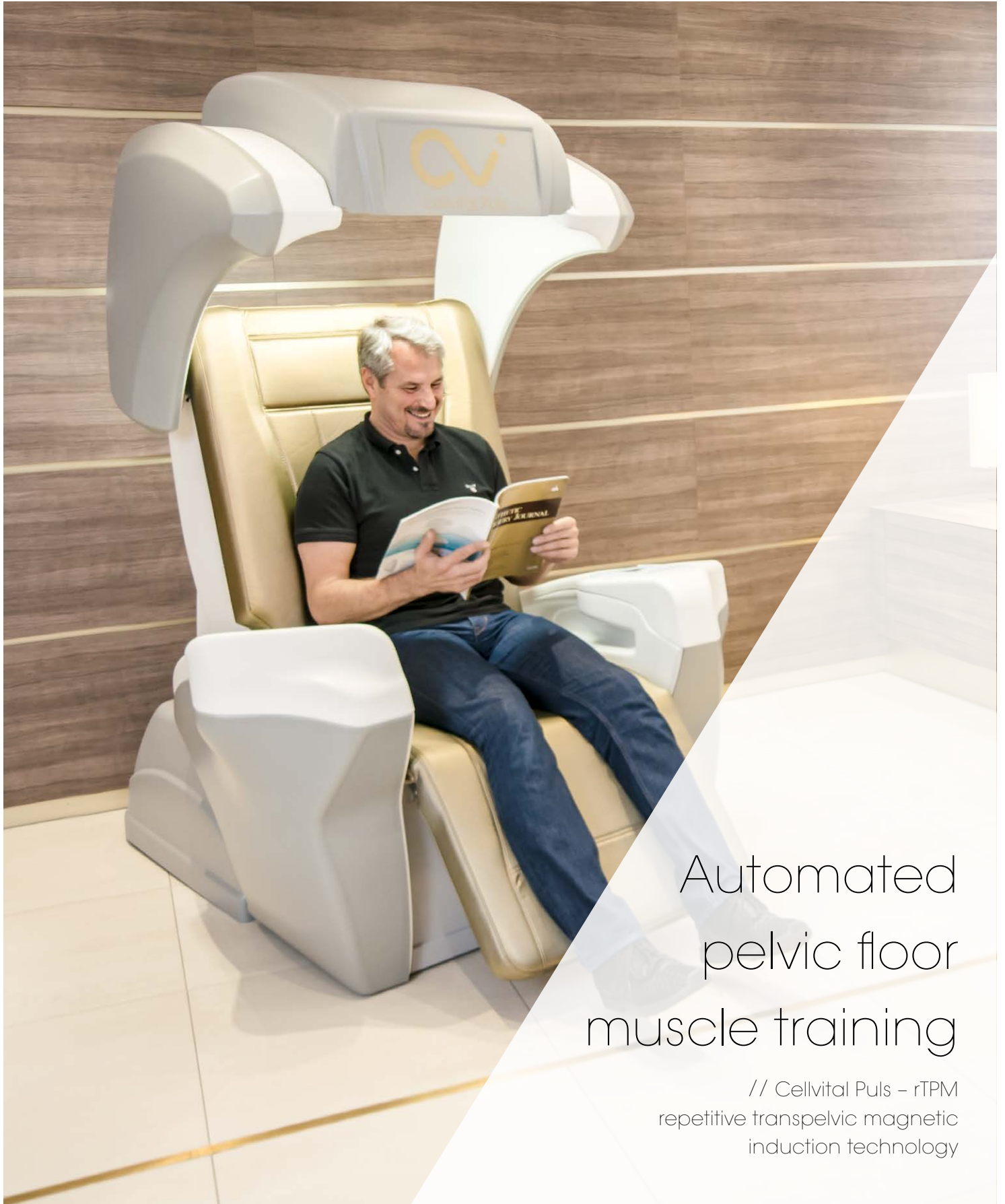




CELLVITAL-PULS THERAPY

REPETITIVE TRANSPELVIC MAGNETIC STIMULATION



Automated
pelvic floor
muscle training

// Cellvital Puls - rTPM
repetitive transpelvic magnetic
induction technology



CELLVITAL PULS

Cellvital

Introduction /

This brochure provides a description of the Cellvital Puls, a unique therapy system based on Extracorporeal muscle stimulation using intermittent repetitive transpelvic magnetic induction technology (called also rTPM). It trains automatically the muscles of the Pelvic Floor and thereby significantly helps restoring continence and improving muscular performance.

