



Silicone Vaginal Dilators



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

The instruction is for physician use



Panpac Medical Corporation
6F-2, NO. 202, Sec. 3, Ta-Tong Road,
Shi-Chih City, Taipei Hsien, 22103
Taiwan

TEL : 886-2-86472242

FAX : 886-2-86472770

LATEX
FREE

Caution:

Federal law restricts this device to be sold by or on the order of a physician.

The Panpac Vaginal Dilator may be used as a fitting kit. The fitting kit must be properly cleaned and disinfected between patients.

Indications:

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

Contraindications:

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

Warnings:

Avoiding the use of force when inserting the device into vagina.

If the symptoms such as bleeding 、 vaginal discharge 、 severe itching 、 unpleasant odor and pain, occur, report to physician immediately.

Instructions:

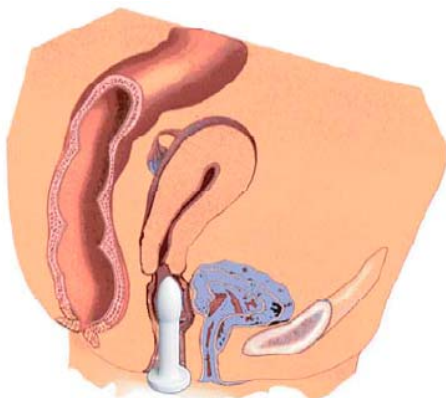
1. Perform a normal pelvic examination prior to the fitting and introduction of a dilator. Determine the appropriate size set for the patient.
2. Vaginal lubricant may facilitate insertion and lessen patient discomfort.
3. Use ruler-finger-uterine sound to estimate the dilator family size.
4. Once the correct dilator family size or set is determined the patient should be instructed to start with the smallest size.
5. The dilator should be large enough for its indication, yet not cause any undue pressure of discomfort.
6. The patient should be instructed to gradually increase the dilator size over a suggested period of time until the patient is comfortable with the insertion of the largest size in the set.
7. Tell the patient to report any discomfort immediately.
8. Be sure the patient is instructed on the dilator's insertion and removal.
9. The length of time a patient should use a vaginal dilator is usually from 5 to 20 minutes per day. The physician may adjust the frequency and duration of dilator usage as the prescribed therapy proceeds to the larger sizes in the set.

Removal, Cleaning and Suggested Follow-Up:

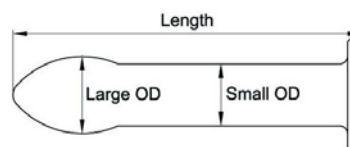
1. To remove a dilator, gently pull downward on the exposed flange until the dilator is completely removed.
2. After removal, wash the whole dilator with mild soap and rub by hand gently. Then rinse with warm water thoroughly. (The physician needs to follow the suggested disinfecting procedures.)
3. Discuss the importance of following instructions and the expected length of time for dilator use.
4. 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.
5. Schedule follow-up visits to fit the needs of the patient.

Instructions for The Physician:

As use of silicone vaginal dilators is recognized for vaginal therapy, it is suggested to begin with the smallest dilator. Physician is advised to select the next dilator size for insertion and so on until appropriate size of dilator is employed. Be ware of not to re-use on another patient and should be discarded while found to not fit for patient. (If physician will use the dilator as a fitting kit, the device must be cleaned and disinfected completely by following the procedures.) At any time, awareness of discomfort of patient should be given. Patient shall be informed of a mild feeling of pressure while gently inserting dilator into vagina.



Available Family Sizes:



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

Recommended Cleaning and Disinfecting Procedure for the Physician

1. Cleaning: submerge in enzymatic cleaner for 20 minutes.
2. Disinfection: use disinfecting solution like Cidex® Activated GTA for 20 minutes and rinse with water thoroughly (be sure to follow manufacturer's instructions)
3. Rinse with sterile saline and place on sterile gauze to dry.
4. After cleaning, wrap around the dilator with PE plastic wrap and place it avoiding sunlight.
5. Before insertion or after removal of the dilator, the physician needs to conduct the cleaning and disinfecting procedures.