

SEP 16 1996**510(K) SUMMARY**

K 962506

The FemRx ^{TURP}STAR™ System is intended for urological transurethral resection by trained professional urologists in hospital environments. This device is intended for resection, morcellation and aspiration of tissue in the urethra, prostate and bladder.

The FemRx ^{TURP}STAR™ System is a refined urologic resectoscope. The device consists of: 1) an electrode/tissue morcellator assembly including drive cable, 2) a sheath and; 3) a motor drive unit. A standard telescope is inserted into the device and coupled to an operative video camera system prior to use. The device is compatible with a variety of standard electro-surgery units (ESUs).

The system is designed to cut and coagulate prostate tissue by sliding the loop/morcellator assembly in an axial manner relative to the handle/spring housing. Cutting and coagulation are accomplished by energizing the electrode with electrocautery current from an approved ESU. All cutting/coagulating occurs under visual control by a surgeon observing a video monitor displaying the view through the telescope. Cutting/coagulating is only performed while the device is moving *towards* the operator. Typically, the surgeon squeezes the finger rings to move cutting end distally; electrocautery is then applied and cutting/coagulating is accomplished by the active end as the spring returns the device to the most proximal resting location. The surgeon uses hand pressure to control the rate of sliding of the active end within the sheath. Separate channels are provided for irrigant inflow and outflow, permitting continuous fluid circulation for good visibility.

The system is identical (substantially equivalent) to the FemRx ^{OPERA}STAR™ System used in gynecological applications.