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Surgical Instruments Instructions for Use

Care, Cleaning, and Sterilization

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1. Purpose

These instructions are recommended for the care, cleaning, maintenance, and sterilization of reusable Canary Medical surgical instruments.

This document is intended to assist hospitals, facilities, central supply management, and health care personnel in safe handling practices, effective reprocessing, and maintenance of Canary Medical reusable devices.

Hospital personnel, including those in receiving and central sterile supply departments (CSSD), as well as in the operating room (OR) may be directly involved in handling Canary Medical surgical instruments. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.

2. Scope

This instruction manual provides information on the care, cleaning, maintenance, and sterilization of Canary Medical surgical instruments and is applicable to all reusable medical devices manufactured and/or distributed for Canary Medical.

All reusable instruments supplied to the end user in a non-sterile state must be cleaned and sterilized before the first use and before each subsequent use.

Table 1 on the following page lists the devices which are covered by this instruction manual.

Device Description	Part Number	Image
Impaction Sleeve	43-5399-001-14	
Tibia Resection Cutting Guide, Left, 5 Degree	43-5399-051-05	
Tibia Resection Cutting Guide, Right, 5 Degree	43-5399-052-05	
Cemented Tibia Drill Bit 15.7mm Dia. x 58mm	43-5399-058-14	
Straight Taper Stem Provisional 14 x 58mm	43-5571-058-14	

Category	How Supplied	Cleaning and Sterilization Requirements
Reusable Surgical Instrument	Non-Sterile	Must be cleaned and sterilized before a single use and then discarded as medical waste
Reusable Surgical Instrument	Non-Sterile	Must be cleaned and sterilized before the first use and each subsequent use
Reusable Surgical Instrument	Non-Sterile	Must be cleaned and sterilized before the first use and each subsequent use
Reusable Surgical Instrument	Non-Sterile	Must be cleaned and sterilized before the first use and each subsequent use
Reusable Surgical Instrument	Non-Sterile	Must be cleaned and sterilized before the first use and each subsequent use

3. Glossary

Chemical: A formulation of compounds intended for use in reprocessing.

NOTE: This includes detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners, and sterilants.

Cleaning: The removal of contamination from an item to the extent necessary for further processing.

Contaminated: State of having been actually or potentially in contact with microorganisms.

Decontamination: The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling or disposal.

Manual Cleaning: Cleaning without the use of an automated washer or washer/disinfector.

Processing/Reprocessing: Activity, including cleaning, and sterilization, which is necessary to prepare a new or used medical device for its intended use.

Sterile: Free from all viable microorganisms.

Sterilization: A validated process used to render a device free from all forms of viable microorganisms.

NOTE: In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. This probability can only be assured for validated processes.

Washer: A machine intended to clean medical devices and other articles used in the context of medical, dental, pharmaceutical, and veterinary practice.

4. Acronyms

BI: Biological Indicator
CJD: Creutzfeldt-Jakob Disease
CSSD: Central Sterile Supply Department
OR: Operating Room
PPE: Personal Protective Equipment
SAL: Sterility Assurance Level
TSE: Transmissible Spongiform Encephalopathy

5. Symbols

Consult Instructions

Caution or Instructions for Use

The catalogue or order number assigned to the device by the manufacturer

The device has not been sterilized

6. Considerations

This instruction manual pertains to all Canary Medical reusable surgical instruments and should be studied carefully.

New and used instruments **must be** thoroughly processed according to these instructions prior to use.

During musculoskeletal surgery, instruments become contaminated from blood, tissue, bone chips, and marrow. The instruments may also become contaminated with body fluids containing hepatitis virus, HIV, or other etiological agents and pathogens. All health care workers should become familiar with the necessary Universal Precautions of preventing injuries caused by sharp instruments when handling these devices during and after surgical procedures and during reprocessing.

NOTE: Saline and other irrigation fluids are often used in copious amounts during surgical procedures and will exert a corroding effect on instruments.

