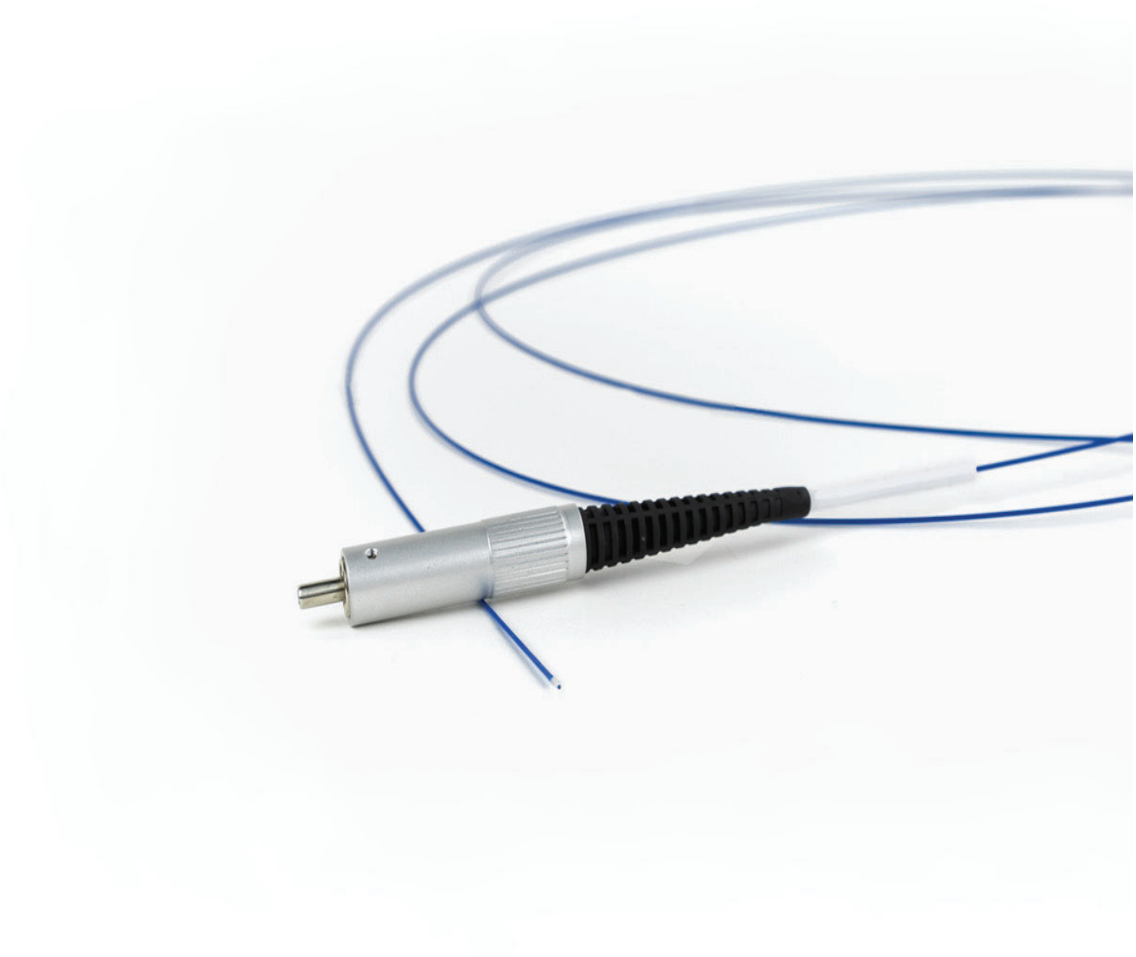
TYPENEX SURGICAL

BAREFIBER LASER PROBE

Reusable



Instructions for Use

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1. Intended Use/Indications for Use

Laser Fibers (BareFiber Disposable, BareFiber Reusable and Endoprobe Disposable) are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adaptors and are indicated for use in laser-based surgical applications and procedures that are performed with compatible lasers operating at wavelengths between 500nm and 2200nm, which have been cleared.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician.

2. Delivery Information

Packaging: Master packing has 5 pieces of single packed laser probes.

Labeling: Product delivery condition and the expiration date is clearly mentioned/indicated on the product label. Please refer to “Direction for Use” to learn how to use the reusable product.

Sterilization: The laser probes are delivered either in sterile or in sterilizable condition. The laser probes delivered in sterile condition are EO sterilized. All laser probes are compatible with autoclave sterilization. The laser probes are reusable and can be used up to 5 times.

