Van Sickle Surgical Instruments, Inc.
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INSTRUCTIONS for USE and REPROCESSING

INDICATIONS

All Reusable, Hand-held, Manually Operated, Minimally Invasive Surgical Instruments (devices) comprising fixed assemblies and simple assemblies, hinges and ratchets; including instruments containing stainless steel, titanium, and aluminum. Non-sterile device.

Federal U.S. laws restrict this device to sale, distribution, and use, by or on the order of a duly licensed physician.

CONTRAINDICATIONS

Instruments are not to be used for anything other than their intended use.

WARNING

If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination. We advise consulting infection control/prevention protocols for such devices.

GENERAL WARNINGS AND CAUTIONS

Variations between what is suggested here and your facility's policies and procedures, or those indicated by your sterilizer manufacturer, should be brought to the attention of the appropriate responsible person(s) at your facility for clear direction before proceeding with cleaning and sterilizing surgical instruments.

Instruments should be used only for the intended purpose for which they are designed, such as cutting, dissecting, clamping, grasping, probing, retracting, and suturing. They are to be used by, or as directed by, a qualified licensed surgeon. The proper surgical technique for the use of surgical instruments is the responsibility of the surgeon.

Reusable Surgical Instruments are supplied non-sterile and, therefore, must be thoroughly and properly sterilized even before its initial use.

Single Use Devices that are supplied non-sterile are to be sterilized and used only once.

Sterile packaged products are labeled accordingly upon delivery.

Inspect the identity, completeness, intactness, and function upon receipt of instruments before making them available for use.

Examine instruments for breakage, cracks, deformations, damage, and functionality before each use. Give particular attention to blades, tips, box locks, locks, ratchets, hinges, and all moving parts. Broken, worn, corroded, deformed, porous or otherwise damaged instruments must be sorted.

Check screws on instruments, especially after ultrasonic cleaning, because vibration from this process may cause screws to loosen or fall out.

RISK OF DAMAGE

To prevent irreparable damage to instruments, they must be used in accordance with their intended purpose.

Fading of color-anodized aluminum instruments may be accelerated if proper cleaning and sterilization recommendations are not followed. Aluminum may be used in certain instruments to make them lighter weight. Only neutral, non-alkaline cleaners and fully de-mineralized water may be used with aluminum instruments.

Careful handling and care are imperative for the proper function and life of a surgical instrument. The surgical instrument is a precision devise. Improper handling, such as dropping, banging, bending, improper stacking or storage, or using it for some purpose other than it's intended use, can cause product malfunction and/or breakage.

OPERATION

Surgical procedures should be performed only by qualified persons having adequate training to do so. The surgeon and all other persons involved in the use of the products are responsible in regard to their field of activity to have appropriate product knowledge based on the current technology standard. This ensures proper use of the product and prevents health or safety risks to patients, users or third parties. Responsibility for proper selection of patients, adequate training, selection and use of product rests with the surgeon.

Additional information for the products may include applicable product catalogs, medical literature, publications, seminars, specialized courses, and medical product advisors. Consult these valuable resources for broader knowledge of use of products, complication, and hazards.

CLEANING & STERILIZATION

PRE-CLEANING

It is imperative that all instruments are cleaned, disinfected, and sterilized before each use. This includes newly delivered instruments that have not yet been used, as they are delivered non-sterile. Remove tip protectors, temporary identification tags and bags, and protection transportation packaging materials from newly delivered instruments before cleaning.

General contamination must be removed from instruments as soon as is reasonably practical after use. Use only a disposable soft brush or soft, clean towel, intended for this purpose, to manually remove excess soil. Never use metal brushes or steel wool to remove excess soil from surgical instruments.

Some instruments require simple disassembly to allow for more complete cleaning and sterilization. Disassembly should not require any mechanical tools such as screwdrivers or pliers.

