MedGyn Products, Inc.

Care and handling of surgical instruments. Directions for use

INDICATIONS FOR USE

Surgical instruments come in various shapes and sizes and styles. They are designed to perform specific intended uses such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or ligating. Surgical instruments may also be used to facilitate the insertion of surgical implants.

CONTRAINDICATION

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

Warning

MedGyn devices are for general surgical procedures and are recommended for reuse with adequate cleaning, disinfection and sterilization procedures. If an instrument is used in a patient with, or suspected of having a transferrable, the device cannot be reused and must be destroyed after exposure as the instruments have not been validated to withstand the chemical and thermal exposure recommended to eradicate prions.

Data on such transferrable diseases can be obtained from National Infection Control Agencies.

Precautions

- MedGyn instruments are supplied non-sterile, unless otherwise noted and must be cleaned, lubricated, and sterilized prior to use according to validated protocol and procedures.
- Inappropriate use of instruments may result in patient injury.
- Proper cleaning, handling, sterilization and standard routine maintenance (such as sharpening, if applicable) will deliver best performance of the instruments.
- Tipped instruments should be protected.
- Do not use dry heat sterilization or use phenols or iodophors.
- Do not apply excessive stress or strain at joints, hinges and box joints.
- Wear appropriate protective gloves, eye protection, and clothing when handling biologically contaminated instruments.
- Instruments manufactured from different metals or with coating should be processed separately to avoid electrolytic action between the different metals.
- Before use, inspect the instruments for possible damage, wear or non- functioning parts. Carefully inspect the critical, inaccessible areas, joints, and all movable parts.
- Damaged or defective instruments should not be used or processed.

Decontamination and Sterilization Procedures

CODES AND STANDARDS:

Follow accepted guidelines as recommended in ANSI/AAMI ST-79- Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities and ISO 17664 - Risk Management.

For Ethylene Oxide sterilization, follow the ANSI-AAMI ST 41 Ethylene Oxide sterilization in health care facilities: safety and effectiveness, 4th edition.

Sterilization of medical devices information to be provided by the manufacturer for the processing of resterilizable medical devices. Instruction of reprocessing reusable surgical instruments is provided according to ISO 17664.

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

DECONTAMINATION Care and Handling

1. PRECLEANING

- Keep instruments moist and do not allow blood and/ or fluids to dry on the instruments.
- Remove gross contaminants with steady stream of lukewarm/ cool water (below 110F/ 43C). Rinse each instrument thoroughly. Do not use saline chlorinated solutions.
- Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations. Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.
- Separate sharps and delicate surgical instruments. Avoid processing instruments of different metallic compositions together.

2. RINSE:

Rinse instruments thoroughly under warm distilled or demineralized water.

3. CLEANING

CLEANING PRECAUTIONS

- If appropriate, disassemble surgical instruments prior to cleaning sterilization.
- Do not soak instruments in hot water, alcohol, disinfectants, or antiseptics to avoid coagulation of mucus, blood or other bodily fluids. Do not exceed two hours soaking in any solution.
- Do not use steel wool, wire brushes, pipe cleaners, or abrasive detergents to remove soil as these will damage the instrument and lead to corrosion.
- Microsurgical, plated, and delicate instruments should be cleaned manually and should not be processes in an ultrasonic cleaner. Carefully protect the tips of delicate microsurgical instruments throughout the entire cleaning and sterilization process.
- Color anodized aluminum instruments may lose their color through the use of conventional, mechanical treatment process.

Manual Cleaning: To prevent the formation of biofilm, cleaning should occur as soon as possible after instrumentation is used.

- Choose a cleaning solution appropriate for surgical instruments and follow manufacturer's instructions for use.
- The use of neutral pH detergents is recommended to avoid corrosion, pitting, and breakage.
- Using a small, clean hand- held brush, remove soil from all surfaces of instrument while fully immersed in solution.

Ultrasonic and Mechanical Cleaning:

- For ultrasonic cleaning. Follow manufacturer's specifications for water level, concentration levels of cleaning agents and temperature.
- Use an ultrasonic cleaner to remove soil from hard to reach surfaces such as grooves, crevices, and moving parts after gross soil has been removed.
- Open or disassemble instruments as appropriate.
- When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other.
- Always follow manufacturer's specifications for automatic washer- sterilizers and use a free- rinsing, low- sudsing detergent with a neutral pH (6.0- 8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal cleaning.

