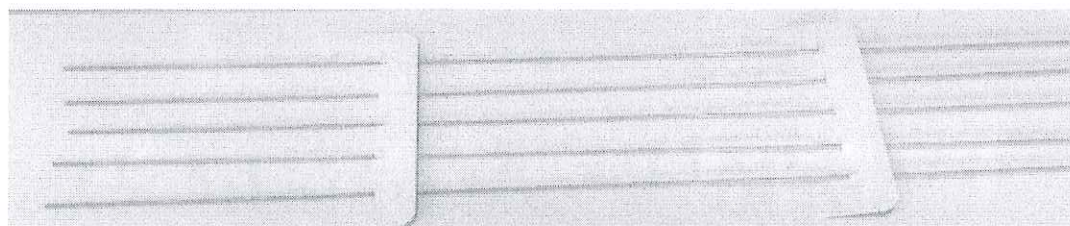


CONMED CORPORATION

HƯỚNG DẪN SỬ DỤNG BẢN TIẾNG ANH

Tên trang thiết bị: **GAO DẪN VÍT**



CÔNG TY TNHH THIẾT BỊ Y TẾ DANH



GIÁM ĐỐC

Nguyễn Quý Hải

Hà Nội - 2022

Instrument Disinfection Guide

Reusable Medical Devices and Accessories In accordance with ISO 17664



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1.0 IMPORTANT INFORMATION

1.1 Introduction

The purpose of this guide is to provide detailed, recommended practices for the disinfection instructions of CONMED manual reusable surgical instruments, battery operated equipment and associated accessories.

All necessary pre-cleaning/cleaning steps for the instrument are expected to be completed according to the instruction for use (IFU) for that device before the use of this manual.

This guide provides two methods of disinfecting CONMED re-usable instruments, a manual method and a method using an automatic washer disinfecter. The two methods have been validated and the processes provided in the instructions have been proven to be effective for disinfection in accordance with the ISO 17664 standard for *Sterilization of Medical Devices: Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Medical Devices*.

Whichever method is used, staff should use suitable protective clothing and equipment at all times.

CONMED, recommends using the automated disinfection method whenever possible. The automated method of disinfecting the devices provides staff with less exposure to contaminated devices and the disinfection agents used.

This guide is intended to assist health care personnel in the proper and effective handling practices during disinfecting, and maintaining the equipment.

This guide should be studied carefully. The user / processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this guide.

This guide is to be a supplement to the device's Instructions For Use and / or User Manual. This guide is intended to be used with the Instructions For Use (IFU) and / or User Manual supplied with the devices and / or on CONMED's website.

In addition, refer to the IFU and / or User Manual technical specifications or cleaning / sterilization recommendations related to the product / system.

Keep all instructions where they are easily accessible for the personnel handling the product during the disinfection process. The Instructions for Use, Manuals and Instrument Disinfection Guide can be found on CONMED's website (www.conmed.com).

If you have any questions or need assistance during a procedure, contact CONMED Customer Service at 1-800-237-0169 or your CONMED Sales Representative. Outside the U.S. contact your local CONMED Representative.

2.0 PRECAUTIONS, WARNINGS, and NOTES (Definitions)

Precautions, Warnings and Notes

The words PRECAUTION, WARNING and NOTE carry special meanings and should be carefully reviewed.

PRECAUTION: Methods or procedures intended to prevent or avoid adverse outcomes.

WARNING: The personal safety of the patient, user and / or surgical staff may be involved. Disregarding this information could result in injury, death or other serious adverse reactions associated with the use or misuse of the device to the patient, user and / or surgical staff.

NOTE: This provides special instructions to make maintenance instructions clearer.

2.1 Precautions

After use (post-operatively) do not allow soiled / contaminated devices to dry prior to pre-cleaning and disinfecting. Consider covering the re-usable device with a cloth saturated with distilled water to avoid drying of soil.

NOTE: If the disinfection process is likely to be delayed and the devices are allowed to dry with blood, body fluid, bone, and tissue debris, it is highly recommended to spray the devices with distilled water to loosen the dried soil before proceeding to the disinfection process.

All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on devices. Immersion of manual instruments in distilled water immediately after use will facilitate cleaning and prevent proteinaceous material from drying on the instruments. Saline solutions may have corrosive effects on some metals and should not be used.

2.2 Warnings

CaviCide® Spray Ready-to-use or a comparable disinfection solution of pH between 11.0 and 12.49 are highly recommended by CONMED. However, the use of alternative methods of disinfection or disinfecting agents outside the scope of this document may be suitable for disinfecting the devices. Alternative disinfection methods must be validated by the end user.

