Instruction of use
Device Description

This device comes with Ethylene Oxide (EO) sterilized and is for single use only. The PowerFlex™ laser delivery device consists of an SMA connector (proximal end) and a 3-meter fiber optic cable terminated with a square, round, or ball tip (distal end). The connector secures the device to the laser output port and the laser energy is transmitted through the fiber optic cable exiting the distal tip of the fiber.

Intended Patient Population: The intended patient population is adults (Age 18 and over) only. The PowerFlex™ laser delivery device is a Class IIa medical device intended for use with the below compatible lasers for surgical procedures involving incision/excision, ablation, and coagulation. The intended use for the fibers is for Urology procedures including Holmium Laser Ablation of the Prostate (HoLAP), Holmium Laser Enucleation of the Prostate (HoLEP), treatment of Benign Prostatic Hyperplasia (BPH), and Urinary Lithotripsy. For safe and correct operation of the device, please read and understand these instructions as well as the appropriate laser operating manual before use.

PowerFlex™ Holmium Single-Use surgical fiber optic laser delivery devices are intended for use with the following Lumenis lasers:

VersaPulse PowerSuite Laser 100W Holmium
VersaPulse PowerSuite Laser 60W Holmium
VersaPulse PowerSuite Laser 80W Holmium/ 100W ND: Yag Dual Wavelength (validated for Holmium use only)
Pulse Laser System 120H

The Indication for Use: The Luvo PowerFlex Surgical Fibers (bare fibers) are indicated for incision/ excision, ablation, and coagulation (hemostasis) when attached to cleared laser systems that provide the Ho:YAG laser wavelength for the indications for which the lasers have been cleared, including for use in urology for procedures such as Holmium laser ablation of the prostate (HoLAP), treatment of benign prostatic hypertrophy (BPH) and urinary lithotripsy. The intended use for the fibers is for Urology procedures.

Intended User: The intended user of the device is a licensed Medical Doctor (MD) or Doctor of Osteopathy (DO) who has been trained in urology procedures. In addition to being a licensed physician, the intended user will be required to undergo training in the safe use of the VersaPulse Ho: YAG laser system. This training consists of detailed in-person training on the correct use of the device and how to safely use the device.

Contraindications
Reuse of devices that have been in contact with patients is contraindicated.
•Do not use in the presence of flammable anesthetics or any combustible materials.
•Not for treatment of patients for whom endoscopic procedures are contraindicated.
•Not compatible other than Lumenis Lasers. (mentioned under Intended Patient population)

Warnings and Precautions
Never inspect the fiber while it is connected to the laser. Improper use of this device or use of a damaged device or one that has not been fully tested before use may result in serious eye or tissue damage, fire, damage to instrumentation, or accidental laser exposure to the treatment room staff or patient. Refer to the laser's operating manual for detailed safety and operating information.

To avoid damage to the fiber
• Do not pull on the fiber when it is connected to the laser.
• Avoid clamping or clipping any devices such as a hemostat onto the fiber. Avoid any contact of metallic instruments with the fiber tip.
• Ensure that the scope port is open before inserting the fiber into the scope.
To avoid damage to accessory devices:
• Avoid direct laser beam contact with accessories.
• Avoid bending the fiber above the maximum bending radius (refer to Specifications section), as it may lead to energy loss and damage to the endoscope.
The fibers should not be used if the sterile packaging is opened or damaged. The fibers should not be used if the labeling is incomplete or illegible. If necessary, the fibers should be returned to the supplier for replacement.

Careful handling of the fiber during setup is important to prevent fiber damage. Fiber damage may impact fiber performance.
If the SMA connector is soaked with any cleaning solution it may cause the device to malfunction or fail prematurely.

Any serious incident that has occurred concerning this device should be reported to the manufacturer and also the competent authority of the Member State in which the user and/or patient is established. Please contact your local representative or email info@Luvo.com

Risks associated with reuse of the single-use fibers:
Reusing single-use devices can lead to potentially serious consequences for the patient: cross-infection, injury, and ineffective care.

Reusing single-use devices can also have a dangerous impact on public health in general by risking possible contamination and infection within hospitals.

