Vaginal cones For pelvic floor

- Helps control or prevent urinary stress incontinence
- Improves pelvic floor tone
- Feminine therapy easy to perform at home
- 15 minute exercise, twice a day
- No medication required

CONSUMER INFORMATION LEAFLET

This leaflet provides information and advice to improve the tone of your pelvic floor by using LadySystem® vaginal cones. Read it thoroughly before starting the therapy.

For any medical advice, you should always consult a healthcare professional to discuss your unique situation.

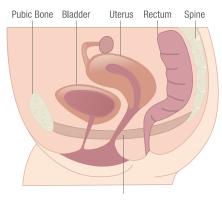




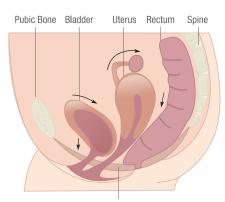
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YOUR PELVIC FLOOR

The pelvic floor is the group of muscles, ligaments and tissues supporting the main organs of the lower abdomen (bladder, uterus, intestine) and provides passage through to the exterior of the body (urethra, vagina and rectum). One of the functions of the pelvic floor is to support the bladder to control urine flow. The musculature of your pelvic floor must be healthy to allow for normal functioning of your abdominal organs. Therefore, it is important that women maintain good internal muscle tone throughout their life.



Normal Pelvic Floor



Weakened Pelvic Floor

Pelvic Floor Weakening

Pelvic floor weakening is a loss of tone of the muscles, ligaments and tissues supporting the bladder, uterus and intestine.

Effects of Pelvic Floor Weakening

- Urinary stress incontinence: involuntary leakage of a variable quantity of urine caused by a pressure on the bladder, for example while coughing, sneezing, laughing, or even jumping, dancing or walking. This is the most common type of urinary incontinence (over 50% of cases).
- Prolapse: drop down of the uterus, bladder or rectum. These conditions may require a surgical procedure.
- Diminished sexual sensitivity and reduced quality of sexual relations.

Causes of Pelvic Floor Weakening

• Pregnancy and childbirth: pregnancy and childbirth are the most common causes of pelvic floor weakening. During pregnancy, the increased abdominal weight stretches the pelvic floor, which can cause it to weaken. It reaches a peak during vaginal birth. Damage to the pelvic floor is aggravated if an episiotomy is carried out, the baby is heavy or has a large cranial diameter, the mother gained a lot of weight during pregnancy, or in the case of a multiple pregnancy. Women who underwent Caesarean section can also experience pelvic floor weakening.

After vaginal or Caesarean section delivery: it is advised to have your pelvic floor assessed by your physician before initiating any exercise programme (e.g. jumping, weight lifting). Some activities may increase the intra-abdominal pressure and thus may weaken the pelvic floor.

- Menopause and aging: hormonal changes associated with menopause and aging can reduce the pelvic floor flexibility and contribute to its weakening.
- Other predisposing factors: some women may have an innate weakness of the pelvic floor and, therefore, may be at an increased risk of developing urinary stress incontinence. Some habits (such as retaining urine for long periods, wearing tight clothes), high impact sporting activities (jumping, running), obesity, chronic cough (lung disease, smoking), frequent constipation and weight lifting can weaken the pelvic floor. Hysterectomy and neurological disorders are among other possible causes. Therefore, it is important to have your pelvic floor assessed if you suspect a weakness.

Advantages of Using Vaginal Cones for Pelvic Floor Reeducation

Pelvic floor reeducation with vaginal cones is a proven method to gradually strengthen your pelvic floor or to prevent its weakening. This therapy is very effective, especially for the treatment of urinary stress incontinence and moderate prolapse; it offers the following advantages:

- Vaginal cones are discreet, personal and easy to use.
- They are safe and do not involve the use of medications.
- The use of vaginal cones allows the pelvic floor to strengthen rapidly (from six weeks to three months on average).
- Progress through the series of increasingly heavier cones, LadySystem allows you to monitor your own progress as your pelvic floor gradually strengthens.
- If surgery is necessary, the use of vaginal cones after the intervention may help strengthen your pelvic floor and may prevent a relapse. It is important to follow your attending physician's instructions carefully.



LADYSYSTEM® THERAPY

Indications

LadySystem® therapy is indicated for women with a weakened pelvic floor, which may cause, for example:

- Urinary stress incontinence
- Moderate prolapse
- Reduced sexual sensitivity

Contraindication

· Vaginal or uterine infection

Warnings

- The cones are for personal use only. Therefore, in order to prevent infections, they should not be shared with others.
- Consult your physician if you have an intrauterine device (IUD) or if you plan to start using LadySystem[®] vaginal cones during pregnancy.
- Consult your physician if you plan on using cones within six weeks following delivery or if you have had a recent episiotomy, a Caesarean section, or any other gynaecological procedure complication.
- In doubt, consult your physician before using LadySystem[®].

Presentation

LadySystem® is offered in a case containing 5 cones of identical shape but of different weights:



No.1 No.2 No.3 No.4 No.5 4.9g 20.5g 32g 44g 55g

LadySystem® does not contain latex.

OBJECTIVE OF LADYSYSTEM® THERAPY

The objective is to gradually strengthen the pelvic floor by using the heaviest cone you can comfortably support for 15 minutes. It is recommended to practise this therapy for 15 minutes, twice daily, for three months.