3. Specific Instructions for BareFiber Laser Probes

For laparoscopic, cystoscopic or endoscopic surgical procedures, refer to your laser system operator’s manual for complete information regarding applications, contraindications, precautions, and warnings when using this fiber. The laser probes are accessories to a laser system operating at wavelengths typically between 500nm and 2200nm.

4. Contraindications

The laser probes are not suitable for application in the central circulatory system and central nervous system. Laser probe should be used only on target area that are fully visible. Refer to your laser system operator's manual for complete information regarding applications, contraindications, precautions and warnings when using this laser probe.

5. Complications

Complications could include pain, post operative fever, discomfort, Edema, local and/or systematic infection, thermal damage to surrounding structures, healing delay, hypertension, bleeding local hematoma, dissection and perforation, tissue adherence or distal tip detachment. In the unlikely event of a detached tip, it may be visually located and removed.

WARNING: Reprocessing of laser probes used in a patient with identifiable risk of CJD, vCJK or other human TSEs is NOT allowed. Do not use the laser probe if the target area is not visible

6. Description

Under the guidance of proper imaging technique, the laser probe is inserted into the body orifice or port-access and depending on the product model, delivers up to 100W laser energy for performing medical or aesthetic surgical procedures. Distal end of the laser probe is used to emit visible light to treat the target application area.

7. Fiber Compatibility

This laser probe is compatible with any laser system equipped with SMA 905/906 or manufacturer specific connector and with 0.22/0.37 NA. Check the laser’s user manual to confirm connector type. The user must determine the maximum permissible laser power for the laser probe, which must be in line with the technical specification mentioned in this IFU, the laser manufacturer’s specifications, and the planned application.

8. Safety

General safety: In order to ensure safe handling the physician must read and fully understand the IFU of both the laser probe and the laser system. Before using the laser probe, the physician must fully understand the safety consideration and use proper technique for which the physician intends to use the laser probe.

Intended user: Only physicians who are trained and qualified in using laser system and laser probe for the desired treatment application are allowed to use the laser probes.

Intra-operative safety: Make sure that after the treatment no part of the laser probe is left inside the body. Physician must use appropriate imaging technique to identify the fiber tip`s location inside the body through the entire treatment and/or when necessary. In rare cases, the distal tip of the fiber can break-off. In the unlikely event of dislodged tip, it must be visually located and removed as soon as possible.

Post-operative safety: Used laser probe must be properly disposed according to the hospital and local waste disposal guidelines.

CAUTION: All personnel inside the treatment room should wear protective laser eyewear appropriate for the used laser system. Refer laser user manual for requirements concerning protective eyewear.

9. Parameter Note

The parameters which are particularly important for safe operation are the design wavelength, the diameter and the numerical aperture of the fiber, the beam diameter and the numerical aperture of the laser as well as the design of the distal end of the laser probe. These parameters must be adapted to the laser system used.

10. Warnings

- Any further reuse of more than 5 times and/or the use of damaged and/or soiled laser probes are at the user's own risk.
- In case of improper reconditioning or reuse of more than 5 times, 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.
- Improper use of laser probe in non-contact mode will increase the risk of back scatter and forward scatter.
- Always prevent the distal end of the laser fiber from coming into contact with reflecting surfaces of other fibers or products used in order to prevent any uncontrolled radiation leakage or damage to the fiber or tissue.
- For information concerning type, characteristics, intensity and distribution of the radiation, please refer to the data published by the manufacturer of the laser system used.
- Using a defective laser probe or improper use may cause severe eye or tissue damage and injury, due to accidental laser exposure to patient or the treatment room personel or fire in the treatment area. Refer to the appropriate laser operating manual for detailed safety information and instructions for protection against laser radiation
- Laser probes must not be used at higher power or energy values than the values mentioned in technical specification. Higher values may not only damage the laser fiber but also may harm patient, user, or third-party present in the treatment room.