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 Cellvital Puls 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 Cellvital Puls for yourself.



THE PELVIC FLOOR – THE POWER FROM WITHIN

Cellvital

Cellvital Puls /

The Cellvital Puls 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 Cellvital Puls 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.

Weaknesses 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 Cellvital Puls takes away these disadvantages and allows for automated, standardized and highly effective training of the PFMs.

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

The Cellvital Puls 4-step-therapy /

The Cellvital Puls with the 4-step therapy is based on the rTPM repetitive Transpelvinen 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 muscular dysfunction as well as lower back pain or irritation of the bladder.



1

*rTPM repetitive
Transpelvine
magnetic stimulation
of pelvic floor
muscles*



2

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



3

*Oxygen therapy
during muscle
activation*



4

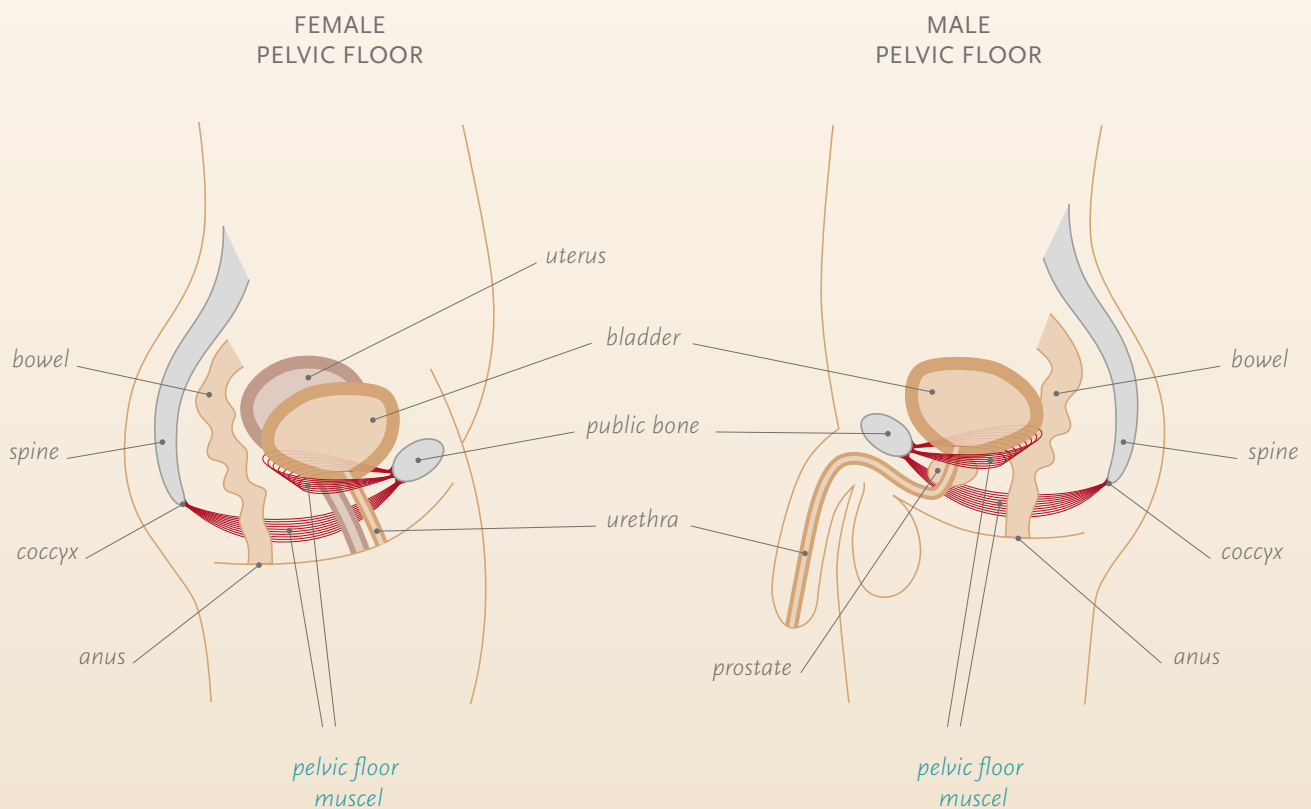
*Cellvital Puls
electromagnetic field
therapy*

