

BIOMATION

Purpose

AQUAFLEX® is a simple but effective exercise aid for treating female urinary stress incontinence and improving pelvic floor function. *Aquaflex* adapts superbly to a wide range of physical conditions and levels of muscle tone. *Aquaflex* is the most versatile cone system available.

For optimum results, a cone system with two sizes and a small increment of 5 g between weights is ideal. *Aquaflex* meets these objectives. You can prescribe *Aquaflex* with confidence for most of your stress incontinence patients.

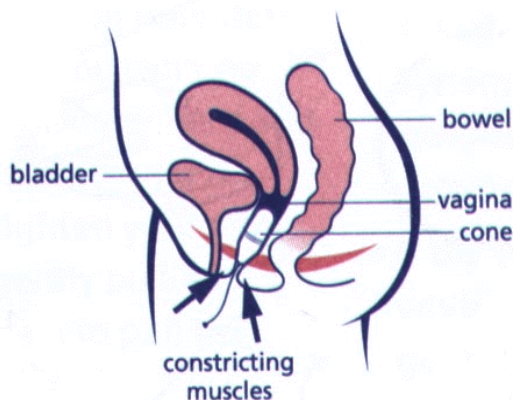
Reasons to prescribe Aquaflex cones are:

1. Easier and faster to teach pelvic floor muscle control.
2. The patient does the therapy at home, reducing the number of clinic visits.

Theory of Operation

The *Aquaflex* method functions by causing the contraction of the pubococcygeus muscle in response to the presence of the weighted cone. This improves muscle recruitment and increases strength; both are essential for developing and maintaining continence control. The weighted cone is especially beneficial for

strengthening the “slow-twitch” postural muscle fibres that are so important for continence, general well-being, sexual response and sexual intensity. When the cone does eventually slip out after a few minutes, this induces a powerful reflex action in the pubococcygeus muscle which activates and stimulates the muscle fibres. Your input and encouragement are important in the success of the Aquaflex method.



There are twelve different weight levels, from zero to 55 g. This gives you exceptional control over the patient’s exercise challenge level. This feature is important so that you can establish an effective and *patient-specific* exercise program. The patient uses the optimum weight for her level of muscle tone and can advance to heavier weights in small steps. This increases motivation by showing the progress achieved. It encourages steady and consistent progress.



AQUAFLEX Clinical Guide

Pelvic Floor Exercise Cones for Female Bladder Control

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Method of Use

The set includes two sizes of cones. The normal progression for home exercising is to start with *Size 2* (the larger size) and then progress to *Size 1* (the smaller size). At the start, the small cone could tend to fall out, even with a low weight. By beginning with the larger cone, this problem is avoided. To remove the cone, the patient relaxes her pelvic muscles and the cone falls out. Alternately, she can use the flexible plastic cord to remove the cone. Very soon, the patient will find that she does not need to consciously squeeze her pelvic floor to keep the cone in place. The main reason that unassisted Kegel exercises often fail is that the patient is not doing them correctly. When the patient uses the *Aquaflex* cones correctly and masters the technique, she will be recruiting the right muscles. In one clinic, the therapist found that it took approximately 45 minutes to properly instruct a patient to do Kegel exercises correctly. In contrast, *Aquaflex* typically took only 15 minutes of instruction.

To use *Aquaflex* in the clinic, it is helpful to start by finding the patient's *active level*. This is the weight that the patient can retain while contracting her pelvic muscles for one minute. Instruct the patient to squeeze and lift the pelvic floor. Verify by palpation that she is not contracting the abdominal, thigh or gluteal muscles. Then reduce the weight by 10 g. This is a good starting weight to find the resting level. The *resting level* is the maximum weight that the patient can retain for one minute while walking about and without contracting.

When used without weights, the cones are also helpful at the start of therapy as a teaching aid for showing the patient how to find and contract the right muscles. Almost all patients will benefit from *Aquaflex* therapy.

