## 1. PROCESSING INSTRUCTIONS

These processing instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of both, hospital owned and loaned Shukla Medical instrument sets.

### A. WARNINGS AND PRECAUTIONS

Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.

Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.

Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.

Do not place heavy instruments on top of delicate devices.

Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used instruments. Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth.

Automated cleaning may not be effective. A thorough manual cleaning process is recommended

Instruments should be removed from trays and cleaned separately

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended

## B. Point of use Preparation, Containment and Transportation

Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning

Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning

Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk

## C. Preparation of Cleaning Agents

Neutral pH enzymatic and low foaming cleaning agents are preferred and recommended by Shukla Medical

All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid)

## D. Manual Cleaning Process

Use the neutral pH enzyme soaking solution that has been prepared

Completely submerge the instrument(s) in enzyme solution and allow it to soak for 20 minutes. Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush)

NOTE: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid)

Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas

Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream

Dry the instrument with a clean, disposable, absorbent, non-shedding wipe

## E. Automated Cleaning Process

Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Orthopedic instruments should be cleaned following the manual cleaning procedure outlined in this document

An automated washer/disinfector may be used as follow-up to the manual cleaning procedure above but is not necessary

## F. Inspection, Maintenance and Lubrication

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process

Visually inspect for device integrity, damage and/or excessive wear
NOTE: If damage or wear is noted that may compromise the function of the instrument, contact Shukla Medical for a replacement

Check the action of moving parts (e.g. hinges, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion

Hinged, rotating, sliding or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations
NOTE: Mineral oil or silicone lubricants should not be used because they 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

## G. Sterilization Instructions

Steam sterilize using a pre-vacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F). When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load is not exceeded. Drying times will vary according to load size and should be increased for larger loads

"Flash" sterilization by exposure at 270° F (132° C), unwrapped, in a gravity displacement sterilizer should only be used as an emergency procedure

Steam sterilization is the preferred method for metal instrument sets. Instrument sets should be properly prepared and packaged in a case or tray that will allow steam to penetrate and make direct contact with all surfaces

The following charts summarize exposure times and temperatures that are customarily recommended by manufacturers of steam sterilizers for metal instruments sterilized alone or in combination with porous materials. Time and temperature relationships indicate holding time after the specific temperatures have been reached and do not include heating or drying times

| Cycle Type | Minimum Temperature | [4] Pressure | [5] Minimum Exposure Time | | [8] Minimum Dry Time |
|---|---|---|---|---|---|
| | | | [6] Wrapped | [7] Unwrapped | |
| [1,2] Prevacuum/ Pulsating Vacuum | 132°C 270°F | 1.86bar 27psi | 4 min | 4 min | 30 mins |
| [2,3] Prevacuum/ Pulsating Vacuum | 134°C 273°F | 3bar 28.5psi | 18 min | 18 min | |

1 Minimum validated steam sterilization temperature required to achieve a $10^{-6}$ sterility assurance level (SAL).
2 Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table
3 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing Instruments where there is concern regarding TSE/CJD contamination
4 Sea Level
5 AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable
6 Rigid sterilization container that complies with ANSI/AAMI ST46
7 Flash (unwrapped) sterilization by exposure at 132°C /270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled
8 Drying times vary according to load size and should be increased for larger loads

### H. Storage Instructions

Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes

Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised

## 2. Hospital Responsibilities for Shukla Medical Loaner/Rental Sets

Loaner/rental sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Shukla Medical. All rental sets are sent out with a Decontamination Certificate that is to be filled out and returned with the set along with any supplementary evidence of decontamination.

Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to Shukla Medical to ensure that the missing/damaged instrument(s) are backfilled.

## 3. Customer Service Information

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