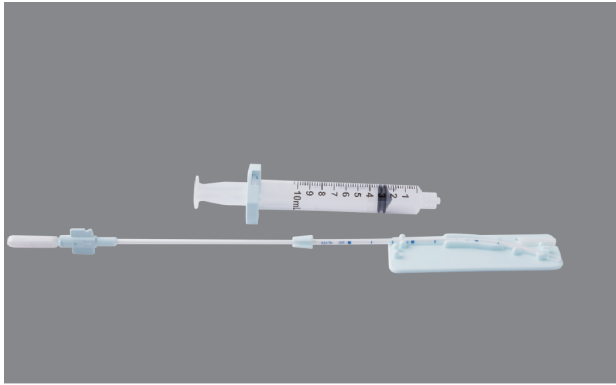




Description

The Curette is a 3 mm (O.D.), single-use, EO-sterilized endometrial suction curette designed to obtain differentiated endometrial tissue samples using vacuum aspiration. It features a Randall-type cutting edge and is paired with a twist-and-lock syringe. The Syringe is fixed by the locking device to prevent back suction. The front end has a curved-tube design to facilitate the operation.

Product Model Basic-UDI : 47198944302009M

• RD003 REF

NOTE: Each package contains a single, sterile device.

Indications for Use

The device is indicated for endometrial sampling in women with suspected intrauterine pathology, including those presenting with abnormal uterine bleeding (AUB) or postmenopausal bleeding. It is intended to obtain endometrial tissue for histopathological examination to support the diagnosis of conditions such as endometrial hyperplasia, polyps, or carcinoma. The device may be used in both premenopausal and postmenopausal women, as determined by clinical evaluation. The device is intended for use by trained gynecologists in clinical environments such as hospitals or outpatient clinics.

Intended purpose

The Curette is intended for obtaining a histologic biopsy of the uterine mucosal lining or for extracting uterine menstrual content for microscopic examination or culturing.

Intended patient population

This product is intended for use in adult females regardless of demographic background. However, it is not intended for use in underage or sexually inexperienced females unless a gynecologist has assessed and confirmed that the procedure is medically necessary and appropriate.

Intended users

This medical device is intended to be used by trained gynecologists with appropriate experience in endometrial sampling procedures.

Contraindications

Do not use this device in the following conditions

- Pregnancy / suspected pregnancy or in a pregnant person
- Pelvic infection
- Cervical infection
- Chronic pathology
- Any conditions contraindicating outpatient surgical procedures

Potential Side Effects

- Vasovagal reaction triggered by cervical manipulation
- Abdominal pain or cramping
- Vaginal bleeding or spotting
- Uterine or pelvic infection
- Uterine perforation (very rare)
- Cervical laceration (very rare)
- Intrauterine adhesion formation, including Asherman's Syndrome

In case of side effects, discontinue the procedure, provide appropriate medical intervention, and report to the manufacturer and the applicable local regulatory authority, as required by local laws and regulations.

Clinical Benefits

- Enables the collection of endometrial tissue and/or uterine contents in a minimally invasive manner for histological, cytological evaluation or microscopic examination/ culturing.
- Supports the diagnosis and assessment of uterine and endometrial conditions by facilitating microscopic examination and culturing of sampled material.

Warnings

1. The Curette is intended for single use only. **DO NOT REUSE, REPROCESS, OR RSTERILIZE.**
Reuse may introduce risks, including, but not limited to:
Allergic reaction, Discomfort / Irritation, Infection, Vaginal inflammation, sepsis.
2. Do not use if the sterile packaging is compromised.
3. If the device shows any signs of discoloration or cracking prior to use, it should not be used and must be reported to the manufacturer.
4. Avoid use in patients with active infection until condition is resolved.
5. This device should be used only by trained and qualified healthcare professionals experienced in gynecologic procedures and endometrial sampling techniques.
6. Intrauterine procedures involving uterine instrumentation may be associated with formation of intrauterine adhesions, including Asherman's Syndrome. Intrauterine adhesions may result in menstrual irregularities, reduced or absent menstrual bleeding, infertility, recurrent pregnancy loss, pelvic pain, or other reproductive health complications.
7. Prior to use, confirm again whether the patient presents any contraindications including suspected pregnancy, active pelvic infection, chronic cervical infection, severe cervical pathology, active genital tract infection or inflammation, or any condition contraindicating outpatient intrauterine procedures.
8. Following the procedure, advise the patient to seek immediate medical attention if the patient experiences abnormal bleeding, low-grade fever, persistent pelvic pain, signs of infection, changes in menstrual bleeding patterns, pregnancy loss following an intrauterine procedure, or difficulty becoming pregnant or other post-procedure complications.

Cautions

1. Verify the integrity of the sterile packaging and check the expiration date prior to use.
2. Use gentle and controlled motion when inserting, rotating, or moving The Curette within the uterine cavity.
3. Insert The Curette only after ensuring the piston is securely fixed within the tube. The piston must not be loose or dislodged.
4. Do not withdraw the piston until the device has been inserted into the uterine cavity.
5. Extreme caution should be taken in patients with cervical stenosis.
6. Use gentle and controlled motion when inserting or rotating the Curette; do not apply excessive force if resistance is encountered.
7. Monitor for adverse reactions during or after the procedure.
8. Store and transport the device according to the manufacturer's recommendations to prevent damage.

