



INDICATIONS FOR USE

Padgett 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.

CONTRAINDICATION

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

WARNING

Consult individual national infection control/prevention protocols for specific guidance regarding processing medical devices with suspected exposure to Creutzfeldt-Jakob Disease (CJD).

CAUTION

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

Padgett surgical instruments are supplied non-sterile, unless otherwise noted, 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 is usually not repairable; for example, a hemostat that is used to clamp tubing can become misaligned and quickly break.

INSPECTION OF ALL INSTRUMENTS

All instruments are carefully inspected before shipment. Because damage may occur during transit, the instruments should be thoroughly inspected upon receipt. **All instruments must be inspected prior to use.**

Handling and Operating Instruments: Instruments should be handled and operated by personnel completely familiar with their use, assembly and disassembly. Before a new instrument is used and prior to each surgical procedure, the instrument must be decontaminated, lubricated and sterilized as described below. Handle the instrument with care. 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 the screws do not move when operating the instrument. Screws can loosen and back out of an instrument as a result of normal operation and/or the vibration during ultrasonic cleaning. 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 it is intended could result in a damaged or broken instrument, or one which provides an unsatisfactory performance. In order to insure warranties and guarantees, instruments in need of repair should be sent to Integra.

DECONTAMINATION AND STERILIZATION PROCEDURES

As with any decontamination procedure, personnel should follow accepted guidelines for hand washing, the use of protective attire, etc. as recommended by A.A.M.I. Standards and Recommended Practice, "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-Clinical Settings", ANSI/AAMI ST35:2003.

Decontamination is a two step process:

- 1) Thorough cleaning and rinsing.
- 2) Sterilization or disinfection.

A. MANUAL DECONTAMINATION

PRECLEANING: Remove gross debris from surgical instruments with a lap sponge and sterile water routinely during the procedure to prevent drying on of blood and body fluids, etc. It is important to rinse instruments that have been exposed to blood and saline solution before these substances dry. Blood and body fluids as well as saline solutions are highly corrosive. In addition, blood can produce a stain that is difficult to remove.

CLEANING: To prevent the formation of biofilm, cleaning should occur as soon as possible after instrumentation is used. Biofilm is an accumulation of a biomass of bacteria and extracellular material that tightly adheres itself to the surface of the instruments. It cannot be easily removed, and protects microorganisms from being easily removed by ordinary cleaning/decontamination methods used in hospitals. It is particularly problematic in lumened medical devices.

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, are available to keep the soil moist. Transport tray of soiled instruments in an impervious plastic bag or container with a tight lid to the decontamination environment (keep the outside of the containment clean).

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 from enzymatic soak after the time period recommended by the enzymatic manufacturer and rinse thoroughly with tap water. Flush lumens until rinse 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. The ideal cleaning agent is nonabrasive, low-foaming and free-rinsing. Using a small clean hand-held brush, remove soil from all surfaces of the instrument while fully immersed in the solution. During manual cleaning, never use steel wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers to remove soil from surgical instruments. These will damage the instruments' protective surface and lead to corrosion. Use a clean soft bristled brush to clean instruments with an accessible channel. Remove the soil from the ratchets, jaws, tips, box locks, and/or hinge mechanism. The box lock and hinge portion of an instrument must be thoroughly cleaned after each use. A build-up of soil, debris, lubricants, etc. in these areas, will make it difficult to use the instrument and eventually irreparably damage it. Vigorously flush channels with the cleaning solution. Deionized water is recommended and preferred because it is free of the many compounds which exist in ordinary tap water. These substances, alone, cause stains and when tap water is combined with some detergents it will form insoluble deposits on the instruments. Manual cleaning should remove all visible residue. It is essential to keep the box locks and hinges open during any manual or automated cleaning process.

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. Contact your local representative for information regarding a cost-effective instrument repair program.

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. Check with a Technical Service representative at 1-800-

431-1123 for questions regarding processing delicate, complex and/or multipart instruments by this method.

C. TERMINAL STERILIZATION

After following the decontamination recommendations, reusable instruments are ready for sterilization. Independent laboratory testing, conducted according to the F.D.A. (21 CFR PART 58) and Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for reusable instruments. See also, AAMI Standards and Recommended Practices, "Steam Sterilization and Sterility Assurance in Health Care Facilities", ANSI/AAMI ST46:2002; "Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use, ANSI/AAMI ST37:3ed. 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)	20 min	20 min
	132° C (270° F)	4 min	20 min
	134° C (273° F)	3 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.

RETURNED GOODS POLICY

Products must be returned in unopened packages with manufacturer’s seals 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 Miltex. Products will not be accepted for replacement if they have been in the possession of the customer for more than 120 days.

REPAIRS AND MAINTENANCE

Should your instruments require repair or maintenance, contact Miltex for return authorization and address. Instruments returned to Miltex for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

PRODUCT INFORMATION DISCLOSURE

MILTEX, INTEGRA AND MANUFACTURER EXCLUDE ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER MILTEX, INTEGRA NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER MILTEX, INTEGRA NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

SYMBOLS USED ON LABELING



Manufacturer



Authorized Representative in the European Community



Catalog number



Lot Number



See instructions for use



Consult instructions for use



Product complies with requirements of directive 93/42/EEC for medical devices



Miltex, Inc.

589 Davies Drive
York, PA 17402

toll free phone: 866-854-8300

phone: 717-840-9335

fax: 717-840-9347



Miltex GmbH

Mühlstr. 6
78604 Rietheim-Weilheim,
Germany

Phone: 49 7461 /9634-14

Fax: 49 7461 /9634-30

Padgett is a registered trademark of Integra LifeSciences Corporation.
The Integra wave logo is a trademark of Integra LifeSciences Corporation.
©2006 Integra LifeSciences Corporation. All Rights Reserved.