Applicable Instruments
These instructions apply to reusable surgical instruments including, but not limited to probes and hooks, scalpel handles, scissors, forceps, hemostats, towel forceps, needle holders, suturing instruments, surgical retractors, cannulas, suction tubes, elevators, curettes, rongeurs, surgical punches, biopsy punches, clamps, dilators, speculums, chisels, osteotomes, dissectors, and uterine sounds.

1. Device Description
These instruments are reusable surgical instruments manufactured from medical-grade stainless steel and are supplied non-sterile.

2. Intended Use
Surgical instruments are designed to perform specific functions 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.

3. Contraindications
Instruments should not be used for anything other than their intended use.

4. Warnings
Creutzfeldt-Jakob Disease (CJD)
If a device has been used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), the device must not be reused and should be permanently removed from service and destroyed. These instruments have not been validated to withstand the chemical or thermal processing methods required for prion decontamination.

Prions are highly resistant to conventional sterilization and disinfection methods.

Consult applicable national infection prevention and control guidelines for specific recommendations regarding the handling and disposal of medical devices potentially exposed to CJD.

5. Precautions
5.1 Non-Sterile Supply

Reusable instruments are supplied non-sterile and must be cleaned and sterilized according to these instructions prior to first use and after each subsequent use.

5.2 Use by Qualified Personnel

Instruments should only be used for their intended surgical purpose by trained healthcare professionals familiar with the use of surgical instruments.

5.3 Packaging Removal

If present, safety caps and other protective packaging materials must be removed prior to the first cleaning and sterilization.

5.4 Recommended Sterilization Method

Ethylene oxide (EO), gas plasma, and dry heat sterilization methods are not recommended for reusable surgical instruments. Steam sterilization (moist heat) is the recommended method.

5.5 Personal Protective Equipment

Appropriate Personal Protective Equipment (PPE) should be worn when handling contaminated or potentially contaminated instruments.

5.6 Handling of Sharp Instruments

Use caution when handling, cleaning, or wiping instruments with sharp cutting edges, tips, or teeth to prevent injury.

5.7 Prevent Drying of Biological Soil

Do not allow biological soil to dry on contaminated instruments. Cleaning and sterilization are facilitated when blood, body fluids, and tissue debris are prevented from drying on used instruments.

5.8 Manual Cleaning of Complex Features

Automated cleaning using a washer-disinfector alone may not be effective for instruments with lumens, blind holes, cannulas, mated surfaces, or other complex features. Thorough manual cleaning of these areas is recommended prior to automated cleaning.

5.9 Cleaning Brushes

Metal brushes and scouring pads must not be used during manual cleaning as they may damage the instrument surface. Use only soft-bristle nylon brushes of appropriate shape and size.

5.10 Handling During Processing

Do not place heavy instruments on top of delicate instruments during cleaning, sterilization, or storage.

5.11 Water Quality

Hard water should be avoided. Softened tap water may be used for most rinsing; however, purified water should be used for the final rinse to prevent mineral deposits.

5.12 Corrosive Chemicals

Saline and cleaning or disinfecting agents containing aldehydes, chlorides, active chlorine, bromine, bromide, iodine, or iodide are corrosive and should not be used.

5.13 Polymer Components

Do not process instruments containing polymer components at temperatures equal to or greater than 140°C (285°F) as damage to the polymer may occur.

5.14 Dissimilar Metals

Instruments manufactured from different metals or with special coatings should be processed separately to avoid electrolytic reactions between dissimilar materials.

5.15 Improper Use

Improper or inappropriate use of instruments may result in patient injury or damage to the instrument.

5.16 Excessive Force

Do not apply excessive stress or strain to instrument joints. Misuse may result in misalignment, cracking, or damage to box locks or jaws.

5.17 Pre-Use Inspection

Prior to use, inspect instruments for damage, wear, or malfunctioning parts. Carefully inspect critical areas including joints and movable components.

5.18 Silver Instrument Tarnishing

Silver or silver-plated instruments may darken (tarnish) over time. This discoloration is a normal oxidation process caused by exposure to air, moisture, skin oils, sulfur-containing gases, or rubber products such as latex. Silver tarnish (Ag_2S) is non-toxic and biocompatible, and a tarnished instrument remains safe for use.

6. Pre-cleaning

6.1 Removal of Gross Soil

Remove gross debris from the instrument using a disposable low-lint or non-linting wipe moistened with water. Flush lumens with water to remove visible debris.

Note: Use of saline-moistened wipes can shorten the service life of surgical instruments.

6.2 Containment and Transport

Contain and transport used instruments in a labeled, closed, puncture-resistant container according to facility procedures.

6.3 Timely Processing

Transport instruments to the reprocessing area as soon as possible after use.