This document includes instructions for all Canary Medical reusable devices. All Canary Medical reusable devices may be safely and efficiently reprocessed using the manual or combination manual/automated cleaning instructions outlined in this document.

To maintain instruments properly it is important to consider the following information and processing instructions:

- Warnings and precautions
- The availability of all instruments required for the procedure (complete instrument set)
- Instrument functionality
- Reprocessing limitations and/or restrictions
- Preparation for reprocessing at the point of use
- Preparation for cleaning (including assembly/disassembly as necessary)
- Cleaning and drying
- Maintenance, inspection, testing and lubrication
- Sterile packaging
- Sterilization
- Storage

7. Processing Instructions

These processing instructions are intended to assist the hospital and central supply management in developing procedures to ensure that Canary Medical surgical instruments are correctly and effectively processed/reprocessed. This information is based on Canary Medical testing and recommendations of the following organizations:

- *AAMI TIR12. Designing, testing, and labeling reusable medical devices or reprocessing in health care facilities: A guide for device manufacturers. Association for the Advancement of Medical Instrumentation, Arlington, VA. (CRD033)*
- *AAMI TIR30. A compendium of processes, materials, test methods, and cceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249)*
- *Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff. U.S. Department of Health and Human Services, Washington, D.C. (CRD256)*
- *ASTM E2314-03, Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test). ASTM International, West Conshohocken, PA. (CRD397)*
- *ASTM F3208:Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices. ASTM International, West Conshohocken, PA. (CRD682)*
- *ASTM F3293:Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices. ASTM International, West Conshohocken, PA. (CRD683)*
- *Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. U.S. Department of Health and Human Services, Washington, D.C. (CRD404)*
- *ANSI AAMI ISO 17664: Sterilization of Medical Devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. International Organization for Standardization, Geneva, Switzerland. (CRD184)*

- *ISO 15883-5:. Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy. Geneva, Switzerland.(CRD684)*

NOTE: These instructions describe the necessary processing steps that both new and used instruments must undergo to attain sterility.

A. Warnings and Precautions

- **Universal Precautions** should be observed by all hospital personnel who 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.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants. Cleaning agents must be easily and completely rinsed from device surfaces to prevent accumulation of detergent residue.
- **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.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
- 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.

- Only devices manufactured and/or distributed for Canary Medical should be included with Canary Medical instruments in instrument trays. These validated reprocessing instructions are not applicable to trays that include devices that are not manufactured and/or distributed for Canary Medical.

B. Receiving Inspection — Instrument set content and functionality verification

- **Upon receipt in the hospital, instrument sets should be inspected for completeness.**
- Markings on instruments used for measuring anatomical dimensions **must be** legible. These may include gauge markings, angles, inner or outer diameters, length or depth calibrations, and right/left indications. Notify your Canary Medical distributor representative if scales and other markings are not legible.

C. Limitations and Restrictions

- **Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning Canary Medical reusable devices. Alkaline agents with pH of 12 or less may be used to clean stainless steel instruments in countries where required by law or local ordinance. It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from devices.**

NOTE: Drill bits should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.

NOTE: It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically for breakdown of fecal matter or other organic contaminants and may not be suitable for use with orthopedic instruments.

- Repeated processing according to the instructions in this document has minimal effect on Canary Medical reusable surgical instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.

