Extracorporeal Magnetic Stimulation (EMS) of the Pelvic Floor

Consent Form (V1.0) Pioneer Health TMS Service (Other Conditions)

Patient Name: _____

Patient DOB: _____

Patient Address: _____

Patient Phone No: _____

Indication for Pelvic Floor EMS:

- ☐ Urinary Stress incontinence
- ☐ Female sexual dysfunction
- ☐ Male erectile dysfunction
- ☐ Other: _____

What is extracorporeal magnetic stimulation (EMS) of the pelvic floor?

EMS is a safe, non-invasive and effective treatment for some forms of urinary incontinence and other issues related to pelvic floor dysfunction. The fully clothed patient is seated on a special chair which has a magnetic coil in its seat cushion. This magnetic coil fires repeated magnetic impulses upwards to penetrate the patient's clothing, and tissues. The magnetic impulses elicit repeated contractions of the patient's pelvic floor muscles. Each treatment session takes 20 to 30 minutes during which the patient receives several thousands of these magnetic stimulations.

We recommend that patients with urinary incontinence have a series of 6 treatment sessions over 2 weeks. Patients may experience benefits after as little as two sessions.

The results of this repeated magnetic stimulation are as follows:

- Strengthening of all layers of the pelvic floor muscles
- Improved pelvic floor muscle endurance
- Enhanced blood flow to the pelvic region
- Improved bladder and bowel function
- Improved sexual function

The role of extracorporeal magnetic stimulation in the treatment of the pelvic floor dysfunction

It is well established that pelvic floor muscles are important for normal bladder and sexual function for both females and males. The pelvic floor muscles consist of levator ani and coccygeus, and when these muscles become weak, issues with incontinence, organ prolapse and sexual dysfunction can occur.

Urinary stress incontinence (USI) is a condition where there is leakage of urine during activities when there is increased pressure within the abdomen, such as coughing, sneezing or heavy lifting. The treatment options for this urinary stress incontinence can be divided into the following three categories:

- **Conservative measures**
  - These include continence pads.

- **Non-sugrical options**
  - Lifestyle changes such as weight loss, smoking cessation, fluid management, optimising bladder and bowel function and modification of activities to reduce abdominal pressure.
  - Pelvic floor exercises which are frequently provided by a pelvic physiotherapist (eg Katie Stan-Bishop at Pioneer Health). Pelvic floor muscle training may focus on improving strength, endurance, timing and coordination.
  - Continence pessaries which are provided pelvic physiotherapists and gynaecologists.

- **Surgical treatment options**
  - Surgery is generally reserved for patients with more severe and treatment resistant symptoms. There are various surgical options which include surgery through the vagina or abdomen for females as well as injection of bulking agents into the urethral wall. Surgery is invasive and comes with potential risks such as not fixing your USI, damage to nearby organs, infection and bleeding.

Extracorporeal magnetic stimulation (EMS) of the pelvic floor is a non-surgical treatment option for USI, and there is a good body of scientific evidence that EMS to the pelvic floor muscles is safe and effective treatment for urinary stress incontinence. EMS devices have been approved by the FDA in the US for urinary incontinence since June 2000. EMS treatment can be administered in conjunction with pelvic floor exercises or if pelvic floor exercises have proven to be unsuccessful.

Potential adverse effects of extracorporeal magnetic stimulation (EMS) of the pelvic floor

EMS to the pelvic floor is a safe, non-invasive procedure and is usually well tolerated. Most side effects are minimal and transient. This makes EMS one of the safest treatments for urinary incontinence.

Whilst EMS is an effective treatment, not all patients will respond to the treatment as hoped. Thus non-response or partial response to EMS is a potential adverse effect of the treatment.

Common minor side effects include:

- Temporary perineal muscle soreness, fatigue or spasms.

- Temporary tingling or prickling sensation in pelvic area or down the legs.
- Discomfort during treatment; a mild cramping or pulling feeling in your pelvis
- Increased vaginal discharge.

