

USER INSTRUCTIONS FOR THE ANIBALL MEDICAL DEVICE

Aniball is a medical device which serves for antenatal preparation and muscle regeneration after childbirth. Aniball is designed to be used for exercising the pelvic floor muscles, preparing the birth canal for delivery and strengthening the pelvic floor muscles after childbirth.

Purpose of Use

Aniball is a well-proven device that effectively helps strengthen the pelvic floor muscles, positively stimulate the vaginal muscles and exercise the perineum by stretching and relaxing it during antenatal preparation for childbirth. The aim of the exercising is to facilitate the expulsion of an infant (easier and faster progress in the ejection phase), to shorten the second stage of labour and to significantly reduce the risks of episiotomy. Using Aniball after childbirth enables the pelvic muscles to regenerate, which contributes to reducing incontinence in subsequent periods.

Aniball consists of:

1. Inflatable ball made of medical silicone (ELASTOSIL LR3003)
2. Mechanical pump
3. Tubing
4. Connecting reduction
5. Two-way valve



Instructions for use

- Before first use it is necessary to sterilize Aniball by immersing it into a water-bath of at least 70° C for about 1 minute. We recommend leaving it in boiling water (we offer a sterilizing cup suitable for microwaves). Although the silicone ball fits tightly around the plastic reduction, it may be manually removed and reconnected after sterilization.
- Before reconnecting the ball to the reduction, let the ball dry properly.
- Before first use it is advisable to inflate the ball to approximately 30 cm in circumference to check whether it is undamaged and properly functioning.
- After each use, the ball must be thoroughly washed under hot running water (prevent the pump and the valve from getting wet) and then let the ball dry (preferably on a

wash-basin surface). To carry out thorough disinfection, you can use the disinfectant recommended on our website www.aniball.eu.

- To increase comfort while using Aniball, you may moisten the surface of the ball using **exclusively preferably water-based lubricants for internal use** (allowing contact with mucosa) **Do not use preparations or condoms containing oil!** Using oils or unsuitable lubricants may lead to degradation of the silicone and cause the ball to burst.
- If the perineum is massaged simultaneously use a suitable lubricating gel instead of massaging oil.
Store Aniball in a dry and dark place! (Do not expose it to sunlight).
- Keep Aniball out of reach of children.
- Make sure Aniball does not come into contact with sharp objects.
- Do not use Aniball in water.

I. ANTENATAL PREPARATION WITH ANIBALL

It is recommended not to start using Aniball earlier than 3 or 4 weeks before your due date. Set aside approximately 15 – 30 minutes for your exercise (this is very individual - if you need more time for correct relaxation and the exercising itself, it may even need a longer period) Find a **position that suits you most** (lie down with your knees slightly bent, kneel, lie on your side, stand, squat). Labour in a position **in which your body feels most comfortable is usually the safest.**

1. Before inserting Aniball first relax and try to stay relaxed during the entire exercise. The ability to focus on tightening and loosening the muscles is essential for good results of your exercising.
2. Hold the ball by the neck and insert its larger round side (about 7 cm) into your vagina. To make the insertion easier, we recommend inflating the ball by pressing it once or twice. You may also lubricate the ball's surface. For more information, see Instructions for use.
3. Once the ball is inserted and not causing you any pain or discomfort, press the pump repeatedly. By inflating the ball you increase the pressure felt in the surrounding muscles and perineum. When exercising for the first time the number of pump squeezes is low (1-5 squeezes) and increases gradually in subsequent exercising. Increasing the size of the ball inside the vagina results in stretching of the muscles and the feeling of tension, which is normal when exercising. You may decrease the ball's size at any time during your exercises by using the valve.

4. When you exercise for the first time it is important that you become aware of where the ball is located and how it behaves inside the vagina by consciously working with your pelvic floor muscles. Tightening and loosening these muscles cause the ball to move slightly inside your vagina. Repeat this exercise for 1-2 minutes at short intervals of 10 seconds: tighten the muscles and then relax them.

5. You must now begin to expel the balloon. Concentrate and try to relax your pelvic floor muscles completely as you breathe in, and imagine that the balloon is spontaneously expelled from your vagina without pushing. Taking deep breaths will help. As you breathe out the balloon remains inside you, as you breathe in, you relax your pelvic floor muscles and the balloon moves out of your vagina. The pressure has to come from the pelvic floor alone (you must not feel any increase in pressure in your head or try to push – a frequent mistake). Your body should be complete loose and relaxed. The feeling of pressure can be best compared to the pressure you feel as you expel a stool. The balloon will stretch your perineum slightly and will then slip out of your vagina. If necessary, hold the balloon steady by the shaft so it doesn't slip out too quickly.

6. Repeat the whole process several times. The results of your exercising can be verified by the tape measure enclosed thereto.