- Automated cleaning using a washer alone may not be effective for orthopedic instruments that are not cleaned within 30 minutes. A thorough manual or combination manual/automated cleaning process is recommended.
- Instruments **must be** removed from metal trays for automated cleaning procedures. Do not clean instruments while in metal trays. Instrument trays, cases, and lids **must be** cleaned separately from the instruments.
- Soaking in disinfectants may be a necessary step to control certain viruses. However, these agents may discolor or corrode instruments (household bleach contains or forms chlorine and chloride in solution and has a corrosive effect similar to saline). Disinfectants containing glutaraldehyde, or other aldehydes, may denature protein-based contaminants, causing them to harden and making them difficult to remove. Where possible, soaking in disinfectants should be avoided.
- Steam/moist heat is the recommended sterilization method for Canary Medical instruments.
- Ethylene Oxide (EO), Gas Plasma Sterilization, and dry heat sterilization methods are not recommended for sterilization of Canary Medical reusable instruments.
- During initial steam sterilization runs, some formaldehyde from polyformaldehyde surfaces may vaporize and cause a noticeable odor. This should not cause concern. After a few sterilization cycles, the odor should no longer be evident.
- Use of hard water should be avoided for processing/reprocessing Canary Medical reusable surgical instruments. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionization (DI), or equivalent.

D. Point of Use Preparation for Reprocessing

- 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.

NOTE: Soaking in proteolytic enzyme solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions break down protein matter and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

- 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.

E. Preparation Before Cleaning

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.

F. Preparation of Cleaning Agents

- Neutral pH enzymatic and cleaning agents with low foaming surfactants are preferred and recommended by Canary Medical. Alkaline agents with pH of 12 or less may be used where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and thorough rinsing.
- 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.
- Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments.
- Fresh cleaning solutions should be prepared when visual debris are evident in existing solutions (bloody and/or turbid).

G. Manual Cleaning Instructions

1. Adequately clean the device as described in the following steps. Adequate sterilization depends on the thoroughness of cleaning.
2. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to holes, crevices and other hard-to-clean areas. Holes should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. pipe cleaner brush).

3. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush holes, crevices and other difficult-to- reach areas.
4. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
5. Rinse instrument in reverse osmosis (RO)/deionized (DI) water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush holes, crevices, and other difficult-to-reach areas.
6. Repeat the sonication and rinse steps above.
7. Remove excess moisture from the instrument with a clean, absorbent, and non-shedding wipe.

NOTE: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as-needed basis.

H. Combination Manual/Automated Cleaning Instructions

1. Adequately clean the device as described in the following steps. Adequate sterilization depends on the thoroughness of cleaning.
2. Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices and other hard-to-clean areas. Holes should be cleaned with a long, narrow, soft nylon-bristled brush (i.e., pipe cleaner brush).

NOTE: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.

NOTE: Use of a syringe or water jet will improve flushing of difficult-to-reach areas and closely mated surfaces.

3. Remove devices from the enzyme solution and rinse in reverse osmosis / deionized (RO/DI) water for a minimum of 1 minute. Thoroughly and aggressively flush crevices and other difficult-to-reach areas.
4. Place instruments in a suitable washer basket and process through a standard instrument washer cleaning cycle. The following minimum parameters are essential for thorough cleaning.

Step	Description
1	2 minute pre-wash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66° C/146-150° F)
6	15 second hot tap water rinse
7	2 minute thermal rinse (80-93° C/176-200° F)
8	10 second RO/DI rinse (64-66° C/146-150° F)
9	7 to 30 minute hot air dry (116° C/240° F)

NOTE: Adhere strictly to the washer/disinfector manufacturer's instructions.

I. Inspection, Maintenance, and Testing

1. Carefully inspect each instrument to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning process.
2. Visually inspect each instrument for completeness, damage, and/or excessive wear. This can include corrosion, discoloration, pitting, warping, bending, fracture, thread damage, surface damage, etc.

NOTE: If you notice damage or wear that may compromise the function of the instrument, contact your Canary Medical representative for a replacement.

3. Check instruments with long slender features (particularly rotating instruments) for distortion.
4. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

J. Packaging for Sterilization

Packaging Individual Instruments

- Use only FDA-cleared sterilization wrap or other FDA-cleared accessory (e.g., container, pouch) that has been validated to allow sterilant penetration and subsequently maintain sterility.
- Commercially available, FDA-cleared steam sterilization pouches (e.g. paper, Tyvek™, or equivalent) of the appropriate sizes may be used to double package single instruments. Ensure that the inner pouch is large enough to contain the instrument without stressing the seals or tearing the packaging but small enough to be placed in a secondary pouch without compromising the integrity of the total package.
- Standard, legally marketed, FDA-cleared steam sterilization wrap may be used to package individual instruments. The package should be prepared using the AAMI double wrap or equivalent method.

