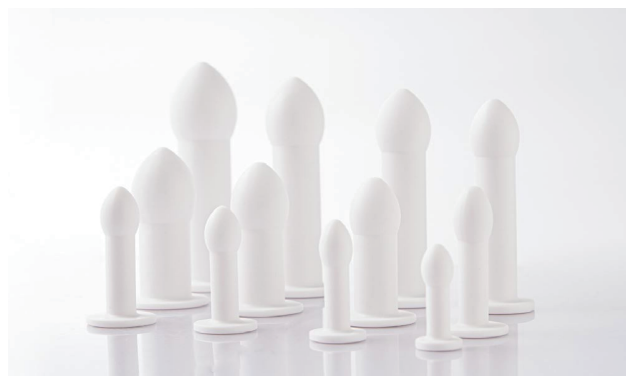




Vaginal Dilator Sets

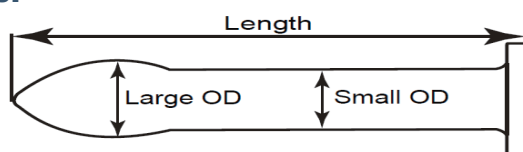
Model: Family A -Large, Family B -Medium, Family C-Small

Not made with natural rubber latex

DESCRIPTION:

Vaginal Dilators are put in the vagina and open it, indicated for women who need vaginal dilation for an examination, a surgical procedure, or for the relief of vaginismus. Vaginal Dilators have a smooth surface, are flexible, light in weight, shaped to stay in place, and can be easily inserted and removed by the patient.

Size:

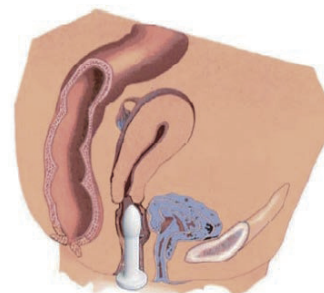


Family A- Large	Length	Small OD	Large OD
DT-A/XL	150.0mm	30.0mm	38.0mm
DT-A/L	138.0mm	25.5mm	32.0mm
DT-A/M	128.0mm	22.5mm	28.0mm
DT-A/S	120.0mm	19.5mm	24.0mm
Family B-Medium	Length	Small OD	Large OD
DT-B/XL	95.0mm	26.0mm	33.0mm
DT-B/L	86.0mm	22.5mm	28.0mm
DT-B/M	78.0mm	19.5mm	23.0mm
DT-B/S	75.0mm	12.5mm	17.0mm
Family C-Small	Length	Small OD	Large OD
DT-C/XL	75.0mm	13.5mm	18.0mm
DT-C/L	65.0mm	12.0mm	16.0mm
DT-C/M	60.0mm	10.5mm	14.0mm
DT-C/S	50.0mm	9.5mm	13.0mm

INDICATIONS:

Vaginal Dilators are indicated for women who need vaginal dilation for an examination, a surgical procedure, or for the relief of vaginismus.

Vaginal Dilators have four different sizes (small, medium, large and extra large) in three family types; Family A, Family B and Family C with variant sizes.



CAUTION:

1. This device is sold by or on the order of a physician.
2. Do not use the device after expiration date.
3. The device is for single patient use only. The device cannot be used in different patients.

CONTRAINDICATIONS:

Dilators are contraindicated in acute genital tract infections, pelvic infections, or non-compliant patients.

WARNING

1. Avoid the use of force when inserting the device into vagina.
2. Prolonged use of the Vaginal dilator treatment may cause vaginal abrasion or ulceration.
3. If symptoms, such as bleeding, vaginal discharge, unpleasant odor, pain or severe itching occur, report them to a physician immediately.
4. Dispose of medical waste properly in accordance with regulations after using.

THE INSTRUCTION IS FOR PHYSICIAN USE

INSTRUCTIONS:

1. Perform a normal pelvic examination prior to placing a dilator. As illustrated in the accompanying illustration, the dilators are arranged into three family set (A, B & C) and each set has four sizes (extra small, small, medium, and large).

Determine the appropriate size family for the patient keeping in mind the family size should be based on the ability of the patient to accommodate the smallest dilator in the family.

2. Personal lubricant should be used to facilitate dilator insertion and to reduce patient discomfort. Please ensure that only a FDA-cleared, waterbased personal lubricant is used.
3. The examiner may use his/her examining finger(s) or a ruler to help determine the dilator size.

4. Once the correct dilator family size or set is determined, the patient should be instructed to begin therapy using the smallest dilator in the set.
5. The dilator should be large enough to fit snugly in the vagina but not be painful or uncomfortable to the patient.
6. The patient should be instructed to gradually increase the dilator size over a period of time that doctor determined to be acceptable.
7. Instruct the patient to report any discomfort or pain associated with dilator use immediately.
8. The patient should be instructed on the proper techniques of dilator insertion and removal and should demonstrate proper insertion and removal. You should recommend a FDA-cleared, water-based lubricant for the patient.
9. Maximum benefit from dilator use usually requires regular daily use of 5 to 20 minutes. The prescribing physician should determine the frequency and duration of dilator use as well as the timing of movement to the next larger dilator or larger dilator family.

REMOVAL AND FOLLOW-UP RECOMMENDATION:

1. To remove a dilator, gently pull downward on the exposed flange until the dilator is completely removed.
2. Discuss the importance of following instructions and the expected length of time for dilator use.
3. Within 24 to 48 hours, be sure the patient is not allergic to the dilators. Examine the vagina and ask the patient if there has been any discomfort, irritation, pressure, sensitivity, or unusual vaginal discharge. Also determine if there has been any improvement in her personal symptoms.
4. Schedule follow-up visits to fit the needs of the patient.

THE INSTRUCTION IS FOR PATIENT USE INSTRUCTIONS:

1. Appropriate size and length of time for use should be determined by your physician according to manufacturer's instruction for physician.
2. To remove a dilator, gently pull downward on the exposed flange until the dilator is completely removed.
3. Report any discomfort to your physician immediately.
4. Ensure that the instruction of dilator's insertion and removal is precisely followed.
5. Vaginal lubrication may make insertion of the dilator easier and lessen discomfort. Ask your doctor for a recommended water-based personal lubricant cleared by FDA.

RECOMMENDED CLEANING PROCEDURE FOR THE PATIENT:

1. Prior to initial use, the Dilator should be washed thoroughly.
2. Rinse Dilator with 20 - 40 °C warm water for 30-40 seconds.
3. Apply mild pH5-9 soap to rub the Dilator gently back and forth for 10 times to lather well.
4. Rinse off Dilator with warm water for 1 minute, repeat and wash if needed.
5. Wash again and rinse Dilator thoroughly with distilled water for 1 minute. Ensure all traces of soap are removed to avoid irritation.
6. Allow to completely air-dry before the reinsert.

Glossary of Symbols

	Batch code
	Manufacturer
	Medical device
	Temperature limit 10-40°C
	Humidity limitation 30-80%RH
	Biological Risk
	Single patient multiple use
	Consult instructions for use
	Expiry Date (YYYY/MM/DD)
	Caution
	Do not use if package is damaged and consult instructions for use
	Non-Sterile
	Catalogue number
	Not made with Natural Rubber Latex

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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