

### Single Use Holmium Laser Fibers Instructions for Use

Model: LF0101X200, LF0101X272, LF0101X365, LF0101X550, LF0101X940  
Holmium and Nd:YAG Fiber

#### Instructions for Use (IFU)

##### Intended Use

The laser probes are accessories intended for the delivery of light in contact and non-contact mode to soft tissues, teeth or calculi for cutting, coagulating, or vaporizing. The laser probes are intended for temporary invasive and non-invasive use during surgical procedures performed in open or port-access operating conditions with a compatible laser source cleared for the desired application.

The laser probes are single-use and delivered in sterile condition.

##### Indication

Indications exist in, but are not limited to, the fields of General Surgery, Urology, Gynecology, Otolaryngology (ENT), Dermatology, Dental/Oral Surgery, Aesthetic/Plastic Surgery, Vascular Surgery, Orthopedic surgery, and/or Endoscopy.

Refer to your laser system operator's manual for complete information regarding applications and indication when using this laser probe.

##### Contraindication

The laser probes shall not be used in or on the central circulatory system and central nervous system.

Refer to your laser system operator's manual for complete information regarding contraindications, precautions and warnings when using this laser probe.
















##### Safety


This IFU must be attached to the documentation for the laser device.

Both this IFU and that of the laser device must have been fully read and understood to ensure a safe handling of the laser probe.

This product may be used by trained and qualified personnel only.

##### Graphic Symbols on Device Labeling

	Caution. The information provided is important and can affect the safety or efficacy of the product		Consult instructions for use
	Do not re-sterilize		Batch code
	Do not re-use		Catalog number
	Manufacturer		Use-by date
	Sterilized using ethylene oxide		Do not use if package is damaged
	Keep dry		Keep away from sunlight
	Temperature limit		Fragile, handle with care
	Humidity limitation		

 **CAUTION: Federal (USA) law restricts this product to sale by or on the order of a physician.**

##### Product Code

The product code indicates the type of laser probe. The product code is shown on the label of the outer packaging.

Please carefully compare the label on your product with the information below.

<b>LF1122X333</b>	
LF	Laser Fiber
11	Disposable (01) or reusable (02) product
22	Descriptor (01 for first version)
X333	Fiber core diameter in µm

##### Warnings and Precautions

- Laser probes in accordance with this operating manual are disposable products and must not be used again.
- In case of reuse the following risks exist for both the patient and the user: Infection due to lack of sterility and biological contamination, break of the fiber due to impaired mechanical strength and insufficient success of therapy due to impaired performance.
- Inspect packaging prior to use. Do not use if the package is damaged. The use-by date must not be exceeded. The sterile laser probe may only be used under surgical-room procedures. Follow the regulations concerning the handling of sterile goods.

- The parameters that are particularly important for safe operation are the wavelength, the fiber diameter, the numerical aperture of the fiber and the laser device, as well as the design of the distal tip of the product. In accordance with the previously stated product code, the Typenex laser probes are suitable for use with laser devices that possess a compatible interface, do not exceed the permitted maximum input power, and release laser energy at a wavelength suitable to the product.
- The numerical aperture of the laser probe needs be compatible to the numerical aperture of the laser device. Further information can be obtained from your supplier or from technical data documents of the laser device used.
- The minimum permitted bending radius must not be exceeded during the procedure. The short-term minimum permitted bending radius equals 100 times the radius of the fiber cladding diameter or, if no cladding diameter is given, that of the fiber core diameter. Information is obtained from the product code.
- The laser probe needs be examined for perceivable damages, especially fractures, before and after removal from its packaging. If any damage is observed, do not use the laser probe and contact the supplier. Always keep a replacement laser probe ready for use.
- Using a defective laser probe or improper use may cause severe eye or tissue damage, accidental laser exposure to patient or the operation room staff or fire in the operation room. Refer to the laser device documentation for detailed safety information and safety instruction about laser radiation.
- It is essential to avoid contact of the distal side of the laser probe with reflecting surfaces of other used laser probes or products. The risk of uncontrolled scattered radiation may potentially result in the destruction of the laser probe and/or tissue damage may occur.
- During the procedure all persons present, patient and personnel, must wear protective eyewear. Requirements for safety equipment depend on the application and have to be taken from the operating manual of the laser device used.
- Details for type, consistence, intensity and spreading of radiation need to be obtained from data from the manufacturer of the laser device.

