Automated pelvic floor muscle training
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PelviCenter has been successfully used in treating a wide range of lower urinary tract and pelvic floor disorders including:

- Male & Female Incontinence
- Pelvic floor rehabilitation
- Postpartum vaginal rehabilitation
Introduction

This brochure provides a description of the QRS®-PelviCenter, a unique therapy system based on Extracorporeal Electromagnetic Stimulation which automatically trains the muscles of the Pelvic Floor and thereby significantly helps restoring continence and improving sexual function.

This brochure is meant for specialists. It describes the indications and contra-indications for using the system. And it describes how a typical treatment is provided.

The QRS®-1010 PelviCenter provides you with a unique system for your clinic and allows you to offer a new highly effective solution to your patients. Please contact one of our representatives to learn more and to try the PelviCenter for yourself.

The Pelvic Floor

The power from within
The QRS®-PelviCenter

The QRS®-PelviCenter is a medical device which automatically trains the Pelvic Floor Muscles (PFM) via standardized programs, based on Magnetic Stimulation. It is a non-invasive and pain free therapy. Patient can be on the treatment fully clothed, comfortably, while reading a newspaper. The QRS®-PelviCenter makes use of a strong homogenous magnetic field which is able to penetrate deep into the Pelvic Floor and thereby to stimulate all surrounding nerves and train each relevant muscles.

Weakeneses in the strength and coordination of the Pelvic Floor Muscles (and the supporting fascia & ligaments) and subsequent prolapse of the urinary and reproductive organs is generally accepted as the most important reason for Urinary & Fecal Incontinence and also is one of the key underlying causes of Erectile Dysfunction.

Doctors generally recommend Pelvic Floor Muscle exercises as first line of treatment. These are normally self exercises (i.e. Kegel) with the help of specialized Pelvic Floor physiotherapists, but these self-exercise have some obvious disadvantages. The QRS®-PelviCenter takes away these disadvantages and allows for automated, standardized and highly effective training of the PFM.

The result is sharp improvement in strength and coordination of the muscles resulting in a faster rehabilitation of continence and sexual function.

The QRS®-PelviCenter 4-step-therapy

The QRS®-PelviCenter with the 4-step therapy is based on the TPM Transpelvine magnetic stimulation system that works simultaneously with oxygen insufflation, a light therapy in the visible spectrum and neurotransmitter activation using low-intensive PEMF pulsed electromagnetic field therapy. The therapy can be used to treat pelvic floor weakness (urinary and/or fecal incontinence) and erectile dysfunction as well as irritation of the bladder.

TPM, Transpelvine magnetic stimulation of pelvic floor muscles

Oxygen therapy during muscle activation

Light therapy at 10,000 lux: for the treatment of seasonal depression

QRS pulsed electromagnetic field therapy
The relevant muscles for ensuring continence include the internal sphincter (under involuntary control), the external sphincter and the Pelvic Floor Muscles. The external sphincter is under voluntary control of the Central Nervous System and consists of skeletal muscle fibers (losing about 2% of its strength each year). The external sphincter is primarily responsible for ensuring continence (“first line of defense”).

The Pelvic Floor muscles (“second line of defense” consist of the Levator Ani and the Coccygeus. The Levator Ani consists of the Pubococcygeus muscle (PC muscle), the Puborectalis and the Iliococcygeus. The PC muscle acts as a “hammock” like muscle that stretches from the pubic bone to the tail bone.

One key function of the Pelvic Floor Muscles is to support and lift the pelvic organs. When the Pelvic Floor Muscles become weak the pelvic organs prolapse. This leads to Incontinence as well as to deterioration of the sexual function.
Indications QRS®-PelviCenter

Indications are all the diseases which are wholly or partially due to:
- Weakening and/or Prolapse of the Pelvic Floor Muscles; or
- Tone of the PFM being too strong/ too tight

The QRS®-1010 PelviCenter has been successfully used in treating a wide range of lower urinary tract and pelvic floor disorders, including:
- Stress Urinary Incontinence
- Erectile dysfunction
- Postpartum pelvic floor rehabilitation
- Interstitial cystitis
- Postprostatectomy urinary incontinence with men
- Urge Incontinence, Bladder Overactivity and Mixed Incontinence

In addition, the QRS®-PelviCenter has proven to be effective in other areas including sacroiliac pain in the lower back, pressure ulcers and cellulite.

QRS®-PelviCenter treatment is normally applied in combination with conservative treatments but also has exceptional results when patients follow only the PelviCenter treatments.

