INSTRUCTIONS FOR USE

CLEANING & STERILIZATION

Manual Surgical Orthopedic Instruments

Revolutionizing the Art of Revision Surgery

1. **INTRODUCTION:** The 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 Pay Per Surgery(PPS) Shukla Medical instrument sets.

   a. Title of this document is Instruction For Use (IFU): "Manual Surgical Instruments. Recommendations for Care, Cleaning, Maintenance and Sterilization."

   b. The ID number for this document is L3-IFU-INS-REVISED: JUNE-06-22. The Rev number indicates the date when this version was approved for release.

   c. This document is controlled by a Document Management System (DMS). If any contents in here need to be updated, the changes shall be processed through an internal DMS process. Upon approval, Rev # in 1-b will be updated.

   d. The most current version of this document is available on the Shukla Medical website.

2. **WARNINGS AND PRECAUTIONS:** Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices.

   a. Caution should be exercised when handling devices with sharp points or cutting edges.

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

   c. Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments.

   d. Soft-bristled, nylon brushes and pipe cleaners should be used.

   e. Do not place heavy instruments on top of delicate devices.

   f. 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.

   g. Remove excess body fluids and tissues with a disposable, non-shedding wipe and cover with a damp cloth.

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

   i. Instruments should be removed from trays and cleaned separately.

   j. 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.

3. POINT OF USE PREPARATION, CONTAINMENT AND TRANSPORTATION

a. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.

b. 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 disassembled (when applicable) and cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

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

4. PREPARATION OF CLEANING AGENTS

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

b. All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer.

c. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agent. Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

5. MANUAL CLEANING PROCESS

a. Use the neutral pH enzyme soaking solution that has been prepared.

b. Completely submerge the instrument(s) in enzyme solution and allow it to soak for 20 minutes.

c. 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.

d. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).

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

f. Remove the device(s) and instrument(s) 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.

g. Unless otherwise specified in surgical technic guide, disassemble all modular components for cleaning. Reassemble for sterilization.

h. 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.

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

j. Inspect instruments for any sign of residual soils. Repeat cleaning steps until no residue is observed.

6. AUTOMATED CLEANING PROCESS

a. For automated cleaning process using an Alkaline Solution, unless otherwise specified in surgical technic guide, disassemble all modular components for cleaning. Reassemble for sterilization. Execute the cycle using a pH alkaline detergent according to the following process:

Motor Speed: High			
Step	**Description**	**Minimum Temperature**	**Minimum Cycle Time**
1	Pre-wash	Cold tap water (Facility)	2 minutes
2	Enzyme wash	Hot tap water (Facility)	4 minutes
3	Wash (Detergent % according to manufacturer specification)	65.5 C (149.9 F)	2 minutes
4	Rinse	Hot tap water	15 seconds
5	Thermal rinse with lubricant (% according to manufacturer specification)	82.2 C (180.0 F) Purified Water (Heated)	1 minute
6	Hot Air Dry	HIGH	6 minutes

7. INSPECTION, MAINTENANCE AND LUBRICATION

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

b. Visually inspect per Reusable Instrument Inspection Manual (FCD-17089) 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.

c. 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.

d. 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.

8. STERILIZATION INSTRUCTIONS

a. Steam sterilize using a pre-vacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F) for US based facilities.

b. Steam sterilize using a pre-vacuum cycle for 3 minutes at a minimum temperature of 134°C (273.2°F) for EU/UK based facilities, as appropriate.

c. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load is not exceeded.

d. Drying times will vary according to load size and should be increased for larger loads.

e. "Flash" sterilization is not recommended for SHUKLA Medical instruments and systems.

f. Following Table 1 summarizes the minimum exposure times and temperatures that have been validated for SHUKLA Medical systems. If a system is not listed, parameters for S9KNEE should be followed.

g. For US use, there are two options for wrapping the system for sterilization. If double blue wrapping, refer to table 1A. If placed in a rigid sterile container, refer to table 1B.

h. For EU/UK use, there are two options for wrapping the system for sterilization. If double blue wrapping, refer to table 2A. If placed in a rigid sterile container, refer to table 2B.

1) STERILIZATION INSTRUCTIONS FOR ALL SHUKLA SYSTEMS (US)						
SHUKLA Part Numbers:	**Prevacuum Pulses**	**Min. Temp.**	**Min. Exposure Time Wrapped**	**Min. Dry Time**	**Min. Open Door Dry Time**	**Min. Cool Down Time**
1A) Wrapped in 2 Layers of Single-Ply Polypropylene Wrap Using Sequential Envelope Folding Techniques						
MKS1031, S9SPINE, S9COPTER	4	132°C/ 270°F	4 min.	30 min.	-	-
MKS1022, S9BLADE, S9MAXI, S9MINI	4	132°C/ 270°F	4 min.	45 min.	-	-
S9KNE/S9KNEE, 120-00/S9HIP-MOD, S9NAIL/S9WINQ, S9NAIL-BR, S9LAG, S9SHLDR, S9SHLDR-BLADE	4	132°C/ 270°F	4 min.	45 min.	-	30 min.
104-00/S9HIP, MKS1017, S9SCRW/ S9SCREW	4	132°C/ 270°F	4 min.	60 min.	-	30 min.
1B) Placed in Aesculap Sterile Container Systems (JK444 or JK446) w/ Lid (JK486) + Single-Use Filters US751 or Equivalent						
All Systems	4	132°C/ 270°F	4 min.	30 mins.	-	-

2) STERILIZATION INSTRUCTIONS FOR ALL SHUKLA SYSTEMS (EU/UK)						
SHUKLA Part Numbers:	**Pre-vacuum pulses**	**Temp. min.**	**Min. Exposure Time Wrapped**	**Min. Dry Time**	**Min. Open Door Dry Time**	**Min. Cool Down Time**
1A) Wrapped in 2 Layers of Single-Ply Polypropylene Wrap Using Sequential Envelope Folding Techniques						
All Systems	4	134°C/ 273°F	3 min.	90 mins.	30	90
1B) Placed in Aesculap Sterile Container Systems (JK444 or JK446) w/ Lid (JK486) + Single-Use Filters US751 or Equivalent						
All Systems	4	134°C/ 273°F	3 min.	30 mins.	-	-

i. For the above table, please note items (ii to v) below:
ii. The temperature listed is the minimum validated steam sterilization temperature required to achieve a 10^-6 sterility assurance level (SAL).
iii. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.
iv. AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable.
v. Drying times vary according to load size and should be increased for larger load.

9. STORAGE INSTRUCTIONS

a. 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.

10. FOR LOANER/RENTAL SETS

a. Loaner/rental sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and sterilization before being returned to Shukla Medical.

b. 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.

Contact us to learn more

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ISO 13485:2016 CE FDA REGISTERED

L3-IFU-INS-REVISED: JUNE-06-22