

Flexiva™ High Power Single-Use Laser Fiber

Prescriptive Information

Refer to the device directions for use for complete instructions on device use. Intended

Use/Indications for Use

The Flexiva Laser Fiber is designed for use with Ho:YAG and Nd:YAG lasers for indications that are cleared for these laser systems, including, but not limited to endoscopic, laparoscopic, and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection, incision of soft and cartilaginous tissue, and fragmentation of urinary and biliary calculi (Ho:YAG wavelength only). The fiber is designed for use with a standard SMA-905 connector that have been cleared for surgical use.

Contraindications

- The Flexiva Laser Fibers are contraindicated for treatment of patients for whom endoscopic procedures are contraindicated.
- Refer to the laser User Manual for contraindications related to the laser system .

Warnings

- For single use only. Do not reuse, reprocess or resterilize.
- Improper use of the device or use of a damaged device may result in severe eye or tissue damage, fire in the treatment room and accidental laser exposure to the treatment room personnel or patient.
- Baskets, guidewires and other ureteroscopic accessories may be damaged by direct contact with the laser treatment beam.
- Do not bend fiber at sharp angles. If visible light (aiming beam) can be seen leaking from the fiber, fiber failure may result when therapeutic energy is applied as the fiber is deflected beyond the optical limits of total internal reflection.
- Fiber should not be clamped with forceps or other securing instruments as it could result in fiber damage or breakage.
- Ensure that all procedure room personnel wear appropriate protective eyewear during the delivery of laser energy. Failure to do so may result in injury.

Warnings can be found in the product labeling supplied with each device.

Potential Adverse Events

The potential adverse effects associated with holmium laser fibers may include but are not limited to:

- Infection
- Thermal damage
- Hematoma
- Perforation
- Discomfort
- Incontinence
- Vesicoureteral Reflux
- Cholangitis
- Post-procedure fever and leukocytosis (associated with tissue destruction)
- Bleeding
- Hypertension
- Vasovagal response
- Edema
- Delay in healing

Precautions

- Do not exceed the recommended maximum power levels associated with the selected fiber size.
- Do not use this laser fiber in the presence of flammable anesthetics or combustible materials.
- 50 W maximum power for the Flexiva 200 Fiber, 100 W maximum power for the Flexiva 365, 550 and 1000 Fiber.

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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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