

Holmium Ablation of the Prostate

With the VersaPulse® PowerSuite™ Holmium Laser

M0068408290.....Lumenis Brand VersaPulse PowerSuite 100 Watt Holmium Laser

M0068408460.....DuoTome SideLite™ 550 Micron Delivery System

INSTRUCTIONS FOR USE

Refer to the Directions for Use provided with this product for complete instructions, warnings and precautions prior to using the product.

INDICATIONS

The DuoTome SideLite™ Fiber delivery device is compatible with the following lasers:

VersaPulse® 2.1 Holmium
VersaPulse Select™ Holmium
VersaPulse Select Dual Wavelength
VersaPulse PowerSuite™ Holmium
VersaPulse PowerSuite Dual Wavelength

The device is intended for use with the compatible lasers in surgical procedures involving open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue, cartilage, and calculi. For the safe use of the devices, read and comprehend these Instructions and the appropriate laser operator manual before use.

CONTRAINDICATIONS

The device is contraindicated for treatment of patients for whom endoscopic procedures are contraindicated. Refer to the laser operator manual for contraindications that may be specific to each surgical specialty.

WARNINGS

When using a fiber optic delivery device, always inspect the fiber optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.

POTENTIAL ADVERSE EFFECTS

The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery.

Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours. Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment.

CAUTIONS

Baskets, guide wires, and other ureteroscopic accessories may be damaged by direct contact with the laser treatment beam.

U.S. federal law restricts this device to sale by or on the order of a physician.

TRADEMARKS

Federal (USA) law and governing law outside the USA restrict these devices to sale by or on the order of a physician. Legal Manufacturer: Lumenis, Ltd. Distributed in the U.S. by: Boston Scientific Corporation. VersaPulse, VersaPulse Select, PowerSuite, DuoTome SideLite are trademarks of Lumenis, Ltd.

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