NOTE: If sterilization wraps are used, they must be free of detergent residues. Reusable wraps are not recommended.

Packaging Instrument Sets in Rigid Trays & Cases with Lids

SAFETY PRECAUTION: The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. When placed in a sterilization container with gasketed lid the total package should not exceed 16kg/35lbs.

- Trays and cases with lids may be wrapped in legally marketed, standard FDA-cleared, steam sterilization wrap using the AAMI double wrap method or equivalent.
- Trays and cases with lids may also be placed in a legally marketed approved sterilization container with a gasketed lid for sterilization.

NOTE: Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.

Instrument trays and cases with defined, preconfigured layouts

- In trays and cases having areas designated for specific devices, use these areas only for the specifically designated devices.

- Optional Canary Medical instruments should not be added to a preconfigured instrument tray or case unless a dedicated universal space or compartment has been included in the design and the guidelines described below for trays and cases without defined layouts or universal spaces can be applied.
- Only devices manufactured and/or distributed by Canary Medical should be included in Canary Medical instrument trays. These validated reprocessing instructions are not applicable to Canary Medical trays that include devices that are not manufactured and/or distributed by Canary Medical.
- All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact.
- The user must ensure that the instrument case is not tipped, or the contents shifted once the devices are arranged in the case. Silicone mats may be used to keep devices in place.
- Only devices manufactured and/or distributed by Canary Medical should be included in Canary Medical instrument trays. Canary Medical-validated reprocessing instructions are not applicable to Canary Medical trays that include devices that are not manufactured and/or distributed by Canary Medical.

K. Sterilization Instructions

- A pre-vacuum steam sterilization cycle using the parameters below has been validated to provide a 10-6 sterility assurance level (SAL)
  - 132˚C
  - 4 minutes full cycle exposure time
  - 30 minutes dry time
- The hospital/facility is responsible for in-house procedures for the inspection, and packaging of the instruments after they are thoroughly cleaned in accordance with the cleaning instructions in this document. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital/facility.
- Moist heat/steam sterilization is the preferred and recommended method for Canary Medical instrument sets.
- Sterilizer manufacturer recommendations should **always** be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.

- Instrument sets should be properly prepared and packaged in trays and/or cases in accordance with directions in this document. Ethylene oxide or gas plasma sterilization methods **should not be** used.

L. 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, vermin, and temperature/humidity extremes.
- Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

NOTE: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be repackaged and sterilized.

NOTE: If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set re-sterilized.

8. Reuse Life/Disposition of Damaged or Improperly performing Instruments

- Orthopedic surgical instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to Canary Medical to be discarded. Notify your Canary Medical distributor representative of any instrument problems.

- The instructions provided in this manual have been validated by Canary Medical in the laboratory and are capable of preparing orthopedic devices for use. It is the responsibility of the hospital/facility to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately

trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

9. Customer Service Information

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This Canary Medical reprocessing manual can be found at **canarymedical.com**.

10. References

AAMI TIR12. *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers.* Association for the Advancement of Medical Instrumentation, Arlington, VA. (CRD033)

AAMI TIR30. A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249)

Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff. U.S. Department of Health and Human Services, Washington, D.C. (CRD256)

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ASTM F3208:Standard Guide for Selecting Test Soils for Validation of *Cleaning Methods for Reusable Medical Devices.* ASTM International, West Conshohocken, PA. (CRD682)

ASTM F3293:Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices. ASTM International, West Conshohocken, PA. (CRD683)

Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. U.S. Department of Health and Human Services, Washington, D.C. (CRD404)

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ISO 15883-5:. Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy. Geneva, Switzerland. (CRD684)

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