

NOTE: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR DENTIST

### INDICATIONS FOR USE

The OmniGuide Handpiece is indicated for use in conjunction with OmniGuide's BeamPath® fibers to enable the surgeon to perform incision, excision, ablation, vaporization, and coagulation of body soft tissue including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology, and pulmonology.

This product is not intended for neurosurgery/neurotology in CE marked recognized European Countries.

### CAUTIONS

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

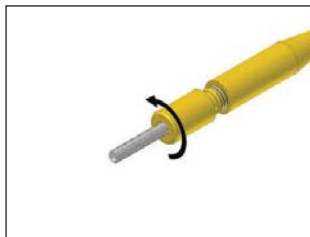
### WARNINGS

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 gripper.

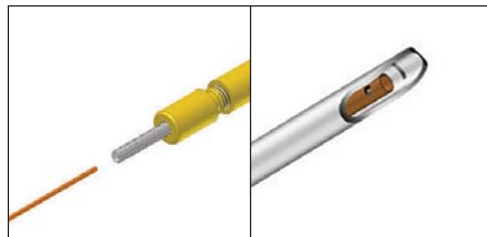
### LOADING THE FIBER FOR USE

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.



Step 1



Step 2



Step 3

### 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. 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. When using OmniGuide Sterilization Trays, do not place more than 8 handpieces in a tray. Recommended settings for unwrapped or wrapped OmniGuide Handpieces are as follows:

Cycle	Sterilization Temperature	Sterilization Time	Minimum Drying Time
Pre-Vac	270°F (132°C)	5 minutes	30 minutes
Pre-Vac	273°F (134°C)	3 minutes	8 minutes

## DEVICE LIFETIME/WARRANTY

The device is designed for consistent and reliable performance under normal usage. Before each use, please inspect the handpiece for any sign of device degradation.

## FIBER USAGE

OmniGuide handpieces are designed for use with OmniGuide fibers of the same product family. For additional handpiece-fiber compatibility information, contact your local sales representative or OmniGuide directly at 1-617-551-8444.

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