

INDICATIONS FOR USE

The OmniGuide handpiece is indicated for use in conjunction with OmniGuide's waveguide fibers to enable the surgeon to perform incision, excision, ablation, vaporization, and coagulation of body soft tissues. It is indicated for laparoscopic surgery and can be used with the following 5mm suction irrigators:

- StrykeFlow™ 2 (REF 250-070-520) by Stryker
- Surgiflex® Wave™ Suction (REF 007200-901) by Gyrus ACMI / Olympus

The handpiece is also indicated for the following 5mm suction irrigators when used with a laser fiber insert adapter such as the Large Fiber Adapter Cap (REF 5102200) by Davol:

- Hydro-Surg™ Plus (REF 0026870) by Davol
- CORE Trumpet (REF CD8190) by ConMed

CAUTIONS

Handpieces are provided non-sterile. It is recommended to sterilize the devices prior to use.

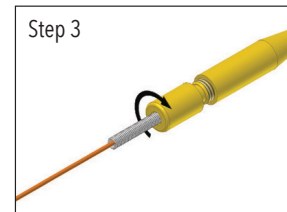
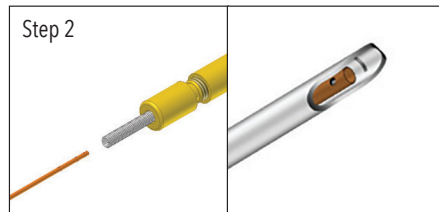
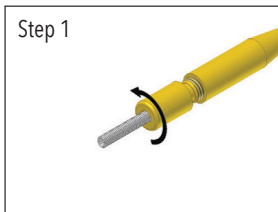
WARNINGS

1. Do not attempt to insert the fiber while the rear sealing cap is tightened.
2. Do not overtighten the rear sealing cap after loading the fiber. Doing so may kink the fiber, leading to performance degradation or failure.
3. Do not sterilize handpiece while rear sealing cap is tightened. Doing so may damage the internal silicone bushing
4. Handpiece must be used in conjunction with a suction irrigator. Do not use handpiece as standalone device.

LOADING THE FIBER FOR USE

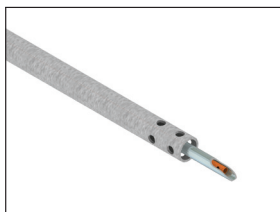
Using aseptic technique, perform the following steps:

1. Loosen the rear sealing cap by turning counterclockwise.
2. Insert the fiber through the rear sealing cap until the distal tip is located between the reference lines of the handpiece.
3. Secure the rear sealing cap by turning clockwise.

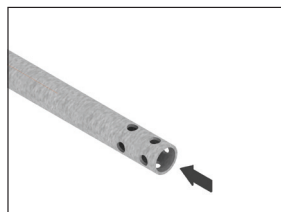


USAGE INSTRUCTIONS

If required, use appropriate adapter to suction irrigator such that handpiece (ø0.083" or ø2.1mm) can be inserted. Insert handpiece into suction irrigator sealing port.



During lasing, extend handpiece so that fiber is fully visualized



During suction or irrigation, retract the handpiece

⚠ DO NOT LASE WHILE HANDPIECE IS RETRACTED WITHIN IRRIGATOR

⚠ DO NOT SUCTION FLUID OR AGGRESSIVELY MANIPULATE TISSUE WHILE HANDPIECE IS EXTENDED

UNLOADING THE FIBER AFTER USE

1. Loosen the rear sealing cap by turning counterclockwise.
2. Remove the fiber.

CLEANING PROCEDURE

The handpiece must be cleaned immediately after use. Charred tissue, blood, and debris may clog the lumen if allowed to dry, making it difficult to insert and remove the fiber. **Note: Perform either manual or autowash procedure.**

MANUAL CLEANING

1. Clean all external surfaces with a solution of enzymatic detergent (e.g. Enzol) and water. Use a 1.78mm (0.070"/5 French) brush to clean the lumen (e.g. Keg Surgical P/N BR-24-070).
2. Rinse thoroughly and dry. Use an air gun to remove liquids from the lumen.
3. Unscrew the rear sealing cap and set aside. Remove the silicone gripper using forceps. Clean the seal housing and seal. Ultrasonic cleaning with non-corrosive solutions is recommended.
4. After cleaning, reassemble the silicone gripper. Place a small amount of lubricant (e.g. Instrument Milk or equivalent) onto the screw threads of the rear sealing cap.

AUTOWASH

1. Remove the rear sealing cap by unscrewing. Remove the silicone gripper using forceps.
2. Prepare enzymatic detergent per manufacturer's recommendation.
3. Immerse handpieces into the prepared detergent. Ensure the detergent completely fills the lumen without trapping air.
4. Use a 1.78mm (0.070"/5 French) brush to clean the lumen (e.g. Keg Surgical P/N BR-24-070).
5. Load handpiece, rear sealing cap and silicone gripper in automatic washer such that all design features can be cleaned and drained easily.
6. Run the automatic wash cycle (see minimum recommendations below):

PHASE	RECIRCULATION TIME	TEMPERATURE	DETERGENT TYPE
Pre-wash	2 minutes	Cold tap water	N/A
Enzyme wash	1 minutes	Hot tap water	Enzymatic Solution (e.g. Enzol)
Wash 1	2 minutes	66°C	Neutral pH detergent (e.g. Polystica 2X Neutral)
Rinse 1	15 seconds	Hot tap water	N/A
Pure water rinse	10 seconds	66°C	N/A
Drying	7 minutes	115°C	N/A

7. Remove handpiece, rear sealing cap and silicone gripper from the washer.
8. Dry interior surfaces of handpiece, seal housings and seals with compressed air.
9. Check instrument for visible soil. Repeat cleaning if needed.
10. Place a small amount of lubricant (e.g. Instrument Milk or equivalent) onto the screw threads of the rear sealing cap. Reassemble the silicone gripper and rear sealing cap.

INSPECTION, MAINTENANCE, TESTING AND LUBRICATION

1. Carefully inspect device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning and sterilization procedures above.
2. Visually inspect device and threads for cracks, kinks, completeness, damage and/or excessive wear.
3. Place a small amount of lubricant (e.g. Instrument Milk or equivalent) onto the screw threads of the rear sealing cap.

STERILIZATION

Autoclave sterilization should be performed in accordance with the instructions provided by the manufacturer of the autoclave. Recommended minimum settings for the handpiece in a wrapped tray are as follows:

Cycle	Sterilization Temperature	Sterilization Time	Minimum Drying Time
Pre-Vac	270°F (132°C)	4 minutes	30 minutes

DEVICE LIFETIME/WARRANTY

The device is warrantied against defects in materials and workmanship under ordinary use for one year after purchase. Please contact OmniGuide for any warranty related questions.

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