The use of a washer/sanitizer or disinfection solution may affect the life expectancy of the device. CONMED does not define the maximum number of uses or number of reprocessing for re-usable devices. The useful life of these devices depends on many factors, including the handling between uses, methods and duration of each use. It is recommended to inspect and test functionality of the devices before each use and to determine the end of serviceable life.

3.0 EQUIPMENT REQUIRED

Automated Disinfection using washer disinfectant:

- Suitable protective clothing
- Washer disinfectant large enough to allow complete immersion of the re-usable instruments. (Do not exceed the temperatures provided in this instrument disinfection guide.)
- Deionized water for rinsing purposes.
- Washer disinfectant with a thermal disinfection program with an approved rinse cycle at 194°F (90°C) for a minimum of five (5) minutes duration.
- Sterile lint free wipes

Manual Disinfection:

- Suitable protective clothing
- Disinfecting area /platform
- Sterile lint free wipes
- CaviCide® Spray Ready-to-use or a comparable disinfection solution of pH between 11.0 and 12.49

4.0 DISINFECTION INSTRUCTIONS

Device Families	Manual Disinfecting Instructions	Automated Disinfecting Instructions
Scopes / Cameras	<ul style="list-style-type: none"> • Fully immerse the device in CaviCide® Ready-to-use disinfection solution for a minimum of three (3) minutes at room temperature. • Manipulate the grabber mechanisms and/or hinges a minimum of three (3) times (when applicable). • Ensure valves are in open position (parallel with the openings) for exposure (when applicable). • Rinse under running deionized water for a minimum of 1 minute. • Thoroughly dry all surfaces of the device using a sterile, lint free wipe, changing wipes when necessary to ensure the device is completely dry. • Proceed to cleaning and sterilization instructions per device Instructions For Use (IFU). 	<ul style="list-style-type: none"> • Place device in an automated washer disinfectant filled with purified water. • Run thermal rinse cycle at 194°F (90°C) for five (5) minutes • Let device cool before handling. • Remove device from washer and thoroughly dry the device with a sterile lint free wipe. • Proceed to cleaning and sterilization instructions per device Instructions for Use (IFU).
Sterilization Trays	<ul style="list-style-type: none"> • Wet a sterile, lint free wipe with CaviCide® Spray Ready-to-use disinfectant until it is fully saturated. • After wetting the wipe, the excess liquid should be squeezed out. NOTE: The wipe should remain wet but not dripping. • Using the wipe, thoroughly wipe the device. Careful attention should be given to seams and recessed areas. Continue to wipe the surface areas for a minimum of thirty (30) seconds. • Ensure the device remains wet for a minimum of three (3) minutes by spraying the device as needed with the CaviCide® Spray Ready-to-use. • Rinse under running deionized water for a minimum of one (1) minute. • Thoroughly dry all surfaces of the device using a sterile, lint free wipe, changing wipes when necessary to ensure the device is completely dry. • Proceed to cleaning and sterilization instructions per device Instructions For Use (IFU). 	<ul style="list-style-type: none"> • Place device in an automated washer disinfectant filled with purified water. • Run thermal rinse cycle at 194°F (90°C) for five (5) minutes. • Let device cool before handling. • Remove device from washer and thoroughly dry the device with a sterile lint free wipe. • Proceed to cleaning and sterilization instructions per device Instructions for Use (IFU).

Device Families	Manual Disinfecting Instructions	Automated Disinfecting Instructions
Batteries	<ul style="list-style-type: none"> • Wet a sterile, lint free wipe with CaviCide® Spray Ready-to-use disinfectant until is it fully saturated. • After wetting the wipe, the excess liquid should be squeezed out. NOTE: The wipe should remain wet but not dripping. • Using the wipe, thoroughly wipe the device. Careful attention should be given to seams and recessed areas. Continue to wipe the surface areas for a minimum of thirty (30) seconds. • Ensure the device remains wet for a minimum of three (3) minutes by spraying the device as needed with the CaviCide® Spray Ready-to-use. • Rinse under running deionized water for a minimum of ten (10) seconds. • Thoroughly dry all surfaces of the device using a sterile, lint free wipe, changing wipes when necessary to ensure the device is completely dry. • Proceed to cleaning and sterilization instructions per device Instructions For Use (IFU). 	<ul style="list-style-type: none"> • Place device in an automated washer disinfectant filled with purified water. • Run thermal rinse cycle at 194°F (90°C) for five (5) minutes. • Let device cool before handling. • Remove device from washer and thoroughly dry the device with a sterile lint free wipe. • Proceed to cleaning and sterilization instructions per device Instructions for Use (IFU).
General Manual Instruments	<ul style="list-style-type: none"> • Spray the device thoroughly with CaviCide® Spray Ready-to-use disinfectant. • Ensure the device remains wet for a minimum of ten (10) minutes by spraying the device as needed with the CaviCide® Spray Ready-to-use. • Ensure valves are in open position (parallel with the openings) for exposure (when applicable). • Manipulate the grabber mechanisms and/or hinges a minimum of ten (10) times (when applicable) • Rinse under running deionized water for a minimum of thirty (30) seconds. • Thoroughly dry all surfaces of the device using a sterile, lint free wipe, changing wipes when necessary to ensure the device is completely dry. • Proceed to cleaning and sterilization instructions per device Instructions For Use (IFU). 	<ul style="list-style-type: none"> • Place device in an automated washer disinfectant filled with purified water. • Run thermal rinse cycle at 194°F (90°C) for five (5) minutes. • Let device cool before handling. • Remove device from washer and thoroughly dry the device with a sterile lint free wipe. • Proceed to cleaning and sterilization instructions per device Instructions for Use (IFU).