11. Precautions

- The laser probes, are intended to be used with laser systems fitted with an interface compatible with the laser probe, which do not exceed the permitted maximum input power values, and emit laser energy at wavelengths compatible with the laser probe.
- The numerical aperture of the laser fiber must be compatible with the numerical aperture of the laser system. If you are uncertain as to compatibility and for details, please contact your supplier(s). Further information can be obtained from your supplier or from technical data documents of the laser system used.
- Inspect packaging prior to use. Do not use if the package is damaged. The expiry date must not be exceeded.
- The essential component of the laser probes is made of glass. Handle the laser probes with due caution, or otherwise fractures and even micro fractures may occur.
- When removing the laser probe from its pouch or tray, secure the distal tip in order to avoid damage or contamination. Do not apply excessive force to the tip of the fiber as breakage may result.
- The minimum bending radius of the laser probe must not be exceeded during the entire use and handling of the fiber. The smallest permissible short-time bending radius corresponds to 100 times the radius of the largest glass diameter, usually the cladding. Certain fibers may be exceeding this minimum bend radius, if there is any question, please contact your supplier(s).
- The laser probe needs to 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. Details for type, consistence, intensity and spreading of radiation need to be obtained from data from the manufacturer of the laser system.
- DO NOT exceed the recommended power levels when using this laser probe. Begin lasing at the lowest possible power setting to achieve the desired effect. Use lower power levels and longer pulses to familiarize yourself with the operation of this laser probe. High power and/or long duration application of laser energy with the fiber tip being in contact with tissue may damage or significantly reduce the life of this laser probe.
- If the fiber tip is visibly damaged or required excessive amounts of energy to be effective, discontinue use and replace with a new fiber for optimum results.
- Before using this laser probe, the user should fully understand the use of the laser system, have read this IFU and the IFU of the laser system used. The user should understand all necessary safety considerations, tissue-laser interaction and the specific technique for the treatment intended.
- User training should include but not be limited to review of published literature, attendance of subject matter conferences, with presentations, didactic courses, hands-on laboratory experience, and observation and participation in cases performed by experienced physicians.
- Before using the laser probe, check the scope condition. Do not use the laser probe if the scope is damaged or deflected as it may hinder the ability to insert the laser probe or may damage the laser fiber.
- Care must be taken to keep the connector clean. Do not touch the exposed fiber surface.
- Do not scrub or use abrasive material.
- Do not pinch or otherwise excessively bend the fiber while lasing. Fiber failure may occur.

12. Products

This IFU also applies to the following Typenex Surgical products:

- LF0201X200
- LF0201X272
- LF0201X365
- LF0201X550
- LF0201X940

13. Product Code

The product code indicates the fiber type and it is indicated on the label of the outer sterile packaging.

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

Code: LF1122X333

Code	Description
LF	Laser Fiber
11	Disposable (01) or reusable (02) product
22	Descriptor (01 for first version)
X333	Fiber core diameter in µm

14. Technical Specification

Data about the fiber core diameter, wavelength range, laser probe length, type of connector and tip as well as the numerical aperture can be found on the label and the product code located on the outside of the product package. 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 272µm	300µm	365µm and higher
max. Input energy *	1,5J	4,0J	4,0J
max. Input power *	20W	40W	100W

Plastic Clad Silica - PCS or Hard Plastic Clad Silica product

Fiber core diameter	200 to 400µm	600µm	800µm and higher
max. Input power *	15W	40W	80W

*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 only when combined with a suitable laser device which documentation states that combination explicitly.

The user carries the responsibility to monitor the temperature of the injected connector and of the fiber during procedure. Heating of one of the components of more than 50°C (122 F) indicates too high input power or wrong numerical aperture. In this case the input power must be reduced respectively another appropriate laser probe must be used. Product damages due to inappropriate operation are not subject to warranty.

WARNING: BareFiber laser probes are verified and validated only for the above-mentioned parameters. Manufacturer takes no liability for applications at higher power or energy values than the above-mentioned input parameters. Higher values may not only damage the laser fiber but also harm patient, user, or third-party present inside the treatment room.

The minimum allowable bending diameter,

- Short term: 100x cladding diameter
- Long term: 600x cladding diameter

15. Directions for Use

- Laser probes that are supplied non-sterile must be cleaned, disinfected and sterilized before every application (refer to the “Reprocessing” section).
- Refer to the laser system user manual for use indications and instructions. All operating room personnel must be provided with the appropriate laser protective eyewear before the procedure begins.
- If required for proper system function and operation, the laser system may be calibrated for use with these fibers. Please refer to your laser operator's manual for calibration requirements and parameters.
- Read all fiber labeling completely. Remove the fiber carefully from its package, avoiding any inadvertent contamination or damage. Visually inspect the fiber before use. If any damage is observed such as breaks, kinks or damaged components, do not use the fiber, retain the device for manufacturer notification and use a replacement or back-up fiber.
- Remove the protective cap. Do not touch the connector protected by the cap. To remove the cap, hold the bend protection or strain relief. Do not touch the nut, or metal parts of the connector while removing the protective cap, this may damage the device.
- Examine the faces of the connector and the distal fiber end of the fiber probe for staining, or contamination with foreign matter. Damaged or stained faces could cause damage to or destroy the product and/or the laser system used.
- Attach the connector to the laser system launch port. Make sure the connector is fully engaged according to the system's operator manual and control panel indicators. Do not use any tools. The connector only needs to be hand tightened; do not over-tighten the connector.
- Turn the laser on. Operate the system's controls in accordance with the operator's manual and at settings appropriate to the procedure.

