# Reusable 5x Holmium Laser Fibers Instructions for Use

**Model: LF0201X200, LF0201X272, LF0201X365, LF0201X550, LF0201940**
**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 reusable up to **05 times** and delivered in sterile or sterilizable condition.

**CAUTION: Laser probes that are delivered non-sterile need to be cleaned, disinfected and sterilized before their first application.**

### 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.**

**Reprocessing of laser probes used in a patient with identifiable risk of CJD, vCJK or other human TSEs is NOT allowed.**

### 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-use more than 05x | LOT | Batch code |
| | Manufacturer | REF | Catalog number |
| STERILE EO | Sterilized using ethylene oxide | | Use-by date |
| | Keep dry | | Do not use if package is damaged |
| | Temperature limit | | Keep away from sunlight |
| | Humidity limitation | | Fragile, handle with care |

**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.

**LF1122X333**

| | |
|---|---|
| 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 that are undamaged and in clean condition can be reused up to **05 times**.
- Any further reuse 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 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

- **Laser probes that are supplied non-sterile must be cleaned, disinfected and sterilized before the first use (refer to the "Reprocessing" section).**
- 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 the optical probe has been used 05 times, it 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.

### 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:

| 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 |

* 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.

## Reprocessing

### 1. General Principles

Laser probes that are supplied already sterilized do not require preparation before the first use.
Laser probes that are supplied non-sterile must be cleaned, disinfected and sterilized before the first use (cleaning and disinfection after removal of the transport packaging, sterilization after packing).

All laser probes must be cleaned, disinfected and sterilized before each use (cleaning and disinfection after removal of transport packaging, sterilization after packing). Effective cleaning and disinfection is an essential prerequisite for effective sterilization.

**CAUTION: If the fiber has been used five times, further re-sterilization is not permitted. The number of re-sterilization cycles already completed must be monitored and recorded by the user.**

Laser probes labelled as disposable products are not designed for preparation and must therefore not be prepared and used again (high risk for patient).

Please note the following with reference to your responsibility for the sterility of laser probes in use:

- Only processes that have been validated for the specific device and product are permitted for cleaning, disinfection and sterilization,
- The devices used for preparation (disinfector, sterilizer) must be regularly serviced and tested and
- The validated parameters must be maintained for every cycle.

Please also follow the applicable regulations of your region and the hygiene specifications of the medical practice or hospital.

Based on the purpose, classification as Critical B in conformity with the Robert Koch-Institute (RKI) guideline is recommended; however, the final classification must always be decided by the user with reference to the actual application and it must be recorded.

### 2. Cleaning

#### Principles

A manual process is required for cleaning and disinfection (laser probes may be damaged if a machine process is used).

#### Pretreatment

The connector must be covered with the attached protection cap immediately after disconnection to prevent contamination of the connector during cleaning and disinfection.

Obvious contaminants must be removed from the laser probe immediately after use (within 30 minutes at the most).

Use running water (thoroughly rinse the connector back in particular for at least 1 minute) and a disinfectant solution (refer to the corresponding documentation for the process duration). The disinfectant should be aldehyde-free (in order to prevent adhesion of blood contamination), of proven efficiency (such as VAH/DGHM or FDA approval and/or CE marking), suitable for disinfecting the laser probe, and compatible with the laser probe (refer to the "Material strength" section). Always use a dedicated, clean, soft piece of cloth, never metal brushes or steel wool, in order to manually remove dirt. After wiping clean, coil up the laser probe to form a ring (see below for permissible bending radii) and wrap the connector end two to three times around the wound-up coil in order to secure the connector end in place and prevent the coil from unwinding.
Please note that the disinfectant used during pretreatment is for personal protection only and does not replace the disinfecting step to be carried out later, following cleaning.

**CAUTION: Mind the minimum allowable bending diameter**
**25 cm** (9.84") **for a fiber jacket diameter up to 720µm**
**40 cm** (15.75") **for a fiber jacket diameter over 720µm**
**See the product code for the diameter of the fiber jacket**

#### Inspecting the Proximal Connector

Inspect the face of the proximal connector with a suitable microscope or magnifying glass at a minimum 40 x or 20 x magnifications, respectively.
It 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 device and is therefore prohibited. The laser probe must not be used again if there is damage.

#### Preparing the Distal End of the Laser Probe

1. Use a pair of ceramic scissors to cut off 10 to 20 mm (0.40 - 0.80").
2. Use a pair of stripping pliers suitable for the fiber diameter to strip off the fiber jacket by about 40 mm (1.60").
3. Remove the fiber jacket by hand.

