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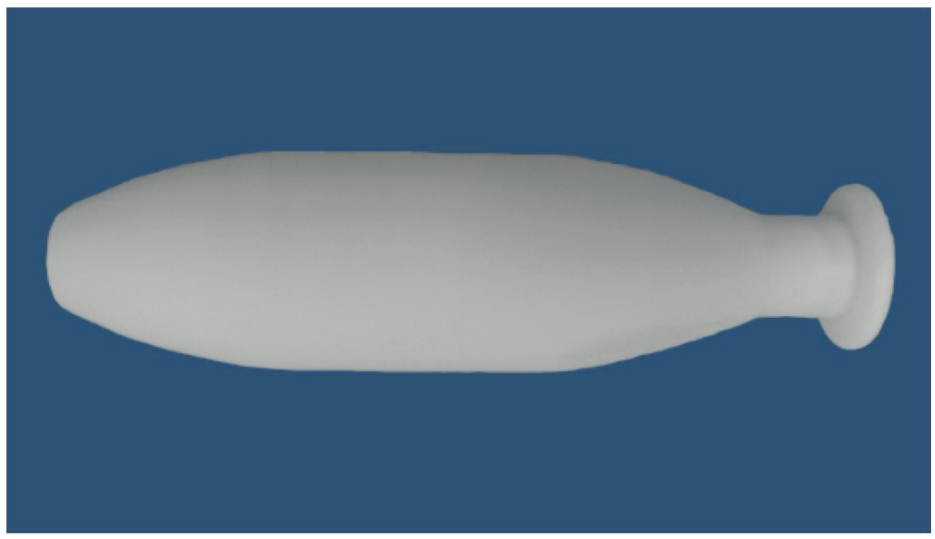
Nichols Silicone Counsellor Dilators



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LATEX

Nichols Silicone Counsellor Dilators
Model: Large, Medium, and Small

Not made with natural rubber latex

DESCRIPTION:

1. Nichols Silicone Counsellor Dilators are constructed of a compression molded medical-grade silicone rubber with 1924 white pigment rubber colorant. They are non-toxicity, and the colorant is mainly made up of titanium dioxide. It is subject to specific FDA regulation, and the ratio of the addition is complied with regulation.

2. The Nichols Counsellor has a smooth surface, is light in weight, is made of silicone, and can be easily inserted and removed by the patient. Vaginal secretions go through the Nichols Counsellor because there is drainage extending the length of the device.

	Length	OD
Large	132.8mm	42.2mm
Medium	124.0mm	33.0mm
Small	118.5mm	28.6mm

INDICATIONS:

1. Nichols Silicone Counsellor Dilators are performed to enlarge a small vagina for the relief of vaginismus, it is usually desirable to support or distend the vaginal canal with a device to: (1) prevent unwanted contraction of the scar or (2) relax the muscles that surround the vagina. Such a device is the Nichols Counsellor.

2. It is used as a tool to dilate the vagina in controlled stages. The device comes in varying sizes; the most appropriate is then selected by physician for use by the patient.

CAUTION:

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

2. Store in a dark, cool, dry place.

3. The device is for single patient use only. Do not share your device with others.

CONTRAINDICATIONS:

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

INSTRUCTIONS(FOR PHYSICIAN USE):

1. Perform a normal pelvic examination prior to placing a dilator. As illustrated in the accompanying illustration, the dilators are arranged into three sizes (Large, Medium, and Small). Determine the appropriate size for the patient keeping in mind the size should be based on the ability of the patient to accommodate the smallest dilator in the device.

2. Personal lubricant should be used to facilite 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 size or set is determined, the patient should be instructed to begin therapy using the smallest dilator in the set.

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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.

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. Ask your doctor for a recommended water-based personal lubricant cleared by FDA.

RECOMMENDED CLEANING PROCEDURE FOR THE PATIENT:

Before insertion or after removal of the dilator, the patient needs to conduct the cleaning procedures.

1. Submerge in warm soap water incorporating gentle rub for 10 minutes, followed by a comprehensive rinse with warm tap water for 5 minutes.

2. After cleaning with warm tap water, wrap around the dilator with plastic wrap and place it avoiding sunlight.

WARNINGS:

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.