The Pelvic Floor Muscles /

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.



PELVIC FLOOR MUSCLES SUPPORT AND LIFT THE PELVIC ORGANS

Cellvital

Core muscle
strenght
training



Improve
potency
and fertility



Rehabilitation
after
prostatectomy



Therapy
for urinary
incontinence
and fecal
incontinence



Women
pelvic floor
rehabilitation
after child birth



Lower back
pain and
arthrosis



Indications Cellvital Puls /

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 Cellvital Puls 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 Cellvital Puls has proven to be effective in other areas including sacroiliac pain in the lower back, pressure ulcers and cellulite.

Cellvital Puls treatment is normally applied in combination with conservative treatments but also has exceptional results when patients follow only the Cellvital Puls treatments.

Cellvital Puls 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 /

The Cellvital Puls 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.

Cellvital Puls
The safe, effective &
painless training. //

A typical 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 Cellvital Puls treatment takes 20 minutes. The doctor does not have to be present during the treatment, the assistant can operate the Cellvital Puls 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 Cellvital Puls may also differ widely between individual patients.

CELLVITAL PULS ALLOWS FOR DIFFERENT THERAPY PROGRAMS

With the Cellvital Puls 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 Cellvital Puls 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 Cellvital Puls 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 Cellvital Puls starts the prescribed treatment plan.

Cellvital Puls Functionality /



EASE OF USE

- > Duration of treatment: 20 minutes
- > No need to undress, treatment fully clothed
- > Pain-free and with no side effects
- > Pre-set therapy programs in CV-smart-card
- > Easy to read instruction