### Operation of the Laser Probes

- After removing the laser probe from its packaging the protective cap needs be removed from the laser connector. Thereby hold the nut of the connector only, and in no case the bend protection or the strain relief. If applicable, also remove the protection cap from the distal side of the laser probe.
- Examine the face of the proximal connector and the distal tip of the laser probe for staining or contamination. Damaged or stained faces could cause damage or destruction of the laser probe and/or the laser system used.
- Insert the laser probe connector into the connector port of the laser device and hand-screw tight, do not use any tools.
- Turn on the laser device according to its instructions for use and set the aiming beam to high intensity.
- Double-check the laser probe for sharp bends, fractures or other damages. Pay careful attention to the aiming beam pattern out of the distal tip: Hold the distal tip towards a white non-reflective surface. The aiming beam must produce a circular light spot, not a frayed one. If any damage is observed, do not use the laser probe and contact the supplier. Always keep a replacement laser probe ready for use.



Optical fiber defective



Optical fiber in an operational condition



**CAUTION: Using a laser probe with incorrect beam pattern may result in overheating of laser probe and may cause harm to the patient.**

- Set the laser unit parameters according to the treatment needed and start the procedure.
- After use, the optical probe has to be disposed of according to the applicable regulations. Liability is excluded in case of violation.

### Storage

The laser probe is to be stored at ambient temperature +15°C (59 F) - +25°C (77 F) and relative air humidity of 40% - 60%. It needs be protected from organic solvents and from exposure to ionizing radiation as well as UV-light. The use-by date stated on the label must not be exceeded.

### Cleaning and Reconditioning

Laser probes in accordance with this operating manual are disposable products and must not be used again.

### Technical Data

Data about the fiber core diameter can be found on the label and the product code located on the outside of the product package.

All Typenex laser probes are 3m in length and terminated with an SMA-905 connector. The laser probe display a numerical aperture of 0.22 and are capable of delivering wavelengths from 500nm in the green to 2200nm in the NIR spectral range.

The user must define the maximum permitted laser power for the product referred fiber core diameter in accordance with recommendations from the laser device manufacturer and the intended application. Values for orientation are stated in the chart below:

All Silica product			
Fiber core diameter	up to 272 µm	300 to 400 µm	500 µm and higher
Max. Input Energy *	1.5 J	4.0 J	4.0 J
Max. Input Power *	10 W	40 W	80 W

Plastic Clad Silica - PCS or Hard Plastic Clad Silica product			
Fiber core diameter	up to 400 µm	600 µm	800 µm and higher
Max. Input Energy *	1.5 J	4.0 J	4.0 J
Max. Input Power *	10 W	40 W	80 W

\* The stated values are benchmarks only. The optical fiber manufacturer takes no liability for applications at higher power or energy values. Higher values may be possible when combined with a suitable laser device which documentation states that combination explicitly.



The user carries the responsibility to monitor the temperature of the incoupling connector and of the laser probe during procedure. Heating of one of the components above 50°C (122 F) indicates an excessive input power, wrong numerical aperture and/or other issues. In this case the input power must be reduced or another suitable laser probe must be used, respectively. Product damages due to inappropriate operation are not subject to warranty.

**Contact Information**

Manufactured for:

Typenex® Surgical  
303 E. Wacker Drive, Suite 1030  
Chicago, IL 60601

Phone: 866-897-3639  
Fax: 312-888-4090