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ReNew Family of Laparoscopic Handpieces 3900 Series Ratcheted and Non-Ratcheted- Instructions For Use

INDICATIONS FOR USE

The ReNew Handpieces and tips are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.

CONTRAINDICATIONS

The ReNew Handpiece and tips are not intended for use except as indicated.

COMPONENTS OF A RENEW HANDPIECE

PRODUCT	CATALOG NUMBERS
ReNew IV Handpieces	3900 Series
ReNew Scissor Tips	3100 Series
ReNew Grasper & Dissector Tips	3200 Series
	3300 Series
	3400 Series
	3600 Series
	3800 Series

PRE-CHECK INSTRUCTIONS

- Carefully inspect the shipping carton and its contents for any sign of damage. If damage is visible, do not use the instrument.
- This instrument is delivered without a tip. Tips are available in various configurations (see above).
- Ensure that the device received is the ReNew handpiece and matches the supplied IFU.

ERGONOMICS

This instrument is delivered with two sets of separately packaged reusable non-latex rings (small & medium sizes). These rings are designed to be mounted around the inside of both handle finger holes and they are intended to maximize surgeon comfort by adjusting the inside size of the handpiece finger rings. Depending on what the surgeon feels most comfortable, the small, medium, or no ring sets may be used during a procedure.

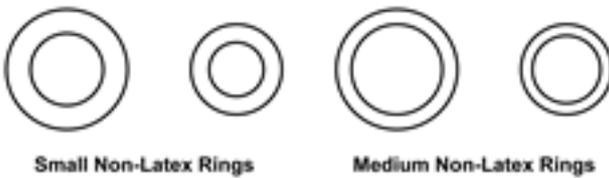


Figure 1

HANDPIECE/TIP ASSEMBLY

- Gently close the blades/jaws with your index finger and your thumb to ensure complete closure (See Fig. 2).
- With blades/jaws of tip and handles of hand piece in their closed position, insert the tip into the shaft.
- Hold the jaws and turn the hand piece rotation knob clockwise until tip is screwed tight.
- The device is ready for use.

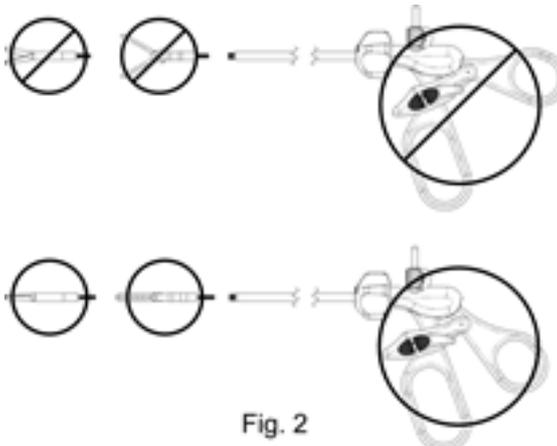


Fig. 2

OPERATING INSTRUCTIONS FOR RATCHETED HANDPIECES

- Push switch (see Fig. 3) forward in order to engage the ratchet mechanism.
- Close the handles to the desired grasping position and let go. The instrument is locked on the tissue.
- To release the grasper jaws, press down on the locking lever.
- In order to use the instrument in non-ratcheted mode, pull the switch toward the back of the instrument. The instrument will open and close freely.

NOTE

Non-Ratcheted mode is necessary to screw a tip onto the handpiece.

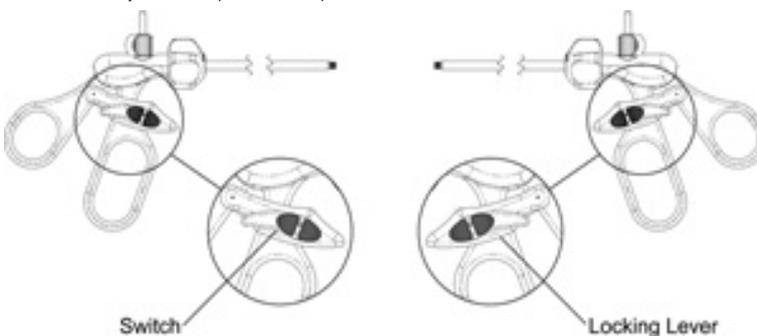


Fig. 3

PRE-PROCESS INSTRUCTIONS

Prior to use, follow the guidelines below for proper cleaning and sterilization.

MANUAL CLEANING

Microline Surgical recommends that tips and non-latex rings be detached from handpiece before cleaning and sterilization. Single patient use disposable tips are to be discarded before cleaning and sterilizing the handpiece. Limited use tips are to be cleaned and sterilized following the instructions below.

- Presoak the components of the instrument and or limited use tip in enzymatic solution detergent per the Manufacturer's Instructions.

- Remove (unscrew) the cautery plug.
- Insert a 60ml luer type syringe filled with warm tap water where the cautery plug was removed. Flush the inside of the shaft and tip clean.
- Brush the distal (working end) of the instrument under water, to avoid airborne contaminants.
- Make sure that all visible bioburden has been removed under water.
- Flush inside of the shaft three (3) times with deionized water for a final rinse.
- Inspect the instrument for functionality and package appropriately for sterilization.

