

STEP	PROCESS	SOLUTION	VOLUME	INSTRUCTIONS
1	Cleaning during surgical use	Sterile water		Wipe visible blood, tissue, and body fluids off instrument.
2	Initial rinse	Tap water	25cc	Flush through cleaning port while operating and closing jaws.
3	Manual cleaning	Neutral pH(7) detergent		Use stiff plastic (nylon) brush.
4	Enzymatic bath	Enzyme solution	10cc	1. Flush through cleaning port. 2. Soak / Immerse for 2 minutes.
5	Rinse	Tap water	25cc	Flush through cleaning port to remove all residue of solution.
6	Final rinse	Air	25cc	To remove all residue of tap water.
7	Lubrication bath	Instrument oil or milk		Lubricate all parts having metal to metal contact.

Autoclave Sterilization

It is recommended to have an empty run during the first stage every day prior to the start of the full sterilization process. Any accumulation of air or condensation in the pipes will be evacuated and cold parts of the autoclave will preheat. The time of exposure recommended shall be measured from the moment the thermometer reaches the specific sterilization temperature of the indicated sterilizer type, cycle and load. Sterilize instruments in the open position with **luer cap removed**.

STERILIZER TYPE	CYCLE	LOAD	CHAMBER TEMP.	EXP. TIME
Gravity	250°F	Wrapped	250 - 254°F	30 min.
Gravity	270°F	Wrapped	270 - 274°F	20 min.
Prevac	270°F	Wrapped	270 - 274°F	15 min.
Prevac	270°F	Unwrapped	270 - 274°F	10 min.

Validation on cleaning and sterilization parameters for all reusable laparoscopic instruments was obtained from an independent testing organization. Following the Cleaning and Sterilization Instructions, sterilization will obtain a Sterility Assurance Level (SAL) of 10⁻⁶.

The instruments must be completely dry at the completion of the autoclave dry cycle.

EXPLANATION OF SYMBOLS



Reorder number



Consult instructions for use



Do not re-sterilize



Do not re-use



Sterilized using Ethylene Oxide



Do not use if package is damaged



Not made with natural rubber latex

R_x Only

U.S. Federal law restricts this device to sale by or on the order of a physician



Manufacturer

NU-TIP®
Non-Insulated Disposable Tips

For Use During Minimally Invasive Surgery

DIRECTIONS FOR USE

PRODUCT NUMBERS:

M2101D

Scissors, Curved Metzenbaum

M2102D

Scissors, Straight

Single-Use Tips • Box of 10



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DESCRIPTION

The Nu-Tip® Non-insulated disposable tips are used in conjunction with the Nu-Tip® Insulated reusable handle and shaft assembly during minimally invasive surgery.

INDICATIONS FOR USE

This device is intended for use during minimally invasive surgery.

PRECAUTIONS

The user should take precautions to ensure that all minimally invasive components including laparoscope, forceps, trocars and sleeves, electrocautery units, cables and patient grounding plate are compatible and intended for minimally invasive surgery.

It is imperative that all electrosurgical instruments be in contact with or next to the tissue or target prior to activation of the genetator to eliminate the possibility of voltage/current seeking an exit through the insulation to the closest “ground”. Activate generator only when instrument is in position.

The reusable handle/shaft assembly must be cleaned and sterilized after each use by the sterilization method describe in this manual.

SCISSOR NU-TIP® PRECAUTION

Use of this device for retraction or dissection could cause breakage resulting in possible risk to patient.

BEFORE USE INSTRUCTIONS

The reusable instrument handles are supplied NON-STERILE and should be cleaned prior to sterilization. Refer to the instruction on **CLEANING AND STERILIZATION**.

DIRECTION FOR USE

To attach single-use tip to instrument

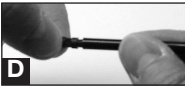
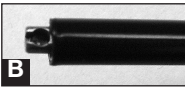
- 1 Open instrument handle (A) to expose push-rod slot (B).
- 2 Insert tip’s ball (C) into push-rod (B).