  Note: While in the "OPERATE" mode, the laser system's aiming beam should always be clearly visible to the user.
- Check the laser probe once again for kinks, fractures and or defects. Pay special attention to radiation leakage of the target beam outside the distal end surface. Direct the distal end towards a non-reflecting surface. The target beam must generate a sharp, defined, non-frayed light spot. If any damage is found, do not use the laser probe! Return the fiber to the supplier.


Laser probe defective


Laser probe in an operational condition

- Place the laser fiber at the desired position to the treatment site. Position the entire fiber length carefully to avoid inadvertent damage or contamination.Confirm that the aiming beam is visible to the operator.
- Use the laser system's switch to activate the laser output.
- Keep the distal tip of the fiber as clean as possible during use to prevent overheating and damage. If removal is necessary to clean accumulated debris, carefully wipe along the fiber axis with a soft gauze and hydrogen peroxide.
- Following the laser procedure, shut the laser system off as described in your operator's manual and remove the fiber assembly from the laser. Immediately place the protective cap over the connector of the fiber assembly.
- After the laser probe has been used 5 times, it must be disposed of according to the applicable regulations. Liability is excluded in case of violation.

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

CAUTION:

- **Do not scrub or use abrasive material.**
- **Do not pinch or otherwise excessively bend the fiber while lasing. Fiber failure may occur.**
- **Care must be taken to keep the connector clean. Do not touch the exposed fiber surface.**

16. Reprocessing

16.1. General Principles

- Before first use, laser probes that are supplied already sterilized do not require further preparation.
- Before first use, laser probes that are supplied non-sterile must be cleaned and sterilized.
- After first use, all reusable laser probes must be cleaned and sterilized according to these instructions before each subsequent use.

CAUTION: If the fiber has been used 5 times, reprocessing is not permitted. The number of completed reprocessing cycles must be monitored and recorded.

- Laser probes labeled as disposable or single-use products are not designed for reprocessing and must therefore not be reprocessed and used again, otherwise there is an increased risk for the patient and user.
- Please note as part of your responsibility for the sterility of laser probes during use,
  - that the devices used for reprocessing (e.g., sterilizer) are regularly serviced and checked, and
  - that the validated parameters are observed for every cycle.
- Please also observe the legal regulations applicable in your countryas well as the hygiene regulations of the doctor’s office or hospital.

16.2. Method

The following steps must be followed for reprocessing:

Initial Treatment at Point of Use	Immediately after the connector has been disconnected, put the attached protective cap over the connector end and wipe visible contaminants from the laser probe before the contaminants have dried. • Use a soft, clean cloth for pre-cleaning, which is soaked in 70/30 isopropyl alcohol (IPA). The dosage instructions of the manufacturer of the cleaning agents needs to be followed. • Wipe the laser probe from the proximal to the distal end of the laser probe. • Repeat the procedure until all obvious soil has been removed. • Rinse thoroughly with warm running tap water of drinking water quality at 22-40°C (71°F to 104°F) for at least 1 min. from the proximal to the distal end. If the contaminants have dried, and cannot be removed, cut off the soiled portion of the fiber.
Preparation before Cleaning	Inspecting the Proximal End • Remove the protective cap from the connector and inspect the face of the proximal connector with a suitable microscope or magnifying glass with minimum 20x magnification. • The fiber surface must not display any scratches, discoloration, deformation or foreign particles. Continued use in the presence of such damage may damage the laser probe and/or the laser system and is therefore prohibited. The laser probe must not be used again if there is damage. Cutting, Stripping, Cleaving the Distal End • Using a cutting device such as a pair of ceramic scissors, cut off 10 to 20 mm (0.40 - 0.80”) of the distal tip fiber. • Using a fiber stripping device suitable for the fiber diameter, strip about 40 mm (1.60”) of the fiber jacket • By hand, remove the stripped fiber jacket, and discard it as hazardous waste. • Using a cleaving device such as a ceramic or diamond blade, score the fiber around 10 mm (0.40”) behind the fiber jacket. • By hand, pull the fiber tip off longitudinally in the direction of the fiber axis; do not turn or bend. • Discard the cleaved distal end of the fiber. • Check the beam pattern as described above. Inspecting the Distal End • Inspect the distal end with a suitable microscope or magnifying glass with minimum 20x magnification • It must not show any scratches, discoloration, deformation, spalling or foreign particles. • If necessary, the beam pattern can be checked again with the aiming beam.
Cleaning	• Use a soft, clean cloth for pre-cleaning, which is soaked in 70/30 isopropyl alcohol (IPA). The dosage instructions of the manufacturer of the cleaning agents needs to be followed. • Wipe the laser probe from the proximal to the distal end of the laser probe. • Repeat the procedure until all obvious soil has been removed. • If the contaminants have dried, cut off the soiled portion of the fiber. • Rinse thoroughly with warm running tap water of drinking water quality at 22-40°C (71°F to 104°F) for at least 1 min. from the proximal to the distal end.