AUTOMATED CLEANING

Microline Surgical recommends that tips and non-latex rings be detached from handpiece before cleaning and sterilization. The minimum automated cleaning requirements are as follows:

- Rinse with running tap water while actuating moving parts to remove gross soil.
- Load device(s) into automated washer. Load device(s) in the open position.
- Automated wash cycle parameters as follows:
- Instrument Cycle: High

Phase	Time	Temperature	Detergent
Pre-Wash	2:00	Cold Tap Water	N/A
Wash 1	2:00	65.5°C	Alkaline or Enzymatic Detergent
Rinse 1	00:15	Hot Tap Water	N/A
PURW Rinse	1:00	90°C	N/A
Dry	6:00	98.8°C	N/A

- Visually Inspect to ensure all soil is removed.

STERILIZATION

- Prior to sterilization, the device must be thoroughly cleaned.
- Wrap the device.

Microline Surgical recommends using the following validated steam sterilization cycles as guidelines:

Sterilization Cycle	Exposure Time
Gravity Cycle	4 minutes at 270°F (132°C)
Gravity Cycle	30 minutes at 250°F (121°C)
Pre-Vacuum Cycle	4 minutes at 270°F (132°C)

STERILIZATION PARAMETERS FOR EUROPEAN COUNTRIES

Microline Surgical recommends the following parameters as minimum sterilization cycle parameters for Europe, except for France and Switzerland:

Sterilization Cycle	Exposure Time at 134°C
Pre-Vacuum Cycle	3-5 minutes

For France and Switzerland, the following minimum sterilization cycle parameters are recommended:

Sterilization Cycle	Exposure Time at 134°C
Pre-Vacuum Cycle	18 minutes

PRECAUTIONS

- Do not use handpiece if the O-ring located on the distal end of the shaft appears worn, damaged or missing.
- If the blades/jaws are not completely closed when screwed onto the handpiece, they may not cut or grasp completely at the distal tip.
- CAUTION: Prior to use, assure that the plastic hub of tip is fully in contact with the insulation tube of handpiece and that no gap exists between the two parts at that contact point.

WARNINGS

- No modification of this equipment is allowed.
- The ReNew Handpiece has a white O-ring at the distal end of the shaft, which is an integral part of the system. Prior to each use, it is very important to verify that the white O-ring is in place and it is not damaged. If the white O-ring is missing or damaged, do not use the instrument.
- This device is latex free.

ELECTROCAUTERY

First, connect the electrosurgical cord (not furnished with the instrument) to the handpiece by placing the female end of the cord on the male adapter pin on the handpiece. Plug the other end of the cord into the monopolar receptacle of the generator.

ELECTRICAL RATINGS

To reduce the risk of electrical burn or shock, handpieces and tips are not to be used beyond their maximum recurring peak voltage ratings:

RATING	MODE	GENERATOR CREST FACTOR
800 Vp	Cut mode (Cut, Cut Pure)	CF< or = 2
1.25 KVp	Coag Burst mode (Blend, Desiccate)	2<CF< or = 6
2.65 KVp	Coag Spray mode (Fulgurate, Spray)	CF>6

ELECTRICAL PRECAUTIONS

- A complete understanding of the principle of monopolar electrocautery surgical procedures is necessary to avoid accidental shocks, burns, or potential gas embolism to the patient.
- Be sure that a return electrode grounding pad has been properly attached to the patient and the generator.
- Do not activate the generator until the metallic end of the tip is in contact with the tissue or is in a position to deliver high frequency energy to the tissue.
- Keep the power as low as possible to achieve the desired effect.
- Use only with safety certified HF generators (IEC 60601-2-2)
- Refer to the HF generator IFU for operating instructions and warnings.
- Refer to the HF generator IFU for selection of HF cable and neutral pad electrode consistent with handpiece ratings.

REUSE LIFE

The ReNew Handpiece will withstand twenty (20) cleaning and sterilization cycles without loss of effective function. The ReNew RS Handpiece (Cat No. 3924) will withstand ninety (90) cleaning and sterilization cycles without loss of effective function.

ENVIRONMENTAL PROTECTION

To reduce contamination risks, the ReNew Take Apart Handpiece and tips shall be disposed of in compliance with all applicable local, state and federal laws and regulations.

WARRANTY

Microline Surgical warrants that its instruments are free from any defects in both material and workmanship. Microline Surgical shall not be held liable for any incidental or consequential damages of any kind. Work performed on an instrument will void this warranty. Gross abuse or neglect of a Microline Surgical instrument will void this warranty.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

SYMBOL DEFINITIONS

Following are the graphical symbols and their descriptions used in the labeling of the ReNew Handpieces:

	Federal (USA) law restricts this device to sale by or on the order of a physician		Catalog Number
	Consult instructions for use		Lot Number
	Manufacturer		Serial Number
	Refer to instruction manual/booklet		Non Sterile

Not made with natural rubber latex.



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