By regular exercising you achieve a wider diameter of the ball. The desired result is to have 28 – 30 cm in circumference after 3-4 weeks of regular use, which tends to be the size of an infant's head when going through the birth canal. Measuring the size of the ball is more an orientation tool. The aim of your exercising is not to achieve a specific diameter, therefore, do your exercises based on your own feeling that you have reached your maximum. It is fine if you get the same result over a period of several days. In spite of that continue exercising, with the due date approaching the perineum will loosen due to hormonal activity.

In case the ball has a tendency to slip too quickly when expelling it hold it gently with your hand. You will then avoid any possible injury.

Contraindications

Do not use Aniball in the following situations:

- high-risk pregnancy
- imminent preterm delivery
- any kind of vaginal bleeding
- planned Caesarean section

- incidence of condylomata or any other infectious pathology in the vagina or vaginal orifice
- vaginal infection
- genital herpes
- genital injuries
- precancerous conditions and other cervical pathologies

Special care and exercises following consultation with a physician are required in the following situations:

- varicose veins in the vagina and external genitals
- low placement of the placenta (ask your gynaecologist)
- restricted perception of pain in the vagina and external genitals
neurological diseases, when taking tranquilisers)
- retreated vaginal inflammation (short-term persistence of fragile vaginal tissues)
- after vaginal surgeries (scars may prevent sufficient elasticity of the vagina)
- lichen sclerosus of the external genitals (chronic skin disease)

Should you encounter any problem while doing your exercises, please do not hesitate to consult your midwife or obstetrician.

II. EXERCISES WITH ANIBALL TO STRENGTHEN THE PELVIC FLOOR MUSCLES IN INCONTINENCE

Pelvic floor muscles

Pelvic floor muscles play an important role in the life of every woman and have a significant impact on the woman's health. They are, however, hidden deep inside the body. Most women are not aware that these muscles exist and therefore do not pay sufficient attention to them. We realize them mostly during the premenstrual period and ovulation. We start paying attention to them no sooner than during pregnancy because this is the period when the first problems appear –the pelvic floor softens due to hormones as the body starts preparing for labour, and back pain related to changes in the centre of gravity of a woman's body occurs.

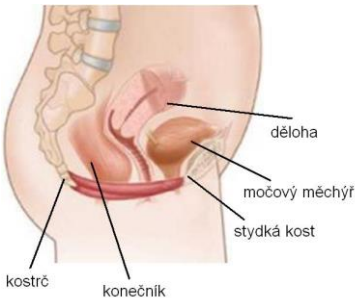
Pregnancy and labour are big challenges for the pelvic floor muscles and therefore they are worth being exercised, thus preventing them from slackening.

What are pelvic floor muscles and what do they serve for? The pelvic floor is formed of the group of ligaments, muscles and tissues, being a supportive apparatus for the

urinary duct, bladder, uterus and rectum, which close the pelvis from below, thus creating a kind of “elastic muscle plate”.

The muscles form three layers:

- a) deep layer (between the pubic bone and coccyx bone)
- b) middle layer (between chance bones)
- c) external layer consisting of the sphincter



It is necessary to exercise all three layers for good functioning of the pelvic floor!

The pelvic floor is not only the mechanical centre of gravity of the human body but it is also the most sensitive barometer in a woman's body.

These muscles are also responsible for correct posture, venous blood outflow from the legs as well as for regular deep breathing.

Their good condition has a significant impact on the overall **process of childbirth**. It facilitates the expulsion of an infant's head, thus contributing to shortening the second stage of labour. It limits possible problems with urinary incontinence and reduces the risk of ptosis or prolapse of the pelvic organs. The ability to experience orgasm depends on them being in good condition, too.

Pelvic floor in pregnancy

Pelvic floor muscles play a significant role in this period. Their elasticity and flexibility enable the womb to remain in the correct position because the womb gains weight along with the growing baby and this way it also increases pressure on the pelvic floor. The strength and resistance of these muscles are tested to the limit for many months. When a baby is coming into the world the pelvic floor must effectively extend during labour. The body hormonally prepares the muscles and ligaments to sustain such pressure. This natural process can be suitably supported by exercising and awareness of the pelvic floor muscles.

Aniball, a medical device, will serve this purpose perfectly well. Thanks to exercising with Aniball you will locate the pelvic floor muscles and discover the way they function.

This will help you relax these muscles, which is fundamental before childbirth. If the pelvic floor is contracted the infant has a difficult journey into the world. After delivery the pelvic floor in many women remains slack for a long time. They often have difficulties resuming their sex life. For more information on doing exercises during pregnancy, please refer to the instructions above.

