

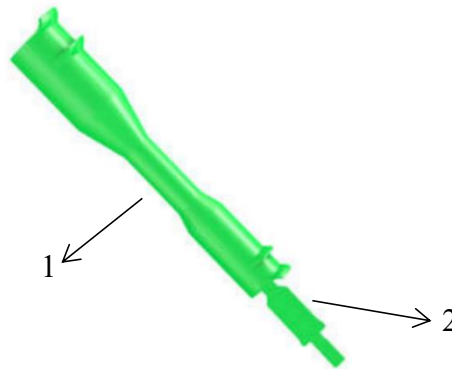
Instruction for Use

1. Product Name

Disposable Uterine Manipulator and Vaginal Delineators

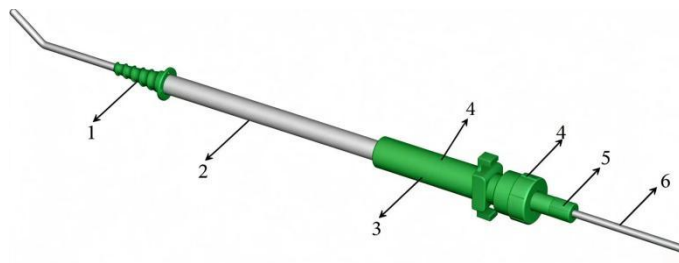
2. Product Structure

The Disposable Uterine Manipulator and Vaginal Delineators is available in four models: CWD, CGD, CBD and SUMC. The CWD model is composed of Colpotomizer and PneumoBloc Occluder. The CGD model is composed of Suture Button, Uterine Cannula, Colpolock, Colpolock Screw, Locking Tail Screw and Adjustable Uterine Tip. The CBD model is composed of Balloon, Bulb Infator, Inflation Catheter and Rotary Air Valve. The SUMC is composed of CWD, CGD and CBD. The schematic diagrams of the composition for the four models are shown in Figures 1, 2, 3 and 4.



1 Colpotomizer 2 PneumoBloc Occluder

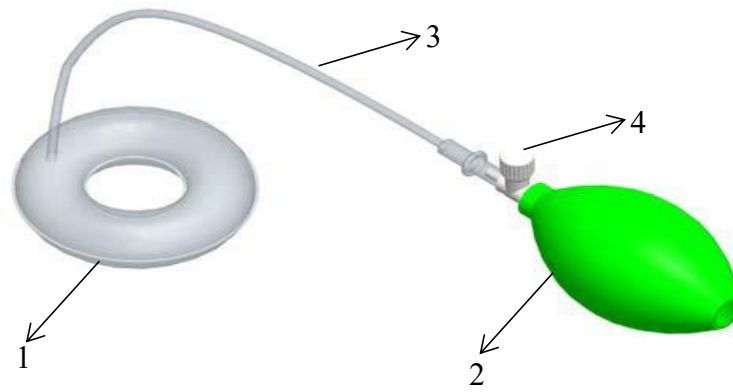
Figure 1. Schematic diagram of the CWD



1 Suture Button 2 Uterine Cannula 3 ColpoLock 4 ColpoLock Screw

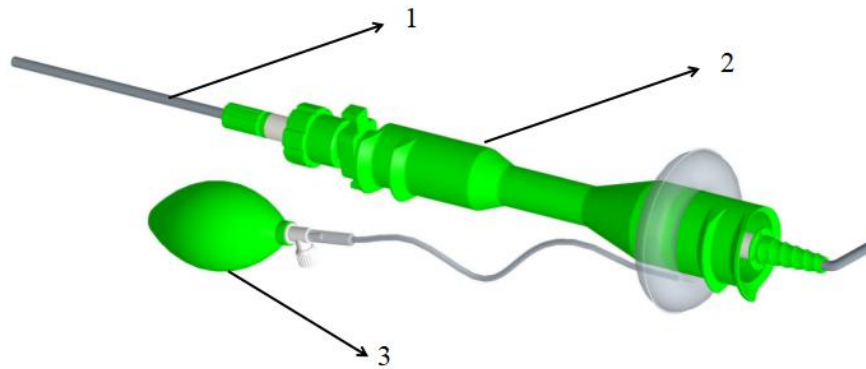
5 Locking Tail Screw 6 Adjustable Uterine Tip

Figure 2 Schematic diagram of the CGD



1 Balloon 2 Bulb 3 Inflatable Catheter
4 Rotary Air Valve

Figure 3. Schematic diagram of the CBD



1 CGD 2 CWD 3 CBD

Figure 4. Schematic diagram of the SUMC

3. Product Model

List of Disposable Uterine Manipulator and Vaginal Delineators

单位 unit: mm

Model	REF	Dimension requirement	
CWD	CWD	Diameter of Colpotomizer large end	$\varnothing 41 \pm 0.2$
		Diameter of Colpotomizer small end	$\varnothing 31 \pm 0.2$
		PneumoBloc Occluder inner diameter	$\varnothing 11(-0.05, +0.1)$
CGD	CGD	Adjustable Uterine Tip diameter	$\varnothing 5(-0.1, 0)$
		Uterine Cannula outer diameter	$\varnothing 12.9(0, +0.1)$