SUPERIOR TECHNOLOGY

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



Comfortable sitting position with adjustable footrest



Easy to read control panel



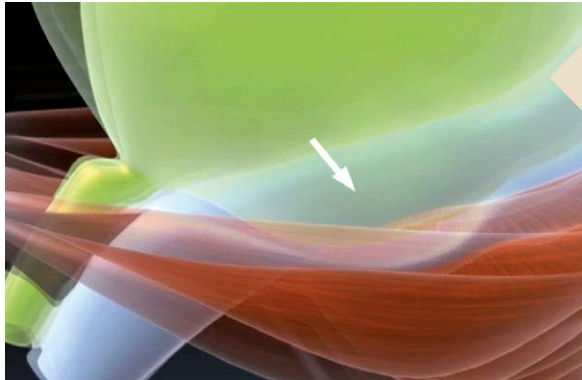
High quality leather finish



Therapy program with CV-smart-card



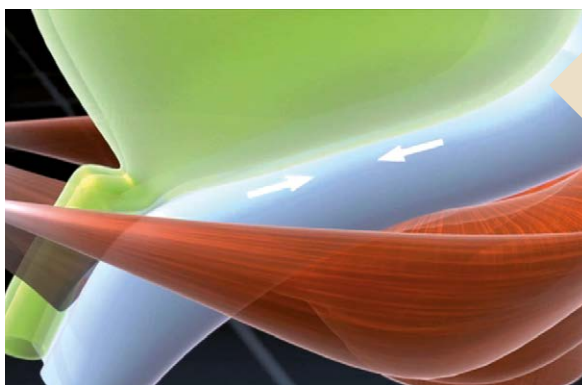
Stress incontinence therapy /



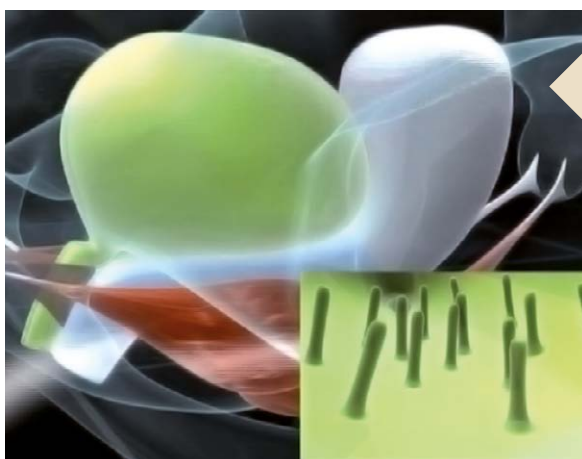
The Pelvic Floor acts as a type of “hammock” and a single functional unit. If a part of the structure is weakened then the hammock has lost some of its original functional and cannot perform efficiently. As a result of stretching of the fascia and ligaments, the urinary and reproductive organs prolapse. The Pelvic Floor Muscles can no longer push the urethra against the pubic bone resulting in Incontinence (DeLancey/ Petros & Ulmsten)



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.

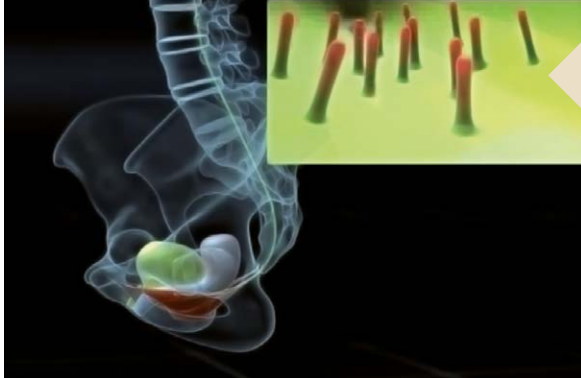
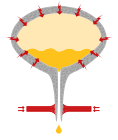


THE CELLVITAL PULS TREATMENT
Magnetic stimulation of peripheral nerves provoke muscle contractions and facilitate the stimulation of autonomic and somatic nerve pathways in the pelvic floor. Motor evoked potentials are triggered in the pelvic sphincter muscles.

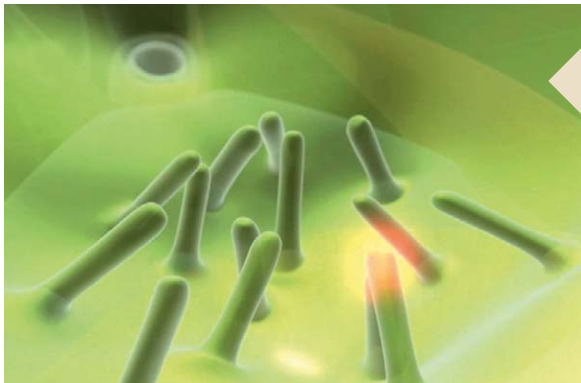


The Cellvital Puls helps the patient to learn how to use certain muscles, resulting in improved function and coordination between the muscles of the Pelvic Floor and increased strength (hypertrophy). The Cellvital Puls trains and strenghtens both the external sphincter muscle and the muscles of the Pelvic 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.

Urge Incontinence & Bladder Overactivity /



Cellvital Puls 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 Cellvital Puls 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.



