PHLEBOLOGY LASER PROBE
Reusable

Information for Use
Revision: 004
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1. Intended Use
The laser probes are accessories to a laser system intended for the delivery of optical radiation in non-contact mode inserted into the vein to be treated for ablation or coagulation. The laser probes are intended for temporary invasive application during surgical or esthetical procedures performed through port-access operating conditions with a compatible laser source cleared for the desired treatment.

⚠️ **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.

**Labelling:** 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 05 times.

⚠️ **CAUTION:** Laser probes that are delivered in unsterile condition need to be cleaned, disinfected and sterilized before first application.

3. Indications
The laser probes are indicated for a variety of endovenous vein surgical procedures including varicose veins, all secondary or associated superficial reflux of Great Saphenous Vein (GSV) and Small Saphenous Vein (SSV). Laser probes should only be used with laser system that has received regulatory clearance for the treatment of varicose veins, all secondary or associated superficial reflux of GSV and SSV. Refer to your laser system operator’s manual for complete information regarding applications, contraindications, precautions and warnings when using this fiber.

4. Contraindications
The laser probes are not suitable for application in the central circulatory system, central nervous system, acute infections at puncture sites, deep vein obstruction where the target vein functions as a collateral, pregnancy, thrombophilia, unable to undergo local anesthesia, decompensated leg swelling, terminal diseases or uncontrolled severe diseases and too small vein. 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 but are not limited to pain, post operative fever, discomfort, edema, infection, thermal damage to surrounding structures, healing delay, bleeding local hematoma, thrombosis, vessel 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, vCJD 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 vein using port access and depending on the product model, delivers up to 30W laser energy for performing medical or aesthetic endovenous vein surgical procedures. Distal end of the laser probe is used to emit visible light to treat the target application area. These devices are 3.0 meters in length and terminated with an SMA-905 connector. The basic delivery systems are capable of delivering wavelengths from 500nm in the green to 2200nm in the NIR spectral range. These include but are not limited to frequency doubled Nd:YAG @ 532nm, Nd:YAG @ 1064nm, Diode @ 810 nm, Diode @ 980nm and Diode @ 1470 nm.

7. Fiber Compatibility
The laser probe is compatible with any laser system equipped with an SMA 905 connector. 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 in order 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 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.
- Improper use of laser probe in non-contact mode will increase the risk of backscatter 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 personnel 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, 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.

12. Products

This IFU applies to the following Typhenex Medical products:

<table>
<thead>
<tr>
<th>P/N</th>
<th>Primary DI</th>
<th>Product Description</th>
<th>Numerical Aperture</th>
</tr>
</thead>
<tbody>
<tr>
<td>097428</td>
<td>00816901020418</td>
<td>NV0614 550µm Si/Si Reusable Thin Wall Fiber</td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMA 905 Connector with Extension Sleeve 900nm – 1600nm</td>
<td></td>
</tr>
<tr>
<td>098309</td>
<td>00816901021750</td>
<td>NV0615 550µm Si/Si Reusable Thin Wall Fiber</td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMA 905 Connector with Extension Sleeve 900nm – 1600nm</td>
<td></td>
</tr>
<tr>
<td>097510</td>
<td>00816901020456</td>
<td>NV0633 600/630/905 Silica/Hard Clad/Tefzel Reusable</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMA 905 Connector with Extension Sleeve 800nm – 1500nm</td>
<td></td>
</tr>
<tr>
<td>097512</td>
<td>00816901020470</td>
<td>NV0635 600/630/750 Silica/Hard Clad/Tefzel Reusable</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMA 905 Connector with Extension Sleeve 800nm – 1500nm</td>
<td></td>
</tr>
</tbody>
</table>
13. Technical data
Data of fiber core diameter, wavelength range, laser probe length, type of connector and tip as well as the numerical aperture are to be learned from label and product code outside of the product package. The user must define the maximum permitted laser power for 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:

Silica product (Refer Table 1 for P/N: 097428 and 098309)

<table>
<thead>
<tr>
<th>Fiber core diameter</th>
<th>up to 272µm</th>
<th>300µm or higher</th>
</tr>
</thead>
<tbody>
<tr>
<td>max. Input energy *</td>
<td>1.5J</td>
<td>3.5J</td>
</tr>
<tr>
<td>max. Input power *</td>
<td>20W</td>
<td>30W</td>
</tr>
</tbody>
</table>

Plastic Clad Silica - PCS or Hard Plastic Clad Silica product (Refer Table 1 for P/N: 097510 and 097512)

<table>
<thead>
<tr>
<th>Fiber core diameter</th>
<th>200 to 400µm</th>
<th>500µm and higher</th>
</tr>
</thead>
<tbody>
<tr>
<td>max. Input power *</td>
<td>15W</td>
<td>30W</td>
</tr>
</tbody>
</table>

*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 injected connector and of the laser probe during procedure. Heating of one of the components of more than 50°C 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.

14. Directions for Use

- 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 SMA-905 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.
- 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.
- 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 (SMA) of the fiber assembly.
- After using the laser probe for 5 times, it must be disposed according to the hospital and/or local waste regulations. Do not reuse or reprocess the laser probe more than 5 times. Liability is excluded in case of violation.

15. Reprocessing

15.1 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.