Expected Clinical Benefits

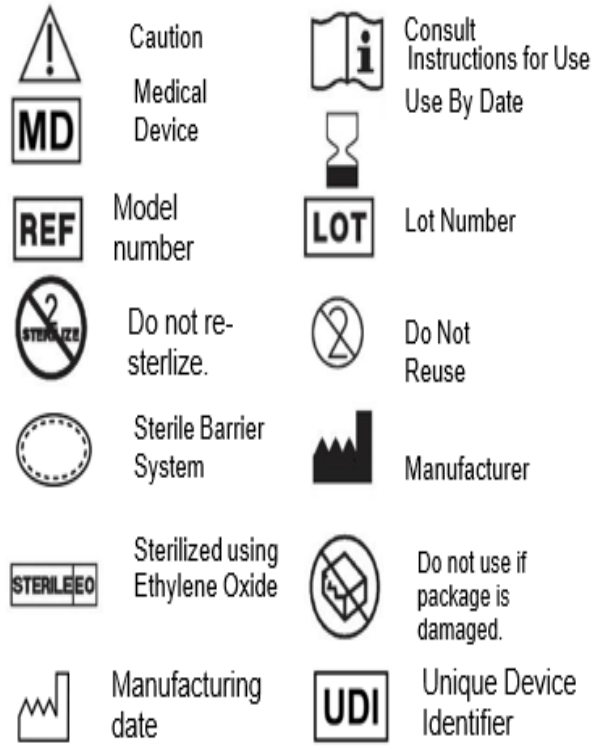
- It can provide access to difficult-to-reach anatomy by using one of the designated handpieces, a flexible endoscope, or with robotically assisted technique.
- It can deliver high energy transmission, renewable tip, and aiming beam.
- It can eliminate the need for reprocessing time and associated central sterile costs.

Patient Selection Criteria

Patients are selected usually based on the below criteria but at the Physician's discretion

- The patient requires laser-based surgical applications, for conditions mentioned in the indication for use
- The patient should not have any contraindications for endoscopic procedures or the use of the laser systems

Watch for these important symbols:



Preoperative Instructions

Follow the instructions below to ensure sterility and safe use of the device.

Circulating nurse:

1. Inspect device packaging for any defects in the protective material. Return to supplier for exchange if any indication of damage to the device or packaging is seen (include "Return Form").
2. Open the outer pouch by peeling back the "chevron" end of the pouch.
3. Present the protruding fiber tray to the Scrub nurse, or deposit the tray on a sterile surface

Scrub nurse:

4. Gently lift the SMA connector from the tray well.
5. **SLOWLY** pull 3 to 6 inches of fiber from the tray.
6. Position the SMA connector towards the Circulating nurse.
7. Hand the SMA connector to the Circulating nurse.

Circulating nurse:

8. Obtain the SMA connector and SLOWLY pull as much fiber as needed to reach the area of the laser console and then gently remove the protective cap from the SMA connector.
9. Insert the SMA connector into the fiber receptacle on the front of the laser console and tighten it clockwise until the connector stops turning.
10. Perform the laser Start-Up procedure as per the laser's operating manual.
11. Set the aiming beam to maximum intensity as per the laser's operating manual.

Scrub nurse:

12. **SLOWLY** pull the balance of the fiber from the tray just before use.
13. Inspect fiber for any sign of defects such as kinks, breaks, color inconsistency, or other damage. If the fiber appears to have any damage or defect, do not use the device; return it to the supplier (include "Return Form").
14. Remove the yellow distal tip protector and discard.
15. Should the fiber not dispense from the tray freely, the round tray lid may be removed from the tray base in order to release the fiber.
16. Aim the tip of the fiber approximately 1 cm perpendicular to a non-reflective surface in order to observe the red aiming beam. If the spot is not circular or has "flares" or if the spot is weak or not visible, return the device to the supplier for replacement (include "Return Form"). If the spot of a new replacement fiber

is also weak or not visible refer to the laser's operating manual for further direction.

Circulating nurse:

17. Set the laser treatment parameters, as described in the laser's operating manual, to the physician's desired levels.

Do not exceed the maximum energy or power settings for this delivery device (see "Device Specifications" for details).

Intraoperative Instructions

1. Refer to the laser's operating manual for detailed instructions on adjusting and using the laser.
2. Position the aiming beam on the target site.
3. If a scope is used ensure the distal fiber tip and the blue jacket are visible past the end of the scope prior to and during laser exposure.
4. Note, the 200SE-RT, 272SE-RT and 365SE-RT models are designed to pass through a fully deflected scope.
5. Place the laser in "ready" mode.
6. Depress the footswitch to deliver the laser treatment beam.
7. IMMEDIATELY DISCONTINUE USE IF:
   a. the aiming beam scatters changes direction or disappears, or
   b. the treatment power seems diminished at the site.