CBD	CBD	Balloon inner diameter(Uninflated)	Ø20±0.2
		Balloon outer diameter(Uninflated)	Ø85±0.2
SUMC	SUMC	Diameter of Colpotomizer large end	Ø41±0.2
		Diameter of Colpotomizer small end	Ø31±0.2
		PneumoBloc Occluder inner diameter	Ø11(-0.05, +0.1)
		Adjustable Uterine Tip diameter	Ø5(-0.1, 0)
		Uterine Cannula outer diameter	Ø12.9(0, +0.1)
		Balloon inner diameter(Uninflated)	Ø20±0.2
		Balloon outer diameter(Uninflated)	Ø85±0.2

4. Intended use

The device is indicated for use by a surgeon in laparoscopic procedures where uterine manipulation and visualization of the position of the vaginal fornices for colpotomy incisions is required, and for maintaining pneumoperitoneum during vaginal vault closure.

5. Indications

The Disposable Uterine Manipulator and Vaginal Delineators is suitable for use in Laparoscopic Assisted Vaginal Hysterectomy (LAVH), Total Laparoscopic Hysterectomy (TLH), Minilaparotomy Hysterectomy, Laparoscopic Tubal Ligation, or Diagnostic Laparoscopy, among other laparoscopic surgeries, for manipulating the uterus. Additionally, it can be used to seal the vagina after vaginal incision to maintain pneumoperitoneum.

6. Intended users

The device should only be used by surgeon with documented experience in gynecological laparoscopic procedures who have been trained on and will adhere strictly to the IFU.

7. Intended patient group

Adult female patients undergoing gynecological surgery (especially uterine interventions) requiring intraoperative uterine manipulation.

8. Directions for use

(1) For best anteversion of the uterus, ensure patient's pubic symphysis is placed at, or over, the

edge of the operating table.

- (2) Open sterile packages and place the contents ready for use.
- (3) Confirm product functions normally.

- 1) Check Adjustable Uterine Tip

When the Locking Tail Screw is loosened, the Adjustable Uterine Tip should slide and rotate within the Uterine Cannula.

When the Locking Tail Screw is tightened, the Adjustable Uterine Tip should be fixed.

- 2) Check Colpotomizer

When the Colpolock Screw is loosened, the Colpotomizer should slide and rotate within the Uterine Cannula.

When the Colpolock Screw is tightened, the Colpotomizer shall rotate rather than slide.

- 3) Check the inflation and deflation function of the CBD

Inflate by squeezing the Bulb (Do not inflate more than 2-3 times, as over-inflation may deform the Balloon).

Deflate by unscrewing the Rotary Air Valve.

Re-inflate by tightening the Rotary Air Valve.

Do not over-tighten the Rotary Air Valve, as this may damage the inflation device.

- (4) Slide ColpoLock and ColpoLock Screw off Uterine Cannula.
- (5) Measure the length of the uterine cavity using a uterine sound. If there is stenosis, dilate the cervix to Hegar 5-7. If there is not stenosis, do not dilate.
- (6) Push out Adjustable Uterine Tip so that the distance between the end of the tip and Suture Button is half the measured uterine length.
- (7) Insert Adjustable Uterine Tip into the uterine cavity and rotate Uterine Cannula clockwise until Suture Button is flush against the external cervix. An optional stay suture can be placed around Uterine Cannula or through one of Suture Button's holes.
- (8) Choose appropriate Colpotomizer end based on size of vagina. Slide the deflated Balloon over the Colpotomizer and place it about 2 cm from the selected end of the Colpotomizer. Ensure the Inflatable Catheter faces downward without folding over the balloon surface. Do not use lubricant when connecting the Balloon.
- (9) Insert Colpotomizer over the tail end of the Uterine Cannula, with lips posterior, and advance it up to the vaginal vault.

WARNING: Insert Colpotomizer with the protruding lips posterior to minimize the possibility of vaginal lacerations.

- (10) Place ColpoLock behind Colpotomizer to prevent Colpotomizer from sliding down, and turn ColpoLock Screw clockwise.
- (11) Under laparoscopic vision, advance Adjustable Uterine Tip slowly to the uterine fundus. Secure it in place by turning Locking Tail Screw clockwise.
- (12) Rotate the Colpotomizer to provide a visual landmark for the lips. Instruct the physician to perform coagulation and colpotomy incisions inside the distal lip. (20mm apart).

