**Prolieve**

**How It Works**

To order Prolieve System Patient Information Kit,

**What to Expect During your Prolieve System Treatment**

- The physician will insert a catheter into your urethra.
- When microwave energy is turned on, it will be transmitted from a special antenna inside the catheter to provide heat to your prostate.
- The heat will reduce the enlarged tissue of your prostate.
- A small balloon that is also part of the catheter will inflate within the section of the urethra close to where the prostate is located.

For your safety, the Prolieve System's computer monitors the temperature surrounding the treatment area by means of a rectal temperature monitor. If the temperature at the monitor reaches 42°C, the system will shut off automatically.

The Prolieve System is FDA approved. The System's design and operating protocol were investigated in clinical studies of other men suffering from BPH. The results showed the Prolieve System is safe and effective.
Figure 1: This is a schematic illustration of a cross section of a prostate BEFORE treatment with the Prolieve Thermodilatation System.

Figure 2: This is a schematic illustration of a cross-section of a prostate immediately AFTER treatment with the Prolieve Thermodilatation System.

Figure 3: This is a schematic illustration of the proper internal position of the Prolieve Thermodilatation System balloon catheter in the prostate.

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Important information about the Prolieve™ Thermodilatation System.

INDICATIONS: The Prolieve™ Thermodilatation System is a transurethral microwave therapy device for the treatment of symptomatic 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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