11.0. Recommended Care, Cleaning and Sterilization Instructions / Instructions for Use for Reusable Surgical instruments & Accessories

Introduction: These instructions are in accordance with ISO 17664 and AAMI ST81. They apply to:

Reusable surgical instruments and accessories supplied by G14 Surgical Supply and intended for reprocessing in a health care facility setting. All G14 Surgical Supply surgical instruments and accessories may be safely and effectively reprocessed using the manual or combination manual/automated cleaning instructions and sterilization parameters provided in this document **UNLESS otherwise noted in instructions accompanying a specific surgical instrument.**

In countries where reprocessing requirements are more stringent than those provided in this document it is the responsibility of the user/processor to comply with those prevailing laws and ordinances.

These reprocessing instructions have been validated as being capable of preparing reusable G14 Surgical Supply surgical instruments and accessories for surgical use. It is the responsibility of the user/hospital/health care provider to ensure that reprocessing is performed using the appropriate equipment, materials and that personnel have been adequately trained in order to achieve the desired result; this normally requires that equipment and processes are validated and routinely monitored. Any deviation by the user/hospital/health care provider from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

11.1. WARNINGS	G14 Surgical Supply reusable surgical instruments are provided **NON-STERILE** and must be cleaned and sterilized according to these instructions prior to use. If present, safety caps and other protective packaging material must be removed from the surgical instruments prior to the first cleaning and sterilization. Ethylene oxide (EO), gas plasma and dry heat sterilization methods are **not recommended** for sterilization of G14 Surgical Supply reusable surgical instruments. Steam (moist heat) is the recommended method. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated surgical instruments. Caution should be exercised while handling, cleaning, or wiping surgical instruments with sharp cutting edges, tips, and teeth. Saline and cleaning/disinfection agents containing aldehyde, chloride, active chlorine, bromine, bromide, iodine or iodide are corrosive and **should not** be used. **Do not allow biologic soil to dry on contaminated devices.** All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on used surgical instruments. Automated cleaning using a washer/disinfector alone **may not** be effective for surgical instruments with lumens, blind holes, cannulas, mated surfaces and other complex features. A thorough manual cleaning for such medical devices is recommended before any automated cleaning process. Metal brushes and scouring pads must not be used during manual cleaning. These materials will damage the surface and finish of the surgical instruments. Use only soft bristle nylon brushes with different shapes, lengths and sizes to aid with manual cleaning. When processing surgical instruments do not place heavy devices on top of delicate surgical instruments. **Use of hard water should be avoided.** Softened tap water may be used for most rinsing however purified water should be used for final rinsing to prevent mineral deposits. Do not process surgical instruments with polymer components at temperatures equal to or greater than 140°C/285°F because severe surface damage to the polymer will occur. Oils or silicone lubricants **should not** be used on surgical instruments. Only qualified person should use the healthcare devices.
11.2. Limitations on Reprocessing	Repeated processing according to these instructions has minimal effect upon metal G14 Surgical Supply reusable surgical instruments and accessories unless otherwise noted. End of life for stainless steel or other metal surgical instruments is generally determined by wear and damage incurred during the intended surgical use. Surgical instruments made by G14 Surgical Supply comprised of polymers or incorporating polymer components can be sterilized using steam however they are not as durable as their metal counterparts. If polymer surfaces show signs of excessive surface damage (e.g. crazing, cracks or delamination), distortion or are visibly warped they should be replaced. Contact you G14 Surgical Supply representative for your replacement needs. Non-foaming,

	neutral pH enzymatic and cleaning agents are recommended for processing G14 Surgical Supply reusable surgical instruments and accessories. Alkaline agents with a pH of 12 or less may be used to clean stainless steel and polymer surgical instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeld-Jakob Disease (CJD) are a concern. **It is critical that alkaline cleaning agents are completely and thoroughly neutralized**
REPROCESSING INSTRUCTIONS	
11.3. Point of Use	Remove excess biologic soil from the surgical instruments with a disposable wipe. Place devices in a container of distilled water or cover with damp towels. **Note: Soaking in an enzymatic solution prepared according to the manufacturer will facilitate cleaning especially in surgical instruments with complex features such as lumens, mating surfaces, blind holes and cannulas.** If surgical instruments cannot be soaked or maintained damp then they should be cleaned as soon as possible (within 60 minutes is recommended) after use to minimize the potential for drying prior to cleaning.
11.4. Containment and Transportation	Used surgical instruments must be transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk
10.5. Preparation for Cleaning	Surgical instruments designed to come apart must be disassembled prior to cleaning. Disassembly, where necessary, is generally self-evident however for more complicated surgical instruments instructions are provided and should be followed. **Note: All recommended disassembly will be possible by hand. Never use tools to disassemble surgical instruments beyond what is recommended.** All cleaning solutions should be prepared at the dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning solutions. **Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (turbid).**
11.6. Manual Cleaning Steps	**Equipment**: Latex Gloves, proteolytic enzyme, non-metallic brush, running water, purified water, container for solution, container for rinsing. **Step 1**: Prepare a proteolytic enzyme solution according to the manufacturer's instructions. **Step 2**: Completely submerge surgical instruments in the enzyme solution and gently shake them to remove trapped bubbles. Actuate surgical instruments with hinges or moving parts to ensure contact of the solution with all surfaces. Lumens, blind holes and cannulas should be flushed with a syringe to remove bubbles and ensure contact of the solution with all surgical instrument surfaces. **Step 3**: Soak surgical instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to crevices, hinged joints, box locks, surgical instrument teeth, rough surfaces and areas with moving components or springs. Lumens, blind holes and cannulas should be cleaned using a snug fitting round nylon bristle brush. Insert the snug fitting round brush into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times. **Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.** **Step 4**: Remove the surgical instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas. **Step 5**: Dry surgical instruments with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.