Symptoms of incontinence:

- urine leak while lifting heavy objects, when sneezing, coughing, jumping on a trampoline
- waking up from sleep due to the urge to discharge
- unexpected urine leak, e.g. when stressed or while asleep
- inability to retain urine flow by squeezing the sphincter. Attention: Perform this test only once – never strengthen the sphincter while urinating

Note.: Urine leak takes place mostly in the evening when the pelvic floor muscles are tired after a long day.

Daily care of the pelvic floor and recommendation:

- never hold back the flow of urine unless it is necessary
- **do not urinate "preventively, in advance" before leaving home if you do not feel you need to**
- do not limit your fluid intake – you should drink 2 litres of fluid daily (or as you need)
- do not force out urine, do not help it flow, let it flow freely until the end
- avoid lifting heavy objects
- avoid wearing high heels frequently
- **do pelvic floor exercises at least once a day**

When exercising it is very important to locate and identify the correct location of this muscle group. It may be difficult to do by yourself. Aniball which effectively supports this identification as well as awareness of the pelvic floor muscles, will help you.

Recommendation for exercising:

1. Correct breathing is essential in all exercises. Remember that you tighten the pelvic floor muscles upwards when you breathe out and release them downwards when you breathe in.
2. Tightening the abdominal and gluteal muscles instead of the pelvic floor muscles is a frequent mistake when doing exercises.
3. Strengthen the muscles regularly (preferably every day), several minutes is enough.

4. Always relax the muscles always between individual exercises – learn how to relax them, always twice as long as you exercise (if you exercise for 2 minutes, relax them for 4 minutes). Initially you may feel fatigue in these muscles – it is all right and shows that you are doing your exercises correctly.
5. Apart from exercising activate the muscles before strain which causes pelvic pressure which may result in urine leak (before sneezing, coughing, etc.)
6. If you feel that you are tightening the muscles less and less (the muscles are getting weak), interrupt your exercising. If you feel significant tension in the lower abdomen reduce the intensity of your exercising or stop exercising.

• Starting position

Lie on your back, slightly bend your knees and move your legs apart up to the width of your loins – to make a V-shape. Move your tiptoes slightly inwards. Now you can insert Aniball which you can lubricate if necessary. Press the pump a few times (1-5) so that you can feel the ball resistance. You will use this counter-pressure when exercising. Do not bend your head, the chin towards the Adam's apple. Turn your palms down against the mat.

• Basic Exercises

These exercises as well as visualisation are suitable for beginners; you can start doing your exercises immediately after childbirth, start exercising with Aniball after the lying-in period (no sooner, not before postpartum injuries have healed).

1. Take a deep breath, directing it downwards to the pelvic floor. When breathing out tighten the pelvic floor muscles upwards (the ball moves slightly inside) and hold – count to five at the maximum contraction and release the muscles while breathing in. Repeat 10 times – take a rest.
2. Take a deep breath, directing your breath downwards to the pelvic floor. When breathing out tighten the pelvic floor muscles as firmly as you can. When the muscles are fully tightened (do not relax them) make 4 quick strong contractions and then relax the muscles. Repeat the whole exercise a maximum of 5 times – take a rest.
3. Take a deep breath, directing it downwards to the pelvic floor. When breathing out tighten the pelvic floor muscles and at the same time slowly, vertebra by vertebra, tilt your pelvis up and elevate it to the point the trunk and gluteus are on one plane (only a few centimetres above the ground, do not bend your back). Try not to lift the chest. The weight of your body should be placed between the blade-bones. When breathing out hold

your pelvis tilted up (count to 5) and then start placing your back vertebra by vertebra on the mat, starting with the chest vertebrae first, then the pelvic vertebrae and finally the gluteus. Repeat 5 times – take a rest

4. "Imitation of walking"– take your starting position. The soles and heels are firmly pressed against the ground. Activate the pelvic floor muscles. Imitate walking – take turns lifting bent legs maximally 3 mm above the ground as if you were walking. This exercise is for advanced exercisers; you can perform it while sitting as well.

• **Basic relaxation position**

Lie down, move your arms slightly apart from the trunk, with your palms upwards, bend your knees and move your legs slightly apart to line up with your loins, knees pointing inwards, feet outwards. Breathe deeply. The time you devote to this basic relaxation position during which you relax the pelvic floor muscles should at least double the time you have devoted to your exercises.

Visualisation, which will help you correctly activate the muscles, is also part of the basic exercises. **Aniball enables women to become more aware of the way the muscles work and to perceive the deep muscles of the pelvic floor during exercising. After inserting the Aniball a woman receives feedback by the ball moving up and down.**

For more advanced exercises, please visit our website: www.aniball.eu.

The Aniball medical device has been developed in accordance with Directive 93/42/EEC, Government Order 54/2015 Coll. and Act N. 268/2014 Coll. on Medical Devices, as amended.



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Last revision: 1.8.2016