Your Partner in Dentistry

HiTeck Surgical Instruments

Instructions for Use and Reprocessing

INDICATIONS FOR USE

HiTeck Surgical instruments are designed to perform a specific function, such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or ligating. For use by, or as directed by, a surgeon. Instruments should be used only for the purpose for which they are designed. The proper surgical technique for the use of instruments is the responsibility of the surgeon.

WARNING: If device is/was used in 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 and eliminate the risk of cross-contamination.

CONTRAINDICATION

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

CAUTION

After cleaning, especially after ultrasonic cleaning, check screws on instruments because the vibration from the ultrasonic cleaning may cause them to loosen or fall out.

HiTeck surgical instruments are supplied **non-sterile** and **must** be cleaned, lubricated and sterilized prior to use according to hospital protocol and the procedures outlined in this document. Failure to follow these procedures will invalidate the instrument's warranty and can cause the instrument to fail.

Inappropriate use of instruments will lead to damage that us usually not repairable.

INSPECTION OF ALL INSTRUMENTS

Prior to use, all instruments should be inspected to ensure proper function and condition. All instruments are carefully inspected before shipment. Because damage may occur during transit, the instruments should be thoroughly inspected upon receipt. Do not use instruments if they do not perform satisfactorily. The instrument must be inspected to assure proper functioning prior to each use with particular attention paid to the condition of all moving parts, tips, box locks, ratchets and cutting edges. Each instrument with a screw must be inspected before and after use to ensure that screws do not move when operating the instrument. Failure to make a complete inspection to assure the proper operation and function of the instrument may result in unsatisfactory performance, perhaps because a part is missing. Do not use if the instrument does not appear to be functioning properly. Use of an instrument for a task other than that for which is intended could result in a damaged or broken instrument, or which provides an unsatisfactory performance.

LIMITATIONS ON REPROCESSING

Repeated reprocessing has minimal effect on instruments. End of life is normally determined by wear and damage due to use.

ATTENTION: Risk of Damage – Surgical instruments are precision devices. Careful handling is important for accurate functioning. Improper external handling (such as bending, banging, dropping, etc.) can cause product malfunction.

OPERATION

Surgical procedures should be performed only by persons having adequate training and familiarity with techniques. In addition, consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure. Before using the product, all instructions regarding its safety features and surgical techniques must be read carefully.

Only sterile instruments are to be inserted into a body. The instrument must be operated only by a trained personnel. Please observe general; operating room technique.

DECONTAMINATION AND STERILIZATION PROCEDURES

Initiate cleaning of device within 2 hours of use.

Excess soil should be removed as soon as possible after use with a disposable cloth, wipe, or gauze.

It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

All devices must be processed in the completely open position (i.e. flushports, jaws, etc.) to allow solution contact of all surfaces.

Use only neutral pH (6-8) detergent solutions.

PREPARATION FOR CLEANING AND STERILIZATION

Disassembly of simple assemblies is necessary to allow more complete cleaning and sterilization. Disassembly should not require any mechanical tooling (i.e., screwdriver, pliers, etc.). Follow cleaning instructions below before sterilization.

A. MANUAL DECONTAMINATION

Step 1. Maintain moisture: Immediately after the surgical procedure, place the instruments in an instrument tray/container and cover with a towel moistened with sterile distilled water. Foam, spray or gel products, specifically intended for use with surgical instruments in an impervious plastic bag or container with a tight lid to the documentation environment.

Step 2. Enzymatic Soak: Immerse fully opened and/or disassembled instruments in an enzymatic solution, specific for use with surgical instruments. Prepare the solution and use per enzyme manufacturer's recommendations, paying special attention to instructions for correct dilution, temperature and soak time. Flush air from lumens and fill them with enzymatic solution for full contact with this inner surface during the soak time.

Step 3. Rinse: Remove instruments from the solution after the time period recommended by the enzymatic manufacturer and rinse thoroughly with tap water. Flush lumens until water runs clear.

Step 4. Cleaning Instruments: Choose a cleaning solution appropriate for surgical instruments and follow the manufacturer's instructions for use. The use of neutral pH detergents is vital to the maintenance of surgical instruments. Contact with acidic or alkaline solution will remove the instruments' protective barrier of chromium oxide, often leading to corrosion, pitting, and breakage. You may find that depending on the type of soil, a detergent that is a little more or less acid or alkaline may be more appropriate.

Step 5. Rinse: Thoroughly rinse instruments by immersing in tap water and wiping with a clean, soft cloth. Flush lumens until water runs clear.

Step 6. Ultrasonic Cleaning and Rinsing: Follow the recommendations of the ultrasonic manufacturer regarding cycle times, detergents, proper placement of the instrument tray, and conditioning ("degassing") of the cleaning solution, etc. Use an ultrasonic cleaner to remove soil from hard to reach surfaces such as grooves, crevices, lumens, instruments with moving parts, etc., after gross soil has been removed. Open or disassemble instruments as appropriate. Place instruments in a mesh bottom stainless steel instrument tray. Place the tray into the ultrasonic cleaner. Flush air out of lumens and fill them with the ultrasonic cleaning solution (under the solution level in the chamber) for effective removal of soil from that inner surface by the ultrasonic activity.

