

**INSTRUCTIONS FOR CLEANING & DISINFECTION/STERILIZATION OF CRYOPEN RE-USABLE TIPS: CT2-T 5003, 5005, 5007 AND 5010  
MODEL: CT-2000**

**DEFINITIONS**

**From FDA Guidance:**

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080268.pdf>

**Cleaning:** The removal of adherent visible soil (e.g., blood, protein substances, and other debris) from medical devices by a manual or mechanical process, as part of a decontamination process.

**Disinfection:** A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilization processes. The lethality of the disinfectant leads to the following subcategories:

- a. **High Level Disinfection:** A lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.
- b. **Intermediate Level Disinfection:** A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative forms of bacteria, but no bacterial spores.

**Sterilization:** The absolute state where all forms of life have been eliminated. In a particular sense absolute sterility cannot be proven, therefore, sterility is considered achieved when organisms are eliminated, inactivated, or destroyed such that they are undetectable in standard media in which they have previously been found to proliferate.

**Table 1: FDA Requirements for Disinfection/Sterilization**

CryoPen Tip Usage (i.e. where cryosurgery takes place)	Intermediate Disinfection	High Level Disinfection/Sterilization
Intact Skin or no likelihood of transmissible bacteria, organisms, etc.	X	
Broken Skin and/or Mucosal Membrane		X

A copy of FDA cleared Sterilants and High Level Disinfectants can be obtained at the following website.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM1335141>

**Procedure for Cleaning & Disinfection/Sterilization of CryoPen® tips:**  
(CryoPen® re-usable tips are in sizes: 3, 5, 7 and 10mm)

1. Thoroughly clean all surfaces of the CryoPen tip prior to sterilization/disinfection.
2. Place in cold soak sterilant fluid (e.g. glutaraldehyde based solutions) or disinfectant per manufacturer’s instructions.
3. Upon removal from fluid or disinfectant, all surfaces must be wiped with CryoPen Reservoir Solution (or an alcohol pad) and allowed to air dry completely.
4. The CryoPen tip is now ready for use.



**OR**

1. Thoroughly clean all surfaces of the CryoPen tip prior to sterilization/disinfection.
2. AutoClave-250-275 degrees F at 20-30psi for a minimum of 15 minutes to 20 minutes maximum.
3. The CryoPen tip is now ready for use.

**CAUTION: Do not attempt to remove or pry aluminum tip from plastic casing. Doing so will render the CryoPen tips inoperable.**

**Note: Re-usable tips should never be placed in an oxidizing chemical such as bleach or hydrogen peroxide.**

**Non-acceptable products for cleaning CryoPen Tips:**

- Madacide-1
- Cavicide (all products)
- CitriGuard II

**Table 2: Acceptable Products**

*Please follow the Manufacturer’s Instructions for Use.*

<u>CLEANING AGENTS</u>	<u>INTERMEDIATE DISINFECTION</u>	<u>HIGH LEVEL DISINFECTION/STERILIZATION</u>
Enzol®	PDI Super Sani-Cloth®	Cidex® OPA
PDI Benzalkonium Chloride Antiseptic Towelette®	Sanizide Plus® Mikrobac® Forte	Cidex® Plus Omnicide™ 28 day Omnicide™ Plus



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