C2 CryoBalloon™ Controller and Foot Pedal Reprocessing Instructions

System Components

The C2 CryoBalloon Ablation System is composed of 1) sterile, single use C2 CryoBalloon Catheter, 2) non-sterile, reusable C2 CryoBalloon Controller, 3) non-sterile, reusable C2 CryoBalloon Foot Pedal, and 4) non-sterile, single use C2 CryoBalloon Cartridge. Please refer to C2 CryoBalloon Catheter and C2 CryoBalloon Ablation System Instructions For Use (IFU) for operation of the system. The components are illustrated (Figure 1) below.



Catheter



Cartridge

Controller



Foot Pedal

Figure 1. C2 CryoBalloon Ablation System

C2 CryoBalloon™ Controller Reprocessing Instructions

The C2 CryoBalloon Controller ("C2 Controller") is a reusable medical device with a one-year reuse life. The C2 Controller should be throughly cleaned and disinfected after each use. The reprocessing instructions are validated and appropriate for the intended use of the C2 CryoBalloon Ablation System.

1. Perform thorough cleaning to physically remove soils and contaminants, then perform disinfection to successfully inactivate microorganisms.
2. The comprehensive reprocessing instructions are based on recommendations found in the following documents. End users are advised to be familiar with these guidelines:

   "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008" by the Centers for Disease Control (CDC), and

The following EPA-registered disinfectants and accessories shall be used to reprocess the C2 Controller:

Wipe: PDI Sani-Cloth® Bleach Germicidal Disposable Wipes

Special Personal Protective Equipment (PPE) is not required. Gloves (i.e. nitrile or latex gloves) should be worn when handling contaminated devices.

Perform the following Manual Cleaning procedure (Table 1), then Disinfection procedure (Table 2) at room temperature prior to initial use and subsequent single uses of the C2 Controller.

⚠ WARNING: C2 Controller must be reprocessed after each use.

⚠ WARNING: Reprocessing of the C2 Controller shall be performed by personnel trained and familiar with medical device reprocessing.

⚠ WARNING: Personnel shall follow their facility policies and procedures and wear appropriate PPE when handling potentially contaminated equipment.

⚠ CAUTION: Do not immerse/soak the C2 Controller – damage to the C2 Controller will occur.

⚠ CAUTION: Failure to perform full contact duration of the procedure will result in improper cleaning/disinfection of the C2 Controller (Tables on the back).

C2 CryoBalloon™ Foot Pedal Reprocessing Instructions

The C2 CryoBalloon Foot Pedal ("C2 Foot Pedal") is a reusable medical device with a three-year reuse life. The C2 Foot Pedal can be cleaned between uses with wipes or a mild soap and water solution, rinsed, and dried (do not submerge the C2 Foot Pedal). Special Personal Protective Equipment (PPE) is not required. Gloves (i.e. nitrile or latex gloves) are recommended.



Foot Pedal

C2 CryoBalloon™ Controller & Foot Pedal Disposal Instructions

Follow your institution's procedures to discard used medical devices

Please refer to C2 CryoBalloon Catheter and C2 CryoBalloon Ablation System Instructions For Use (IFU) for operation of the system.

C2 Controller Manual Cleaning Procedure

Step	Manual Cleaning Procedure	Contact Duration
1	Remove the Cap from the C2 Controller. 	NA
2	Using TWO (2) bleach wipes (one in each hand), clean all exposed surfaces of the C2 Controller. 	2 minutes
3	Using the SAME TWO (2) bleach wipes (one in each hand), wipe the interior and exterior surfaces of the Cap. 	2 minutes
4	Using a single NEW wipe, clean all exposed surfaces of the C2 Controller. 	5 minutes
5	Perform visual inspection of the C2 Controller and Cap. If visible soil remains, use a new wipe and clean the C2 Controller and Cap to remove the visible soil. If seals appear to be cracked, then dispose of the Controller.	NA

C2 Controller Disinfection Procedure

Step	Disinfection Procedure	Contact Duration
1	If necessary, remove the Cap from the C2 Controller. 	NA
2	Using TWO (2) bleach wipes (one in each hand), clean all exposed surfaces of the C2 Controller. 	Wipe: 2 minutes Dry: 2 minutes
3	Using the SAME TWO (2) bleach wipes (one in each hand), wipe the interior and exterior surfaces of the Cap. 	Wipe: 2 minutes Dry: 2 minutes
4	Allow Controller to dry before use. Remove residue on screen with a clean paper towel if desired.	NA
5	Screw Cap back onto C2 Controller. Store device per facility practice to allow device to remain clean and dry.	NA

The above suggestions and other information, which may include both Merit and third-party products, are for the practitioner's convenience and for general information purposes only. This information does not constitute medical or legal advice, nor is it meant to endorse or guarantee the suitability of any of the referenced products or methods for any specific patient or procedure. Before using, refer to the Instructions for Use (IFU) for indications, contraindications, warnings, precautions, and directions for use.

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