Liposuction Cannulas

11.7.1. Combination Manual/ Automated Cleaning Steps

Equipment: Latex Gloves, proteolytic enzyme, non-metallic brush, running water, purified water, container for solution, container for rinsing, ultrasonic cleaning unit fitted with heater

Step 1: Prepare a proteolytic enzyme solution according to the manufacturer's instructions.

Step 2: Completely submerge surgical instruments in the enzyme solution and gently shake them to remove trapped bubbles. Actuate surgical instruments with hinges or moving parts to ensure contact of the solution with all surfaces. Lumens, blind holes and cannulas should be flushed with a syringe to remove bubbles and ensure contact of the solution with all surgical instrument surfaces.

Step 3: Soak surgical instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to crevices, hinged joints, box locks, surgical instrument teeth, rough surfaces and areas with moving components or springs. Lumens, blind holes and cannulas should be cleaned using a snug fitting round nylon bristle brush. Insert the snug fitting round brush into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times.

Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.

Step 4: Remove the surgical instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas.

Step 5: Place surgical instruments in a suitable validated washer/disinfector. Follow the washer/disinfector manufacturer's instructions for loading the surgical instruments for maximum cleaning exposure; e.g. open all surgical instruments, place concave surgical instruments on their side or upside down, use baskets and trays designed for washers, place heavier surgical instruments on the bottom of trays and baskets. If the washer/disinfector is equipped with special racks (e.g. for cannulated surgical instruments) use them according to the manufacturer's instructions.

According to the manufacturer's instructions. The following minimum wash cycle parameters are recommended:

Cycle	Description
1	Pre-wash --▪-- Cold Softened Tap Water --▪-- 2 minutes
2	Enzyme Spray & Soak --▪-- Hot Softened Tap Water --▪-- 1 minute
3	Rinse --▪-- Cold Softened Tap Water
4	Detergent Wash --▪-- Hot Tap Water (64-66°C/146-150°F) --▪-- 2 min.
5	Rinse --▪-- Hot Purified Water (64-66°C/146-150°F) --▪-- 1 minute
6	Hot Air Dry (116°C/240°F) --▪-- 7 to 30 minutes

Notes:

- The washer/disinfector manufacturer's instructions should be followed.

- A washer/disinfector with demonstrated efficacy (e.g. FDA approval, validated to ISO 15883) should be used.

- Dry time is shown as a range because it is dependent upon the load size placed into the washer/disinfector.

- Many manufacturers pre-program their washer/disinfectors with standard cycles and they may include a thermal low-level disinfection cycle after the detergent wash. The thermal disinfection cycle should be performed to achieve a minimum value A_0 = 600 (e.g. 90°C/194°F for 1 minute according to ISO 15883-1) and is compatible with G14 Surgical Supply surgical instruments.

- If a lubrication cycle is available that applies a water-soluble lubricant such as Preserve®, Surgical instrument Milk or equivalent it is acceptable to use on G14 Surgical Supply Surgical instruments unless otherwise indicated.

11.7.2. Disinfection

G14 Surgical Supply Surgical instruments must be terminally sterilized prior to use. See sterilization instructions below.

Low level disinfection may be used as part of a washer/disinfector cycle but the devices must also be sterilized before use.

11.7.3. Drying

Dry surgical instruments with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.