Erectile dysfunction & fertility improvement /

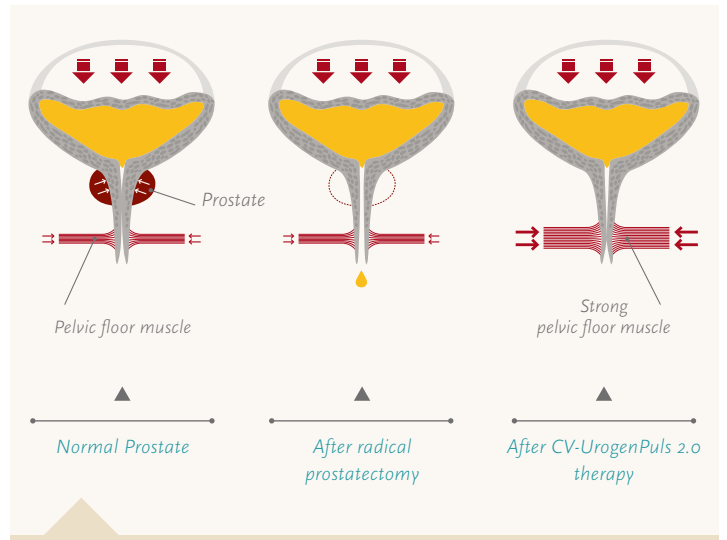
Erectile Dysfunction can be caused by a combination of various factors including psychological, hormonal, neurologic or vascular. Key risk areas include lifestyle factors, certain diseases (i.e. Cardiovascular; Diabetes Mellitus, Parkinson), side effects of prescription drugs (i.e. anticholinergic) and 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 Cellvital Puls 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 Cellvital Puls 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).

Stronger muscles for better performance //

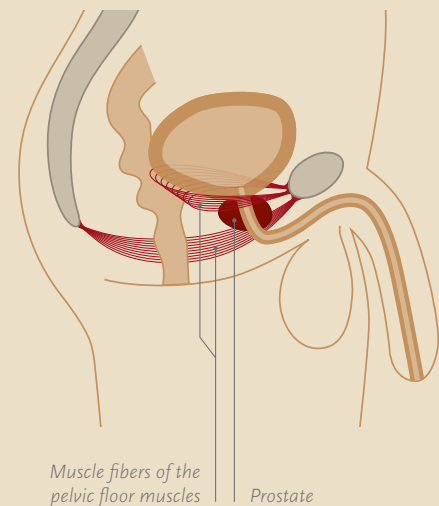


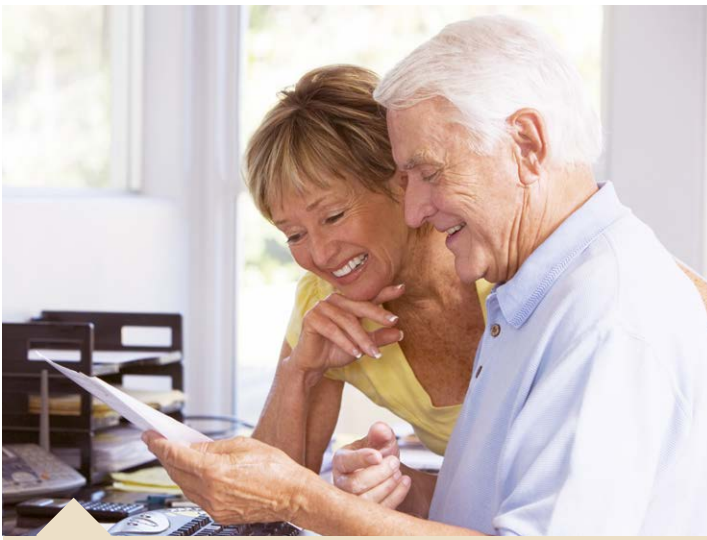
Rehabilitation after prostatectomy /

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 CELLVITAL PULS THERAPY

International has treated many patients suffering from incontinence after Prostatectomy. The CV-UrogenPuls 2.0 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.





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 Cellvital Puls 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. Cellvital Puls reaches the same improvements with Urge Incontinence as a conventional drug therapy but without the negative side effects.

