PERINEAL PROBES
FOR THE TREATMENT OF
INCONTINENCE
BY ELECTROSTIMULATION
& BIOFEEDBACK

PERIPROBE®
Perineal electro-stimulation

The reeducation of urinary incontinence exploit the perineal electro-stimulation to obtain inhibitory action on involuntary contractions of the bladder muscle (detrusor), in case of URGE incontinence (detrusor instability). In the cases of stress incontinence, the perineal electro-stimulation allows to develop muscle tone of the pelvic floor and improve the control of continence, during abrupt variation in abdominal pressure (effort, coughing, sneezing ...). Alternatively to the vaginal access, the pelvic floor muscles are also accessible via the anus. For this reason, perineal stimulation can be performed with vaginal probes, in adult female patients, or anal probes in the male patients, or when the vaginal access is unsuitable or not recommended.

Perineal biofeedback

Another therapeutic possibility for incontinence is represented by electromyographic (EMG) or manometric biofeedback techniques. The first one consists of detecting the muscular action potential generated by the pelvic floor muscles, the second one consists of detecting the intra-vaginal pressure during the contraction of the involved muscles. The therapy using biofeedback promotes awareness and voluntary control, by the patient, of the pelvic floor, in circumstances that could cause urinary incontinence.

Perineal electro-stimulation and perineal biofeedback are not alternative but complementary therapeutic techniques. Both perineal electrostimulation and perineal biofeedback involve the use of special vaginal or anal probes.

One patient, one probe

It is important that any patient may use his/her own personal perineal probe. Using the same probe on more patients is, more than ever, disadvantageous due to the complicated and not completely safe sterilisation by liquid sterilisers.

The perineal probes PERIPROBE® are intended for personal use and then no sterilisation process is required. Simply clean with tap water and mild soap after each session and the probe is ready for the next treatment.
PERIPROBE® - V2ST
Smart connection vaginal probe for perineal reeducation by electrical stimulation or EMG biofeedback

The particular constructive shape, in addition to ensuring perfect anatomical fit with the vaginal walls, allows easy introduction and comfortable retention by the patient. A large plastic ring defines the insertion limit of the probe. It has to remain outside the vagina and is aimed to separate the internal portion of the probe by the external connecting area.

The connection to the therapeutic unit is carried out by means of the PERIPROBE®-ST adapter.

Connecting the ST adapter to a personal probe VAG-2ST or ANA-2ST is easy and rapid: simply insert the plug of the adapter into the hole at the back of the probe and then push.

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<thead>
<tr>
<th>Code</th>
<th>ø min / max (mm)</th>
<th>Length (mm)</th>
<th>Weight (g.)</th>
<th>Colors</th>
<th>Elec. Surfaces cm²</th>
<th>Connection</th>
<th>N. Register</th>
</tr>
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<tbody>
<tr>
<td>RU-V2ST</td>
<td>15 / 25</td>
<td>110</td>
<td>30</td>
<td>White / Pink</td>
<td>5.7 / 13.6</td>
<td>Adapter ST</td>
<td>660550</td>
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The anal probe PERIPROBE® A2ST is characterised by 2 large-surface ring electrodes, gold-plated with nickel-free technique; therefore it can also be used by patients with allergies to that metal. It is predominantly indicated for electrostimulation while it is little or no indicated for EMG biofeedback.

PERIPROBE® A2ST has no wires and must be connected to the therapeutic equipment using the special PERIPROBE® ST adapter. The latter is equipped with a standard DIN 3 connector and can be connected to any therapeutic apparatus provided capable of generating symmetrical biphasic pulses strictly zero mean value.
Why the pressure biofeedback?

Either the EMG signal produced by perineal muscles contraction or the pressure generated by perineal muscles squeezing the balloon may be suitable to obtain a biofeedback signal. Although EMG biofeedback is widespread, we recommend to use the manometric biofeedback with the PERIPROBE® VAG-2STF balloon probe since it is easier to practice and less influenced by hormonal changes in the vaginal mucosa.

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<tr>
<th>Code</th>
<th>∅ min / max (mm)</th>
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<tr>
<td>RU-V2STF</td>
<td>15 / 25</td>
<td>110</td>
<td>35</td>
<td>White / Pink</td>
<td>5.7 / 13.6</td>
<td>2 mm F</td>
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The V2STFW model does not require the special STL adapter; the electrical connection is obtained by means of two wires while the pneumatic connection consists of a luer-lock (ISO 594) female termination. Through the electrical connection it can be used for perineal stimulation or for EMG biofeedback, through the pneumatic connection the probe can be used for the pressure biofeedback. While in the V2STF model the balloon pressure is converted to an electrical signal already at the STL adapter level (connected to the probe), in the conventional connection model (V2STFW), the balloon pressure is transferred to the biofeedback instrument through the tube.

A model without electrodes is also available (VBFT) and it is suitable only for pressure biofeedback.