4.RINSE AND DRY

- Rinse all instruments thoroughly with distilled, pyrogen- free water to remove all traces of debris and cleansing agents. Make sure all internal lumens and ratchets are thoroughly rinsed.

- Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/ cloth to dry external surfaces. Compressed air may be used to aid in the drying process.

5.LUBRICATE

The use of a water soluble instrument lubricant that is compatible with the method of sterilization to be used is recommended before instruments are sterilized.

- After thoroughly cleaning instruments, proper application of lubricants to all joints and movable mating surfaces will keep them moving freely and aid in protecting surfaces from mineral deposits.
- Proper lubrication is required for all instruments, regardless of surface coatings.
- Note that ultrasonic cleaners remove all lubrication; therefore, this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization.
- If following the lubricating procedure, do not rinse after this step.

STERILIZATION

- After following decontamination recommendations, reusable instruments are ready for sterilization.
- See ANSI/AAMI ST79
- AAMI standards recommend that sterilizer manufacture's written instructions for cycle parameters should also be followed. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than minimum indicated by sterilizer manufacturer but must never be shorter. It is the responsibility of the user to establish whether sterilizer meets these minimum recommendations.
- Instruments may be packaged in ridged containers, or packing cleared for use in sterilization. Packaging should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination.
- Recommended steam sterilization parameter to achieve Sterile Assurance Level (SAL) of 10-6

Independent laboratories testing conducted according to ISO 17664, has validated the following sterilization parameters.			
Sterilization Method	Temperature	Exposure Time	Dry Time
High Vacuum Steam (Pre- Vacuum)			
Wrapped	270°F (132°C)	3 minutes minimum	N/A

Independent laboratory testing, referencing FDA (21CFR Part 58) Good Laboratory Practice Regulations has validated the following parameters.			
High Vacuum Steam (Pre- Vacuum)			
Unwrapped in containers Perforated stacked/ unstacked Solid unstacked	270°F (132°C)	4 minutes minimum	20 minutes
Gravity Steam			
Unwrapped in containers Perforated unstacked	250°F (121°C)	45 minutes	20 minutes
Gravity Steam			
Wrapped in cassettes	250°F (121°C)	30 minutes	20 minutes
Ethylene Oxide (EtO)			
Unwrapped in containers Perforated unstacked Solid unstacked	131°F (55°C)	60 minutes (minimum) Concentration: 725 mg/l Humidity:70% Aeration time: 8 hours	

WARRANTY

All hand-held stainless steel instruments are warranted by MedGyn Products to be free from defects in material and workmanship for a period of 1 year from invoice date providing MedGyn's "Instrument Warranty and Care" is followed. During this period, MedGyn or its authorized distributor will, at their option and without charge, either repair or replace any part(s) found to be defective in material or workmanship.

MedGyn Products is not responsible for any injury resulting from repairs made by other individuals or organizations not certified by MedGyn.

This warranty does not apply to the following:
1. Instruments subjected to misuse, abuse, negligence, or accident.
2. Sharpening of instruments e.g. Biopsy Punches, Scissors etc needing re-sharpening from normal wear and tear.
3. Improper use of cleaning methods or chemicals which have caused damage to

Thank you for your purchase of MedGyn stainless steel instruments. In an effort to reduce the cost and expense associated with maintaining surgical instruments and to help prolong the useful life span of the instruments, we have developed this standard program for instrument care.

Cleanliness, lubrication, correct handling and storage procedures will help insure proper instrument performance. In order to lengthen the serviceable life of your surgical instruments, you should also troubleshoot the entire instrument cleaning process by regularly inspecting your instruments for signs of corrosion, stain and wear.

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MEDGYN PRODUCTS, INC.
100 W. Industrial Rd.Addison,IL 60101 USA
t: **630.627.4105**
f: **630.627.0127**
toll-free: **800.451.9667**
e: info@medgyn.com
www.medgyn.com