Aquaflex is complementary to biofeedback therapy. It is very useful to have an *Aquaflex* set available in the clinic. At the beginning of a series of treatment sessions, you could introduce the cones to the patient as part of a home exercise plan. She will quickly become familiar with the concept. If suited to her interest and goals, you can prescribe the exercise cones as the primary exercise aid, or, you can use them to augment other methods, such as FemiScan EMG biofeedback and E-Stim. *Aquaflex* will help your patient to increase her resting muscle tone more quickly than by Kegels alone.

The *Aquaflex* cone is designed with the optimum slope and shape for maximum muscle response during exercise. The starting weights are located mainly in the pointed portion of the cone to avoid any problems of the cone tipping sideways while in place, which would decrease effectiveness.

Detailed self-teaching instructions are included. *Aquaflex* will encourage the patient to exercise correctly between sessions in the clinic.

Many patients who otherwise might have difficulty in keeping up with unaided pelvic exercises find that the cones are an easy-to-use confidence builder and an ideal exercise aid. The *Aquaflex* system, can help your patients to

achieve overall better outcomes by encouraging home exercise.

After a successful program, you can suggest a lifetime plan to maintain pelvic fitness. At least once per month, between periods, and at the same time during the day, she can exercise with *Aquaflex*. If she can no longer hold the same weight, then daily exercise is needed to restore muscle tone.

Patients tend to remember what they see. Two videos are available from Biomation for you to show your patients:

1. *Aquaflex* Instructional Video
2. Treating Urinary Incontinence - A Guide to Behavioural Methods

Prescribing Information

Aquaflex is especially effective when prescribed for daily use at home. The method appeals especially to the busy and active patient who is aware of the importance of physical fitness and preferably exercises regularly.

A typical exercise plan is 15 to 20 minutes, twice per day. To start, you can recommend a shorter exercise period of one to five minutes depending on the patient's endurance and level of muscle tone. When *Aquaflex* is the primary treatment, the exercises should be performed once or twice daily for eight to twelve weeks.

You will need to tailor the exercise plan to fit your patient's situation and daily routine. The patient will likely need to decrease the weight level in the evening. This will illustrate the amount of fatigue developing in the pelvic muscles during the day. Very little extra time is needed each day because

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she can do other light activities while using the cone. Your guidance will be important to encourage slow steady progress because this will give the best results. Increases in the *resting level* correlate with improvements in continence.

Adding *Aquaflex* therapy into the patient's daily morning and evening routine is recommended. As in other forms of exercise therapy, the patient should not attempt to advance to the heavier weights too quickly.

You can also prescribe *active exercise* to increase effectiveness. Increase the weight by about 10 g over the resting level. The patient uses the squeeze and lift technique to hold the weight in place for about one minute. Repeat three times. Increase up to two minutes.

After using *Aquaflex* successfully, you can add Kegel exercises. These could consist of flicks, strength, incremental steps and endurance exercises, working up to 50 repetitions per cycle and four cycles per day.

For some patients, there can be faster progress with an exercise progression:

- Three weeks of *Aquaflex* therapy to help find, recruit and strengthen the correct muscles
- Three weeks of active Kegel exercises
- Three weeks of *Aquaflex* therapy to further develop the postural muscles

In general, you can suggest that she should work to a target increase of 20 g over her starting weight. By this time there should be total dryness or at least a significant improvement. Lifestyle changes can also be important. Each patient is different, and perhaps she will advance all the way to 55 g, but, on average, a 20 g increase is a reasonable objective.

Aquaflex does not need a lubricant, but a small dab of water-soluble lubricant such as K-Y™ or Muko® or wetting the surface of the cone with water can help insertion and exercising. If needed, a lubricant can make the exercise more intense and effective.

The patient will need to disassemble and wash the cone after each use.

Post menopausal women can use *Aquaflex* with the aid of estrogen cream, if required, when there is vaginal dryness.

You should stress that the objective is to achieve full bladder control. Otherwise the patient might tend to stop exercising before the full benefits are realized.

The *Aquaflex* cones should not interfere with a pessary, provided that the pessary is placed high up.

Falling within the category of a physiotherapy aid, and being used for a diagnosed medical condition, the cost of *Aquaflex* is covered by many extended-health insurance plans that cover physical therapy, continence products or medical equipment, when supported by a prescription.

