OMNIGUIDE ADVANCED ENERGY FIBERS: VELOCITY™ High Performance Fiber

INSTRUCTIONS FOR USE

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Caution: Federal Law restricts this device to sale by or on the order of a physician or dentist.

SECTION I: DEVICE DESCRIPTION

STERILE R 20% 90% (Humidity limitation: The range of humidity to which the fiber can be safely exposed)

The OmniGuide VELOCITY™ High Performance Fiber is a flexible fiber that delivers CO_2 laser energy to enable minimally invasive surgery. The VELOCITY High Performance Fiber also transmits up to 3.2 liter/min of Helium gas flow, cooling the fiber and clearing the surgical field of smoke or blood. The fiber attaches to an OmniGuide Fiber Enabled Laser System (IntelliGuide FELS-25A) upgraded to v1.4 software or greater, and is indicated for use with compatible OmniGuide Surgical Handpieces or endoscopes. Compatible OmniGuide Surgical Hand pieces include:

- GYN Series Rigid Handpieces
- LGT Series Rigid Handpieces
- LapFlex Handpiece
- FlexGuide™ Ultra Fiber Conduit
- ELEVATE™ ENT Series Rigid Handpieces

The device is provided sterile, for single use only.

SECTION II: INDICATIONS FOR USE

The OmniGuide VELOCITY High Performance Fiber is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues in the following specialties:

- General Surgery
- Gynecology
- Head & Neck Surgery
- Laparoscopic Surgery
- Oral Surgery
- Otorhinolaryngology
- Pediatric Surgery
- Urology

Contraindications: The VELOCITY High Performance Fiber is contraindicated for use with Legacy ENT Series Rigid Handpieces, NEURO Series Rigid Handpieces and OTO Series Rigid Handpieces.

Note: The indications for use of the OmniGuide VELOCITY High Performance Fiber are dependent upon the cleared indications for use of the laser system and attached laser system accessories.

SECTION III: ⚠ WARNINGS

Caution: Fiber design results in higher gas flow at the same input pressure compared previous OmniGuide fibers.

The VELOCITY High Performance Fiber transmits up to 3.2 liter/min of Helium gas flow in order to cool the fiber and clear the surgical field of smoke or blood.

Please note: This is a higher gas flow than other OmniGuide Fibers.

Please notify the anesthesia team about use of 3.2 liters/min of helium flow with the laser prior to starting the case.

- Pressurized gas exiting the fiber tip during the laser procedure may cause gas embolism if fiber comes in contact with blood vessels or vascular tissue, leading to serious injury or death.
  - Do not bring the fiber tip into direct contact with blood vessels or vascular tissues.
  - Monitor vital signs of the patient and blood oxygen level for symptoms of gas embolism.
  - Stop using the laser if you see sudden or unexplained changes of the levels of end tidal carbon dioxide, subcutaneous emphysema, sudden change in oxygen tension via oximetry or sudden changes in hemodynamics.
  - For airway cases, the fiber should not be used below the carina.
- For adult glottic and subglottic cases, do not increase gas input pressure above 50psi due to quicker O_2 depletion and increased risk of gas embolism.
- Using pressurized gas during some endoscopic and laparoscopic procedures could lead to over-insufflation and the risk of tissue perforation:
  - Use of insufflators or other approved gas evacuation devices that are equipped with a sensor for internal pressure and a pressure relief valve are recommended.
- For airway procedures, make sure airway outlet is present so that gas pressure does not build up. For pediatric airway applications, maximum input pressure is limited to 30psi and ≤ 10W input power setting due to increased safety risks.
- Pressurized gas exiting the fiber's tip during the laser procedure may cause temporary inflation and separation of sub-mucosal flaps or emphysema under superficial layers of tissue.
  - To reduce this risk, use a longer working distance between the fiber tip and tissue.
  - Any signs of subcutaneous emphysema or hemodynamic instability during use, immediately stop using laser and proceed to standard treatment protocol.
- Inspect fiber packaging. Do not use if package is damaged or opened.
- Fiber is intended for single use only. Do not re-sterilize or reuse.
- Fiber reuse may pose the risk of infection.
- Re-sterilization/reprocessing of the fiber could lead to fiber damage, resulting in fiber failure leading to potential:
  - Laser radiation exposure
  - Fiber overheating
  - Fiber foreign material being left in the patient
- Handle the fiber with care. Do not bend it excessively (radius < 3 cm) to avoid damage and increased possibility of failure during use.
- Medical Grade Helium gas must be flowing through the fiber at specified settings throughout the procedure to avoid increased possibility of failure during use.
- The laser should be activated only when the laser treatment site is clearly visible and the fiber tip is directed at it.
- Laser energy can cause eye damage, burns, and ignite flammable materials.
  - User should wear appropriate laser eyewear and skin protection in accordance with the facility's laser safety policies.
  - Avoid reflective materials and combustible materials near the surgical site.
  - Flammable prep solutions must not be used during laser procedures.
  - Fire extinguisher must be available for the operating room when the laser is being utilized.
- When the laser is used during ENT or Pulmonary procedures, extra caution must be taken to avoid potential fire hazards in the airway:
  - The anesthesia oxygen concentration must be kept at or below 25%.
  - A special laser-safe endotracheal tube (ET) or wrap must be used.