Less common more significant side effects include:

- Pain in the perineum, back or legs. (If this happens we would generally reduce the intensity of the magnetic simulation.)
- Bladder and bowel symptoms such as bladder irritation, constipation or diarrhea.

Who should NOT have EMS of the pelvic floor?

The following conditions are contraindications to EMS treatment:

- Pregnancy
- Intrauterine devices containing metal
- Following some hip replacement
- Pacemaker devices
- Certain types of pelvic pain syndromes
- Vaginismus/ pain with intercourse

If you have any of these conditions or devices please let your doctor or nurse know.

What about EMS to the pelvic floor for males?

EMS to the pelvic floor is similarly effective in treating male urinary stress incontinence, particularly after prostate cancer surgery or radiation.

Other Indications

What about EMS to the pelvic floor for female sexual dysfunction?

There is emerging evidence that EMS to the pelvic floor improves female sexual function. By repeatedly recruiting pelvic floor and per-vaginal muscles, magnetic stimulation may increase muscle bulk, endurance, improved vaginal support and perceived tightness. These neuromuscular changes can reduce coital leakage and urgency, increase genital blood flow and diminish pain, thereby improving sexual desire, arousal, orgasm, satisfaction and confidence.

What about EMS to the pelvic floor for male erectile dysfunction?

There is emerging evidence that EMS to the pelvic floor improves erectile function in men with various causes of erectile dysfunction (ED) including neurogenic, vasculogenic and psychogenic causes. The mechanism of action is believed to be stimulation of the peripheral nerves and muscles of the pelvic floor, including the cavernous nerve and deep dorsal nerve of the penis. This helps nerve and blood vessel regeneration, which is particularly beneficial for penile rehabilitation after procedures like radical prostatectomy. EMS may also be useful treatment for men with ED who have failed treatment with phosphodiesterase-5 inhibitor medications such as Viagra.

What is the cost of EMS of the pelvic floor?

In Australia extracorporeal magnetic stimulation is currently not covered by Medicare. This means that patients wishing to access this treatment need to pay privately. Part of the EMS treatment cost may be covered by some private health insurers, so please check with your private health insurer.

The cost of EMS treatment is $100 per session. This means a full treatment cycle of 6 sessions over 2 weeks to treat urinary stress incontinence will cost $600. If you are in financial hardship, please discuss this with the treating EMS doctor.

Please be aware that the extracorporeal magnetic stimulation fee is not refundable.

If you require a further treatment cycle in the future, a separate fee will apply.

How long do the benefits last?

The evidence for EMS to the pelvic floor seems to suggest that improvements in continence last for approximately 6 to 12 months, though many patients report significant long term improvements in incontinence and quality of life. All patients should continue with appropriate pelvic floor exercises to maintain good pelvic floor function after EMS treatments. Some patients may benefit from EMS maintenance sessions once or twice per year.

Your Quote

Your extracorporeal magnetic stimulation treatment cycle quote: $_____

Your number of magnetic stimulation treatments covered by this quote: _____

Patient Research Consent

I consent to be involved in the Pioneer Health EMS research project. Your de-identified data would be used for the purposes of research, publications and case reports.

- ☐ Yes
- ☐ No

Patient Safety Check List

Do you have any of the following:

Medical condition	Yes	No	Comment
Current pregnancy?			
Current intrauterine contraceptive device?			
Past hip replacement?			
Pacemaker implant?			
Past or current pelvic pain syndrome?			
Past or current vaginismus?			
Any genital piercings?			

Patient Consent

I verify that I have read and understood the above information and that I have had sufficient opportunity to discuss my extracorporeal magnetic stimulation therapy with the doctor.

I verify that I have understood the cost of my extracorporeal magnetic stimulation treatment cycle, and that I have agreed to pay the full quoted treatment cycle fee. I understand that non-payment of the quoted fee will result in cessation of the magnetic stimulation therapy. I also understand that the treatment cycle fee is nonrefundable.

Patient's Name: _____

Patient Signature: _____

Date: _____

Doctor's / Physiotherapist Name: _____

Doctor's / Physiotherapist Signature: _____

Date: _____