

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

Products referenced are unregistered or registered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are the property of their respective owners.

Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

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

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found with product labeling.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

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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Cleaning and Sterilization of Repeated Use Products

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).