QRS®-PelviCenter treatment provides a useful alternative for:
- Patients doing self exercises and who have difficulty with locating the relevant muscles that need to be trained and performing a correct contraction.
- Patients who do not respond to drug therapy; or who suffer from the negative side effects of the drugs.
- Patients who are poor surgical candidates
- Patients who lack the agility to manage electrical stimulation devices
- Patients who feel uncomfortable to undress and who finds typical incontinence treatment shameful
- Patients who have a desire to avoid being continually occupied with the Incontinence problem and who do not have the stamina to comply with the daily exercise regimen.

Side effects and contra-indications

QRS®-treatment is safe. There are no negative side effects and no risk of tissue damage. However there are some cautionary measures:

Absolute Contra-Indications:
- Pregnancy
- Electronic and metal implants
- Epilepsy
- Surgical operations < 3 weeks
- Severe cardiac arrhythmia

Relative contra-indications
- Menstrual period
- Acute urinary tract infection,
- Painful hemorrhoids
- Infections in the pelvic area.
A typical QRS®-treatment plan

Role of the specialist
It is important to note that every treatment plan must be set individually for each patient. This can only be realized in close cooperation with a professional doctor, who can give a prescription on the treatment plan. One QRS®-PelviCenter treatment takes 20 minutes. The doctor does not have to be present during the treatment, the assistant can operate the PelviCenter based on the treatment prescription given by the doctor.

Each patient requires an individual therapy program
The neuromuscular structure of the pelvic floor can vary widely between individual patients, specifically with respect to the amount of functional muscle mass present and the order or disorder of activity among the resident population of motor units. For example, inducing contractions within a pelvic floor that is characterized by severely atrophic muscles requires higher thresholds, compared with a case of mildly weakened pelvic musculature. The composition of the nerve fibers targeted by the QRS®-PelviCenter may also differ widely between individual patients.

QRS®-PelviCenter allows for different therapy programs
With the QRS®-1010 PelviCenter the doctor can choose different standardized, and proven, treatment plans. For example there is a standard plan for Stress, Urge, Mixed Incontinence and for Radical Prostatectomy. The doctor can also customize an individual treatment plan by changing amplitudes, duration, frequencies of the pulses as well as the recuperation (“off”) time between the series of individual pulses.

Standard treatment plan involves 16 treatments
A standard QRS®-PelviCenter treatment plan involves 16 treatments of 20 minutes each. Whereby in an optimal situation there must be 3 or 4 days between each treatment. Initial results are already noticeable after 2 or 3 treatments. Initially the patient must start the treatment with a low intensity (i.e. 20% of capacity), and during the course of the treatment plan gradually increase, depending on the situation and progress of the patient.

Chip card functionality
The QRS®-PelviCenter allows the doctor to program the required treatment plan (including number of treatments required) on a chip card, which can be passed on to the assistant/ operator. By inputting the chip card, the QRS®-PelviCenter starts the prescribed treatment plan.
Therapy for urinary incontinence and fecal incontinence

Cellulite treatment

Rehabilitation after child birth

Improve potency and libido

Rehabilitation after prostatectomy

For the general well-being
QRS®-PelviCenter Functionality

Ease of use
- Duration of treatment: 20 minutes
- No need to undress, treatment fully clothed
- Pain-free and with no side effects

Superior technology
- Top performance in high tesla range
- Built for high utilization rate
- Low noise even at high intensity

Ease of use
- Pre-set therapy programs in QRS smart card
- Easy to read instruction

Comfortable sitting position with adjustable footrest
Easy to read control panel
High quality leather finish
Therapy program with QRS smart card
With growing age, the strength of the muscles of the external sphincter deteriorates, about 2% per year. The effect is greater with women after having given birth or after muscles and nerves have been damaged because of surgery.

The QRS®-PelviCenter treatment:
Magnetic stimulation of peripheral nerves provoke muscle contractions and facilitate the stimulation of autonomic and somatic nerve pathways in the pelvic floor. Motor evoked potentials are triggered in the pelvic sphincter muscles.

The QRS®-PelviCenter helps the patient to learn how to use certain muscles, resulting in improved function and coordination between the muscles of the Pelvic Floor and increased strength (hypertrophy). The QRS®-PelviCenter trains and strengthens both the external sphincter muscle and the muscles of the Pelvic Floor. Thereby it ensures that the Pelvic Floor Muscles are able to respond better to a sudden increase in intra-abdominal pressure. And also ensures improving of the resting urethral closure pressure.
QRS®-PelviCenter therapy leads to a suppression of involuntary detrusor activity while increasing bladder capacity and compliance. This is realised by various effects on neurological pathways including pelvic floor afferents, autonomic efferents and somatic motor fibers.

