

## INSTRUCTIONS FOR USE

### Dornier GentleFlex Laser Fiber Single Use Holmium Fiber

**Introduction and Application:** The GentleFlex Laser Fiber is a sterile-packed, single-use fiber cable appropriate for use with all Dornier Medilas H Holmium Lasers. The GentleFlex Laser Fibers are appropriate for both contact applications and non-contact applications in liquids.

**Indications for Use:** The GentleFlex Laser Fiber is intended to be used as an accessory for Dornier Medilas H Holmium Lasers. The lasers are intended for cutting, vaporization, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopes), or for open surgery for contact or non-contact surgery with or without a handpiece for use in incision/excision, vaporization, ablation and coagulation of soft tissue. The Lasers are indicated for use in medicine and surgery, in the following medical specialties: Arthroscopy, Urology, Lithotripsy, Pulmonology, Gastroenterology, Gynecology, ENT, General Surgery. The GentleFlex Laser Fibers which are described in this manual, are qualified for short time invasive human application. The fibers are authorized for single use, i.e. one usage cycle (Usability).

**Description:** The GentleFlex Laser Fiber is a silica-glass core fiber with a spherical fiber tip. The fiber consists of approximately 3.0 meter length of fiber terminated with a SMA 905 connector and distal tip.

**Safety:** Follow all safety instructions concerning Laser radiation as provided in the Operator's Manual of the Laser being used. User must have completely read and fully understood Operating Manual of the Laser.

**Caution:** The GentleFlex Laser Fibers are fragile and must be handled with utmost care. Avoid bending or coiling fiber beyond the manufacturer recommended minimum bend diameter (reference Fiber Specifications); doing so may result in light leakage or fiber breakage that could cause personal injury if Laser is fired. (Refer to Laser Operator's Manual). Confirm scope is undamaged before inserting the GentleFlex Laser Fiber. A damaged scope could cause fiber damage. The GentleFlex Laser Fiber can be inserted into a deflected ureteroscope only before energy has been applied. Inserting a GentleFlex Laser Fiber through a deflected scope after energy has been applied could cause scope damage.

**Warning:** Only trained and qualified personnel are authorized to operate GentleFlex Laser Fibers. Ensure that fiber cable remains sterile prior to use and heed valid regulations concerning handling of sterile devices. All persons present during fiber use must wear protective Laser eyewear. See the Laser Operating Manual for requirements concerning protective eyewear.

**Operation:** This section describes preparation and operation of the GentleFlex Laser Fibers.

- Carefully remove fiber cable from sterile package and attach SMA connector end to fiber cable adapter on the Laser.
- Point fiber tip away from persons in the room. Turn Laser on and in standby mode set the desired power output.  
**-Maximum power for the GentleFlex Laser Fiber is 35 Watts in liquids.**

- Illuminate onto a non-reflective surface with distal end of fiber cable and observe the output pattern. A well-defined circular pattern with minimal distortions of light should be observed. Inspect entire length of fiber for flaws or defects before using.
- Refer to Operating Manual of the Laser for operation information.
- Confirm adequate eye protection is used when performing treatment procedure.

**Storage and Handling:** Each GentleFlex Laser Fiber is to be stored within the original package in a clean, dry location until utilized. Follow environmental storage conditions as indicated on the fiber box. Do not use if sterile package appears to be damaged. The GentleFlex Laser Fibers are fragile and must be handled with utmost care. Avoid bending or coiling fiber beyond the manufacturer recommended minimum bend diameter (reference Fiber Specifications below); doing so may result in light leakage or fiber breakage that could cause personal injury if Laser is fired (Refer to Laser Operating Manual). Fiber cables should be handled using gloves to prevent contamination.

**Return Policy and Procedure:** Prior to returning any product, please contact your local GentleFlex Laser Fiber Sales Representative to request return approval and a (RMA) Return Material Authorization number. Please provide the product part number and lot number. Returned product should be returned in original packaging (when possible) and marked with the RMA number on exterior of the package.

**Note:** To comply with U.S. Postal and Transportation law, any used product returned for repair or replacement must be properly decontaminated with a chemical germicide that has been cleared for use as a "Hospital Disinfectant". To ensure that the product has been properly decontaminated, a signed Decontamination Certificate must be enclosed in the package.

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




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**Fiber Specifications: 3 fibers per box**

GentleFlex Laser Fiber Box Part Number	Fiber Color Code	Core Diameter	Min. Bend Diameter	Fiber Length	Max. Power Input
HOL20058TBX	White	272 micron	≥ 17 mm	3.0 meter	35 W In liquids

**Symbol Legend:**

	Do Not Re-Use
	Do not use if package is damaged
	Quantity
	Use-by Date
	Product sterilized using Ethylene Oxide
	Catalog Number
	Batch Code
	Consult Instructions for Use
	Manufacturer
	Authorized EC Representative
	Keep Away From Sunlight
	Keep Dry
	Storage Temperature
	Storage Humidity
	Phthalate-Free
	Latex-Free
	For Prescription Use Only