

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 use.

CAUTIONS

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

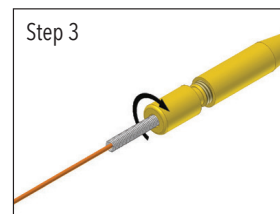
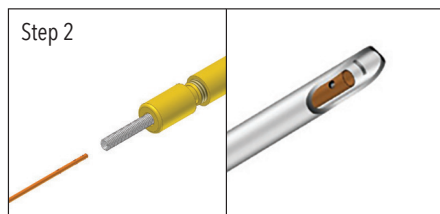
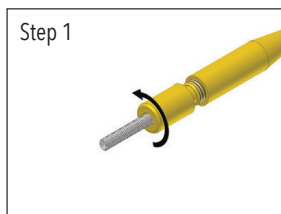
WARNINGS

1. Prior to each use inspect the instrument for damage. If damage is evident, do not use.
2. Do not attempt to insert the fiber while the rear sealing cap is tightened.
3. Do not over tighten the rear sealing cap after loading the fiber. Doing so may kink the fiber, leading to performance degradation or failure.
4. Do not sterilize handpiece while rear sealing cap is tightened. Doing so may damage the internal silicone bushing.

LOADING THE FIBER FOR USE

Using aseptic technique, perform the following steps:

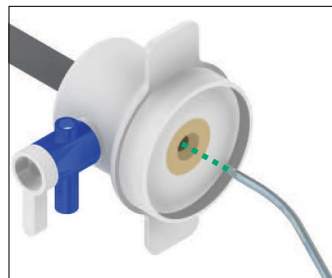
1. Loosen the rear sealing cap by turning counterclockwise.
2. Insert the fiber through the rear sealing cap until the distal tip is located between the reference lines of the handpiece.
3. Secure the rear sealing cap by turning clockwise.



LOADING HANDPIECE INTO TROCAR

The handpiece is designed for use with 5mm trocars.

1. Align distal tip of handpiece with trocar entrance (see photo).
2. Insert handpiece into trocar until the angled portion is fully inserted.
3. Straighten handpiece and insert fully. It is normal to feel gentle resistance.
4. Continue insertion until 5mm handpiece cannula passes trocar seal. 5mm handpiece cannula must remain past trocar seal to maintain proper insufflation pressure.



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.

CLEANING PROCEDURE (CONT'D)

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 handpiece 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. Prolystica 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 warranted 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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