

INSTRUCTIONS FOR USE

**Dornier SmartFlex Laser Fiber
Reusable Holmium Fiber**

Introduction and Application: The Dornier SmartFlex Laser Fiber is a sterile-packed, reusable fiber appropriate for use with all Dornier SmartFlex Lasers. The Dornier SmartFlex Laser Fiber may also be used with other Holmium Lasers that utilize a SMA 905 connector. The Holmium fibers, excluding the 270 micron sized fibers, may be used up to 100 watts maximum power as specified in the Operation section below.

Indications for Use: Dornier SmartFlex 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.

Description: The Dornier SmartFlex Laser reusable fiber is a silica-glass core fiber with flat 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: Dornier SmartFlex 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).

When using Dornier SmartFlex Laser Fiber with other Holmium Lasers, a dosimeter test must be performed prior to use to verify compatibility of the fiber with the laser system.

Warning: Only trained and qualified personnel are authorized to operate Dornier SmartFlex 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 Laser Operating Manual for requirements concerning protective eyewear.

Operation: This section describes preparation and operation of the Dornier SmartFlex Laser Fiber.

- Carefully remove fiber 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 270 micron sized fibers is 35 watts.

-Maximum power for the 400, 600, and 1000 micron fibers is 100 watts.

- Illuminate onto a white flat 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.

CAUTIONS:

Limitations on Reprocessing: After 10 sterilization cycles were completed, no performance degradation was noted in this product. Sterile pouch and fiber coil bracket are not reusable.

Prior to reuse:

- A Dornier SmartFlex Laser reusable fiber may be reprocessed a **maximum of ten (10) times**.
- Before reuse, the Dornier SmartFlex Laser Fiber must be cleaned, stripped, cleaved, inspected and sterilized following these guidelines.
- Single-use fibers cannot be reused according to these guidelines and should be disposed after single usage.

REPROCESSING INSTRUCTIONS:

Point of use: Rinse with tap water and remove excess soil with disposable cloth/paper wipe.

Containment and transpiration: No particular requirements. It is recommended that fibers are reprocessed as soon as is reasonably practical following use.

Preparation for cleaning: No particular requirements. Disassembly not required.

Cleaning:

A. Manual Cleaning:

Equipment: Detergent, gauze, RO/DI water.

Method:

- Replace the protective cap on the SMA connector. Wear gloves when handling fibers. Completely immerse the fiber for five minutes in a prepared enzymatic detergent, Enzo^l (1 oz per gallon of warm tap water) or equivalent.
- Following the soaking period, use a soft gauze pad soaked in the enzymatic detergent to wipe the fiber. Remove all residue and debris.
- Rinse under reverse osmosis/deionized (RO/DI) water for 5 minutes minimum. Rinse water should be sterile or filtered (<10organisms/ml) containing no endotoxins.
- Dry the fiber with a soft gauze pad and inspect for visible soil. If visible soil is present, repeat the process.

B. Automated Cleaning

Equipment: Washer

Method:

- Replace the protective cap on the SMA connector. Load fibers such that the fiber is not bent or susceptible to breakage.
- The following parameters were validated with an AMSCO STERIS[®] 444 Single Chamber Washer/Disinfecter with the instrument cycle selected:

Phase	Recirculation Time (Minutes)	Water Temperature	Detergent Type and Concentration (If Applicable)
Pre-wash	02:00	Cold Tap Water	N/A
Enzyme Wash	01:00	Hot Tap Water	Prolystica [®] 2x Concentrate Enzymatic (1/8 oz per gallon) or equivalent
Wash 1	02:00	60.0°C (Set Point)	Prolystica [®] 2x Concentrate Neutral (1/8 oz per gallon) or equivalent
Rinse 1	05:00	65.5°C (Set Point)	N/A

- When unloading, check for complete removal of visible soil.
- Dry the fiber with a soft gauze pad and inspect for visible soil. If visible soil is present, repeat the process.

Maintenance:

Stripping and scribing the fiber:

- Carefully cut approximately ½ inch of the distal end of the fiber with ceramic scissors.
- Using the appropriate size stripper tool for the fiber cable, insert the distal end of fiber into the stripper until it reaches the ½ inch stop.
- Gently squeeze the handles completely closed and quickly pull the fiber out of the stripping tool.
- Score the exposed fiber at the mid-point and pull the distal end until approximately ¼ inch of fiber is removed.

Warning: Use only strippers and scribes recommended for use on Dornier SmartFlex Laser Fiberfibers. Using incorrect strippers or scribes may result in fiber breakage or damage.

Inspection and function testing:

Inspections:

- Connect the fiber to a Laser illuminator such as the red or green pilot diode Laser found on Dornier Medilas H Holmium Lasers.
- Illuminate onto a white flat surface to observe the fiber output pattern. A good cleave will produce a well-defined circular pattern with minimal distortion of light. If a skewed light is observed, repeat the stripping and scribing process until an acceptable circular light pattern is produced.
- Inspect the fiber cleave with an endoscope or microscope (6x or greater magnification) to insure a smooth and perpendicular cleave surface.

Packaging: A standard packaging material may be used. Ensure that the pack is large enough to contain the fiber without stressing the packaging seals and without going below the minimum bend radius. Replace the protective cap on the SMA connector.

STERILIZATION:

A. Steam – Gravity Displacement

- Place the loosely coiled fiber into a steam sterilization pouch and seal per manufacturer’s instructions.
- Steam sterilize with the following parameters using a gravity displacement sterilizer:
 - 15-minute exposure cycle time
 - Temperature 270°F (132°C)
 - Drying cycle 30 minutes minimum

B. Steam – Pre-Vacuum

- Place the loosely coiled fiber in a steam sterilization pouch or container and seal per manufacturer’s instructions.

- Steam sterilize with the following parameters using a pre-vacuum sterilizer:

- 3 preconditioning pulses
- 4 minute full cycle
- Temperature 270°F (132°C)
- Drying cycle 30 minutes minimum

C. Sterrad

- 100S short cycle

Storage and Handling: Each Dornier SmartFlex 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 Medilas Dornier SmartFlex 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 SmartFlex 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 genocide that has been cleared for use as a "Hospital Disinfectant". To ensure that the product has been properly decontaminated, a signed Decontamination Certificate should be enclosed in the package.

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Fiber Specifications: 3 fibers per box

SmartFlex Laser Fiber Box Part Number	Fiber Color Code	Core Diameter	Min. Bend Radius	Fiber Length	Max. Power Input
HOL200RBX	White	272 micron	≥ 7 mm	3.0 meter	35 W
HOL270RBX	Blue	272 micron	≥ 7 mm	3.0 meter	35 W
HOL400RBX	Yellow	365 micron	≥ 29 mm	3.0 meter	100 W
HOL600RBX	Green	550 micron	≥ 58 mm	3.0 meter	100 W
HOL1000RBX	Red	940 micron	≥ 73 mm	3.0 meter	100 W

Reusable Fiber Accessories:

SmartFlex Laser Fiber Box Part Number	Reusaable Fiber Stripper Part Number	Fiber Scribe Part Number
HOL200RBX	BK-100FS-27	SCR-A
HOL270RBX	BK100-FS-2050-B	SCR-A
HOL400RBX	BK100-FS-4	SCR-A
HOL600RBX	BK100-FS-6	SCR-A
HOL1000RBX	BK100-FS-10	SCR-A

Symbol Legend:

	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