CAUTION: Automated cleaning methods are not compatible with this device.

Drying	Allow the fiber surface to air dry. Do not wipe or cover the fiber for at least 2 min. to achieve maximum efficacy.
Inspection	Check all laser probes for cleanliness, corrosion, damaged surfaces, chipping and contamination. • Discard devices with scratches, burrs, dents, or deformation as hazardous waste. • Ensure that all obvious soil dirt has been removed. • Check whether the distal end has not been damaged during cleaning. Otherwise, reprocess the distal end of the laser probe according to the instructions provided in sections “Preparation before Cleaning” and “Cleaning”.
Packaging	• Carefully coil the laser probe to a diameter that is no less than 20cm (8”). • Place the coiled laser probe in a sufficiently large single-use, single or double layer sterilization pouch. • The package and sterile barrier system should comply with AAMI/ISO 11607 and should be suitable for steam sterilization with temperature resistance up to at least 141°C (286°F) and sufficient steam permeability. • The cardboard (and/or coil) from the laser probe’s original packaging must not be reused. • Label the packaging similar to the original label.
Sterilization	• Ensure that the protective cap covers the connector end. • Place the packaged laser probe into an ISO/AAMI 17665 compliant steam sterilization system Steam Sterilization Parameters: • Gravity Displacement: - Exposure Time at 121°C (249.8°F): 30 minutes | Drying time: 20 minutes • Pre-Vacuum: - Exposure Time at 132°C (270°F): 4 minutes | Drying time: 20 minutes - Exposure Time at 135°C (275°F): 3 minutes | Drying time: 16 minutes
Storage	• Store the laser probe in the sterilization pouch at ambient temperature of +15°C - +25°C and relative air humidity of 30% - 60%. • Protect the laser probe from organic solvents and from exposure to ionizing radiation as well as UV-light. • Observe the expiry date on the original label.

CAUTION: All other sterilization processes are not permitted. Do not remove the laser probe from the autoclave before it reaches maximum temperature of 57°C

The general suitability of the laser probes for effective steam sterilization was proven by an independent, accredited test laboratory using both the fractioned vacuum process and the gravitational process. Typical conditions in hospitals and doctor’s offices as well as the above-described process were taken into consideration.

17. Material Strength

When selecting cleaning and disinfecting agents, please ensure that the following ingredients are not present:

- Organic, mineral and oxidizing acids (minimum permissible pH of 5.5)
- Base (maximum permissible pH of 9.5, neutral/enzymatic cleaning agent recommended)
- Organic solvents (such as alcohols, ethers, ketones, benzenes)
- Oxidants (such as hydrogen peroxide)
- Halogens (such as chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons
- Oils

CAUTION: Never use metal brushes or steel wool to clean any of the laser probes.

18. Storage

The laser probe is to be stored at ambient temperature +15°C - +25°C and relative air humidity of 30% - 60%. It needs to be protected from organic solvents and from exposure to ionizing radiation as well as UV-light. Date of expiry stated on the label must not be exceeded.

19. Disposal

Used laser probe must be properly disposed according to the hospital and local waste disposal guidelines.

20. Graphic Symbols on Device Labeling, if applicable

Symbol	Ref. / Title	Description	Symbol	Ref. / Title	Description
	5.4.4 / Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.		5.4.3 / Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.2.7 / Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.		5.1.5 / Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not re-use more than 05x	Indicates a medical device that is intended for not more than 5 uses.		5.1.6 / Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	5.1.1 / Manufacturer	Indicates the medical device manufacturer		5.1.4 / Use-by date	Indicates the date after which the medical device is not to be used.
	5.2.3 / Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.		5.2.8 / Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.3.4 / Keep dry	Indicates a medical device that needs to be protected from moisture.		5.3.2 / Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	5.3.7 / Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	RxOnly	21 CFR 801.109 / Prescription only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	5.3.1 / Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.		5.3.8 / Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	7.8.10 / MR Unsafe	Indicates unacceptable risks to the patient, medical staff, or other persons within the MR environment.			

Symbols according to:

- ***ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements.***
- ***ASTM F2503-20 – Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.***

21. Manufacturer

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22. Distributor

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