



Description

Disposable cervical dilators are sterile, single-use devices primarily intended for dilating the cervical os to facilitate various diagnostic or therapeutic procedures. They are made of polyethylene, a material that is smooth, flexible, and lightweight, allowing for easy insertion and removal according to their intended use. It is important to avoid applying excessive force during use, and these instruments should not be used for prolonged periods.

The following descriptions apply to different models:

The OS Finder

A single molded band above the tactile handle and opposite the distal end of the device identifies the disposable OS Finder. The OS Finder may be used to find and gently dilate the external OS. Gradual dilation in combination with its tip flexibility and smooth surface will ensure maximum patient comfort. The sound of the OS Finder is tapered from 3 mm to an intermediate diameter of 3.8 mm.

The Canal Locator

Two molded bands above the tactile handle identify the Canal Locator from the OS Finder and the Fundus Locator. Its sound or longer tapered tip is 45 mm and extends to an intermediate diameter of 3.8 mm. The Canal Locator may be used to slowly dilate the length of the cervical canal.

The Fundus Dilator

The Fundus Dilator has three molded bands opposite the distal tip that identifies this instrument from the others in the 3 pieces OS Finder Set. The sound or tapered length from the distal tip is 85 mm. The Fundus Dilator is designed to pass through the entire length of the cervix to dilate the internal OS.

Product Model Basic-UDI : 47198944304019Z

- OS265BA-1  / OS Finder
- OS265BA-2  / Canal Locator
- OS265BA-3  / Fundus Dilator

NOTE: Each package contains a single, sterile device.

Indications for Use

The disposable cervical dilator is indicated for the gradual dilation of the cervical canal to enable access to the uterine cavity for diagnostic or therapeutic gynaecological procedures. These include, but are not limited to, hysteroscopy, dilation and curettage (D&C), endometrial biopsy, intrauterine device (IUD) insertion, surgical abortion, and the management of cervical stenosis. The device is intended for use by trained gynecologists in clinical or surgical settings. The device is intended for use by trained gynecologists in clinical environments such as hospitals or outpatient clinics.

Intended purpose

The Disposable Cervical Dilator is a sterile, single-use medical device intended to dilate the cervical os to facilitate access to the uterine cavity for diagnostic or therapeutic procedures.

Intended patient population

This medical device is intended for use in adult female patients requiring cervical dilation to facilitate diagnostic or gynecological procedures.

Intended users

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

Clinical Benefits

Successful cervical dilation following the use of device.

Contraindications

Do not use this device in the following conditions

- Acute genital tract or pelvic infections.
- A pregnancy or the suspicion of a pregnancy.
- Any invasive cancer that is visible upon examination.
- Any non-compliant patient.
- Severe cervical scarring or anatomical abnormalities that preclude safe insertion.

Potential Side Effects

- Cervical or uterine perforation.
- Bleeding (light spotting is common; heavy bleeding requires evaluation)
- Pain or discomfort during or after the procedure.
- Vasovagal reaction (e.g., dizziness, fainting).
- Infection (rare).
- Allergic reaction to device materials (extremely rare).

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. Cervical Dilator 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 cervical dilator. 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 disposable cervical dilator 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. A tenaculum should be used to grasp the cervix.

NOTE: During dilation, the tenaculum should remain stable to absorb resistance and prevent injury to surrounding anatomical structures.

2. Select an appropriate type of disposable cervical dilator based on the clinical need.
3. Open the sterilized bag (see Figure 1) and carefully take out the device.

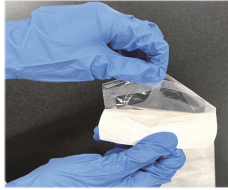


Figure 1. Open the sterilized bag

4. Hold the dilator like a pen, gently insert it to dilate the external cervical os and gain access to the endocervical canal.
5. Apply slight and controlled movements to gradually overcome any resistance caused by connective tissue. Proceed slowly to allow the cervix to gently stretch and accommodate the dilator.

NOTE: In postmenopausal patients, the cervix may be atrophic and rigid. Follow the above method to minimize patient discomfort.

6. Avoid applying excessive force. Care should be taken to reduce the risk of uterine perforation or tearing of the internal cervical os.

NOTE: If resistance is encountered, leave the dilator in place for a few seconds to allow the tissue to relax and expand.

7. Gently remove the dilator by following the cervical canal natural curvature and avoiding any forceful extraction.
8. If further dilation is required, select a larger-diameter dilator and repeat steps 3 to 6. After use, remove the dilator as described in step 7. Then proceed with the intended gynecological procedure.

NOTE: For optimal procedural flow, this device is recommended to be used sequentially with the OS Finder (OS265BA-1), followed by the Canal Locator (OS265BA-2), and then the Fundus Dilator (OS265BA-3).

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.

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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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