**CAUTION: The fiber jacket is made of Tefzel. The stripping should occur smoothly by pulling once.**
**Otherwise start the fiber preparation again at point 1.**

4. Use a ceramic or diamond blade to scribe the fiber around 10 mm behind the fiber jacket.
5. Pull the fiber tip off longitudinally in the direction of the fiber axis; do not turn or bend.
6. Check the beam pattern as described above.

#### Inspecting the Distal End of the Laser Probe

Inspect the distal end of the laser probe with a suitable microscope or magnifying glass at a minimum 40 x or 20 x magnification, respectively.
It must not show any scratches, discoloration, deformation, spalling or foreign particles.
The beam pattern can be checked again with the aiming beam if necessary. Follow the instructions detailed in the Operation of the Laser Probes section.

**3. Manual Cleaning and Disinfection**

When selecting the cleaning and disinfecting agents to be used, make sure that

- These are generally suitable for cleaning and/or disinfecting laser probes made of metal and plastic
- The cleaning agent – if applicable – is suitable for ultrasonic cleaning (no foaming)
- That a disinfectant with tested efficiency (such as VAH/DGHM or FDA approval and/or CE marking) is used and that this is compatible with the cleaning agent used
- That the chemicals used are compatible with the laser probes (refer to the "Material strength" section)

If possible, combined cleaning/disinfecting agents should not be used. Combined cleaning/disinfecting agents can only be used in cases of very low contamination (no visible soiling). The concentration and exposure times specified by the manufacturers of the cleaning and disinfecting agents must be observed under all conditions. Always use freshly prepared solutions, sterile or almost sterile (maximum of 10 germs per ml) as well as low-endotoxin (maximum of 0.25 endotoxin units per ml) water (such as purified water / highly purified water) and/or filtered air for drying.

Cleaning

1. Place the wound-up laser probe (refer to the "Pretreatment" section) individually into a sufficiently large wire basket. Make sure that the fiber end is not damaged by the basket.
2. Place the wire basket with the laser probe into the cleaning bath (with ultrasonic support, if necessary) for the specified treatment time in such a manner that the laser probe is sufficiently covered.
3. Subsequently remove the wire basket containing the laser probe from the cleaning bath and thoroughly rinse it with water at least three times and in accordance with your cleaning agent's guidelines.
4. Check the laser probes (refer to the "Final Inspection" section).

Disinfection

1. Place the wire basket with the laser probe into the disinfecting bath for the specified treatment time in such a manner that the laser probe is sufficiently covered.
2. Remove the wire basket containing the laser probe from the disinfecting bath and rinse it thoroughly with water at least five times and in accordance with your cleaning agent's guidelines.
3. Use filtered air in order to blow the laser probe dry inside and outside.
4. Pack the laser probe, if possible, immediately after removal (refer to the "Packaging" section. If necessary, additionally re-dry in a clean place).

The general suitability of the laser probe for effective manual cleaning and disinfecting was proven by an independent, accredited test laboratory using the Cidezyme/Enzol cleaning agent and the Cidex opa (Johnson & Johnson GmbH, Norderstedt) disinfecting agent. The process described above was taken into consideration.

**4. Final Inspection**

Inspect all laser probes after disinfection for corrosion, damaged surfaces, splitting and contamination and discard damaged laser probes. Laser probes that are still dirty must be cleaned and disinfected again.

If the distal end of the laser probe is damaged, it must be prepared again (see the section on "Inspecting the distal end of the laser probe" and "preparing the distal end of the laser probe"). In this case, the cleaning and disinfection processes must be repeated.

**5. Packaging**

**CAUTION: Open the protective cap of the connector.**

Please pack the laser probes while rolled up in sufficiently large disposable sterilization packs (single or double packs) that conform to the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilization (temperature resistant to min. 141 °C (285.8 F) and sufficiently steam-permeable)
- Sufficient protection of laser probes and sterilization packs from mechanical damage
- The cardboard tray from the original package must not be used again after opening

**6. Sterilization**

Only steam-sterilization processes are permitted with the following requirements:

- Fractioned vacuum process or gravitational process (with sufficient product drying)
- Steam-sterilizer conforming to DIN EN 13060 and DIN EN 285
- Steam sterilization process conforming to DIN EN ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134) validated (valid IQ/OQ (commissioning) and product-specific performance qualification (PQ))
    - minimum sterilization temperature 134°C (273.2 F), tolerances according to the norm
    - maximum sterilization temperature 138°C (280.4 F), tolerances according to the norm
- Sterilization time (exposure time at the sterilization temperature) of at least 3 min (fractioned vacuum process) or 5 min (gravitational process)

**CAUTION: All other sterilization processes are not permitted.**

The general suitability of the laser probes for effective steam sterilization was proven by an independent, accredited test laboratory using a Systec V-150 steam sterilizer (Systec GmbH Labor-Systemtechnik, Wettenberg) and 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.

### 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

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

### Contact Information

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