SECTION IV: ⚠ PRECAUTIONS

- Observe all laser and compressed gas safety precautions as specified in the laser system User Manual.
- Do not use the fiber outside its recommended parameters in Section VI. SPECIFICATIONS below. Always use the minimum appropriate laser power and gas settings required for a given procedure.
- See the Fiber Procedural Setting Guide (DOC-GEN-3) for recommended power and gas ranges.
- Laser surgical procedures should be performed only by a licensed physician or dentist adequately trained and familiar with such surgical techniques and clinical use of CO_2 lasers.
- A smoke evacuation system or suction should be utilized to remove surgical plume.
- Do not touch the fiber tip to tissue or fluids as it will increase the risk of tip clogging and/or product failure. If tissue or debris buildup occurs, set gas pressure to at least 20psi and clean the fiber tip by dipping it in saline solution.
- There is a possibility that an OmniGuide VELOCITY High Performance Fiber will fail during the course of a surgical procedure. Therefore, do not start a surgical procedure unless you have at least two fibers or another surgical tool available.

ADVERSE REACTIONS

- Inflammatory reaction at the sites where energy is applied.
- As with any surgical tool, iatrogenic injury may occur.

SECTION VI: SPECIFICATIONS

		SPECIFICATIONS
LASER SETTINGS	*Maximum input power (laser setting)*	30W (Continuous Wave) 10W (Superpulse)
	Recommended minimum working distance between fiber tip and tissue	2.0mm
	Recommended working distance for coagulation	20-30mm
	Medical grade helium input pressure	*See the Fiber Procedural Setting Guide (DOC-GEN-3) for specific procedure settings.* *Pediatric airway applications: maximum input pressure 30psi and maximum input power setting 10W For adult glottic and subglottic cases: maximum 50 psi*
	Gas flow at recommended pressure at 90psi	3.2 liter/minute maximum
		SPECIFICATIONS
PRODUCT SPECS.	*Fiber Length*	2.0m
	Nominal spot size at fiber tip	0.32mm
	Beam divergence	> 60 mRad (3.4°), < 200mRad (11°)
	Estimated output power of straight fiber with laser set to 30W *Note: Additional output power variation may occur depending on usage conditions, including bending of the fiber.*	20W

COMPATIBLE LASER SYSTEMS AND SURGICAL INSTRUMENTS

OMNIGUIDE SURGICAL LASER SYSTEMS	VELOCITY High Performance Fiber
IntelliGuide FELS-25A (v1.4 or higher)	•
FELS-20L, FELS-25M, and FELS-30C	
OMNIGUIDE SURGICAL INSTRUMENTS	
GYN Series Rigid Handpieces	•
LGT Series Rigid Handpieces	•
FlexGuide Ultra Fiber Conduit	•
ELEVATE ENT Series Rigid Handpieces	•
LapFlex Handpiece	•
NEURO Series Rigid Handpieces	
OTO Series Rigid Handpieces	
Gas Filter Unit (GFU) System	•
OTHER COMPATIBLE INSTRUMENTS	
Rigid or Flexible Endoscope with working channel diameter > 1.6mm, bend radius > 3cm, and at a maximum input power of 15W	•

DIRECTIONS FOR USE

See laser system operating manual for detailed instructions, maintenance, and additional warnings and precautions.

For sterile cases, use of a Gas Filter Unit (GFU) is required. See GFU instructions for details.

⚠ Inspect fiber packaging. Do not use if package is damaged or opened.

Note: See product packaging for expiration date.

1. Use sterile technique to open the fiber package.
   ⚠ Handle the fiber with care. Do not bend it excessively (radius <3 cm) to avoid damage and increased possibility of failure during use.
2. Insert the fiber into a compatible surgical instrument (see table above)
   Note: See surgical instrument instructions for use for detailed instructions, additional warnings and precautions.
3. Turn on gas supply and set gas pressure.
4. Attach the fiber connector to the laser adapter. Ensure fiber connector is securely locked to the adapter. Verify gas is flowing from the fiber tip.
5. Activate the laser energy to cut, ablate, or coagulate soft tissue for the desired application.
   ⚠ Do not use the fiber outside its recommended parameters in the Specification Table. Always use the minimum appropriate laser power and gas settings required for a given procedure.
   See the Fiber Procedural Setting guide (DOC-GEN-3) for recommended power and gas settings.
   Note: The CO_2 laser beam diverges as it exits the distal end of the fiber. Refer to Specification Table for spot size at the fiber tip and beam divergence.
6. Turn off the laser system and gas supply after procedure completion.
7. Disconnect the fiber connector from the laser adapter and remove the fiber from the surgical instrument.
8. Visually inspect the fiber and verify that no portion is missing.
9. Treat and dispose of used fibers as biohazardous material according to facility guidelines.

FOR FURTHER INFORMATION

If further information on this product is needed, please contact OmniGuide Customer Service at (888) OMNI-GUIDE in the US, or your authorized distributor. See www.omni-guide.com/patents for information about the coverage of this OmniGuide® product by U.S. and/or foreign patent rights.

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