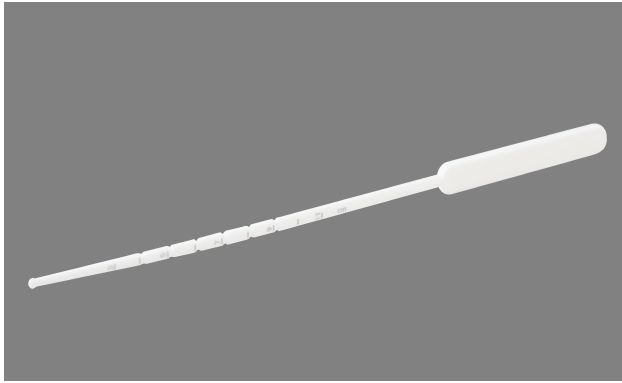




Description

The uterine sound is a sterile, single-use gynecological instrument designed to measure the length and determine the orientation of the uterine cavity during intrauterine procedures. Measurement and evaluation are primarily conducted using the graduated scale located at the distal end of the device. The body of the uterine sound is flexible to accommodate anatomical variations, and its surface features centimeter markings for measurement purposes. The proximal end of the uterine sound has a diameter of 3.5 mm, tapering to 2.5 mm, and features a rounded tip to reduce the risk of perforation.

Product Model Basic-UDI : 4719894430801AM

• BA100 REF

NOTE: Each package contains a single, sterile device.

Indications for Use

The uterine sound is intended for measuring the depth and determining the orientation (direction) of the uterine cavity in women undergoing intrauterine procedures. It is intended to facilitate safe uterine cavity access and proper orientation during procedures such as intrauterine device (IUD) insertion or removal, endometrial sampling (biopsy), hysteroscopy, dilation and curettage (D&C), and embryo transfer.

Intended purpose

The Uterine Sound is a sterile, single-use gynaecological medical device designed to measure the length and determine the orientation of the uterine cavity during intrauterine procedures. Its purpose is to facilitate accurate assessment of uterine cavity access, ensuring safe and effective placement of intrauterine instruments or devices.

Intended patient population

This medical device is intended for use in adult female patients to assess the position and length of the uterine cavity during gynecological procedures, in order to facilitate subsequent diagnostic or therapeutic interventions.

Intended users

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

Clinical Benefits

- Uterine Sound enables assessment of uterine cavity length prior to intrauterine procedures.
- Supports determination of uterine cavity orientation to guide intrauterine access.
- Contributes to safe and effective placement of intrauterine instruments or devices by providing uterine cavity measurements.

Contraindications

Do not use this device in the following conditions.

- Known or suspected pregnancy.
- History of recent uterine perforation.
- Cervical or uterine anomalies preventing safe insertion.
- Known hypersensitivity to device.

Potential Side Effects

- Uterine perforation
- Bleeding or spotting
- Infection
- Pain or cramping

In case of side effects, discontinue the procedure, provide appropriate medical intervention, and report to the manufacturer and competent authority per MDR requirements.

Warnings

1. Uterine Sound is intended for single use only. **DO NOT REUSE.** 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. Excessive insertion force may result in uterine perforation.
4. Seek immediate medical attention if the patient experiences abnormal bleeding, low-grade fever, or persistent pelvic pain after the procedure.
5. Avoid use in patients with active infection until condition is resolved.
6. Use only by trained and qualified gynecologists.
7. Prior to use, confirm again whether the patient presents any contraindications, such as infection or inflammation.
8. 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.

Cautions

1. Verify the integrity of the sterile packaging and check the expiration date prior to use.
2. Use gentle force when inserting the uterine sound. If resistance is encountered, do not force insertion.
3. Store and transport the device under recommended conditions to prevent damage.

Precautions

1. Wear gloves and appropriate personal protective equipment to prevent contamination during use.
2. Ensure that all equipment used during the procedure is sterile.
3. Monitor the patient during and after the procedure for signs of vasovagal reactions (e.g., paleness, dizziness, nausea, or weakness).
4. Allow the patient to rest for at least 15 minutes post-procedure if vasovagal symptoms occur, and administer mild analgesics if necessary.

User Error Preventions

1. Ensure correct orientation of the uterine sound by aligning the curvature with the uterine axis before insertion.
2. If unexpected resistance is felt during insertion, withdraw the device and reassess the uterine path; do not force advancement.
3. Always monitor the insertion depth by referring to the graduated scale to avoid over-insertion and potential perforation.
4. Do not bypass user training requirements; improper use by untrained personnel may lead to patient injury.

Instructions for Use

1. Use a speculum to aid in visualizing the cervix.
2. Open the sterilized bag (see Figure 1) and carefully take out the device.

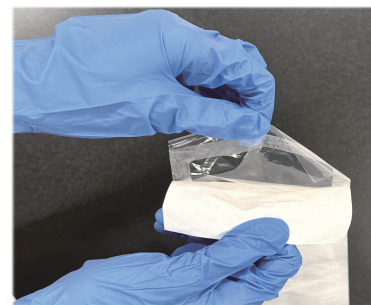


Figure 1. Open the sterilized bag

3. Apply medical-grade water-based lubricant to the tip of the uterine sound, then carefully insert it through the cervix into the uterine cavity until resistance is felt.

NOTE: If necessary, use your thumb and index finger to gently curve the uterine sound to match the natural contour of the cervical canal.

4. Once resistance is encountered, remove the uterine sound and measure the uterine depth using a ruler marked with centimeter graduations.

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

	Batch code
	Manufacturer
	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
	Authorized representative in the European Community/European Union
	Catalogue number
	Medical device
	Product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations
	The product conforms to the UK Device Medical Regulation 2002. The product applicable marketed in Great Britain (England, Wales and Scotland)
	Authorized responsible person in the United Kingdom
	Indicates the entity importing the medical device into the locale

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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