Step 7. FINAL RINSE should be with "treated water". Softened or deionized water should be used for the final rinse to better remove detergents etc. Softening water removes calcium and magnesium ions that cause water to be hard. Iron ions may also be removed by this treatment. Deionization removes ionized salts and particles from the water. Excessively hard water can spot or stain instruments and excessive chlorine in water can cause pitting of the instrument. Deionized water is preferred for the final rinse.

Step 8. Decontaminate Clean Instruments: Once instruments have been cleaned they must be rendered safe for handling, inspection and assembly. They may be steam sterilized without a wrapper or disinfected following the instructions from the instrument, sterilizer and disinfectant manufacturers.

Step 9. Visual Inspection and Instrument Set Assembly: Visually inspect the instrument for cleanliness and to ensure all parts are in proper working order, as the set is assembled. Inspection is a vital part of proper care and maintenance. Instruments in need of repair will not perform accurately in surgery and breakage is likely to occur. **DO NOT USE** damaged instruments. Worn ratchets, loose box locks and misaligned jaws can be repaired at a fraction of the cost of new instruments.

Step 10. Lubricate: The use of an instrument lubricant, that is compatible with the method of sterilization to be used, is recommended before instruments are sterilized. Be certain that the instrument lubricant is diluted and maintained properly, according to the manufacturer's instructions. This type of lubricant is referred to as "instrument milk" and is usually applied by spraying into the box locks and moving parts or by dipping the opened instruments into a solution. Lubricants that are too concentrated or too heavily applied will result in slippery instruments that will also be mistaken as wet after sterilization. After thoroughly cleaning instruments, proper application of lubricants to joints will keep them moving freely and aid in protecting the surface from mineral deposits. Note that ultrasonic cleaners remove all lubrication; therefore this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization. Proper lubrication is an integral step in maintaining the long-life of the surgical instrument. Lubrication will prevent the friction of metal on metal and preserve the smooth function of the instrument thus avoiding corrosion by friction. Furthermore, routine use of lubricating agents, on thoroughly clean instruments, will prevent hinged and other movable parts from sticking. Lubrication will aid in protecting the entire instrument surface from mineral deposits.

Step 11. Drying: Before instruments are wrapped for sterilization or storage, they must be thoroughly dry. If a set of instruments is wet when wrapped for sterilization it is likely to come out of the sterilizer wet. "Wet Packs" are not suitable for use after sterilization because they may be easily contaminated when handled. In addition, remaining moisture, particularly in box locks and hinges may result in corrosion that will weaken the instrument and lead to breakage during use. Prepare instrument sets for sterilization using a wrapper, pouch or rigid sterilization container that is appropriate for the method of sterilization to be used. The Association for the Advancement of Medical Instrumentation (AAMI) and individual sterilizer manufacturers provide guidance for the proper preparation of surgical instrument trays for sterilization. Some sterilizer manufacturers can also provide information regarding wet pack problem solving. See also, Sterilization for the Healthcare Facility, 2nd Edition, Reichert, M.; Young, J., "Wet Pack Problem Solving", Lee, S. (Frederick, MD: Aspen, 1997).

B. MECHANICAL DECONTAMINATION

General surgical instrumentation may be processed in a washer sterilizer or washer decontaminator/disinfector. Some of these processes include an enzyme application phase and a lubrication phase that is designed into the cycle. Follow the manufacturer's specifications when using automatic washer-sterilizers or washer decontaminators/disinfectors. They usually require the use of a low foaming, free rinsing detergent with a neutral pH (7.0). A high-foaming detergent may clean effectively but will often leave residual deposits on the instruments and do harm to mechanical washers. Automated washer sterilizers and washer decontaminator/disinfectors usually have adjustable wash and rinse times. Some washers enable the user to customize extra cycles to process heavily soiled surgical instruments more effectively.

C. TERMINAL STERILIZATION

After following the decontamination recommendations, reusable instruments are ready for sterilization. AAMI standards recommend that the sterilizer manufacturer's written instructions for cycle parameters should also be followed. Steam sterilization of lumened instruments requires that they be flushed with sterile water just prior to wrapping and sterilization. The water generates steam within the lumen to move air out. Air is the greatest enemy to steam sterilization, preventing steam contact if not eliminated. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter. Below are the recommended sterilization parameters:

Sterilizer	Exposure Temperature	Exposure Time	Minimum Dry Time
Pre-Vacuum (Wrapped)	121° C (250°F) 132° C (270°F) 134° C (273°F)	20 Min 4 Min 3 Min	20 Min 20 Min 15 Min
Pre-Vacuum (Unwrapped)	132° C (270°F)	4 Min	
Gravity Steam (Wrapped)	132° C (270°F)	18 Min	

MAINTENANCE PROCEDURES

Improper, ineffective, and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instrument's warranty. We cannot make any statement about how long an instrument will last. Designed and crafted to exacting specifications, instruments will perform for a reasonable number of years when the following steps are observed:

Protect Instruments: The most effective method of dealing with instrument problems is to prevent them from occurring. The use of "treated water", careful preliminary cleaning, the use of neutralized pH solutions, adherence to manufacturer's instructions, and visual inspection, will help to keep instruments performing accurately and cosmetically free of troublesome stains. It is important to act quickly should a problem arise. Delay will compound the problem and irreparable harm may result.