Cellvital Puls treatment offers equal benefit to younger and older patients //



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 Cellvital Puls treatment can assist in quickly restoring the tone of the relevant muscles. The treatments can start soon after having given birth.

Cellvital Puls – Technical Data /



Dimension	187cm x 134cm x 173cm (HxBxT)
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	1 Tesla
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	IPXo

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 CELLVITAL PULS

- > 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



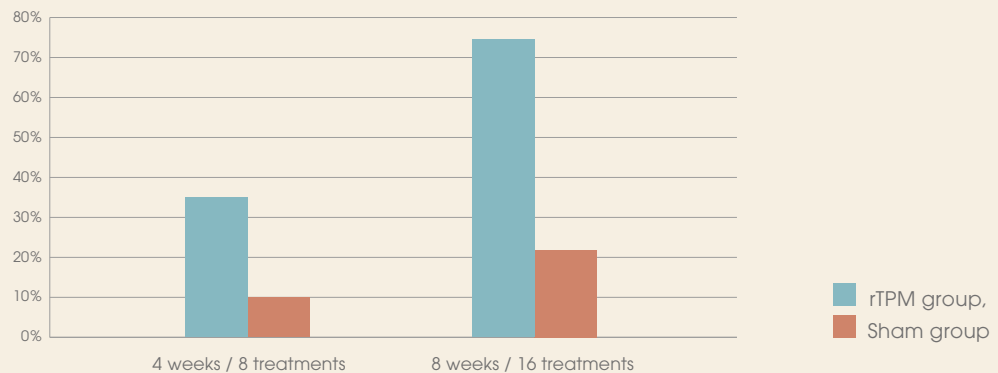
RESULTS OF CLINICAL STUDIES

Cellvital Puls

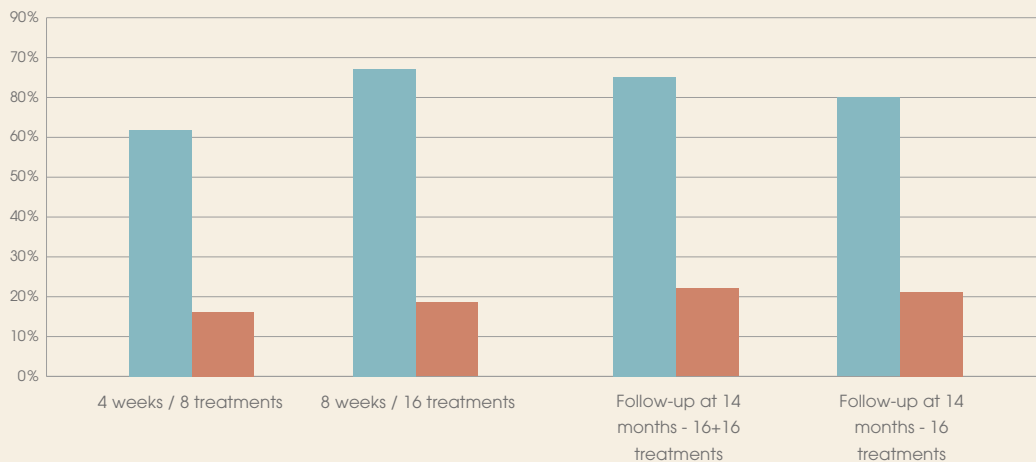
Study for stress urinary incontinence /

ABSTRACT: JOURNAL OF UROLOGY, 11-2016: Randomized, double-blind, sham-controlled parallel-group trial to evaluate the efficacy of magnetic stimulation (rTPM) for stress urinary incontinence

TRIAL RESULTS: The primary outcome measure consist of the number of patients having ≥ 5 point reduction on the ICIQ-UI SF scale (1-21), results: rTPM Stimulation group: 75% responder after 16 treatments, Sham group: 21,7% responder after 16 treatments. P value < 0,001.