Indications for Use

1. Diagnosed urinary stress incontinence
2. First stages of mild stress incontinence, to counteract progression to more severe incontinence
3. First degree prolapse
4. Weakness and improper recruitment of the pubococcygeus muscle due to childbirth or menopause
5. Pelvic therapy for patients awaiting corrective surgery for stress incontinence
6. Post operative physical therapy to reduce the incidence of a relapse.

Contraindications

1. Severe prolapse of the bladder or uterus
2. Dementia or inability to follow instructions
3. Pregnancy
4. Within six weeks of birth, where grazing or incisions have not yet healed
5. Within six weeks of vaginal corrective surgery
6. Vaginal infection or inflammation
7. Cervical or uterine cancer

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Beneficial Effects

1. Reduction or elimination of involuntary urine leakage
2. Increased pelvic muscle tone
3. Increased energy level, reduced feeling of tiredness
4. Resumption of a normal active lifestyle
5. Increased mobility and higher fluid intake produces significant overall health benefits
6. Decreased fear and anxiety about future long-term incontinence problems
7. Tendency for an increase in the libido, sexual response and sexual intensity
8. Savings on expenditures for pads and protective clothing

Problem Solving

1. The patient reports that the cone falls out even when using the large cone with no weight.

This is OK, but she is likely using the wrong muscles. She is bearing down with the abdominal muscles instead of squeezing and lifting up with the pubococcygeus muscle. This is a learned response; success can be expected after a few more exercise sessions. More instruction is needed.

2. In a new patient, the cone stays in— even with all weights.

The patient has inserted the cone too far and it has tipped over. It will not be very effective in this position. She should not insert it so far. Look for a rectocele. Use a lubricant.

3. The cone stays in easily and the patient does not think it is helping very much.

Use a lubricant, use the smaller cone and increase the weight to give a more intense exercise level.

Sterilization

It is intended that each patient should have her own personal Aquaflex set. However, as well as the patients' personal Aquaflex sets, you should have additional sets available for use in the office. After use, the set must be disassembled, washed, rinsed and then subjected to a high-level disinfection protocol by chemical soaking or by ETO gas.

Clean and disinfect the cone shells and the weights. To disassemble an *Aquaflex* cone, unscrew the two parts of the plastic cone shell, remove the weights and remove the plastic spindle.

Wash with soap or detergent. An enzymatic detergent such as Empower or Klenzyme, is preferable, if available, because it cleans away any protein material more quickly and effectively.

After cleaning, you can easily disinfect the set by chemical soaking such as in activated 2% glutaraldehyde (available as Metricide) or Cidex OPA. Soak for 20 minutes; then rinse and dry, or follow the recommendations of your facility's infection control guidelines.

Ordering Information

AF-55 Aquaflex Pelvic Floor Exercise Set

Distributed in Canada by:

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Clinical Trials: Weighted Vaginal Cones

