



Vaginal Dilator Sets Model:
Family A - Large, Family B - Medium. Family C - Small

Caution

1. This device is to be sold by or on the order of a health-care professional only.
2. The device is for single patient use only. The device cannot be used in different patients.

Indications

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

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

Contraindications

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

Warnings

1. Avoid the use of force when inserting the device into the vagina.
2. Prolonged use of the Vaginal dilator treatment may cause vaginal abrasion or ulceration.
3. If symptoms, such as bleeding, vaginal discharge, unpleasant odour, pain or severe itching occur, report them to a physician immediately.

Device Description

1. ProFem Vaginal Dilators are constructed of a compression moulded medical-grade silicone rubber with white pigment rubber colorant. They are non-toxic and latex-free.
2. ProFem Vaginal Dilators have a smooth surface, they are flexible, light in weight, shaped to stay in place, and can be easily inserted and removed by the patient.

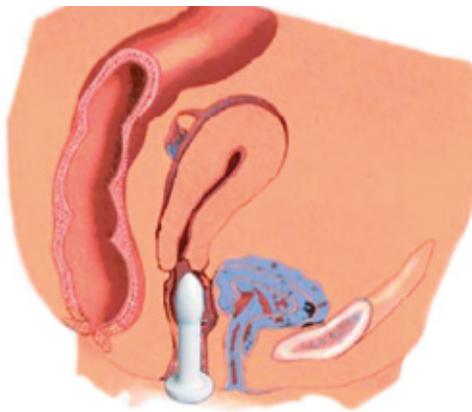
Instruction for physician use

Instructions

1. Perform a normal pelvic examination prior to placing a dilator. As illustrated in the accompanying illustration, the ProFem Vaginal Dilators are arranged into three family sets (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 set 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 water based 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 the 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 to the proper technique of dilator insertion and removal. You should recommend a water-based lubricant for the patient.
9. Maximum benefit from the 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 the 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.



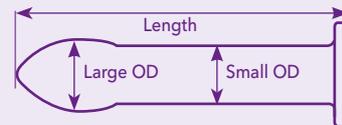
Instructions for patient use

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. After removal, wash the whole dilator with mild soap and rub by hand gently. Then rinse with warm water thoroughly.
4. Report any discomfort to your physician immediately.
5. Ensure that the instruction of dilator's insertion and removal is precisely followed.
6. Vaginal lubrication may make insertion of the dilator easier and lessen discomfort.

Suggested Cleaning Procedure for the Patient

Before Insertion or after Removal of the dilator, the patient needs to conduct the cleaning procedures.

1. Submerge the dilator in warm soap water incorporating gentle rub for 10 minutes, followed by comprehensive rinse with warm tap water.
2. After cleaning with warm tap water, wrap around the dilator with plastic wrap and place it avoiding sunlight.



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

All measurements are in mm

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