

## INSTRUMENT DESCRIPTION

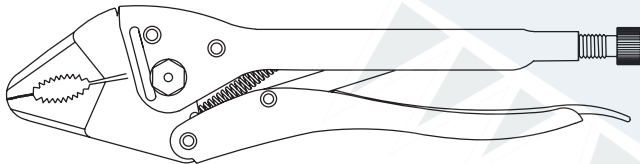
The following instructions are for metal reusable complex design instruments that are characterized by the following design features:

- a. Non-accessible surfaces (requires manipulation to gain access)
- b. Blind holes
- c. Non-accessible apertures
- d. Adjustable spring tension
- e. Cannot be disassembled to simpler components or sub-assemblies

- Lowman Bone Clamp



- 10" Heavy-duty locking pliers



For additional information or guidance on Cleaning and Sterilization instructions, contact your Empire Sales Representative or Empire Customer Service.

## INDICATIONS FOR USE

Empire instruments are designed to perform a specific function, such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating and suturing. Instruments are for use by, or as directed by, a trained medical professional. Instruments should be used only for the purpose for which they are designed. The proper technique for the use of the instrument is the responsibility of the medical professional.

## PREPARATION AT POINT OF USE

Directly after use, remove coarse contamination from the instrument and keep the instrument moist for transit to the processing site. Prior to cleaning and sterilization do not use any fixing agents or hot water >104°F (>40°C) since this may lead to the fixation of residue and can interfere with the cleaning process.

## TRANSPORTATION

During the transportation of the instrument to the processing site, store contaminated instrument securely in a closed container to avoid damage to the instrument and/or contamination of the environment.

## PREPARATION FOR REPROCESSING

Where applicable, instruments must be disassembled and/or opened for cleaning and sterilization. Open ring handled instruments so that ratchets are not engaged. Failure to properly clean and sterilize the instrument could lead to contaminated instruments being placed back into circulation.

## CLEANING, DISINFECTION AND DRYING INSTRUCTIONS

### Automatic Processing Instructions For Use with Alkaline or Enzymatic Detergents

#### PRE-CLEANING

- Soak the instrument in lukewarm tap water for a minimum time of 5 minutes.
- Brush the instrument under lukewarm tap water until all visible contamination is removed.
- Rinse the instrument, particularly lumen, luer-loks, hinges, gaps and cavities with a water jet pistol (pressure gun, static pressure greater than 4 bar) for 10 seconds.
- Soak the instrument in an ultrasonic bath for 10 minutes at (104°F) 40°C with 0.8% solution of enzymatic cleaner (See Note below).
- Rinse the instrument, particularly lumen, luer-loks, hinges, gaps and cavities with a water jet pistol (pressure gun, static pressure greater than 4 bar).

#### CLEANING

##### Automatic Cleaning (Enzymatic)

- Place the opened instruments in a wire basket on the slide-in tray and start the cleaning process.
- Pre-rinse for 1 minute with cold water.
- Empty.
- Pre-rinse for 3 minutes with cold water.
- Empty.
- Wash for 5 minutes at 113°F (45°C) with a 0.8% enzymatic detergent.
- Empty.
- Neutralize for 3 minutes with cold water.
- Empty.
- Rinse for 2 minutes with cold water.
- Empty.

##### Automatic Cleaning (Alkaline)

- Place the opened instruments in a wire basket on the slide-in tray and start the cleaning process.
- Pre-rinse for 1 minute with cold water.
- Empty.
- Pre-rinse for 3 minutes with cold water.
- Empty.
- Wash for 5 minutes at 131°F (55°C) with a 0.5% alkaline detergent.
- Empty.
- Neutralize for 3 minutes with cold water.
- Empty.
- Rinse for 2 minutes with cold water.
- Empty.

**Note:** The concentration, temperature and application time of the cleaning agent must be according to the instructions for use of the manufacturer. Examples of detergents used in validation studies: Enzymatic Detergent: Cidezyme/Enzol; Alkaline Detergent: Neodisher Mediclean.

### Manual Processing Instructions For Use with Enzymatic Detergents

- Automatic cleaning only.