Device Families	Manual Disinfecting Instructions	Automated Disinfecting Instructions
Arthroscopic Procedure Devices	<ul style="list-style-type: none"> • Fully immerse the device in CaviCide® Spray Ready-to-use disinfection solution for a minimum of three (3) minutes at room temperature. • Ensure valves are in open position (parallel with the openings) for exposure (when applicable). • Manipulate the grabber mechanisms and/or hinges a minimum of ten (10) times (when applicable) • Rinse under running deionized water for a minimum of thirty (30) seconds. • Thoroughly dry all surfaces of the device using a sterile, lint free wipe, changing wipes when necessary to ensure the device is completely dry. • Proceed to cleaning and sterilization instructions per device Instructions For Use (IFU). 	<ul style="list-style-type: none"> • Place device in an automated washer disinfectant filled with purified water. • Run thermal rinse cycle at 194°F (90°C) for five (5) minutes. • Let device cool before handling. • Remove device from washer and thoroughly dry the device with a sterile lint free wipe. • Proceed to cleaning and sterilization instructions per device Instructions for Use (IFU).
Handpieces	<ul style="list-style-type: none"> • Spray the device thoroughly with CaviCide® spray Ready-to-use disinfectant. • Ensure the device remains wet for a minimum of ten (10) minutes by spraying the device as needed with the CaviCide® Spray Ready-to-use. • Rinse under running deionized water for a minimum of one (1) minute. • Thoroughly dry all surfaces of the device using a sterile, lint free wipe, changing wipes when necessary to ensure the device is completely dry. • Proceed to cleaning and sterilization instructions per device Instructions For Use (IFU). 	<ul style="list-style-type: none"> • Place device in an automated washer disinfectant filled with purified water. • Do not immerse the device paddle connector. When applicable, disconnect the paddle connector from the handpiece. NOTE: Proceed to the individual device Instructions For Use (IFU) for cleaning and/or sterilization for the paddle connector. • Run thermal rinse cycle at 194°F (90°C) for five (5) minutes. • Let device cool before handling. • Remove device from washer and thoroughly dry the device with a sterile lint free wipe. • Proceed to cleaning and sterilization instructions per device Instructions for Use (IFU).

5.0 REFERENCE INFORMATION

1. Disinfection validations were performed by NAMSA and Nelson Laboratories.
2. ISO 17664: Sterilization of Medical Devices Information To Be Provided By The Manufacturer For The Processing Of Re-sterilizable Medical Devices.
3. ISO 15883-1 Washer-disinfectant-Part-1 General requirements terms, and definitions and tests.
4. Requirements Concerning Hygiene During the Reprocessing of Medical Devices, Federal Health Gazette, 2012. 55:1244-1310.

6.0 EXAMPLES OF EACH FAMILY GROUP

The tables below contain types of devices for each family group:

General Manual Instruments	
Forceps	Awls
Cannulas	Graspers
Guides	Handles
Clamps	Brushes
Drill Guides	

Arthroscopic Procedure Devices	
Taps	Reamers
Punches	Suture Hooks
Scissors	Bur Guards
Obturator	Stop Cocks
Tendon Stripper	Badgers
Endura Blades/Burs	Suture Passers

Scopes/Cameras	
Eyecup Scopes	Cartridge Scopes
Laparoscopes	Camera Heads
Endoscopes	Arthroscopes

Sterilization Trays	
Arthroscopy Trays	Laparoscope Trays
Sterilization Cases	Endoscope Trays
Insert Trays	Rigid Containers
Charging Cases	Baskets
Aluminum Trays	Radel Trays

Handpieces	
Autoclavable Remote Controls	Drill Handpieces
Attachments	

Batteries	
Lithium Batteries	Transfer Batteries