CLEANING - MANUAL (Required if Automatic Washer or Disinfector Method is not Utilized)

- All instruments must be cleaned in the fully opened, unlocked position (or disassembled, if appliable).
- Prepare the instrument soaking solution using a neutral pH enzymatic detergent (that is specific for use with surgical instruments) based on the enzymatic detergent manufacturer's instructions. Pay close attention to proper dilution, temperature, and soaking time. Likewise, follow the manufacturer's instructions regarding changing and discarding used solution.
- Flush air from lumens and fill them with enzymatic solution to allow for full contact with the inner surface during soaking time. Use of a syringe or disposable pipe cleaner may be helpful.
- NOTE: Use of acidic or alkaline solutions with surgical instruments will remove the protective chromium oxide barrier, which can lead to corrosion, pitting, staining and breakage.
- NOTE: High alkaline detergents are not recommended for aluminum instruments.
- NOTE: Change enzyme solution when it becomes grossly contaminated (bloody and/or turbid).
- Soak instruments. Be certain they are fully immersed in the prepared enzymatic soaking solution for a minimum of 1 minute. Check the detergent manufacturer's and surgical facility's recommendations for further instruction on this procedure.
- Movable parts of instruments should be actuated while soaking to ensure complete penetration of enzymatic solution into hard-to-reach areas.
- Scrub the device using a soft bristled brush. Do not use a metal brush or steel wool pad. Pay close attention to all movable parts (such as hinges, box locks, ratchets), crevices, lumens and other hard to reach areas (such as serrated jaws) to ensure all visible soil and contaminants have been removed.
- Flush lumens vigorously with detergent during the soak at least 7 times, using an appropriately sized syringe. Prepare a neutral pH enzymatic detergent in the sonicator (as per the manufacturer's directions) and sonicate the instruments for a minimum of 10 minutes.
- Rinse all instrument surfaces in running reverse osmosis deionized water for a minimum of 3 minutes to remove detergent and remaining debris. While rinsing, give special attention to movable parts, crevices, lumens and other hard to reach areas. Flush lumens at least 3 times.
- Dry the instrument with a clean, soft cloth.
- Examine each instrument for cleanliness. If visible soil is present, repeat the cleaning procedure.

CLEANING: AUTOMATIC

- Follow the Manual Cleaning Instructions above for Preparing the Soaking Solution, Soaking and Scrubbing of all instruments.
- After each instrument has been soaked and scrubbed, they are ready for automatic cleaning.
- Clean devices in a washer/disinfector using the equipment and detergent according to the instructions of the equipment and detergent manufacturers.
- Examine each instrument for cleanliness. If visible soil is present, repeat the cleaning procedure.
- Rinse instruments with distilled or deionized water for a minimum of 3 minutes to remove residual solution. Flush lumens appropriately and adequately.
- Make certain all instruments are dry prior to sterilization.

INSPECTION AND FUNCTION TESTING

Examine each instrument for cleanliness and functionality. Instruments in need of repair will not perform properly and should be sorted. Inspect the blades of scissors, jaws, teeth, ratchets, hinges, screws, etc. Instruments that are mis-aligned, damaged (e.g, cracked, chipped, broken, or worn), or have tarnished surfaces should be repaired or replaced immediately. The instrument specialists at Van Sickle can assist with both repairs and replacement of surgical instruments.

NOTE: DO NOT USE DAMAGED INSTRUMENTS.

DISCOLORATION

It is common for instruments to become stained or spotted despite the best efforts of manufacturers and staff at hospitals and private practices. Generally these problems result from minerals deposited upon the surfaces of instruments and/or insufficient cleaning.

- **Rust Spots:** It is highly unlikely for surgical grade stainless steel to rust. Although it appears to be rust, it is often residual organic matter or mineral deposits that have been baked on the surface of the instrument. High iron content in some localities can cause a metallic film on the instruments. This may be prevented by using deionized water in the final rinse.
- **Black Stains:** Contact with ammonia may be the cause of black stains on instruments. Instruments must be well rinsed, as many cleaning products contain ammonia.
- **Blue Stains**: Solutions must be prepared and changed according to the manufacturer's instructions. Corrosion can occur if solutions are used beyond the recommended time. Blue stains are usually the result of cold sterilization techniques. Using distilled water and a rust inhibitor are helpful in slowing discoloration.
- **Brown Stains**: Certain detergents may dissolve copper elements in the sterilizer, causing an electrolytic reaction. This reaction results in copper being deposited on the instruments. Try a different detergent or check the volume being used. A dull blue or brown stain generally is caused by a build-up of oxidation on the surface of the instrument. This does not indicate the instrument has been harmed. It actually protects the instrument from serious corrosion.
- **Light or Dark Spots**: Spotting can be caused by condensation remaining on instruments and then drying. Positioning instruments that have flat and/or concave surfaces on its edge surface will help condensation drain off more readily and dry faster. This may eliminate spotting. Use distilled water in the final rise so that minerals found in water are not able to contribute to these residual spots. Be sure to follow the sterilizer manufacturer's instructions for preparing instruments for sterilization.
    - Additionally, instrument wraps must be thoroughly rinsed of laundry detergents. They should receive a final rinse prepared with a pH between 6.8 and 7.0.