11.7.4. Inspection and Testing	After cleaning, all devices should be thoroughly inspected for residue biologic soil or detergent. If contamination is still present repeat the cleaning process. Visually inspect each device for completeness, damage and excessive wear. If damage or wear is observed that might compromise the function of the device, do not process them further and contact your G14 Surgical Supply representative/distributor for a replacement. When inspecting devices look for the following: o Cutting edges should be free of nicks and have a continuous edge. o Jaws and teeth should align properly. o Movable parts should operate smoothly throughout the intended range of motion. o Locking mechanisms should fasten securely and close easily. o Long thin surgical instruments should be free of bending or distortion. o Where surgical instruments form part of a larger assembly, check that all components are available and assemble readily.
11.7.5. Maintenance and Lubrication	After cleaning and before sterilization, surgical instruments with moving parts (e.g. hinges, box-locks, sliding or rotating parts) should be lubricated with a water-soluble lubricant such as Preserve®, Surgical instrument Milk or equivalent material intended for surgical instrument application. Always follow the lubricant manufacturer's instructions for dilution, shelf life and application method.
11.8. Packaging for Sterilization	Single devices may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization pouch or wrap. Care should be used when packaging so that the pouch or wrap is not torn. Devices should be wrapped using the double wrap or equivalent method (ref: AAMI ST79, AORN Guidelines). Reusable wraps are not recommended. Surgical instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) general-use perforated tray or case along with other devices under the following conditions: o Arrange all devices to allow access of steam to all surfaces. Open hinged devices and ensure devices are disassembled if it is recommended. O The case or tray must be wrapped in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization wrap by following the double wrap method or equivalent (ref: AAMI ST79, AORN Guidelines). O Follow the case/tray manufacturer's recommendations for loading and weight. Total weight of a wrapped case or tray should not exceed 11.4kg/25lbs. Surgical instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) rigid container systems (i.e. those with filters or valves) along with other devices under the following conditions: o The container manufacturer's recommendations should be followed regarding preparation, maintenance and use of the container. O Arrange all devices to allow access of steam to all surfaces. Open hinged devices and ensure devices are disassembled if it is recommended. O Follow the container manufacturer's recommendations for loading and weight. Total weight of a filled container system should not exceed 11.4kg/25lbs. We recommend bio-burden testing according to ISO 11737-1 before sterilization
11.9. Sterilization	**Equipment:** Complete autoclave unit (moist heat/ steam sterilization). Moist heat/steam sterilization is the recommended method for G14 Surgical Supply surgical Instruments. Use of an approved chemical integrator (class 5) or chemical emulator (class 6) within each sterilization load is recommended. Always consult and follow the sterilizer manufacturer instructions for load configuration and equipment operation. Sterilizing equipment should have demonstrated efficacy (e.g. FDA clearance, EN 13060 or EN 285 compliance). Additionally the manufacturer's recommendations for installation, validation, and maintenance should be followed. Validated exposure times and temperatures to achieve a 10^{-6} sterility assurance level (SAL) are listed in the following table.

	Cycle Type	Minimum Temperature	Minimum Exposure Time	Pressure
For Europe recommended parameters	Pre-vacuum/ Vacuum Pulse	134°C/273°F	3 minutes	28 p.s.i.
For USA recommended parameters	Pre-vacuum/ Vacuum Pulse	132°C/270°F	4 minutes	28 p.s.i.

Drying&Cooling

The recommended drying time for single wrapped surgical instruments is 20 minutes unless otherwise noted in device specific instructions.

Drying times for surgical instruments processed in containers and wrapped trays can vary depending upon the type of packaging, type of surgical instruments, type of sterilizer and total load. A minimum dry time of 30 minutes is recommended but to avoid wet packs, extended dry times greater than 30 minutes may be needed for larger loads under certain conditions or if otherwise recommended in accompanying documentation. For large loads verification of dry times by the health care provider is recommended.

A 30 minute minimum cooling time is recommended after drying but longer times may be necessary because of load configuration, ambient temperature and humidity, device design and packaging used.

Note: Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing surgical instruments where there is a concern about TSE/CJD contamination are: 134°C/273°F for 18 minutes. G14 Surgical Supply surgical instruments are compatible with these parameters.

11.10. Storage	Sterile packaged surgical instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes. **Note: Inspect every package before use to ensure that the sterile barrier (e.g. wrap, pouch or filter) is not torn, perforated, shows signs of moisture or appears to be tampered with. If any of those conditions are present then the contents are considered non-sterile and should be re-processed through cleaning, packaging and sterilization.**
11.11. Operating Instruction	- Wear Gloves while using the instruments - Be careful of the sharp point of the instruments, if any - Be careful of the moving parts of the instruments. - The instruments must be stored in dry place and must be handled with care to prevent damage - Only qualified person should use the healthcare devices. Use only for its intended purpose to ensure maximum effectiveness,
11.12. Manufacturer:	G14 Surgical Supply Muzaffar Pur, Hammer Wala Gla, Roras Road,, Sialkot-Pakistan Tel : +92 345 6724741 E-mail: sales.g14surgical@gmail.com
11.13. Authorized Representative EC REP	CMC Medical Devices & Drugs C/ Horacio Lengo N18, 29006, Málaga, Spain Phone: **+34 951 214 054** Email: **info@cmcmedicalservices.com**
11.14. CE Mark CE	The medical device (Class Ir) to which this document is accompanied are CE Marked