

INSTRUCTIONS FOR USE

**Dornier SingleFlex High Energy Laser Fiber
Single Use High Power Holmium Fiber**

Introduction and Application: The Dornier SingleFlex High Energy Laser Fiber is a sterile-packed, single-use fiber appropriate for use with Dornier Medilas H 140 and Dornier Medilas H 100 Holmium Lasers. The Dornier SingleFlex High Energy Laser Fiber may be used at various power levels as specified in the Operation section below.

Indications for Use: Dornier SingleFlex High Energy Laser Fiber is intended to be used as an accessory for the Dornier Medilas H 140 and Dornier Medilas H 100 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.

Description: The Dornier SingleFlex High Energy Laser Fiber is a silica-glass core fiber with flat or ball 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 Dornier Laser being used. User must have completely read and fully understood Operating Manual of the Laser.

Caution: Dornier SingleFlex High Energy Laser Fibers are fragile and must be handled with utmost care. Avoid bending or coiling fiber beyond the manufacturer recommended minimum bend radius (reference Fiber Specifications); doing so may result in light leakage or fiber breakage that could cause personal injury if Laser is fired. (Refer to Dornier Laser Operator's Manual).

Warning: Only trained and qualified personnel are authorized to operate Dornier SingleFlex High Energy Laser Fibers. Ensure that fiber 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 Dornier SingleFlex High Energy Laser Fiber.

- Carefully remove fiber from sterile package and attach SMA connector end to fiber 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 200 micron and 270 micron sized fibers is 30 watts.
 - Maximum power for the 400 micron sized fiber is 102 watts.
 - Maximum power for the 600 and 1000 micron fibers is 140 watts.
- Illuminate onto a white flat surface with distal end of fiber 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 Dornier Laser for operation information.
- Confirm adequate eye protection is used when performing treatment procedure.

Storage and Handling: Each Dornier SingleFlex High Energy 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. Dornier SingleFlex High Energy Laser Fibers are fragile and must be handled with utmost care. Avoid bending or coiling fiber beyond the manufacturer recommended minimum bend radius (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). Fibers should be handled using gloves to prevent contamination.

Return Policy and Procedure: Prior to returning any product, please contact your local Dornier SingleFlex High Energy 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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Fiber Specifications: 3 fibers per box

SingleFlex High Energy Laser Fiber Box Part Number	Fiber Color Code	Core Diameter	Min. Bend Radius	Fiber Length	Max. Power Input
HOL200SHE	White	200 micron	≥ 6 mm	3.0 meter	30 W
HOL200SBTHE	White	200 micron (ball tip)	≥ 6 mm	3.0 meter	30 W
HOL270SHE	Blue	272 micron	≥ 7 mm	3.0 meter	30 W
HOL400SHE	Yellow	365 micron	≥ 29 mm	3.0 meter	102 W
HOL600SHE	Green	550 micron	≥ 58 mm	3.0 meter	140 W
HOL1000SHE	Red	940 micron	≥ 73 mm	3.0 meter	140 W

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