- CAUTION

If tip ball (C) is not inserted into push-rod slot (B), Nu-Tip® will only open and not close.
- 3 Grasp Nu-Tip® at the base end (D). Screw Nu-Tip® into instrument until finger tight. **DO NOT OVER-TIGHTEN.** Excessive tightening may result in damage to tip.
 - 4 Instrument is now ready for use.

To detach single use tip from instrument

- 1 Grasp Nu-Tip® at the base end (D). Unscrew Nu-Tip® from instrument.
- 2 Open instrument handle (A) to expose push-rod slot (B), disengage Nu-Tip® ball from push rod slot (B).
- 3 Dispose of Nu-Tip® in sharps container.



HANDLE ASSEMBLY

To assure proper cleaning, proper disassembly and assembly of the instrument.

- Assembly
- 1 Push seal (B) into place making sure it is properly seated.
 - 2 Slide back handle ball socket onto the push for ball (D) and screw handle screw (A) to attach handle.

NOTE Handle screw is attached on the left hand side of the instrument, opposite side of the cleaning port.

- 3 Check for proper function of instrument.

- Disassembly
- 1 Remove handle screw (A) and slide back handle off the push rod ball (D).
 - 2 Remove seal (B) during the manual cleaning for flushing and cleaning.
 - 3 Remove luer cap (C) during processing and sterilization.

CLEANING MATERIALS AND PRACTICES

Quality of Water
Water that has an excessive ion concentration may lead to damage of surgical instruments during cleaning.

PITTING may occur with content of approximately 240mg chloride per liter; corresponding to 400mg per liter sodium chloride NaCl.

NO PITTING is likely to occur if there is a chloride content of approximately 120mg per liter; corresponding to 200mg per liter sodium chloride NaCl.

Heavy metal ions in the water may cause discoloration and stains such as oxidation tints (brown, blue, rainbow colored). NOTE: This is discoloration not corrosion. Discoloration caused by heavy metal ions can be removed with the use of acetic acid, phosphoric acid or citric acid.

Disinfectant
Do not use disinfectant containing bleach or benzyl ammonium chloride.

Brushes
Do not use steel wool, scouring powder or wire brushes (except special stainless steel wire brushes for knurled areas or serrations) during manual cleaning.

Cleaning Metals
Do not mix dissimilar metals (stainless, chrome plated, brass, etc.) as this may cause contact corrosion.

CLEANING AND STERILIZATION

The recommended cleaning steps must be performed prior to the initiation of sterilization of the instruments.

Nu-Tip® Reusable Handle
Open and close handle to expose tip receptacle for cleaning and removal of all gross debris.

- 1 **Cleaning During Surgical Use**
Visible blood, tissue, and body fluids should be wiped off from the instrument with a sponge dampened with sterile water. Soiled instruments should be placed in a suitable container that will minimize the potential risk of bloodborne pathogen exposure to employees.

- 2 **Initial Rinse**
Immediately after surgery, utilize a syringe to flush 25cc of tap water through the cleaning port. Open and close jaws during the initial rinsing process to remove all blood, body fluids, tissue and saline.

- 3 **Manual Cleaning**
Remove all tissue and stains with stiff plastic (nylon) brush and lukewarm, fresh, neutral pH (7) detergent solution.

- 4 **Enzymatic Bath**
Immerse the instrument in an enzyme bath and utilize a syringe to flush 10cc of the enzyme solution into the cleaning port to ensure contact with the shaft lumen and push-rod. Allow the instrument to be soaked/immersed for two minutes.

- 5 **Rinse**
Rinse thoroughly and utilize a syringe to flush 25cc of tap water through the cleaning port to remove all residue of enzyme solution.

- 6 **Final Rinse**
To remove remaining tap water within the instrument flush 25cc of air (an empty syringe) through the cleaning port.

- 7 **Lubrication**
After every cleaning, lubricate all hinge points, parts having metal to metal contact, and if applicable, rotating shaft. Use only surgical lubricants such as instrument oil or instrument milk. DO NOT use industrial lubricants or silicone.