LUBRICATION

- A regular regimen of lubricating the moving parts of hand-held surgical instruments is an important process in maintaining the use, function, and life of the device. This important step aids in preventing metal-on-metal friction that can cause corrosion, and also protects the metal surface from mineral deposits. Proper lubrication preserves the integrity of the metal, as well.
- Use an instrument lubricant, generally called “milk”, that is compatible with the method of sterilization being used. Follow the lubricant manufacturer’s instruction for accurate dilution, use, and maintenance of the lubricant. The “milk” can be sprayed on the box locks and other moving parts of the instrument, or the instrument can be dipped in the solution, depending on the guidelines established by the facility or central sterilizing manager.
- NOTE: Using a heavy concentration of “milk”, or over-application the “milk”, will result in the instrument feeling slippery. This can cause the instrument to be mistakenly considered wet after sterilization.
- NOTE: Lubricants are removed by ultrasonic cleaners. Therefore, it is important to establish a routine of lubricating instruments after ultrasonic cleaning and before sterilizing.

PACKAGING

Instruments can be wrapped in sterilization wraps according to the instructions of the equipment manufacturer.

STERILIZATION PREPARATION

- Be certain instruments are thoroughly dry before sterilizing. “Wet packs” are not suitable for use after sterilization, as they may be more readily contaminated when handled. Any remaining moisture on instruments may cause corrosion on box locks, hinges, and other moving parts.
- Be certain that the instrument container is sealed in appropriate packaging for sterilization.
- Sterilize in compliance with the local guidelines for hospital or private practice hygiene.

STERILAZTION BY AUTOCLAVE

Van Sickle hand-held, reusable surgical instruments meet the AAMI standards for sterilization.

- Temperature and time configurations for sterilization will vary according to the type of sterilizer used, cycle design and packaging material.
- Testing should be conducted at each healthcare facility to ensure that the specific configuration of instrument sets is acceptable for the sterilization process.
- Do not sterilize instruments at temperatures above 285°F (141°C).
- All ring-handled instruments must be in the fully open position to prevent craking of the box lock (e.g., scissors, needle holders, hemostatic forceps).
- All instruments with ratchets and spring-locks should be in the open, unlocked position.
- All instruments must be cleaned in the fully opened position and/or disassembled (based on their specific design). Applicable instrument disassembly should not require tools, such as screwdrivers or pliers, for disassembly.
- All flush ports are to remain fully opened.
- All instruments are to be positioned to allow steam contact on all surfaces.
- All instruments with concave surfaces are to be positioned so that condensation can drain from the surfaces and not pool up.
- Consult the sterilizer manufacturer's written instructions to verify their specific parameters.
- "Flash" sterilization is not recommended as it may shorten the life of instruments.

Recommended Sterilization Parameters

Be sure to refer to the operation manual of the sterilization equipment being used for the manufacturer's instructions and recommendations regarding usage, temperatures, times, and precautions for the specific type of sterilization process being implemented.

Sterilizer	Exposure Temperature	Exposure Time	Minimum Dry Time
Pre-Vacuum (wrapped)	250°F (121°C) 270°F (132°C) 275°F (135°C)	20 minutes 4 minutes 3 minutes	20 minutes 20 minutes 15 minutes
Pre-Vacuum (unwrapped)	270°F (132°C)	4 minutes	
Gravity Displacement	270°F (132°C)	25 minutes	

STORAGE

- After instruments are sterilized, they should remain in their sterilization wraps and be stored in a clean, dry cabinet or case.
- Remember to protect jaws, tips, blades, etc. from damage during storage.