Cleaning and Sterilization of Repeated Use Products

SUMMARY

Boston Scientific repeated use products can be used more than once to support the implantation and monitoring of implantable cardiac devices, provided that proper cleaning and sterilization techniques are implemented prior to re-use.

This article provides cleaning and sterilization techniques for certain Boston Scientific Repeated Use Products.

Products Referenced

Model 6577 Telemetry Wand, Model 6888 Lead Tunneler and Pulling Tips, Model 6860 Magnet, S-ICD System: Model 4520 Magnet, Model 3203 Telemetry Wand

For comprehensive information on device operation, reference the full instructions for use found at: **www.bostonscientific-elabeling.com**.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator

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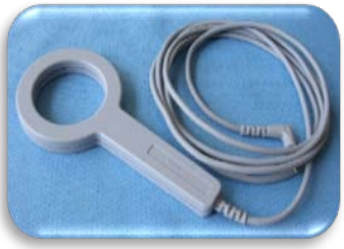
The cleaning and sterilization processes provided below are described in the applicable device labeling. Boston Scientific CRM has not conducted testing using any cleaning or sterilization methods on these products other than those described herein. Products designated as single-use only should not be reused or re-sterilized.

Model 6577 Telemetry Wand

Cleaning



- The exterior of the telemetry wand and cord can be cleaned with a soft cloth dampened with mild cleaning solution such as green soap, green soap tincture, Borax, or alcohol-free hand soap.
- Use a fresh cloth dampened with sterile water to remove residue.
- Air or towel dry.
- Do not use an abrasive cloth or volatile solvents to clean any portion of the wand.
- Do not use an ultrasonic cleaner.
- Do not immerse the telemetry wand.
- Do not allow any fluids to enter the wand cavity.

Sterilization

CAUTION: The Model 6577 Telemetry Wand is shipped non-sterile. If the telemetry wand is to be used in a sterile field, it must be actively sterilized before use, or encased within a disposable sterile surgical sheath during use.

NOTE: *For example, a Model 3320 Intraoperative Probe Cover.*

CAUTION: Remove the telemetry wand from all packaging material before sterilization.

Either ethylene oxide (EO) or steam may be used for active sterilization. Follow the cleaning instructions before beginning the sterilization process.

Ethylene Oxide (EO) gas sterilization method: Follow the recommendations of the EO sterilization equipment manufacturer and allow the specified aeration time to fully elapse prior to use.

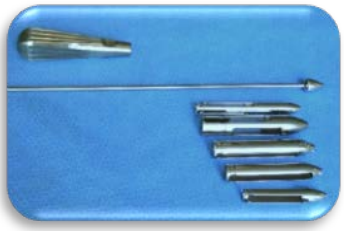
Steam sterilization method: Follow customary autoclave procedures for wrapped goods and limit temperature to 132° C (-0°C, +5°C), 270° F (-0°F, +9°F).

NOTE: *The wand has been tested to withstand 25 sterilization cycles. Additional cycles are not recommended. The wand should be discarded if surface cracks appear in the plastic, and/or the cable discolors or becomes worn, regardless of the number of completed cycles.*

Model 6888 Lead Tunneler and Pulling Tips

Cleaning

- Disassemble the lead tunneler kit and lead pulling tips into distinct parts.
- Clean all parts, including crevices and holes, with a brush to ensure all visible tissue and blood are removed.
- Visually inspect all parts after cleaning to ensure all visible tissue and blood has been removed.
- Place all parts into a neutral pH enzymatic detergent for five minutes.
- Thoroughly rinse off parts with a minimum of 250 mL of sterile water.
- Repeat the visual inspection.
- Thoroughly rinse off parts with a minimum of 500 mL of sterile water.
- Dry all parts.



Sterilization

CAUTION: The tunneler is packaged non-sterile. The Model 6888 tunneler must be sterilized before each surgical use.

CAUTION: Remove the tunneler from all non–sterilized packaging material, remove the protective end caps from the ends of the rods, completely disassemble the tunneler, and put it in appropriate sterilization packaging before sterilizing.

