

## Prolieve Thermodilatation\* System Ordering Information

Order Number	Description
M0068808000	Prolieve Thermodilatation System
M0068808022	Prolieve Thermodilatation System Kit
M0068808030	Prolieve Thermodilatation System Temperature Monitor
M0068808121	Prolieve Thermodilatation System Console Printer Paper – Box 2
M0068808130	Prolieve Thermodilatation System Microwave Cable
M0068808100	Prolieve Thermodilatation System User Manual

### INSTALLATION REQUIREMENTS

#### 10.1 Site Access

The Prolieve Thermodilatation System is delivered in a large box, and it is therefore essential that adequate space for both unloading and unpacking is available at a convenient office access point.

#### 10.2 Shipping Dimensions and Weight

The Prolieve Thermodilatation System is shipped in a cardboard container that measures 26 in (66 cm) wide, 47 in (119 cm) long and 28 in (71 cm) high. The weight of the complete container is approximately 159 lbs (71 kg).

#### 10.3 Room Requirements

The treatment room itself should not only provide sufficient floor space to accommodate the Prolieve Thermodilatation System and any ancillary equipment (such as the ultrasound unit and treatment table), but also adequate working space for the operating staff and patient. A total floor area of approximately 144 sq. ft. would be appropriate.

The floor should be suitably covered to facilitate easy movement of the equipment.

Air conditioning must be available in order that the ambient room temperatures are maintained between 15°C (59°F) and 28°C (82°F), and the relative humidity be maintained between 20% and 80%.

While the Prolieve Thermodilatation System does not produce any noxious gases, the room ventilation system should provide at least 8 to 10 air changes per hour for natural odor removal.

The treatment room lighting should be of sufficient intensity to permit patient preparation and allow observation during the treatment period. Care must be taken with the lighting configuration to avoid possible screen glare.

#### 10.4 Electrical Requirements

The Prolieve Thermodilatation System requires a single phase and ground supply, and can accept voltages of 100, 120, 220 and 240 VAC at 50/60 Hz frequency.

Maximum voltage fluctuations in the range of ±10% can be tolerated. Where possible, the electrical supply to the Prolieve Thermodilatation System should be fed directly from the main supply transformer for the treatment suite, as this will minimize any voltage fluctuations. If large fluctuations cannot be avoided, a voltage stabilizer should be fitted.

A circuit breaker must be fitted to handle starting surge currents and a ground leakage current detector may also be fitted in line with the supply.

In order to minimize the possibility of mains-borne interference with other equipment, the supply ground impedance should be as low as can be achieved.

#### 10.5 Inspection

Carefully inspect the equipment immediately upon receipt. If external shipping damage is apparent, do not open crate or carton, and file a claim with the carrier immediately. Retain all packing material until the unit has been installed and is working properly. If there are electrical or other system problems, consult the factory or local agent.

#### 10.6 Power Cable Assembly

The Prolieve System is supplied with a hospital-grade insulated power cable 3 meters long for connection into a local AC line voltage power source. The Prolieve System is factory set prior to shipment and to the customer's preferred AC line voltage, 240/220/120 or 100 VAC.

Individuals depicted in this material are models and included for illustrative purposes only; models depicted are not users and do not endorse the Prolieve\* System.

#### 10.7 Microwave Output

The System provides a single output with SMA-type female connector for microwave output at an impedance of 50 ohms. The connectors are labeled as follows:

J1-Microwave power, 100 watts, maximum.

#### WARNING

**THIS UNIT MUST NOT BE OPERATED WITHOUT ATTACHING THE RF CABLE AND CATHETER TO THE MICROWAVE OUTPUT PORT.**

#### 10.8 On-Site Initial Installation

The System is shipped completely assembled, in a single box. Boston Scientific authorized installation personnel will install, connect and test the unit at the customer's location. It is important, however, to read the Operation Section (Section 10) in the user's manual carefully and completely before using the system.

#### ABBREVIATED DIRECTIONS FOR USE

Please refer to user manual for complete directions for use.

**INDICATIONS** The Prolieve Thermodilatation System is a transurethral microwave therapy device for the treatment of asymptomatic Benign Prostatic Hyperplasia (BPH) in men with a prostate size of 20 to 80 grams and prostatic urethra length between 1.2 cm and 5.5 cm and in whom drug therapy (finasteride or Proscar\*) is typically indicated.

**CONTRAINDICATIONS** Patients who have significantly decreased pain responses, severe urethral stricture prohibiting catheterization, current urinary or prostatic infection, penile or urinary sphincter implants, prostate sizes <20 g or >80 g, peripheral arterial disease with intermittent claudication or Leriche's Syndrome, protruding median lobe with obstruction, metallic implants, implanted cardiac pacemakers or defibrillators, previous transurethral prostatectomy, renal impairment, coagulation disorders, neurological disorders that may affect bladder function, bladder stones, evidence of prostate or bladder cancer or have an interest in the preservation of future fertility.

**WARNINGS AND PRECAUTIONS** All components of the Prolieve System must be used in accordance with the User Manual. The emission of microwave energy must be off during placement and removal of the catheter. Patient comments of pain or excess heat should be investigated. Failure to monitor adequately and deliver the procedure per User Manual may lead to decreased patient safety and/or reduced clinical effectiveness. A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period, may result in temporary or permanent sterility. No anesthetic other than aqueous-based topical intraurethral anesthetic used for catheter placement is recommended. The safety and effectiveness of the Prolieve System for men <50 and >80 years old has not been established in clinical studies. If procedure kit seal or internal sterile packaging seals are damaged or broken, the contents may not be sterile and could cause infection.

**POTENTIAL ADVERSE EFFECTS** that may occur include but are not limited to bleeding, bowel irritation, urethral injury (irritation), chronic pain at site, bladder spasms, urinary retention (complete or incomplete), urinary incontinence, prostatitis, pressure sensation, urinary urgency, urinary tract infection, urethral tear, anal irritation, urethral stricture, infertility, retrograde ejaculation and erectile dysfunction.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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