INSTRUCTIONS

Using LadySystem®

Read the instructions thoroughly before initiating LadySystem® therapy. They will help you select the most suitable cones for your therapy and reeducate your pelvic floor effectively and safely. You might not be required to use all five cones.

The cone is inserted into the vagina (like a tampon) and is held in place by reflex contraction of the pelvic floor muscles (passive contraction) or by a little effort of voluntary contraction (active contraction).

LadySystem® vaginal cone therapy may be temporarily postponed during menstruation as it may be difficult to retain the cone on heavier flow days.



Relaxed Pelvic Muscles



Contracted Pelvic Muscles

Before using the vaginal cones

 Before inserting a cone, attempt to urinate. If you need to pass urine once the cone is inserted, remove it first, and replace it afterwards. Before using the vaginal cones (cont'd)

· Wash your hands thoroughly and make sure the cones you are using have been cleaned with water and mild fragrance-free soap. Do not sterilize the cones (they can be damaged if in contact with boiling water or alcohol, or if they are sterilized with ethylene oxide).

After using the vaginal cones

- · Wash your hands thoroughly.
- Wash the cones that you have used with water and mild fragrance-free soap. Dry them with a clean towel and place them in their case.

I - Selecting the Most Suitable Cone to Use when Starting LadySystem® Therapy

The first time you use the LadySystem® cones, start with the lightest one. Insert cone No. 1 gently into the vagina, like a tampon, with the cone tip and the nylon cord pointing downward (see illustration below). You can moisten it with water or a water-base lubricant to ease its insertion. Find a safe and comfortable position (e.g. support yourself standing next to a steady surface with your legs slightly apart or with a leg lifted up on a chair). Be careful not to slip or fall.

The cone should be near vertical in the vagina, with the nylon cord outside. If the cone is in the correct position, it should be held in place by a slight passive and active contraction. However, if the cone stays in place with no effort on your part (without any active contraction), it means that the cone is too light. Remove it by gently pulling the nylon cord down, and repeat the above procedure to insert the next heavier cone.

When you feel that you have to make a slight effort to hold the cone in place, it means that you have found the right cone to begin your therapy. Now, follow the steps described hereafter (Starting LadySystem® Therapy). Otherwise, remove the cone and try the next cone until you find the right cone to start the therapy.

The nylon cord of the cone is very strong and unbreakable with normal use. If for any reason (e.g. incorrect insertion) you cannot find it, simply stand upright and relax. The cone will descend under its own weight and come out. It is advisable to wear tight underwear to retain the cone in case it slips out accidentally.

II - Starting LadySystem® Therapy

- 1. Insert the chosen cone gently in the vagina, like a tampon, with the cone tip and nylon cord pointing downward. The objective is to hold this cone comfortably for 15 minutes without any particular effort while standing, walking, or doing your daily activities (the therapy will not work if you are sitting or lying down).
 - Using the cones for more than 15 minutes will not accelerate the process of pelvic floor reeducation and could cause a temporary muscle fatique (discomfort) following the exercise. Remember that the strengthening of any muscle takes a certain time.
- 2. Practise this exercise twice every day, for about two weeks or until you can easily hold the cone for 15 minutes. After your 15-minute therapy, gently pull the nylon cord down to remove the cone.
 - It is possible that, after two weeks of therapy, you may still need to make an effort to retain the cone in your vagina. Keep doing your therapy with this cone until you can hold it comfortably without effort for 15 consecutive minutes.
- 3. Once you can hold the cone without effort for 15 minutes, try the next heavier cone (e.g. No. 2 if you had started with No. 1) by following steps 1 and 2 above. Each time you use a heavier cone, you need to make a conscious effort to contract your muscles to prevent the cone from slipping out.
- 4. Keep using progressively heavier vaginal cones until you find you cannot change to the next one. Use the heaviest cone you can comfortably support to complete your exercise programme. Like any exercise programme, LadySystem® therapy should be carried out on a regular basis to reach the objective.

ADDITIONAL INFORMATION

Some women may have a weaker pelvic floor than others and may need to use the same cone for several weeks. The objective is to be able to hold the heaviest cone you can comfortably support. The success of the therapy does not depend on your capability to reach cone No. 5. However, if after three months of therapy, you notice no improvement of your symptoms caused by a pelvic floor weakening (e.g. if the frequency of urine leakage has not reduced), consult your physician.

It is recommended to have your physician evaluate your pelvic floor tone during your annual check-up, or in the case your symptoms recur. Your physician may suggest that you resume the LadySystem® therapy. In such case, you will have to determine again which cone you should use to re-initiate the therapy.

You may feel temporary muscle fatigue (discomfort) following the exercise. If this symptom persists for more than a few days, or if you have other symptoms, consult your physician.

Keep LadySystem® out of reach of children.

For any information about LadySystem® therapy, please contact our Medical Information Department:

1888666-0611 medicalinfo@duchesnay.com www.ladysystem.ca

The materials used in the manufacture of LadySystem® Pelvic Floor Therapy comply with international standards of pharmacological safety, including United States Pharmacopoeia XXII Class VI (biocompatibility).

ABOUT DUCHESNAY

Duchesnay is a Canadian pharmaceutical company who is dedicated specifically to the health of the pregnant woman and her unborn child, and to her quality of life during pregnancy and postpartum.



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To know more about urinary stress incontinence, or to share your concerns and Oops! experience with other women, join the Web

community Laughing without Leaking: www.laughingwithoutleaking.ca

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