

CARE AND MAINTENANCE OF SURGICAL INSTRUMENTS

PRODUCT INFORMATION

Surgical instruments from Xinhua Surgical Instrument Co., Ltd. (XSI) are used for intended surgical purpose such as cutting, clamping, dissecting, exploring, retracting, irrigation, absorbing, suturing or ligature etc. Surgical instruments may be damaged if used for unintended purpose.

Proper cleaning, handling and sterilization will ensure surgical instrument perform as intended and extend their useful life.

HOW SUPPLIED

XSI surgical instruments are supplied **non-sterile**. Each instrument must be cleaned and sterilized prior to use according to the procedures outlined in this document.

INSPECTION

Before use, inspect surgical instruments for possible damage, wear or non-functioning parts. Carefully inspect joints and all movable parts. Damaged or defective instruments should not be used or processed. Contact your local sales representative or Xinhua Surgical

Instrument Co., Ltd. for repair or replacement.

PRECAUTIONS

1. Delicate surgical scissors require special handling to prevent damage to the tips. Use fiber-free sponge to remove all the blood and dirt during cleaning and sterilization.
2. Do not apply excessive stress and strain at jaws or joints. Misuse will result in misalignment or crack at jaws or joints.
3. Bone rongeurs and shears are only used for cutting bones instead of wire or pin. Do not twist or apply excessive stress during application.
4. Wear protective gloves, glasses and clothes during handling biologically contaminated instruments.
5. Surgical instruments with dissimilar materials should be handled separately to avoid electrolyte action.
6. Delicate instruments should be handled separately from general instruments to prevent damage to delicate parts.

CARE AND HANDLING

The procedures outlined below should be followed to ensure safe handling of

biologically contaminated instruments. All the instruments must be sterilized prior to use.

PRE-CLEANING

1. Keep instruments moist and do not allow blood and/or body fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.
2. Use a steady stream of lukewarm/cool water (below 43 °C), rinse each instrument thoroughly to remove gross debris.
3. Unlock and dismantle all the instruments with hinges, joints and other moving parts during cleaning to thoroughly clean its joints and moving parts etc.

CLEANING

1. PRECAUTIONS FOR CLEANING

- ✚ Unlock and dismantle surgical instruments before cleaning and sterilization.
- ✚ Do not immerse instruments in hot water, alcohol or disinfectant to avoid body fluids and blood concreting. Do not exceed two hours soaking in any solution.
- ✚ Micro, delicate and plated instruments should be manually

cleaned instead of ultrasonic cleaning and delicate tips and other parts should be protected carefully during cleaning and sterilization.

2. MANUAL CLEANING

- ✚ Hand wash the instruments using a low-sudsing, neutral PH(7), protein dissolving detergent. Follow manufacturer's directions regarding concentration, temperature and contact time.
- ✚ Totally immerse instruments during cleaning to prevent aerosolization.
- ✚ Do not use steel wool, wire brushes, pipe cleaner or abrasive detergents. Use stiff nylon brush to clean instruments.
- ✚ Use syringe or flush ports to thoroughly clean the inner-lumens of the instruments.

3. ULTROSONIC CLEANING

- ✚ Place instruments in open position into the ultrasonic cleaner,. Make sure that sharp blades such as scissors, knives, osteotomes etc do not touch other instruments.
- ✚ Rinse instruments after ultrasonic cleaning with distilled or deionized water to remove ultrasonic cleaning solution.

4. AUTO WASHER-STERILIZER

Follow manufacturers' recommendations.

5. RINSING

After cleaning, rinse instruments thoroughly under running water (distilled water is best).

DECONTAMINATION/DISINFECTION

Note: The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section.

Select a high-level disinfectant. Follow the cleaning agent's recommended directions regarding concentration, temperature, contact time and solution re-use. Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfectants.

RINSING

Thoroughly rinse the instruments with distilled water to remove all traces of the disinfecting solution. Rinse the inner lumen of the instruments via the flush port. USE STERILE WATER ON THE FINAL RINSE.

DRYING

1. Instruments must be thoroughly dried to remove residual moisture before they can be stored.
2. Use a soft, absorbent towel or cloth to dry external surfaces.
3. Use compressed air or a 70% alcohol rinse to aid the drying process.

LUBRICATION

Lubrication is essential every time instruments are processed.

1. Lubricate all movable parts with a non-silicone, anti-microbial, water soluble instrument lubricant such as instrument milk. The lubricating solution should not be rinsed or wiped off the instrument.
2. The instruments should be assembled and inspected just prior to sterilization. Check for nicks, misalignment, crack and other defects.
3. Mechanically test the working parts to verify proper function.

STERILIZATION

1. Surgical instrument can be wrapped for sterilization, which should ensure that after sterilization instruments keep sterile until it is taken out from the wrap for use.

2. Sterilization of surgical instruments may be accomplished by steam or EO. Only under urgent circumstances, quick sterilization method can be used.
3. Surgical instruments can also be sterilized in special sterile container with hospital acceptable conditions.

Below is recommended sterilization parameters:

Sterilization Method	Temperature	Minimum Exposure Time	
		Wrapped	In a sterile container
Pre-vacuum	134°C	4 min.	4 min.
Gravity	125°C	15-30 min.	40 min.
	134°C	10-25 min.	30 min.
EO	55°C	20% EO – 80% CO ₂ 750mg/L, 6 hours	
	37°C	At least 10 hours	

Steam or EO sterilization cycling period for wrapped products, refer to "Disinfection and Sterilization Laboratory technique standards".

STORAGE

1. Store the instruments in sterilization trays to prevent damage to the instrument.
2. Keep the stored instruments on carts on shelving in a storage area free of dust, insects, chemical vapors and extreme changes in temperature and humidity.