



REF X-VPK

Kegel Trainer - Vaginal Probe



INSTRUCTIONS FOR USE
READ CAREFULLY BEFORE USE

TensCare™

Indications for Use

For use as an intravaginal probe in the treatment of female urinary incontinence with muscle stimulation.

CONTRAINDICATIONS

Do not use a Muscle Stimulator if the following are present:

- Implanted pacemaker - *May affect correct operation of the device*
- Pregnancy - *Effect on foetal development is not known*
- Bladder or vaginal infection, or recent surgical scar - *Probe insertion may aggravate infection*
- With a history of carcinoma at the site of stimulation - *Laboratory tests show that electrical stimulation may enhance cell division*

Caution is advised

- On patients with altered or reduced tissue sensation - *Excessive stimulation may cause tissue inflammation*
- If the user has a history of epilepsy - *Use of electrical stimulation may lower seizure threshold*
- If the user has a severe prolapse - *Introduction of the probe, or muscle contraction, could damage the prolapsed tissue*



WARNINGS

For single patient use only. May be re-used by the same patient

Wash before first use

Do not use if pack is open or damaged

Do not immerse the probe in a liquid.

Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the socket.

Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber causing it to become less elastic and crack.

Warning: If you have active cancer, consult with your clinician before use due to concerns for stimulation potentially spreading cancerous cells.

Warning: Caution should be used if you have suspected or diagnosed heart problems because stimulation devices can affect heart rhythm in certain circumstances.

Warning: Caution should be used if you have suspected or diagnosed epilepsy as unexpected seizures may impair usage.

Warning: Caution should be used if you have a bleeding disorder as stimulation increases blood flow to the stimulated region.



CAUTIONS

Caution: Read all instructions before use. Failure to follow these directions may result in personal injury or damage to the equipment.

Caution: It is important that the probe is cleaned before and after each use. *Ineffective cleaning may lead to irritation or infection.*

Caution: Never insert or remove the probe unless the control unit is powered OFF as insertion or removal when stimulation is active may cause discomfort or tissue irritation.

Caution: If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment to prevent injury.

Caution: Do not use a silicone-based lubricant on the stimulation contacts as it may decrease the effectiveness of the device's muscle stimulation.

Caution: Caution should be used if you have total/partial prolapse of the uterus/vagina because this may impair your ability to fully insert the device and properly position stimulation contacts.

Caution: The stainless steel in the Trainer electrodes contains some Nickel. This could cause a reaction if you have Nickel allergy.

Caution: Electrode surface area is 8.58 cm². At high output settings on some devices, this could result in a current density greater than 2mA

RMS/cm². High current density may be associated with localised tissue damage or minor non-thermal burns. Increase intensity carefully and reduce if you experience sharp pain during use or discharge or bleeding after use.

Cleaning

The **Kegel Trainer** is designed for single patient use. Before first use, and after each subsequent use, the unit should be cleaned as follows:

Wash electrode including cable in warm soapy water. Rinse thoroughly in clean water.

Dry the electrode with a clean cloth/paper towel and allow to air dry before returning to the plastic bag.

Disposal

Clean thoroughly and dispose of according to local regulations

Technical Specifications:

Material: Electrode body: Plastic ABS PA-757

Electrodes: Stainless steel #304

Cables: PVC over copper tinsel conductor

Weight: 20 g

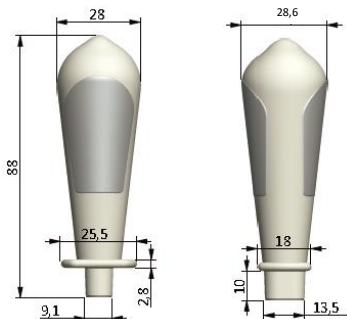
Length: 75.2 mm (inserted part)

Width: 28 mm diameter (widest point)

Connections: 2 mm pins

Electrode surface area: 8.58 cm²

“In Use” product lifetime: 6 months

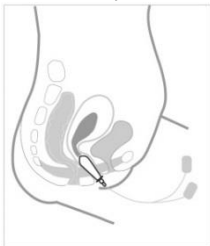


This symbol on the device indicates the need for the user to consult the instructions for use for important cautionary information.

Instructions for Use

1. Remove the Trainer from the packaging and clean as above.
2. Insert the lead in this pack into the Trainer
3. Choose a comfortable position, such as leaning back or lying down on your bed with your knees raised.

4. You may want to lubricate the Trainer with a water based personal lubricating gel or water, although this isn't always necessary.



5. Insert the Trainer into the vagina, in the same way as you would a tampon, until only the plastic rim at the base of the Trainer is visible.
6. Ensure that the control unit is turned off and connect the unit to the electrode via the connector ends.
7. After use, turn off equipment. Disconnect the cable from the electrode and clean as follows.



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