The QRS®-PelviCenter therapy for Bladder Overactivity uses low frequency, rhythmic magnetic pulses. These reduce the overactive sensory triggers from the bladder. And also ensure inhibition of reflexes and impulses coming from the central nervous system reacting on these overactive impulses.
Rehabilitation after child birth

Vaginal delivery is an important cause of stress urinary and fecal incontinence and pelvic organ prolapse. In addition, the sexual function / quality of vaginal climax is often affected.

The QRS®-PelviCenter treatment can assist in quickly restoring the tone of the relevant muscles. The treatments can start soon after having given birth.

A conservative continence treatment for the elderly

Urinary incontinence is one of the key problems of the elderly and affects every aspect of an elderly person’s life. One of the aspects of UI is the self-imposed social isolation because of constant fear of incontinence in public, ultimately resulting in loss of self-esteem.

The economic costs of urinary incontinence to the individual and to society are enormous but the personal loss to the individual is by far the worst. Unfortunately, since urinary incontinence in the elderly is not a fatal disease, many people think it is part of the aging process.

The QRS®-PelviCenter offers a conservative treatment for the elderly in treating urinary incontinence. There is no need to implant electrodes. Only limited participation by the patient is required, as compared to active pelvic muscle exercises. QRS®-PelviCenter reaches the same improvements with Urge Incontinence as a conventional drug therapy but without the negative side effects.

QRS PelviCenter treatment offers equal benefit to younger and older patients
Erectile Dysfunction can be caused by a combination of various factors including psychological, hormonal, neurologic or vascular. Key risk areas include lifestyle factors, certain diseases (i.e. Cardiovascular; Diabetes Mellitus, Parkinson), side effects of prescription drugs (i.e. anticholinergic) and hormonal factors.

Normal penile erection (for the men) and normal sexual activity for the female requires coordinated involvement of the:
- intact central and peripheral nervous systems
- the bulbospongiosus, ischiocavernosus and pubococcygeus muscles
- normal arterial blood supply and venous outflow

The QRS®-PelviCenter works in all these areas. It activates the afferent fibers within the pudendal nerve. The pudendal nerve is of key importance to normal sexual activity, both with men and women. In addition QRS®-PelviCenter results in a sharp improvement of the tone of the relevant muscles, and has a strong positive effect on blood flow (amongst others via Nitric Oxide).

Prostatectomy results in a high incidence of Urinary Incontinence and Erectile Dysfunction. Prostate removal often results in damaging soft muscle tissue and pudendal and cavernosal vessels. After prostatectomy the external sphincter becomes primarily responsible for ensuring continence. The treatment of significant sphincteric incompetence is often surgical by means of the placement of an artificial urinary sphincter.

The QRS®-PelviCenter therapy
QRS®-International has treated many patients suffering from incontinence after Prostatectomy. The QRS®-PelviCenter treatment results in a rehabilitation of the strength of the sphincter and pelvic floor muscles. Already after a few treatments do the patients notice significant improvements.

Better sexual life for men and women
QRS-PelviCenter – Technical Data

**Dimension:** 187cm x 134cm x 173cm (H x B x T)

**Weight:** 120 kg

**Maximum load:** 135 kg

**Input voltage:** 230V ~, 50Hz

**Input Power:** max. 750W

**Fuse:** 2x T6,3A L 250V

**Output Signal**

- **Maximum Flux:** 1Tesla
- **Maximum QRS PEMF intensity:** 5V, 170mA, 40µT
- **Light therapy module, illumination:**
  - 2x 36 Watt, 10000 Lux within 20cm distance
- **Oxygen output / Oxygen concentration:**
  - 87 – 96% with 0.5 to 5 l/min
- **Medical device category:** Class IIa
- **Protection class:** I
- **Protection grade:** B
- **Encapsulation:** IPX0

**Environmental conditions**

**Operation of the device:**
- Temperature range: +13 °C to +30 °C
- Relative humidity: 30 to 75%

**Transport and storage:**
- Temperature range: +5 °C to +50 °C
- Relative humidity <90%, non-condensing

**Operation of the PelviCenter**
- Smart card controlled
- Pre-defined treatment programs
- Intuitive menu control
- Therapy programming on the PC

**Certification**
- Certified in accordance with Directive 93/42/EC
- Medical Devices
Clinical Trials

Over the last 10 years, more than 75 studies have been carried out into various forms of electro stimulation and magnetic stimulation. In total more than 3,000 patients have been included in the clinical trials.

QRS®-International has perfected the technology and has introduced the QRS®-1010 PelviCenter. Currently various Randomized Clinical Trials are underway in Europe, Asia and in the Middle East. Please contact one of our representatives for more information about the status and conclusions of these trials.