WARNING: Laser probes are verified and validated only for the above-mentioned parameters. Laser probe 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 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

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 SMA-905 connector clean. Do not touch the exposed fiber surface.

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 SMA-905 connector clean. Do not touch the exposed fiber surface.

EFFECTIVE CLEANING AND DISINFECTATION OF LASER FIBER
Laser probes labelled as disposable laser probes 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 (disinfectant, 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.

15.2 Cleaning

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

15.2.2 Cleaning

- 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.
- 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.

15.2.3 Inspecting the 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.

15.2.4 Preparing the distal end of the laser probe

b. Use a pair of stripping pliers suitable for the fiber diameter in order to strip the fiber jacket by about 40 mm (1.60”).

15.2.5 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 magnifications, respectively.

15.3 Manual cleaning and disinfecting

When selecting the cleaning and disinfecting agents to be used, make sure that
- The devices 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) water (such as purified water / highly purified water) and/or filtered air for drying.

15.3.1 Cleaning

a. Place the wound-up laser probe (refer to the “Cleaning” section) individually into a sufficiently large wire basket. Make sure that the fiber end is not damaged by the basket.

b. 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.

c. Subsequently remove the wire basket containing the laser probe from the cleaning bath and thoroughly rinse it with water at least three times in accordance with your cleaning agent’s guideline.

d. Check the laser probes (refer to the “Final inspection” section).
15.3.2 Disinfection

a. 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.
b. 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.
c. Use filtered air in order to blow the laser probe dry inside and outside.
d. 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.

15.4 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.

16. 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

17. Sterilization

Only steam-sterilization process 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 sterilization temperature) of at least 3 min (fractioned vacuum process) or 5 min (gravitational process)
- Let the laser probe cool down to maximum 57°C or minimum to room temperature before removing it from the autoclave.

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 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.

18. 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.

19. Storage

The Laser probe is to be stored at ambient temperature +15°C - +25°C and relative air humidity of 40% - 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.

20. Disposal

Used laser probe must be properly disposed according to the hospital and local waste disposal guidelines.
21. Graphic symbols on device labeling, if applicable

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Ref. / Title</th>
<th>Description</th>
<th>Symbol</th>
<th>Ref. / Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Caution] (5.4.4)</td>
<td>Caution</td>
<td>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.</td>
<td>![Consult instructions for use] (5.4.3)</td>
<td>Consult instructions for use</td>
<td>Indicates the need for the user to consult the instructions for use.</td>
</tr>
<tr>
<td>![Non-sterile] (5.2.7)</td>
<td>Non-sterile</td>
<td>Indicates a medical device that has not been subjected to a sterilization process.</td>
<td>![Batch Code] (5.1.5)</td>
<td>Batch Code</td>
<td>Indicates the manufacturer’s batch code so that the batch or lot can be identified.</td>
</tr>
<tr>
<td>![Do not re-use more than 05x]</td>
<td>Do not re-use more than 05x</td>
<td>Indicates a medical device that is intended for not more than 5 uses.</td>
<td>![Catalogue number] (5.1.6)</td>
<td>Catalogue number</td>
<td>Indicates the manufacturer’s catalogue number so that the medical device can be identified.</td>
</tr>
<tr>
<td>![Manufacturer] (5.1.1)</td>
<td>Manufacturer</td>
<td>Indicates the medical device manufacturer.</td>
<td>![Use-by date] (5.1.4)</td>
<td>Use-by date</td>
<td>Indicates the date after which the medical device is not to be used.</td>
</tr>
<tr>
<td>![Sterilized using ethylene oxide] (5.2.3)</td>
<td>Sterilized using ethylene oxide</td>
<td>Indicates a medical device that has been sterilized using ethylene oxide.</td>
<td>![Do not use if package is damaged] (5.2.8)</td>
<td>Do not use if package is damaged</td>
<td>Indicates a medical device that should not be used if the package has been damaged or opened.</td>
</tr>
<tr>
<td>![Keep dry] (5.3.4)</td>
<td>Keep dry</td>
<td>Indicates a medical device that needs to be protected from moisture.</td>
<td>![Keep away from sunlight] (5.3.2)</td>
<td>Keep away from sunlight</td>
<td>Indicates a medical device that needs protection from light sources.</td>
</tr>
<tr>
<td>![Temperature limit] (5.3.7)</td>
<td>Temperature limit</td>
<td>Indicates the temperature limits to which the medical device can be safely exposed.</td>
<td>![Prescription only] (21 CFR 801.109)</td>
<td>Prescription only</td>
<td>Caution: Federal law restricts this device to sale by or on the order of a physician.</td>
</tr>
<tr>
<td>![Fragile, handle with care] (5.3.1)</td>
<td>Fragile, handle with care</td>
<td>Indicates a medical device that can be broken or damaged if not handled carefully.</td>
<td>![Humidity limitation] (5.3.8)</td>
<td>Humidity limitation</td>
<td>Indicates the range of humidity to which the medical device can be safely exposed.</td>
</tr>
</tbody>
</table>

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.

22. Manufacturer
Leoni Fiber Optics Inc.
209 Builnants Boulevard
Williamsburg, VA 23188

23. Distributor
Typenex Medical
303 E. Wacker Dr. Suite 1030
Chicago, IL 60601
Phone: 866-897-3639
Fax: 312-888-4090