• Certain compounds are highly corrosive to stainless steel and will cause serious damage despite the passivated protective surface. If instruments are inadvertently exposed to any of the following substances, they should be rinsed immediately with copious amounts of water.

Instruments should never be exposed to:

Aqua regia, Iodine, Ferric chloride, Sulfuric acid, Hydrochloric acid

The following substances should be avoided whenever possible: Aluminum chloride, Mercury chloride, Barium chloride, Potassium permanganate, Bichloride of mercury, Potassium thiocyanate, Calcium chloride, Saline Carbolic acid, Sodium hypochlorite, Chlorinated lime, Stannous chloride, Dakin's solution

• Any kind of corrosion will lead to rust on steel. Because rust particles can be transferred from one instrument to another, corroding instruments should be removed from service to prevent the formation of rust on other instruments.

• Instruments must be sterilized in the open position or disassembled as appropriate. Steam will only sterilize the surface it can directly touch.

• Every effort should be made to protect sharp cutting edges and fine working tips during all maintenance procedures. Avoid loading retractors and other heavy items on top of delicate and hollow instruments.

Diagnosing Spots and Stains: It is common for instruments to become stained or spotted despite the best efforts of the manufacturers and the hospital staff. In nearly all cases these problems are the result of minerals deposited upon the surfaces of the instruments, as well as insufficient cleaning. Adhering to proper technique during cleaning and sterilizing procedures will prevent most staining occurrences. However, they will sometimes arise very suddenly and will not disappear on their own. The following identifies some of the various instrument-related problems hospitals may encounter.

Brown Stains: Detergents containing polyphosphates may dissolve copper elements in the sterilizer. This results in copper being deposited on the instruments by an electrolytic reaction. The hospital may try a different detergent or check the quantities used. Usually a dull blue or brown stain is simply a build-up of oxidation on the surface. This film is harmless and will actually protect the instrument from serious corrosion.

Blue Stains: Blue stains are usually the result of cold sterilization techniques. It is important to prepare the solution according to exact proportions and to change the solution when recommended. Serious corrosion may occur if the solution is used beyond the manufacturer's specified time limit. The use of distilled water and a rust inhibitor in the solution will help retard discoloration.

Black Stains: Black stains may be the result of contact with ammonia. Many cleaning compounds contain ammonia and it will remain on the instruments unless they are well rinsed.

Light or Dark Spots: Spots are often the result of condensation pooling and then drying on flat and concave instrument surfaces. The mineral content of the water remains on the instrument. Using "treated water" as the FINAL rinse will help to remove the minerals found in water that can cause these residual spots. It is also important to follow the sterilizer manufacturer's instructions for preparing instrument sets for sterilization. Standing instruments that have flat and concave surfaces "on edge" will enable the condensate to drain off and more readily dry, usually without spotting. An additional cause of spotting can be traced to the instrument wraps. During laundering procedures, it is vital that detergents are thoroughly rinsed out, and that the final rinse is prepared so that the wraps have a pH between 6.8 and 7.0. In addition, healthcare professionals should check the cleanliness of the sterilizer chamber. Steam can lift soil and poorly rinsed chamber cleaning detergents from the chamber walls and deposit them onto instruments and wrappers.

Rust Deposits: It is very unlikely for surgical grade steel to rust. What appears to be rust is often residual organic matter in box locks or mineral deposits which have been baked onto the surface of the instrument. In localities where the water has a high iron content, for example, an iron deposit will result in a metallic film on the instrument. This may be prevented with the use of "treated water" for the FINAL rinse during cleaning procedures. The most effective method of dealing with instrument problems is to prevent them from occurring. The use of "treated water", careful preliminary cleaning, using neutralized pH solutions, following manufacturer's instructions, and visual inspection, will help to keep instruments performing accurately and cosmetically free of

troublesome stains. It is important to act quickly should a problem arise. Delay will compound the problem and irreparable harm may result. .

PRODUCT INFORMATION DISCLOSURE

HITECK EXCLUDE ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. HITECK SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. HITECK DOES NOT ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM TO ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS

RETURNED GOODS POLICY

Products must be returned in unopened packages with manufacturer's seal intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by HiTeck. Products will not be accepted for replacement if they have been possession of the customer for more than 30 days.

SYMBOLS USED ON LABELLING

 Manufacturer

 See Instructions for use

 Non-Sterile – Sterilize prior to use

 Consult Instructions for use

REF Catalogue Number (Product Code)

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