WARNING:

- 1) Harmonic shears and cutting diathermy ($\geq 60W$) can damage Colpotomizer material.
 - 2) For best results, perform incisions inside Colpotomizerlip without touching lip directly.
 - 3) To avoid uterine perforation, never hold or push on Adjustable Uterine Tip
- (13) If Balloon leakage occurs during use, re-inflate immediately. Do not over-inflate. If the Colpotomizer is difficult to rotate, deflate the Balloon first. Then rotate the Colpotomizer to the new position and re-inflate if necessary.
 - (14) When colpotomy is complete, deflate the Balloon, remove the uterus and disassemble the device.
 - (15) Use Colpotomizer as a vaginal vault closure probe by screwing PneumoBloc Occluder clockwise into its tail end. The PneumoBloc Occluder contains airtight port for inserting a instrument or retrieval bag with outer diameter $\leq 10mm$. If gas leakage occurs during the procedure, re-inflate the Balloon sufficiently to seal the leak. Do not over-inflate.
 - (16) For surgery requiring only the CGD model of the Disposable Uterine Manipulator and Vaginal Delineators, please follow only steps 1-3, 5-6, and 11. The Colpolock can be used as a forceps holder. Simply screw the Uterine Cannula into place to secure it at the cervix.
 - (17) For surgery requiring only the CWD model of Disposable Uterine Manipulator and Vaginal Delineators, please follow steps 8-9 and 12-13, and assemble the Colpotomizer and PneumoBloc Occluder according to step 15.

9. Precaution

- (1) Operators must be surgeons experienced in gynecological laparoscopic surgery who strictly adhere to the IFU and understand the procedure's complications, hazards, risks, and benefits.

- (2) Do not use if packaging is damaged. Verify the expiration date on the package. Do not use it after the expiration date
- (3) This device shall not be used for purposes outside its scope of application.

10. Warning

- (1) Confirm the Uterine Cannula rotates freely on the Adjustable Uterine Tip.
- (2) Only advance the Adjustable Uterine Tip up to the uterine fundus under laparoscopic vision.
- (3) Insert the Colpotomizer with the protruding lips posterior to minimize the possibility of vaginal lacerations.
- (4) Harmonic shears and cutting diathermy ($\geq 60W$) can damage the Colpotomizer material.
- (5) For best results, perform incisions inside the Colpotomizer lip without touching the lip directly
- (6) To avoid uterine perforation, never hold or push on Adjustable Uterine Tip.
- (7) Discontinue Balloon inflation immediately after gas leakage ceases.
- (8) Over-inflated Balloon impedes Colpotomizer rotation.
- (9) Over-inflation can lead to deformation or rupture of the Balloon.
- (10) To avoid Balloon deformation, do not squeeze the Bulb more than 3 times during inflation.
- (11) The PneumoBloc Occluder is only compatible with instruments with outer diameter of $\leq 10mm$. Usage beyond this specification is strictly prohibited.
- (12) SINGLE-USE DEVICE. Do not reuse, reprocess, or resterilize. Reuse/reprocessing may cause contamination or cross-infection leading to patient injury, illness, or death.
- (13) This product has been sterilized with EO. Do not use if the packaging bag is damaged.
- (14) Do not use if: primary package is compromised, components are detached, or foreign matter is present. Destroy immediately.
- (15) After use, Isolate and manage as biohazard waste per local regulations. Do not store or discard indiscriminately to prevent infection/microbiological hazards.
- (16) Report any serious incidents to both the manufacturer and the competent authority of the Member State where the user/patient is located.

11. Contraindications

The device should not be used if the patient is pregnant or is suspected of being pregnant, planning an IVF procedure, fitted with an IUD, or otherwise unsuitable for the use of the device in

the opinion of the surgeon.

12. Side-effect

- (1) Laceration of the interior of the vagina
- (2) Cuff dehiscence
- (3) Uterine perforation
- (4) Injury to urinary system traumas, bowel or large artery injuries
- (5) Bleeding.

13. Transportation & Storage

- (1) The product shall be stored in a clean, well-ventilated indoor area at temperatures ranging from -20°C to 50°C, with relative humidity $\leq 80\%$, free from corrosive gases, and protected against rodents, fire, and insects. Do not use after expiration.
- (2) During transportation, protect the product using standard methods. Prevent heavy compression, puncture by sharp objects, and exposure to sunlight or rain.

14. Shelf life

The device is sterilized by ethylene oxide, and shelf life is 3 years.

No.	Symbol	Meaning	No.	Symbol	Meaning
1		MANUFACTURER	11		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
2		USE-BY DATE	12		COUNTRY OF MANUFACTURE
3		UNIQUE DEVICE IDENTIFIER	13		HUMIDITY LIMITATION
4		BATCH CODE	14		DO NOT USE IF PACKAGE IS DAMAGED
5		STERILIZED USING ETHYLENE OXIDE	15		CONSULT INSTRUCTIONS FOR USE
6		DO NOT RE-USE	16		KEEP AWAY FROM SUNLIGHT

7		KEEP DRY	17		DO NOT RESTERILIZE
8		MEDICAL DEVICE	18		CAUTION
9		THE PRODUCT HAS PASSED CE CERTIFICATION	19		MODEL NUMBER
10		STERILIZED USING ETHYLENE OXIDE WITH SINGLE STERILE BARRIER SYSTEM	20		TEMPERATURE LIMIT



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