6.4 Instrument Separation

Separate heavy instruments from delicate instruments during handling and transport.

6.5 Prevent Instrument Damage

Do not place heavy instruments on top of delicate instruments.

6.6 Maintain Moisture

Do not allow blood or biological debris to dry on instruments prior to cleaning. Keep instruments moist between the point of use and decontamination to prevent drying of blood, body fluids, and tissue debris.

7. Cleaning

7.1 Cleaning Precautions

If appropriate, disassemble surgical instruments prior to cleaning and sterilization.

Do not soak instruments in hot water, alcohol, disinfectants, or antiseptics, as these may cause coagulation of mucus, blood, or other body fluids. Do not exceed two (2) hours soaking in any solution.

Do not use steel wool, wire brushes, pipe cleaners, or abrasive detergents to remove soil, as these materials may damage the instrument surface and lead to corrosion.

Microsurgical, plated, and delicate instruments should be cleaned manually and should not be processed in an ultrasonic cleaner. Carefully protect the tips of delicate microsurgical instruments throughout the entire cleaning and sterilization process.

To preserve the surface coating of ebonized instruments, keep them separate from other instruments and avoid mechanical cleaning or abrasive cleaners that may scratch or remove the coating.

Color anodized aluminum instruments may lose their color when exposed to conventional mechanical cleaning processes.

7.2 Initial Cleaning Procedure

Cleaning should occur as soon as possible after pre-cleaning.

After performing the steps below, proceed to either **Manual Cleaning (7.3)** or **Automated Cleaning (7.5)**.

7.2.1 Rinse
Rinse the instrument with deionized water for two (2) minutes.

7.2.2 Brushing
Use a clean, soft-bristled brush to remove visible soil from lumens and external surfaces.

7.2.3 Lumen Flushing
Flush lumens with 50 mL of deionized water using a syringe or similar device.

7.2.4 Enzymatic Solution Preparation
Prepare an enzymatic cleaning solution according to the detergent manufacturer's recommendations.

7.2.5 Enzymatic Soak
Immerse fully opened instruments in the prepared solution for ten (10) minutes.

7.2.6 Final Rinse
Rinse the instrument and flush lumens with deionized water for two (2) minutes.

Proceed to **Manual Cleaning (7.3)** or **Automated Cleaning (7.5)**.

7.3 Manual Cleaning

1. Prepare an enzymatic cleaning solution according to the detergent manufacturer's instructions.
2. Fully immerse the instruments in the prepared solution.
3. Using a clean, soft-bristled brush, remove visible soil from all external surfaces.
4. Clean lumens and internal channels using an appropriately sized soft-bristled brush while the instrument remains immersed.
5. Flush lumens using 50 mL of deionized water with a syringe or similar device.
6. Rinse instruments thoroughly with deionized water for a minimum of two (2) minutes.
7. Prepare fresh enzymatic cleaning solution in the ultrasonic cleaner according to the solution manufacturer's instructions.
8. Degas the ultrasonic cleaner for five (5) minutes prior to use.
9. Place instruments in the ultrasonic cleaner tray ensuring that:

- instruments are in the open position
- lumens are fully exposed
- dissimilar metals are separated

10. Sonicate instruments for ten (10) minutes.
11. Remove instruments from the ultrasonic cleaner and rinse thoroughly with deionized water for two (2) minutes.
12. Visually inspect instruments for cleanliness.

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7.4 Drying

1. Force filtered air through lumens and channels until no visible water remains.
2. Place instruments on a lint-free cloth and allow them to dry for at least twenty (20) minutes.
3. Confirm instruments are completely dry prior to packaging or sterilization.

7.5 Automated Cleaning

1. **Pre-Flush Lumens**
   Flush lumens and internal channels with 50 mL of deionized water using a syringe or similar device.
2. Place instruments in a wire basket or instrument tray suitable for a washer-disinfector.
3. Ensure instruments are positioned in the open position and arranged so water can drain freely.
4. Connect lumened instruments to the injector carriage or appropriate irrigation attachment.
5. Separate instruments made from different metals to avoid electrolytic reactions or metal transfer during processing.
6. Place the baskets into the washer-disinfector.
7. Select a validated washer-disinfector cycle and use an appropriate detergent.

7.6 Recommended Washer-Disinfector Cycle Parameters

Wash Phase
Maximum washing temperature: 55°C (131°F)
Wash time: minimum ten (10) minutes

Neutralization Phase
Perform neutralization if required by the detergent manufacturer.

Intermediate Rinse
Rinse for at least two (2) minutes.

Final Rinse
Use deionized or demineralized water.

Thermal Disinfection
Thermal rinse for ten (10) minutes at 93°C (199.4°F).

Drying Phase
Dry instruments for at least twenty (20) minutes at ≤110°C (230°F).

