GUIDELINES FOR REPROCESSING GRAY SURGICAL REUSABLE MEDICAL DEVICES

WARNINGS

• Instruments must not be soaked in Sodium Hypochlorite. Irreversible corrosion and pitting will render the instruments unsafe for further use.
• Wherever possible avoid the use of mineral acids and harsh, abrasive agents.
• If manual cleaning is used, scourers or wire brushes must not be used on any part of the instruments.
• The use of filtered, softened or demineralised water is recommended. Water with high mineral content may interfere with the efficacy of cleaning agents and may lead to discolouration, pitting and corrosion, permanently damaging and shortening the life of the instruments.
• No part of the sterilization process shall exceed a temperature of 140°C.
• Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.

Note: when reprocessing medical devices, always handle with care, wearing protective clothing, gloves, and eyewear in accordance with local Health & Safety procedures.

LIMITATIONS ON REPROCESSING

• Repeated processing has minimal effect on these instruments.
• End of life is normally determined by wear and damage in use.
• Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.

INSTRUCTIONS

POINT OF USE

• Wherever possible, do not allow blood, debris or bodily fluids to dry on instruments.
• For best results, and to prolong the life of the medical device, reprocess immediately after use.
• If the instrument cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help protect soil from drying.

PREPARATION FOR DECONTAMINATION

• Reprocess all instruments as soon as it is reasonably practical following use.
• Clamps and cams are opened prior to cleaning.
• Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available from the manufacturer.

CLEANING

Gray Surgical reusable medical devices are suitable for manual, automatic and ultrasonic cleaning.

CLEANING: MANUAL

Manual cleaning is not advised if an automatic washer-disinfector is available.
If manual cleaning is required, use the following process:-
1. Use a double sink system (wash / rinse) dedicated for instruments cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C.
2. In the first sink, keeping the instrument submerged, with an autoclavable brush, apply CE marked cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body and avoiding splashing.
3. In the second sink, rinse instruments thoroughly with soft, high purity water which is controlled for bacterial endotoxins, so that the water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet.

Note: manual cleaning is NOT a disinfection process: when manual cleaning is used it may not be possible to disinfect the device prior to further handling.

INSPECTION

After cleaning, visually inspect all surfaces, ratchets, joints, holes, threads and cams for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

DISINFECTION

• Disinfectant solutions may be used in accordance with label instructions.
• If automated cleaning is employed, a final rinse at 80-90°C (176-194°F) for a minimum holding time of 1 minute and a 20 minute drying cycle may be used to effect thermal disinfection.

DRYING

Mechanical drying of the instruments is recommended to prevent linting and to reduce contamination prior to inspection and assembly.

MAINTENANCE

• For optimal function all screw threads should be lubricated with a suitable heat stable, miscible lubricant after cleaning and before sterilization.
• With the Gray Liver System, the threaded knobs on the Upper Hoop require regular maintenance. They must be lubricated with a heat stable, miscible lubricating compound before sterilizing.

INSPECTION AND TESTING

• Visually inspect and check all instruments for damage and wear. Ensure jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms fasten securely and close easily; any component parts fit and assemble correctly with mating components.
• Remove for repair or replacement damaged instruments.

Note: if an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilized and be accompanied by the relevant documented evidence.

PACKING

• All instruments to be packed following local protocol.
• Check instruments for efficacy of the cleaning process and ensure that no damage has occurred.
• The products should be arranged with clamps open and cams loosened.
• The products should be packed with the heavier items at the bottom to prevent damage to the lighter structured instruments.
• Cellulose or non-cellulose based wraps are recommended for wrapping.
• Instruments may be packaged into Gray Surgical Sterilizing Trays.
• Packaging of equipment must ensure that the sterilizing agent can come in contact with all surface areas.
STERILIZATION

- Either CE marked or validated vacuum autoclave operating at 134-137°C 2.25 bar for a minimum holding time of 3 minutes – always following the instructions of the machine manufacturer.
- When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer manufacturer’s stated maximum load is not exceeded.
- Metal mass in each sterilizing load should be monitored. Heavy metal loads may inhibit effective steam sterilization, resulting in condensation and thereby inhibiting the drying process.
- Downward displacement (Flash) sterilization without a drying cycle is not recommended.
- Ensure instruments are dry before sterilization.

STORAGE

- All instruments to be packed following local protocols.
- The sterilized instruments should be stored and handled in a manner that maintains the integrity of the packs and prevents contamination from any source.

ADDITIONAL INFORMATION

The National Coordinating Committee on Therapeutic Goods Australia (NCCTG) Expert Working Group on Reusable Medical Devices (Expert Working Group) has produced the document "REDUCING PUBLIC HEALTH RISKS ASSOCIATED WITH REUSABLE MEDICAL DEVICES" to assist health care facilities and health care professionals reduce the potential public health risks associated with reusable medical devices.

The document discusses issues (other than those covered by the relevant Standards) that affect the ability to clean and sterilize reusable medical devices. The document can be downloaded from:-

The Instrument Preparation Working Group (Germany) booklet ‘PROPER MAINTENANCE OF INSTRUMENTS’ provides detailed instructions for the correct handling of surgical instruments. It provides detailed information on instrument care, processing, disinfection, sterilization and the selection of materials for cleaning and treatment.

The document can be downloaded from:-
http://www.a-k-i.org/pdf/red_eng.pdf

These reprocessing guidelines do not cover equipment that may be contaminated with ‘unconventional infective agents’. These are causative agents of the ‘prion’ associated diseases Creutzfeldt-Jakob disease (CJD) and other transmissible Spongiform Encephalopathy’s (TSEs). It is therefore recommended that the policies and procedures specific to the health care facility be followed.

Further information relating to these diseases may be accessed from the United States Centers for Disease Control and Prevention website at:
http://www.cdc.gov/ncidod/dvrd/cjd/qtqa_cjd_infection_control.htm#sterilization

NOTE:
IT IS THE RESPONSIBILITY OF THE PROCESSOR TO ENSURE THAT THE REPROCESSING AS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY ACHIEVE THE DESIRED RESULTS. THIS REQUIREMENTS VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE, ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.

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