaneously and removed the device carefully.

PRECAUTIONS:

- Prior to use, read entire instructions for use. Failure to do so may result in severepatient injury.
- Do not use the device after expiry date.
- ***STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE***
- In lithotomy position, clean the cervix as per hospital protocol. A vaginal speculum is typically used to aid in cervical cleansing and catheter placement.
- Do not use the device if the unit package is damaged or opened.
- Do not re-sterilize the Device,
- Inflate the balloon (Uterine or Vaginal) appropriately with sterile water only.
- Do note reuse the device.

Note: *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.*

SIDE EFFECTS:

- Isolated cases of allergic reactions to latex.
- Placental abruptions
- Uterine rupture
- These products contain natural rubber latex which may cause allergic reactions. Allergic patients can use silicone Device.

- Spontaneous rupture of membrane
- Device expulsion
- Device fragmentation
- Maternal discomfort during and after insertion
- Spontaneous onset of labour
- Failed dilation
- Cervical lacerations
- Bleeding
- Risk of preterm labor

CLINICAL BENEFITS:

- Decreased risk of Caesarean section
- Low risk of uterine hyperstimulation.
- Low risk of fetal heart rate abnormalities
- Reduced risk of uterine tachysystole
- Improve Patient Satisfaction
- Shorter Induction to delivery interval
- Decrease healthcare related cost
- Safe and effective to induce labor in women

RESIDUAL RISKS:

- Fetal Death
- Infection
- Vaginal Bleeding

STERILITY:

This device is sterilized by ethylene oxide gas. Discard opened, unused catheters.

STORAGE:

These products should be stored in their original box in a dry place between 05 °C - 45° C, preferably away from the direct and indirect sources of light and heat.

***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.*

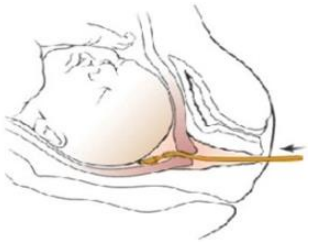
SUPPLY: Sterimed Cervicath (Cervical Ripening Balloon Catheter) SMD 811

SYMBOLS:

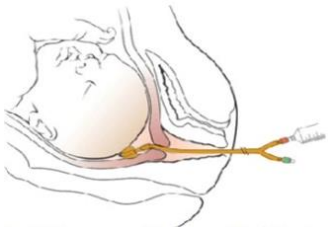
REF	Catalogue No.	Rx ONLY	Medical Prescription
	See instructions for Use		Cautions
	Do not use it if the packaging is damaged.		Keep Dry
	Single-Use	45°C 5°C	Keep in a dry place between5°c to 45 °C
LOT	Batch / Lot No.	STERILIZE	Do not Re-sterilize
	Manufacturer	MR	MR Conditional
STERILE EO	Sterilized using Ethylene Oxide	LATEX	Contains or presence of natural rubber latex
	Date of Mfg.		Date of Exp.
	Avoid Direct Sunlight		Sterile Barrier System
UDI	Unique Device Identifier	MD	Medical Device

STERIMED CerviCath®

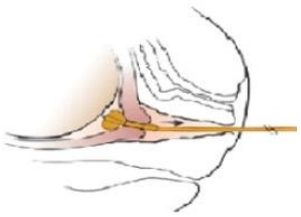
Procedure for Inserting Cervicath (Cervical Ripening Balloon Catheter)



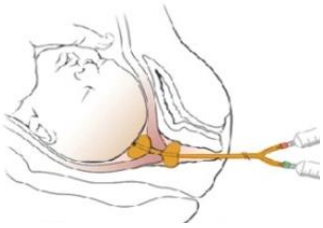
1. *Insert the cervical Ripening Balloon through the cervix until both Balloons have entered the cervical canal.*



2. *Inflate the Uterine Balloon with 40 ml sterile water. Once the uterine balloon is inflated, the device is gently pulled back until the balloon abuts the internal cervical os.*



3. *The Vaginal Balloon is now visible outside the external cervical os. Now fill the Vaginal Balloon with 20 ml Sterile water and place cervical in proper position.*



4. *Once the Balloon are situated on either side of cervix, Sterile water is added to a maximum of 80 ml per Balloon. Placement of the Balloon should be timed so that it is in place no longer than 12 hours before active labor is induced.*

STERIMED®

Sterimed Group, 501 Ring Road Mall,
21, Manglam Place, Rohini Sec-3 Delhi-85
Manufactured by:
Sterimed Medical Devices Pvt. Ltd.
Plot No. 211A, Sector-16, HSIIDC, Bahadurgarh,
Jhajjar, Haryana - 124507 (INDIA)
Customer Care No.: +91-11-42466196/396
Email : info@sterimedgroup.com
Website : www.sterimedgroup.com
EN ISO 13485:2016 Certified Company
Mfg. Lic. No.: MFG/MD/2018/000086