1.	Testing and Training of the Pelvic Floor Muscles after Childbirth. Acta Obstet Gynecol Scand 68:301 - 304	<u>A. Jonasson</u>	Sweden	1989
2.	The conservative management of patients with symptoms of stress incontinence: A randomized, prospective study comparing weighted vaginal cones and interferential therapy. Am J Obstet Gynecol 162:87 - 92.	<u>K. Oláh</u>	England	1989
3.	Cones: A New Conservative Management for Genuine Stress Incontinence. British Journal of Obstetrics and Gynaecology vol. 95. Pp. 1049 - 1053	<u>A.B. Peattie</u>	England	1988
4.	Cones versus Physiotherapy as Conservative Management of Genuine Stress Incontinence. Neurourol Urodynam 7:265 - 266.	<u>A.B. Peattie</u>	England	1990
5.	Vaginal Cones for the Treatment of Genuine Stress Incontinence. Aust NZ J Obstet Gynaecol 30: 156 - 160.	<u>P.D. Wilson</u>	New Zealand	1990
6.	Use of Vaginal Cones for Pelvic floor Conditioning of Postpartum Women and for Treatment of Urinary Incontinence. Zentralbl Gynakol 118: 18 - 28.	<u>W. Fischer</u>	Germany	1996
7.	A Randomized Trial of Vaginal Cones and Pelvic Floor Exercises in the Management of Genuine Stress Incontinence. Kings College Hospital, London.	<u>J. Haken</u>	England	1990
8.	Effectiveness of Vaginal Cones in Treatment of Urinary Incontinence. Urologic Nursing, June 1992, v. 12 Number 2 69 -72.	<u>K. Moore</u>	Canada	1992
9.	Weighted Vaginal Cone Use in Patients with Stress Urinary Incontinence.	<u>A. Karan</u>	Istanbul	—
10.	Specialists and Users Endorse Cone Therapy.	<u>DePuy Healthcare</u>	England	1996
11.	Pelvic Floor Reeducation for Stress Incontinence. Comparing British Journal of Community Nursing, 2001 Vol6 No5.	<u>J. Laycock</u>	UK	2001
12.	Stress Incontinence. Weights prove an advance in treatment. Professional Care of Mother & Child, November 1991, p110-111.	<u>M.E. Dolman</u>	England	1991
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14.	Conservative Treatment of Stress Urinary Incontinence in Women A Systematic Review of Randomized Clinical Trials. British Journal of Urology (1998), 82 181-191.	<u>LCM Berghmans</u>	The Netherlands	1998
15.	Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones and no treatment in management of genuine stress incontinence in women. BJM	<u>K. Bo</u>	Norway	1999

Clinical Trials

16.	Vaginal weight cones. Theoretical framework, effect on pelvic	<u>K. Bo</u>	Norway	1995
17.	Conservative Treatment of Stress Incontinence in Sportswomen. Institute Francophone de Réadaptation Uro Génitale, Paris. 1990 Urodynamics Society Symposium Abstracts.	<u>A. Bourcier</u>	France	1990
18.	A Prospective Trial Comparing Interferential Therapy and Treatment Using Cones in Patients with Symptoms of Stress Incontinence. Dept of Physiotherapy and Dept of Urology, Selly Oak Hospital, Birmingham.	<u>N. Bridges</u>	England	1988
19.	Treatment of Stress Incontinence with Pelvic Floor Exercises and Biofeedback. American Geriatric Society 38:341-344, 1990.	<u>P. Burns</u>	New York	1990
20.	Active Vaginal Cone Therapy: A New Form of Treatment for Genuine Stress Incontinence. Northern Sydney Regional Urodynamic Service, Sydney, NSW, Australia, 1993.	<u>G. Burton</u>	Australia	1993
21.	Pelvic Floor Exercisers versus Vaginal Weighted Cones in Genuine Stress Incontinence. European Journal of Obstetrics & Gynaecology and Reproductive Biology 77 (1998) 89-93.	<u>H. Cammu</u>	Belgium	1997
22.	Conservative Therapy of Female Genuine Stress Incontinence with Vaginal Cones. European Journal of Obstetrics & Gynaecology and Reproductive Biology 62 (1995) 213-215.	<u>A. Dellas</u>	Switzerland	1995
23.	Current Status of Research on Pelvic Muscle Strengthening Techniques. JWOCN March 1998.	<u>M. Dougherty</u>	N. Carolina	1998
24.	Urinary incontinence: The basics: Ostomy Wound Management Vol41, No7, August 1995.	<u>KL. Kennedy</u>	Indiana	1995
25.	Conservative Management of genuine Stress Incontinence in Women. Vol 319. 17 th July 1999.	<u>BMJ</u>	London	1999
26.	Prospective Analysis of the Vaginal Cone Treatment for Stress Incontinence: Dept of Urology, Nagoya University Hospital and Dept of Research, Kodama Ltd, Tokyo, Japan.	<u>A. Kondo</u>	Japan	1993
27.	Randomised Prospective Trial of Vaginal Cones versus Kegel Exercises in Postpartum Primiparous Women: Dept of Obstetrics & Gynaecology, University of Utah School of Medicine, Salt Lake City, Utah. NeuroUrol Urodyn 1990; 9:434-5	<u>P. Norton & J Baker</u>	Utah	1990
28.	The physiological basis of pelvic floor exercises in the treatment of stress urinary incontinence: Kvinno Centre, South Perth, Australia.	<u>P. Papa Petros</u>	Australia	1998
29.	Pelvic Floor Exercise alone or with Vaginal Cones for the Treatment of Mild to Moderate Stress Urinary Incontinence in Premenopausal Women: Dept of Obstetrics and Gynaecology, University of Graz, Austria. International Urogynecology Journal 1995; 6:1, 14-17	<u>K. Tamussino</u>	Austria	1995
30.	New Method for Testing and Strengthening of Pelvic Floor Muscles: Urological Clinic, University Clinical Centre, Ljubljana, Slovenia. Proc Internet Continence Soc.	<u>S. Plevnik</u>	Slovenia	1985

