

COMMODITY DESCRIPTION

H.S. NO	ITEM NO.	DESCRIPTION	QUANTITY	UNIT
		Transurethral water vapor ablation system (Generator)	1	system

A. FEATURES :

1. This product utilizes steam (water vapor, steam) for tissue necrosis, alleviating the symptoms and disorders of benign prostatic hyperplasia and facilitating the removal of prostate tissue.
2. The product consists of a generator, a delivery device, a sterile water injection device, and a sterile spike adapter. Sterile water is required for steam delivery and serves as a physical means to transfer thermal energy to the tissue.
3. The sterile water is heated into steam within the delivery device by the generator's RF power. This steam flows through the delivery device's shaft and is injected into the prostate tissue through a steam release port located at the tip of a needle positioned within the tissue.
4. The steam disperses convectively through the interstitial spaces of the prostate tissue, releasing direct thermal energy to the cells during condensation. This ensures that cell death and tissue necrosis occur only within the targeted and therapeutic areas of the prostate tissue.
5. Condensation occurs immediately upon injection into the tissue, rapidly transferring thermal energy directly to the membranes of affected tissue cells, thereby denaturing the membranes and inducing immediate cell death.

B. CONSIST OF :

1. Transurethral water vapor ablation system (Generator) 1 set
2. Accessories
 - 1) Cart
 - 2) Operating manual 1 copy
 - 3) Service Manual (Included circuitary information for trouble-shooting) 1 copy

C. SPECIFICATIONS :

1. Generator
 - 1) Water Flow Rate
 - Treatment State; 2.8 ± 0.1 mL/min
 - Idle State; 0.18 ± 0.025 mL/min
 - 2) Amount of Water Supplied Per Treatment; 0.37 ± 0.06 mL
 - 3) Saline Flow Rate
 - Normal flush; 90 ± 18 mL/min
 - Turbo flush; 185 ± 37 mL/min
 - 4) RF Output Settings
 - Treatment Output; 124 ± 3 Watt
 - Idle Output; 7.1 ± 1 Watt
 - 6) Hydropressure measurement



- 20 PSI $\pm$ 5 PSI(1034 $\pm$ 258 mmHg)
- 70 PSI $\pm$ 5 PSI(3620 $\pm$ 258 mmHg)

D. REMARKS :

1. Installation

- Supplier or contractor should be responsible for installation of this equipment.

2. Warranty

- Supplier or contractor should be responsible for free of charge after - service whatever there is any defect or any trouble for three years after being accepted by customer.
- If contractor and supplier do not supply appropriate service manual, the period of time for warranty is six years.
- If a warranty of less than three years is provided for all or part of the equipment, it is separately described in section B. Consist of.

3. Etc.

- If there is a request from the user department, the supplier provides hospital computer data linkage (1-year warranty) such as EMR, PACS, and LIS free of charge, and the procedures of data link should be proceeded with the department of medical information in KYUNGPOOK NATIONAL UNIVERSITY HOSPITAL.
- The operating system required for operating the equipment should be based on Win11Pro. In case of lower versions, the supplier must report to the KNUH Information Security Team and should perform free upgrades of the operating system and operating software according to future equipment updates.