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7.7 Post-Cleaning Inspection

1. Remove instruments from the washer-disinfector.
2. Inspect instruments to confirm:

- no visible soil remains
- components function properly
- no damage is present

3. Confirm instruments are completely dry prior to packaging or sterilization.

8. Inspection and Maintenance

1. **Inspection Environment**
   Inspect instruments in a clean, well-lit area. A lighted magnifier is recommended for detailed inspection.

2. **Inspection of Moving Components**
   Inspect joints, box locks, ratchets, and jaws while the instrument is in the open position, viewing both sides of the instrument.

3. **Cleanliness Verification**
   Verify that the instrument is clean and completely dry. If visible soil or moisture remains, repeat the cleaning and drying procedures.

4. **Inspection for Damage**
   Inspect the instrument for signs of damage or wear, including but not limited to:

- corrosion
- broken insulation or coating
- loosening or loss of tension
- bent, deformed, cracked, worn, or fractured components

5. **Lubrication**
   Apply a water-soluble lubricant intended for surgical instruments to moving parts (e.g., box locks, hinges, and joints) as needed. Use only lubricants designed for surgical instruments.

6. **Functional Check**
   Verify proper instrument function by opening and closing moving components to ensure smooth operation.

7. **Removal from Service**
   Remove damaged or inoperative instruments from service and follow the facility's procedures for repair or replacement. Instruments that cannot be adequately cleaned, repaired, or restored to proper function must be permanently removed from service.

9. Packaging for Sterilization

1. **Protection of Sharp Edges**
   Protect sharp edges and delicate tips to ensure the safety of healthcare workers and to prevent damage to sterilization packaging materials.

2. **Instrument Arrangement**
   Arrange instruments in a manner that allows adequate exposure to the sterilant. Instruments with hinges or ratchets should be placed in the open position.

3. **Packaging Materials**
   Use FDA-cleared sterilization packaging, such as sterilization pouches, wraps, or rigid sterilization containers, according to the packaging manufacturer's instructions.

4. **Instrument Trays**
   When using sterilization trays, ensure instruments are arranged to avoid stacking or overcrowding, which may interfere with sterilant penetration and drying.

5. **Preparation for Sterilization**
   Ensure instruments are clean, dry, and properly assembled prior to packaging and sterilization.

10. Sterilization

10.1 Recommended Sterilization Method

Moist heat (steam sterilization) is the recommended method for sterilizing reusable surgical instruments.

Always consult and follow the sterilizer manufacturer's instructions for proper load configuration and equipment operation. Sterilization equipment should have demonstrated efficacy (e.g., FDA clearance or compliance with applicable sterilization standards such as EN 13060 or EN 285).

The sterilizer manufacturer's instructions for installation, validation, operation, and maintenance should be followed.

10.2 Steam Sterilization Parameters

The following steam sterilization parameters are recommended for wrapped surgical instruments.

Extended cycles may be used for heavier instrument trays or larger loads.

Method	Temperature	Exposure Time	Minimum Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	≥30 minutes
Gravity Displacement	132°C (270°F)	15 minutes	≥30 minutes
Pre-Vacuum (Dynamic Air Removal)	132°C (270°F)	4 minutes	≥20 minutes
Pre-Vacuum (Extended)	132°C (270°F)	10 minutes	≥20 minutes

Healthcare facilities are responsible for validating sterilization processes according to their facility procedures and sterilization equipment.

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10.3 Drying

The recommended drying time for single wrapped instruments is 20 minutes, unless otherwise specified in device-specific instructions.

Drying times for instruments processed in rigid containers or wrapped trays may vary depending on:

- packaging type
- instrument configuration
- sterilizer type
- total load mass

A minimum drying time of 30 minutes is recommended for larger instrument trays. Extended drying times may be required to prevent wet packs.

Healthcare facilities should verify appropriate drying times for larger loads during sterilization validation.

10.4 Cooling

A minimum cooling period of 30 minutes after completion of the sterilization cycle is recommended prior to handling or use.

Longer cooling times may be required depending on:

- load configuration
- ambient temperature and humidity
- instrument mass
- packaging type

11. Storage

1. Store instruments that are properly cleaned, dried, packaged, and sterilized in a clean, dry, and dust-free environment.
2. Sterilized instruments should be stored in a manner that protects the packaging from damage and maintains sterility until use.
3. Avoid conditions that may compromise packaging integrity, such as excessive humidity, moisture, temperature extremes, or physical damage.

12. Instrument Life / Disposal

1. The service life of surgical instruments depends on proper use, handling, maintenance, and reprocessing.
2. Instruments showing signs of damage, excessive wear, corrosion, or malfunction must be removed from service.
3. Instruments that cannot be repaired or restored to proper function should be disposed of in accordance with applicable facility procedures and local regulations.

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