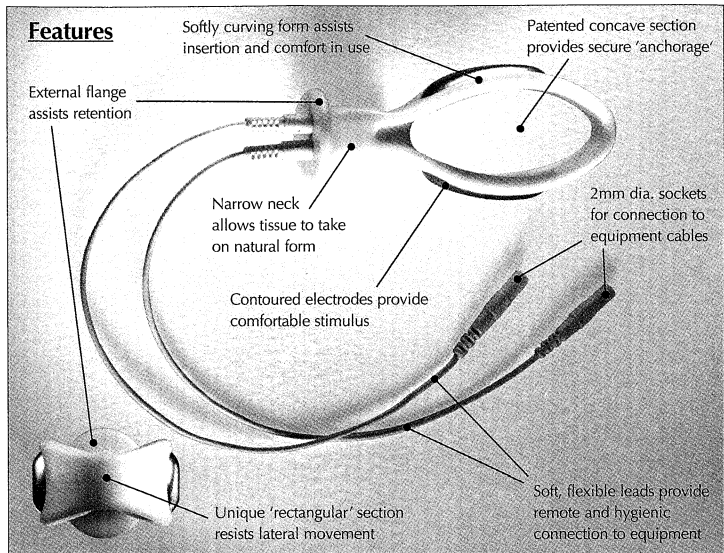


Intra-Vaginal Probe for Muscle Stimulation and Biofeedback.

The Periform® Intra-Vaginal Probe has been fully designed to produce more comfortable and effective use of both clinical and home-use muscle stimulator systems. The improved interface it provides also allows better use of EMG biofeedback equipment and, with its revolutionary Pelvic Floor Contraction Indicator, provides both you and your medical adviser with valuable information that will assist in the development of a healthy pelvic floor.



The revolutionary patented shape of the Periform® means that, for the majority of users, the probe will remain securely in place. This allows more accurate assessment in the standing position and permits complete freedom of movement when using a muscle stimulator at home.

Indications.

For use as an intra-vaginal probe in the treatment of 'Stress', 'Urge' and 'mixed' urinary incontinence. For use only with muscle Stimulation and EMG Biofeedback equipment approved to EN 60601-1. For SINGLE PATIENT USE ONLY – may be re-used by the same patient.

Contraindications.

Do not use if pregnant. **Do not** use with electrical stimulation if fitted with a CARDIAC PACEMAKER. **Do not** use if the package seal is not intact. **Do not** use if an infection, tissue damage or recent surgical scar is present. **Do not** use intra-vaginally during menstruation. **Do not** use electrical stimulation in patients with a history of carcinoma in the pelvic area.

Precautions.

Caution is advised when using electrical stimulation on patients with altered or reduced tissue sensation. **Caution** is advised during electrical stimulation if the user has a history of EPILEPSY - seek informed medical guidance. **Caution** is advised when using the Periform® with equipment capable of delivering outputs in excess of 2mA r.m.s./cm². If in doubt contact either the equipment manufacturer or your medical adviser. Discontinue use if an irritation or discomfort occurs - seek medical guidance.

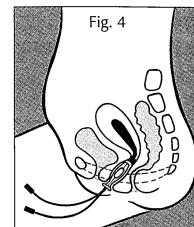
Cleaning.

Before use, always wash the Periform® in warm soapy water, rinse thoroughly and dry. **DO NOT USE BOILING WATER.** Repeat after each use and ensure that the Periform® is completely dry before storing. For additional hygiene, the Periform® may be disinfected once every two weeks using a solution of 1% sodium hypochlorite, leaving the last 10cm of cable outside the solution. Rinse thoroughly in clean water before drying and storage.

The Periform® Intra-Vaginal Probe may be used with or without the Pelvic floor Contraction Indicator. For instructions on the use of the indicator please see section below.

Instructions for use

N.B. Before first use: Wash probe including cables and indicator gently in mild soapy water. Rinse thoroughly in clean water, shake off excess moisture and dry.



1. Take clean, dry probe and spread a light coating of lubricating gel (e.g. KY Gel) over the main body of the probe to ease insertion. If it is to be used with muscle stimulation or EMG biofeedback equipment, ensure both metal electrode surfaces are completely coated with gel. **DO NOT** connect to equipment cables before insertion. If using the probe with the indicator connect the two together as directed below before insertion.
2. Insert the lubricated probe into the vagina ensuring an 'East-West' position, i.e. the metal electrode surfaces face towards each hip. Do not place too far into the vagina. (see Fig.4). The external flange should sit comfortably between the labia.
3. Ensure any muscle stimulation equipment to be used is turned off. Connect the equipment cable and use as directed by your medical adviser.
4. After use, turn off equipment, disconnect equipment cable and remove the Periform® probe. Do not pull on cables.
5. Clean, dry and store as instructed overleaf.

Pelvic Floor Contraction Indicator.

When fitted with the Pelvic Floor Contraction Indicator the Periform® may be used on its own (i.e. without EMG biofeedback or muscle stimulation equipment) to provide an extremely effective means of demonstrating the correct way to contract the pelvic floor (downwards deflection as shown in Fig.3)

In addition to the functions listed below, the indicator may also be used as a very simple exerciser and also provide valuable motivation that will assist progress throughout the regeneration programme.

The Periform® Intra-vaginal probe plus Indicator will also:

1. Quantify the strength and duration of both voluntary and involuntary (stimulated) contractions. Involuntary contractions can be reinforced by voluntary contractions resulting in a further deflection of the indicator.
2. Indicate the need to use muscle stimulation to strengthen a weak pelvic floor. (Little or no deflection of the indicator).
3. Teach bracing techniques to reduce upward deflection and leakage when coughing and straining.
4. Demonstrate success of a pelvic floor exercise programme.

To connect the Indicator to the Periform® Intra-vaginal Probe.

Most users find it easier if the indicator is first connected to the probe before insertion into the vagina.

1. As in Fig.1 carefully place the flat end of the indicator between cables. Slide the indicator forwards until it reaches the end stop of the probe. The ridge on the flat end of the indicator should now sit securely on the cables going into the probe.
2. As in Fig.2 the free end of the indicator should now be pointing away from the probe.

When the pelvic floor muscles contract correctly the indicator will move downwards as shown by the ✓ in Fig.3.

An upward deflection indicates incorrect muscle contraction as shown by the X in Fig.3.