#### CLEANING

- Manual cleaning not recommended. Automatic cleaning only.

CLEANING, DISINFECTION AND DRYING INSTRUCTIONS	
Automatic Processing Instructions For Use with Alkaline or Enzymatic Detergents	Manual Processing Instructions For Use with Enzymatic Detergents
<b>DRYING</b> Dry the outside of the instruments using the drying cycle of the cleaning equipment. If necessary, the instruments can be dried by hand with a lint-free cloth. Compressed, filtered air can be used for instruments with lumens.	<b>DRYING</b> Dry instruments with a lint-free cloth. Compressed, filtered air can be used for instruments with lumens.
<b>DISINFECTION</b> Empire does not provide disinfection instructions due to the sterility instructions provided.	<b>DISINFECTION</b> Empire does not provide disinfection instructions due to the sterility instructions provided.

### INSPECTION AND FUNCTIONAL CHECK

Inspect the instrument after each sterilization cycle and prior to each use as it may be damaged during transit to the customer, during receiving at the customer site, during use in a previous procedure or during the cleaning or sterilization process. All moving parts, tips, box locks, ratchets, serrations and cutting edges, if applicable, must be inspected for wear and confirmed to be functional. Confirm smooth operation during opening and closing of a hinged instrument and that tips/blades align properly. Screws may become loose during normal operation of an instrument. Inspect before sterilization and prior to use in order to ensure proper function. Inspect the instrument for rust, pitting, cracking or burrs, staining or discoloration, readability of device markings as applicable and worn or broken parts. Repair or replace any instrument found not to be acceptable.

### MAINTENANCE, HANDLING AND OPERATION OF SURGICAL INSTRUMENTS

The assembly and disassembly of the instrument must only be performed by personnel trained to the institution's training requirements. The instrument must be cleaned, lubricated and functionally checked prior to each use. Use a non-silicone, water-based lubricant prior to sterilization. Do not use mineral oil, petroleum or silicon-based lubrication products. Do not use an instrument with broken, cracked or worn parts. Only use the instrument for its intended use. Misuse and improper handling may result in damage, potentially resulting in user or patient injury. If repair is required, return clean and sterile instruments to Empire.

### PACKAGING

After cleaning and inspection, place the instrument in terminally sterilized packaging (as per ISO 11607) or a sterilization container which will protect the instrument from the environment as well as permit sterilization. After sterilization the instrument should remain in the packaging or sterilization container for protection from the environment and to maintain sterility.

### STERILIZATION

Instrument should be arranged in a disassembled/open position, where applicable. Engaged ratchets can result in damage to the instrument. To avoid electrochemical reactions, separate instruments fabricated from different materials.

The following steam sterilization cycles may be used for instruments:

Sterilization Method	Instrument Configuration	Temperature	Exposure Time (minimum)	Drying Time (minimum)
Pre-vacuum	Wrapped	270°F (132°C)	4 minutes	10 minutes
Pre-vacuum	Wrapped	273°F (134°C) to 279°F (137°C)	3 minutes	10 minutes
Pre-vacuum	Wrapped	275°F (135°C)	3 minutes	10 minutes
Gravity Displacement	Wrapped	270°F (132°C) to 275°F (135°C)	10 minutes	10 minutes

**Note:** Flash sterilization is not recommended for use with these instruments.

### STORAGE

Instrument must be stored in a dry, clean, chemical-free and dust-free environment. Instrument must remain wrapped or within the sterilization container to maintain sterility.

### ADDITIONAL INSTRUCTIONS

Use of cleaning and sterilization methods other than those provided by Empire Medical must be validated by the health care facility using appropriate validated laboratory methods.

### WARNING

Instruments which are used consciously on patients with a prion based disease (transmissible spongiform encephalopathy disease, CJD, BSE, etc.) or on patients suspected of having one of these diseases are not safe to be reused and must be disposed of as per approved hospital procedures.

Do not clean and/or sterilize instruments suspected of prion-contamination prior to disposal, as introducing these instruments to the reprocessing facility may lead to contamination of other instruments and/or the reprocessing facility equipment.

### PRODUCT INFORMATION DISCLOSURE

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