

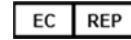
Vaginal Pressure Probe



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SA9005



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Product Name: Vaginal Pressure Probe

**Insert Number/
Revision** IS9005 rev 5
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The Vaginal Pressure Probe (Product No. SA9005) is designed for the Thought Technology Pressure Sensor for MyOnyx (Product No. SA9003) and the MyOnyx device (Product No. SA9020). It is not designed for other products.

Intended Purpose

This probe is intended for use in a medical or physiotherapy clinic. It is designed for biofeedback in the treatment of urinary incontinence, including stress, urge, and mixed incontinence. Other uses include muscle re-education, restoring neuromuscular control, and relaxing muscles in spasm.

Specifications



Dimensions

Size: 33*105 mm

Classification

Weight: 35 g

Type BF equipment

Environmental Conditions

Temperature: 5°C – 40°C,

Humidity: 80% or lower

Air pressure: 86 kPa – 106 kPa

Storage Conditions

Temperature: -20°C – 55°C

Humidity: 93% or lower

Air pressure: 70 kPa – 106 kPa

Altitude

2000m or lower

Caution

- RxOnly – US Federal law restricts this device to sale by or on the order of a physician
- Single User Only
- Do not sterilize
- Do not use this device in conjunction with electrical stimulators
- If irritation or discomfort persists, discontinue use and notify your doctor or health care professional immediately.

Medical Precautions and Contraindications

Before using the pressure probe, it is recommended that a proper evaluation of the patient be performed by a qualified medical practitioner. This would include, if relevant, a proctologic, urologic, and/or gynecological evaluation. Determining whether or not to use pressure feedback must be left to the medical practitioner based upon his or her professional judgment.

Use only after consulting a medical doctor, when patients are

- Pregnant, menstruating, or using contraceptives, such as diaphragms, cervical caps, or pessaries
- Undergoing artificial insemination
- Experiencing active symptoms of any pelvic disease, such as herpes, a sexually transmitted disease (STD), vaginitis, or yeast infection may aggravate symptoms.
- Have inflammation, infection, or dilated veins in the area of the vagina, malignant tumors, prolapsed uterus, or sustained hypertension of the pelvic floor.

Warnings / Precautions

- Do not use the pressure probe for six weeks following childbirth or pelvic surgery as this may interfere with healing.
- To diminish the risk of spreading communicable diseases, always use good hygiene practices. In all cases, refer to your facility's infection control procedure.

- If the patient feels the pressure in the probe is so high that she feels uncomfortable, she should pull out the tube connector immediately. This will deflate the probe.

Adverse Reactions

There are no known adverse effects in using pressure biofeedback for urinary incontinence. If irritation persists, discontinue use and notify your clinician immediately.

Maintenance and Care Instructions

Clean the pressure probe before using it for the first time and immediately after every use. Wash and lather your hands with soap in flowing lukewarm water and then liberally apply the same lather to the sensor. Rinse all soap residue from the sensor and your hands. Dry the pressure probe with a clean cloth or paper towel, allow it to completely air dry and store it in a plastic bag. Never subject the probe to extreme temperatures or abrasive detergents. Do not boil or autoclave the probe. Store at room temperature. Handle and dispose of the probe in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Instructions for Use

1. Clean the probe, as described in the Maintenance and Care section.
2. Instruct the patient to empty her bladder (and bowels, if necessary) before the biofeedback session in order to avoid later interruption.
3. You may need to lightly lubricate the tip of the sensor with a water-soluble lubricant. Place a dab of lubricant on a paper towel; then touch the tip of the probe to the lubricant. Usually, lubricating the tip is enough to facilitate insertion. Using too little lubricant may make insertion difficult. Using too much may impede proper measurement and cause the sensor to pop out as soon as the patient contracts her muscles.
Note: Never use a petroleum-based lubricant.
4. Instruct the patient to insert the probe gently into her vagina. She can adjust the depth and angle.
5. Connect the probe to the pressure sensor as described in the document accompanying the Pressure Sensor.

Notes: Do not disassemble the pressure probe as this will invalidate this warranty.

Do not alter or modify any cables or connectors. Doing so could affect the product safety and will invalidate the warranty.

The pressure probe is designed for single patient use. It is recommended to replace it after six weeks of regular use.

Important: This product is sold only in sealed packages. Do not accept or use the device if the seal was not intact upon delivery. Additional pressure probes are available from Thought Technology Ltd. by calling (514) 489-8251.

Thought Technology 90 Day Limited Product Warranty

Thought Technology Ltd. warrants to you, the first purchaser of this product, that this product will be free from defects in materials and workmanship for a period of 90 days from your date of purchase. The liability of Thought Technology Ltd. under this limited product warranty will be limited to repair or replacement of the defective product, in Thought Technology's Ltd. sole discretion or refunding your net price paid in the event repairing is impractical and replacing is impossible.

If you believe this product is so defective, you should immediately contact your local Thought Technology Ltd. sales representative. If you do not know who that representative is, please call Thought Technology's Customer Service Department at (514) 489-8251 or (800) 361-3651 (inside North America). Thought Technology will determine whether it may be repaired in the field, or if it should be returned to Thought Technology for repair, replacement, or refund. Wear and tear from normal use or defects resulting from misuse of this product is not covered by this limited warranty.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES RESPECTING THIS PRODUCT, WHETHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT WILL THOUGHT TECHNOLOGY BE LIABLE TO YOU FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

USERS IN THE EUROPEAN UNION

Any serious incident that has occurred in relation to the device(s) in which this Instructions for Use applies should be reported to the manufacturer identified in this Instructions for Use and the competent authority of the Member State in which the user and/or patient is established.