1-JAHR FOLLOW-UP:



CONCLUSIONS: The encouraging long-term response rates show that pulsed magnetic stimulation is an attractive nonsurgical alternative for patients who do not want to undergo surgery.

RESULTS: At 2 months 45 of 60 subjects (75%) in the active arm vs 13 of 60 (21.7%) in the sham arm were treatment responders ($p < 0.001$). After 2 months 24 subjects (40%) in the active arm and 41 (68%) in the sham arm elected additional active pulsed magnetic stimulation. At 14 months, subjects who received 32 sessions of active pulsed magnetic stimulation had the highest percentage of treatment responders (18 of 24 or 75.0%), followed by those who received 16 sessions (26 of 36 or 72.2% and 28 of 41 or 68.3%) and those who did not receive any active pulsed magnetic stimulation (4 of 19 or 21.1%) ($p < 0.001$).

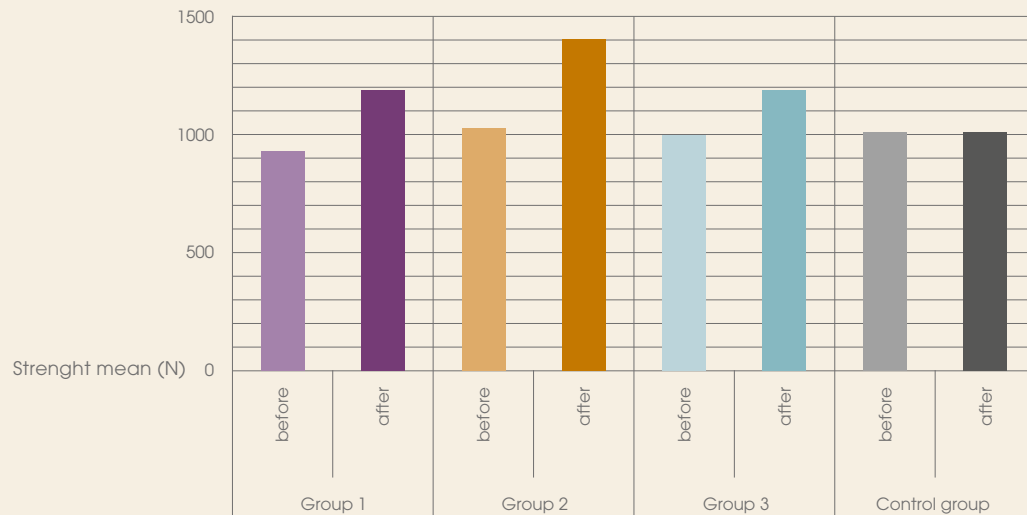
Ref. Renly Lim,*,† Men Long Liong, Wing Seng Leong, Nurzalina Abdul Karim Khan and Kah Hay Yuen

From the School of Pharmaceutical Sciences, Universiti Sains Malaysia (RL, NAKK, KHY) and Departments of Urology, Island Hospital (MLL) and Lam Wah Ee Hospital (WSL), Penang, Malaysia, and School of Pharmacy and Medical Sciences, University of South Australia (RL), Adelaide, South Australia, Australia