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<tr>
<td>RU-V2STFW</td>
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<td>110</td>
<td>35</td>
<td>White / Pink</td>
<td>5,7 / 13,6</td>
<td>2 mm F + Luer-Lock</td>
<td>1377112</td>
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<tr>
<td>RU-VBFT</td>
<td>15 / 25</td>
<td>110</td>
<td>35</td>
<td>White / Pink</td>
<td>-</td>
<td>Luer-Lock</td>
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Unlike the VAG-2ST model, the electrical connection to the electro-stimulation unit is obtained by two 20 cm long cables and therefore does not require the PERIPROBE®-ST adapter. The particular constructive shape, in addition to ensuring perfect anatomical fit with the vaginal walls, allows easy introduction and comfortable retention by the patient. A large plastic ring defines the probe insertion limit and separates the invasive part of the probe from the outside, intended for electrical wiring.

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<tr>
<th>Code</th>
<th>(\varnothing) min / max (mm)</th>
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<tr>
<td>RU-V2STW</td>
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<td>110</td>
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<td>White/Pink</td>
<td>5,7 / 13.6</td>
<td>2 mm F</td>
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PERIPROBE® A2STW is an anal probe featuring two large-surface ring electrodes gold plated by means of nickel-free technique. Unlike the ANA-2ST model, the electrical connection to the electro-stimulation unit is obtained by two 20 cm long cables and therefore does not require the PERIPROBE®-ST adapter.

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<td>110</td>
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<td>White/Pink</td>
<td>5.0 / 5.0</td>
<td>2 mm F</td>
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The PERIPROBE® Minima vaginal probe is characterised by two semi-circular electrodes ensuring a wide contact surface with the vaginal walls. Due to its "tampon-like" shape and particularly small dimensions, it can be used with any type of vaginal anatomical conformation and is also suitable for patients sitting or standing.
Cylindrical shape vaginal probe with conventional wired connection, for perineal electrostimulation or EMG biofeedback

In addition to the anatomical model VAG- 2STW, a cylindrical shape model is also available. Its name is PERIPROBE® Classica and it is characterised by two asymmetrical incomplete ring-like electrodes. They allow avoiding to stimulate the bladder, when the probe is correctly inserted.

<table>
<thead>
<tr>
<th>Code</th>
<th>( \varnothing ) min / max (mm)</th>
<th>Length (mm)</th>
<th>Weight (g)</th>
<th>Colors</th>
<th>Elec. Surfaces cm(^2)</th>
<th>Connection</th>
<th>N. Register</th>
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</thead>
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<tr>
<td>RU-VClassica</td>
<td>25</td>
<td>110</td>
<td>37</td>
<td>White</td>
<td>5,23 / 7,85</td>
<td>2 mm F</td>
<td>660566</td>
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PERIPROBE® Analis, with its particular shape, facilitates insertion and retention. Shape and arrangement of the lateral electrodes allow for an effective and comfortable stimulation and a precise acquisition of the EMG signal.

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<tr>
<td>RU-AAAnalis</td>
<td>10 / 15</td>
<td>140</td>
<td>13</td>
<td>Transparent</td>
<td>1.76</td>
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The PERIPROBE® perineal probes are made entirely of biocompatible plastic material, with gold plated electrodes.

The electrical connection to the stimulation or EMG biofeedback unit is made using 2 mm connectors (female on the probe side). Alternatively, in the RU/A2ST and RU/V2ST models, the connection is made via a separate adapter (RU/ST) optionally supplied, which includes the connection contacts with the probe and the connection cable to the equipment.

Each probe is supplied non-sterilised, in a single sealed bag or in individual box together with the leaflet with instructions of use.

**Common features for all probes**

- **Materials in contact with the patient**: ABS/PC/TPE + gold. Plating is obtained by nickel-free galvanic process
- **Invasiveness**: vaginal or anal orifice for a period up to 1 hour.
- **Packaging**: Provided in a single (non sterile) package with warranty label and user instructions.
- **Cleaning and disinfection**: with water and possibly mild soap. If required, disinfect with alcohol and rinse with water before use. DO NOT sterilise.
- **Personal use**: It can be used for 60 sessions by the same patient (it can not be used by multiple patients).
- **Combined use**: it must be used with any electromedical pulse generator (with CE marking) equipped with a 2 mm plug ending wires, delivering biphasic pulses at zero mean value.
- **Production quality control**: In ISO9001 - ISO13485-certified system.
- **Operating and storage environmental limits**: + 5 ° to + 35 ° C with R.H. between 20% and 80%.
- **CE Marking**: Class IIa device according rule 5 Annex IX 93/42 / EEC - CE0051 marking, issued by IMQ, according to Annex II of Directive 93/42 / EEC.

**Contraindications**

- Vaginal or vesical infections,
- Colo-rectal or genito-urinary cancer,
- Pregnancy,
- Cardiac pace-maker holders (consult the doctor who prescribed the pace-maker),
- vesico-ureteral reflux
- hypotonic bladder

It is a CE marked medical device, carefully read the instructions before using it.