Clinical Trials

31.	Effect of mediolateral episiotomy at delivery on pelvic floor muscle strength evaluated with vaginal cones: Dept of Obstetrics & Gynaecology, Karolinska Institutet Huddinge, Huddinge, Sweden.	<u>G. Rockner</u>	Sweden	1991
32.	Weakness of the Pelvic Floor: Urological consequences:	<u>R. Thakar</u>	London	1997
33.	Stress incontinence: Treatment using pelvic floor re-education.	<u>J. Unsworth</u>	England	1995
34.	Vaginal cones: A conservative method of treating genuine stress incontinence.	<u>E.Versi</u>	London	1988
35.	Stress incontinence and pelvic floor exercises: Professional Nurse, December 1990	<u>M. Wells</u>	London	1988
36.	Obstetric practice and the prevalence of urinary incontinence three months after delivery: British Journal of Obstetrics and Gynaecology.	<u>P. Wilson</u>	New Zealand	1991
37.	The Effect of Training with Vaginal Weighted Cones and Pelvic Floor Exercises on the Strength of the Pelvic Floor Muscles: A Pilot Study. The International Uro gynaecology Journal.	<u>T. Wrigley</u>	London	1995
38.	Nursing Management of Stress Urinary Incontinence in Women:	<u>J. Haslam</u>	London	2004
39.	Urinary Incontinence in Women: Have we anything new to offer?	<u>L. Cardozo</u>	London	1988
40.	Urinary Incontinence in the community-analysis of a MORI poll.	<u>J.C. Rocklehurst</u>	England	1993
41.	A randomized prospective study comparing new vaginal cone and FES-Biofeedback.	<u>J.T.Seo</u>	South Korea	2004
42.	Weighted vaginal cones for urinary incontinence.	<u>P. Herbison</u>	New Zealand	2002

Clinical Trials

In the clinical trials, what do the researchers say about vaginal cones?

“Training with vaginal cones provided significantly better pelvic floor muscle strength than did exercise without cones.” (1)

“The tendency of a vaginal cone to slip out again when inserted, giving the patient a feeling of ‘losing the cone’, produces a powerful sensory feedback, triggering pelvic contraction around the cone to prevent its dropping out.” (1)

The study found compliance to be significantly higher [with cones] as compared to pelvic floor exercise alone. (1)

“Vaginal cones would seem to be a simple and practical means of identifying and strengthening pelvic floor contractibility and hence improving genuine stress incontinence.” (5)

“Cone therapy is less invasive than surgery, can be performed by the patient at home without disrupting home life, is considerably less expensive and may be as effective as surgical correction.” (3)

“The patients who benefit the most from this therapy are those with stress urinary incontinence of less than two years duration.” (8)

“Because they require less medical or nursing time to teach, vaginal cones are a very cost effective option for the conservative management of genuine stress incontinence.” (7)

“After training, the capability of voluntary and reflex contraction of pelvic floor muscles was restored in all women [in the study].” (6)

“The use of vaginal cones has been found to be effective and a preferable treatment method.” (9)

“The patient needs commitment to use the cones effectively, and this is easier to achieve if there is an input from health professionals.” (12)

“The therapy has no side effects and only require that the patient is motivated enough to put the cone in the vagina and take it out after the prescribed time period. Everything else is automatic.” (37)