Variation of strenght: Verum versus Placebo /

rTPM STIMULATION EFFECT ON SKELETAL MUSCLES

Research study based on blinded experiment



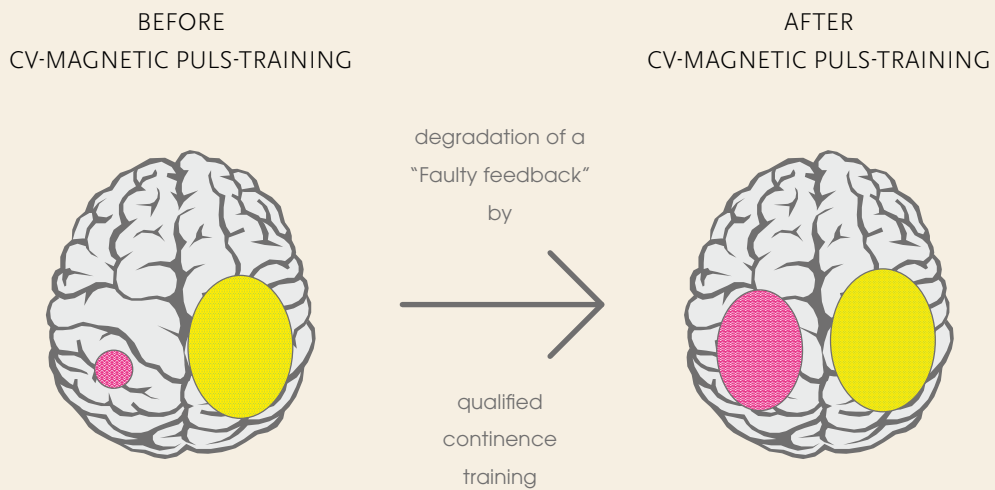
The effect of rTPM stimulation on the skeletal muscles ¹

- // For this purpose, the subjects expose their legs on a modified device (without backrest)
- // Study design
- // 105 subjects / 3 groups of 34 / placebo group à 33
- // Stimulation with rTPM
- 2 times per Week / duration: 6 weeks
- // Stimulation of the weak leg / M. gastrocnemio

1: Penka G et al. Bundeswehr-Universität München-Neubiberg 10.01.2011

Cortical motor representation areas: before and after treatment /

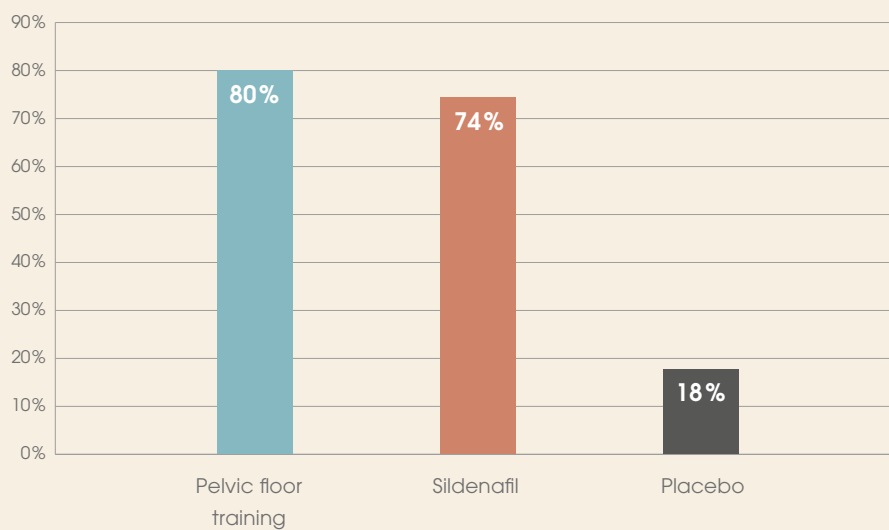
FIGURE: MOTOR REPRESENTATION AREAS IN THE CEREBRAL CORTEX



- Gravitationally active muscles, for example, pelvic floor
 - Artificially inserted skeletal muscle, for example, Abdominal, gluteal, thigh muscles
- Reahab clinic Bad Füssing – Germany – Dr. M. Zellner – Urology depart. 2015

COMPARISON STUDY: PELVIC FLOOR TRAINING VS. SILDENAFIL

Study: Sommer F. Uni Köln 2004 / double blind / 104 female / 3 x week / for 3 months





SIMPLE – COMFORTABLE – EFFECTIVE

Cellvital Puls

CELLVITAL GMBH
SCIENCE OF LONGEVITY

Arnulfstraße 199 / 80634 München / T + 49 (0) 89 660 61 475 / F + 49 (0) 89 218 98 592 / info@cellvital-puls.com / www.cellvital-puls.com