Examine the device for breaks, fractures, damage, or debris at the tip, along the length of the cable, and at the SMA connector. Discard the device if a defect is found. If no damage is apparent, confirm the circular shape and intensity of the aiming beam as described in "Preoperative Instructions - Step 16".

Postoperative Instructions

1. Disable or shut down the laser system according to the instructions in the laser's operating manual.
2. Disconnect the SMA connector from the laser console.
3. Prepare for disposal according to hospital policy regarding disposal of sharps and infectious or hazardous waste.

Device Storage

Store the unused device in the original packaging at room temperature in a dry area until used. Use the device prior to the expiry date listed on the packaging label.

Laser Safety

The Laser Safety Officer is responsible for all laser safety conditions in the area of laser operation.

Ensure all persons within the controlled area are wearing appropriate laser safety eyewear. For additional information refer to the laser's operating manual.

Side Effects

Burns, swellings, bleeding, pain, infection, paraesthesia due to injury of adjacent sensory nerves, and perforation in case of application in the vicinity of sensitive areas.

Residual Risk

- The fiber is not intended to reuse, it may cause tissue damage for the patient.
- Disposal according hospital policy regarding disposal of sharps and infectious or hazardous waste.

US Federal law restricts this device to sale by or on the order of a physician

CAUTION: Improper use of this device or use of a damaged device or one that has not been fully tested prior to use may result in serious eye or tissue damage, fire, damage to instrumentation or accidental laser exposure to the treatment room staff or patient. Refer to the laser's operating manual for detailed safety and operation information.

CAUTION: Surgical instruments and accessories may be damaged by direct contact with the laser treatment beam or cause reflections of the laser beam which may cause unexpected results or harm to surrounding tissue. Refer to operating manuals and laser safety guidance documents for additional information.

CAUTION: The PowerFlex Holmium Single Use Laser Fiber Delivery Devices are intended for single use only. Do not attempt to clean, resterilize or reuse the device. Such an attempt may damage or compromise the performance or safety of the device.

Warranty

This device is to be free from defects in material and workmanship and to perform to the specifications under the conditions provided in this instruction guide. Replacement of the device will be provided if the device is found to be defective upon initial inspection or upon first use. This is a single use device and as such there is no warranty or provision for replacement of this device after first use.

Product Information Disclosure:

Luvo Medical Technologies Inc. excludes all warranties whether express or implied by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness.

Handling, processing and storage of this device, as well as other factors surrounding the use of this device may affect the device and the results obtained with its use Luvo Medical Technologies Inc. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. Luvo Medical Technologies Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the use of this device.

Product Return Decontamination

All used product determined to be defective due to warranty issues must be sterilized at the customer's facility prior to shipment. **The supplier will not accept return of any used product that has not been sterilized.** Sterilization and product lot numbers must be verified on shipping documentation for acceptance of replacement or credit. For further assistance on product returns, please contact your local representative or distributor.
Note: any serious incident that has occurred in relation to the device should be reported to the manufacturer.

Device Specifications

Specifications subject to change without notice

Maximum Input Specifications		
Wavelength 2,100nm	For use in saline environment	
	Model	**Parameter**
Maximum Energy Input	200SE-RT*, 272SE, 272SE-RT, 272SE-3MM	**1.5 Joules**
	365SE, 365SE-RT, 365SE-3MM	**6.0 Joules**
	550SE	**6.0 Joules**
	1000SE	**6.0 Joules**
Maximum Power Input	200SE-RT, 272SE, 272SE-RT, 272SE-3MM	**45 watts**
	365SE, 365SE-RT, 365SE-3MM	**120 watts**
	550SE	**120 watts**
	1000SE	**120 watts**

Energy and resultant power should not exceed the maximum settings as shown above.
****reduce energy settings by 25% for typical use***

Fiber Specifications	**200SE-RT**	**272SE 272SE-RT 272SE-3MM**	**365SE 365SE-RT 365SE-3MM**	**550SE**	**1000SE**
Core diameter (um)	**242**	**272**	**364**	**545**	**910**
Maximum Outer diameter (um)	**450**	**450**	**580**	**780**	**1450**
Total Length (m)	**3**	**3**	**3**	**3**	**3**

Model	Distal Tip Profile	Distal Tip Diameter (um)	Distal Tip Length (mm)
200SE-RT	Ball	415-423	5
272SE	Square	339-373	5
272SE-RT	Round	340-350	5
272SE-3MM	Square	339-373	3
365SE	Square	409-451	5
365SE-RT	Round	410-421	5
365SE-3MM	Square	409-451	3
550SE	Square	599-661	5
1000SE	Square	984-1086	5

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