Precautions

1. Wear gloves and appropriate personal protective equipment to prevent contamination during sample retrieval.
2. Ensure that all instruments used are sterile.
3. Monitor the patient during and after the procedure for signs of vasovagal reactions (e.g., paleness, dizziness, nausea, or weakness).
4. If such symptoms occur, they are typically self-limiting and can be relieved by resting for 15 minutes and/or taking mild analgesics.

User Error Preventions

1. Always confirm the piston is fully seated before insertion.
2. Do not force the Curette if resistance is encountered.
3. Use the enclosed "stopette" to avoid over-insertion.

Instructions for Use

1. Prepare the vagina and cervix using standard sterile technique, as for any intrauterine procedure.
2. Use an appropriate speculum to expose the cervix.
3. If necessary, grasp the cervix with a tenaculum. For an anteverted uterus, grasp the anterior lip of the cervix; for a retroverted uterus, grasp the posterior lip. Apply gentle traction to straighten any cervical curvature.
4. Carefully insert a uterine sound to assess the depth and orientation of the uterine cavity.
5. Open the sterilized bag (see Figure 1) and carefully take out the device.
6. Insert the Curette while observing the embossed scale on the sleeve (Figure 2) or using the enclosed "stopette" to assist. This provides an additional safeguard against uterine perforation.

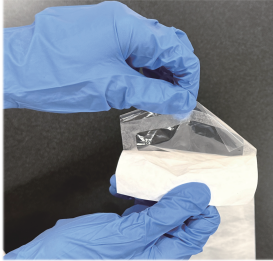


Figure 1. Open the sterilized bag

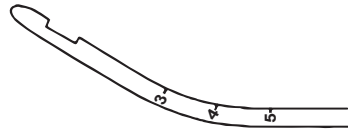


Figure 2. Embossed scale on the Curette sleeve

7. Confirm that the piston of the Curette is fully seated against the base of the tube. Please note that the "arrow" at the proximal end of the Curette indicates the orientation of the cutting edge's sampling point at the distal tip.
8. Then, gently pass the device through the cervical canal and into the uterine cavity. At this point, discontinue any traction previously applied with the tenaculum.
9. Remove the piston. The withdrawal motion should be smooth and steady until the piston reaches the proximal end of the Curette.
10. Please note that the piston of the Curette's syringe must be completely depressed before connecting the syringe to the base of the Curette.
11. With one hand holding the proximal end of the Curette, withdraw the piston of the syringe with your free hand creating a vacuum within the Curette. Now grasp the syringe piston near the blue locking mechanism and lock it in place by turning the piston 1/4-turn clockwise. (See Figure 3) Test to ensure the piston is securely locked. Once locked, the syringe will provide sufficient vacuum or suction during the procedure.
12. After the piston has been retracted and locked to generate suction, rotate the Curette through all four quadrants of the endometrium using long, slow strokes.

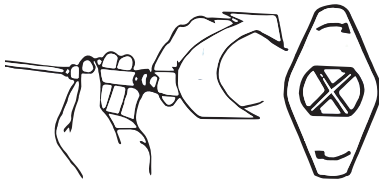


Figure 3. Lock in the piston 1/4-turn clockwise

13. Should the syringe fill with tissue and/or blood and you need additional negative pressure, disconnect syringe from curette, leaving the curette in the uterine cavity. Unlock syringe by twisting plunger to the left (counter-clockwise) 1/4 turn. Empty contents of syringe into collection jar containing fixative. Now reattach syringe to curette as directed in Steps 11 to 13.
14. The Curette should be gently removed from the uterus. Upon inspection of the device, a histological-quality sample from the endometrium should be visible. Bleeding, if present, is usually minimal.
15. Unlock the syringe by turning the piston 1/4-turn counterclockwise and expel the specimen into an appropriate transfer vial, or temporarily store the specimen in the syringe using the enclosed white cap.

Disposal Instructions

- Dispose of the used device in an approved biohazard container.
- Dispose of the device as a single-use medical device in accordance with local regulations for biohazardous or medical waste.
- Do not attempt to clean, reuse, or recycle the device.

Storage & Transportation Conditions

- The shelf life of this device is 3 years from the date of manufacture.
- Store in a clean, dry environment with a temperature between 10–40°C and relative humidity between 30–80% RH.
- The device contains no sensitive materials, liquids, or gases, and is not considered precision machinery.
- It should be transported under normal atmospheric conditions in accordance with the manufacturer's recommendations to prevent damage.
- The transportation methods for export include truck, ship, and airplane, while inland transportation is primarily conducted by truck.

Glossary of Symbols

LOT	Batch code
	Manufacturer
UDI	Unique Device Identifier
	Temperature limit 10–40°C
	Humidity limitation 30–80%RH
	Do not re-use
	Consult instructions for use
	Expiry Date (YYYY/MM/DD)
	Caution
	Do not use if package is damaged and consult instructions for use
	Single sterile barrier system and using ethylene oxide
REF	Catalogue number
MD	Medical device

Reporting of Serious Incidents

If a serious incident related to the device occurs, immediately report the incident to Bioteque Taiwan Ltd. and to the applicable competent authority having jurisdiction in their locale.



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For further assistance, please contact Bioteque Taiwan Ltd.