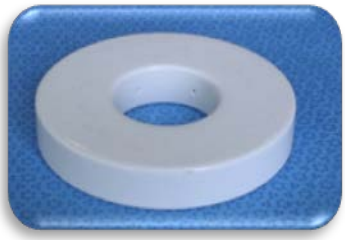
EO gas sterilization or steam sterilization method: When using this method, the user is responsible for determining appropriate sterilization process and parameters based on the sterilization equipment that is used. If sterilizing with EO, the validated aeration time must be observed before using the tunneler**.**

Steam sterilization method: Sterilization of the Model 6888 tunneler was validated using a standard 4 minute, 132°C pre-vacuum steam cycle with a 30 minute dry time.

Model 6860 Magnet and S-ICD System Model 4520 Magnet

Cleaning

Follow hospital cleaning guidelines.



Sterilization

The magnet is packaged non-sterile. Boston Scientific has not validated a sterilization procedure for magnets. If the magnet is to be used within a sterile environment, consider placing the magnet in a sterile bag.

S-ICD System Model 3203 Telemetry Wand

Cleaning

- Do not use harsh chemicals, cleaning solvents, or strong detergents to clean the wand.
- Gently wipe with a soft, clean, dry cloth.
- Clean the wand by wiping it with an isopropyl alcohol-moistened cloth.
- Dry immediately to remove residue.

Sterilization

CAUTION: The wand is a non-sterile device. **Do not sterilize the wand.** The wand must be contained in a sterile barrier before use in a sterile field.

The Model 3203 telemetry wand **should not be sterilized.** If the wand is to be used within a sterile environment, it must be contained in a sterile barrier (for example, a Model 3320 Intraoperative Probe Cover).

ZOOM™ LATITUDE™ Programming System from Boston Scientific

Intended Use
The Programmer/Recorder/Monitor (PRM) is intended to be used as part of the ZOOM™ LATITUDE™ Programming System to communicate with Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literaturefor the pulse generator being interrogated.

Contraindications
The PRM is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator. For contraindications for use related to the pulse generator, refer to the associated product literature for the pulse generator being interrogated.

Warnings
The use of any cables or accessories with the PRM or Zoom Wireless Transmitter (ZWT) other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the PRM or ZWT. Do not simultaneously touch the patient and any accessible connector contacts on the PRM (e.g., USB, parallel port, external VGA monitor, stimulation input, analog output, and expansion port). Other equipment may interfere with the PRM and ZWT, even if that equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. To avoid the risk of electric shock, only connect the PRM to a grounded/earthed power source. Do not use the PRM or ZWT adjacent to or stacked with other equipment. **PRM and ZWT must remain outside sterile field.** Operation of the PRM with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. Do not simultaneously touch the patient and the parts inside the printer door. The PRM and ZWT are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices1. No modification of this equipment is allowed unless approved by Boston Scientific.

Precautions
For specific information on precautions, read the following sections of the product labeling: General, Preparations for Use, Maintenance and Handling.

Adverse Effects
None known.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse effects. Rx only. (Rev. F)

S-ICD™ System from Boston Scientific CRM Indications for Use

The S-ICD™ System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications
Unipolar pacemakers are contraindicated for use with the S-ICD System.

Warnings and Cautions
The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the SICD System with care at all times and maintain proper sterile technique. All Cameron Health implantable components are designed for use with the Cameron Health S-ICD System only. Connection of any S-ICD System components to any other ICD system will result in failure to deliver lifesaving defibrillation therapy.

General
- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.
- The S-ICD System has not been evaluated for pediatric use.
- The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

Potential Adverse Events related to implantation of the S-ICD System may include, but are not limited to, the following:
Acceleration/induction of atrial or ventricular arrhythmia; Adverse reaction to induction testing; Allergic/adverse reaction to system or medication; Bleeding; Conductor fracture; Cyst formation; Death; Delayed therapy delivery; Discomfort or prolonged healing of incision; Electrode deformation and/or breakage; Electrode insulation failure; Erosion/extrusion; Failure to deliver therapy; Fever; Hematoma; Hemothorax; Improper electrode connection to the device; Inability to communicate with the device; Inability to defibrillate or pace; Inappropriate post-shock pacing; Inappropriate shock delivery; Infection; Keloid formation; Migration or dislodgement; Muscle stimulation; Nerve damage; Pneumothorax; Post-shock/post-pace discomfort; Premature battery depletion; Random component failures; Stroke; Subcutaneous emphysema; Surgical revision or replacement of the system; Syncope; Tissue redness, irritation, numbness or necrosis.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. D)