



INNOVATIVE
HEALTH

Category Spotlight

Coronary Sinus (CS) Catheters



Cleaning

Upon receipt of the clinically used medical devices, the reprocessing of these devices and returning them to our customers to be used again starts with the critical step of cleaning. The cleaning process is designed to remove soil and chemical residue. The removal of organic and inorganic contamination is necessary to ensure that terminal sterilization is effective. In addition, the chemicals (cleaning agents) utilized to clean the devices must also be removed once the cleaning process has been completed.

Innovative Health's validated cleaning process has been specifically designed and tested to provide consistent and repeatable results with high confidence and reliability. The first step in the reprocessing process is the reduction of organic and inorganic contamination (e.g. hemoglobin, protein) and chemical residue (e.g. Total Organic Carbon (TOC)). This is achieved utilizing manual debris removal techniques, enzymatic cleaners, and Reverse Osmosis (RO) water.

The process has been validated in accordance with AAMI TIR-30: Compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices and FDA recommendations. This standard is considered to be the gold standard in cleaning medical devices.



Testing and Inspection

Physical, mechanical and electrical testing is performed to provide objective evidence that the reprocessed device meets specifications and functions as intended. All testing is designed with the clinical procedure in mind. Testing methods mimic clinical conditions and are used to challenge the device under worst case conditions.

The following tests are performed on all CS catheters:

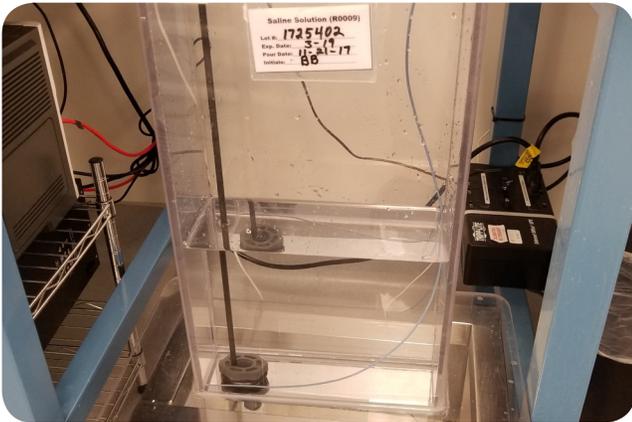
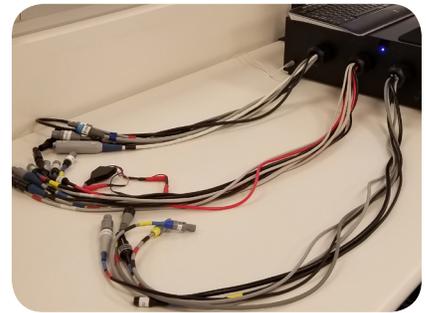
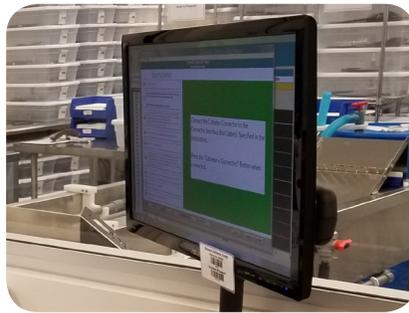
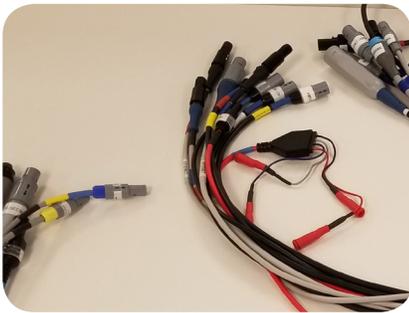
- Visual inspections – Inspection of device under magnification to assess defects and identify any imperfections to the product.
- Curve template/tip deflection testing – Device curves and deflection patterns are verified using controlled and validated curve templates and compared to new original manufacturer devices.
- Auto ID Verification (as applicable) – Devices are tested to ensure the compatibility with current EP consoles that are found in EP labs. The proprietary software verifies that information on a device meets the verification activities needed by the original manufacturer's console.
- Static and dynamic continuity testing – Electrical testing is completed during full deflection to represent clinical use. The electrical properties are assessed during a full range of motion and under worst case conditions during the movement of the tip and shaft of the device.

Utilization

Coronary Sinus (CS) diagnostic EP catheters are designed for electrophysiology mapping of cardiac structures, stimulation and recording. The devices are comprised of a flexible polymer shaft with platinum/iridium electrodes on the distal tip that are attached to conductors contained within the shaft. The shaft is attached to a proximal handle with a bi-directional steering mechanism that allows the user to control the curve/deflection of the distal tip. An electrical connector at the proximal end of the handle allows the device to be connected via an accessory cable to the console that generates and receives the electrical impulses.

Reprocessed CS catheters from Innovative Health provides highly valuable functionality to the EP procedure. They are as safe and effective equivalent to costly options sold by the original equipment manufacturer.

A lab that uses 6 CS catheters per week can save more than \$136,000 per year.



Item Number	Description	Available Date	Manufacturer	Size
BD710DF282RTS	Webster CS Bi-Directional	6/22/17	Biosense Webster	7F
BD710FJ282RTS	Webster CS Bi-Directional	6/22/17	Biosense Webster	7F
BD710DF282CT	Webster CS Bi-Directional	6/22/17	Biosense Webster	7F
BD710FJ282CT	Webster CS Bi-Directional	6/22/17	Biosense Webster	7F

Developing a 510(k) to achieve FDA Clearance to Reprocess Single-Use Devices

The FDA requires reproprocessors to demonstrate that a reprocessed device is substantially equivalent to that of the Original Manufacturer (OM) device prior to marketing the device. The FDA is able to determine that the device is substantially equivalent from the evidence presented in a 510(k) submission.

Innovative Health evaluates OM devices to determine their eligibility for reprocessing. This evaluation includes, but is not limited to, reverse engineering, OM characterization, and testing to ensure the finished reprocessed devices meet the appropriate product specifications and are safe and effective as the original device.

Cleaning validations through independent laboratories, based on the industry standards AAMI TIR30 and FDA guidelines, are completed to ensure that the cleaning process reduces residual biomarkers (i.e. organic soil, bioburden and endotoxins) on devices to acceptable levels to ensure the cleanliness. Exhaustive extractions are performed to determine the number of viable organisms and contaminants that are present on inoculated devices. Repeated extractions are performed to calculate extraction efficiencies which determine the effectiveness of the cleaning process.

Biocompatibility testing was performed in accordance with AAMI/ANSI/ISO 10993 (and related subparts) Biological Evaluation of Medical Devices to ensure that devices are not toxic, injurious, or physiologically reactive and do not cause immunological rejection. In vitro and in vivo safety evaluation studies are conducted and may include: chronic cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and hemocompatibility testing.

Detailed test plans are developed for each device that are intended to test the mechanical, electrical, and simulated use properties of the device under worst case conditions. Innovative Health engineers work closely with clinicians to understand clinical use and translate this into appropriate testing methods.

During production, each device is inspected and function tested prior to packaging and labeling and all production lots are tested to ensure an acceptable level of bacterial endotoxins in accordance with ANSI/AAMI ST72 to support the non-pyrogenic labeling.

Innovative Health devices are sterilized using Ethylene Oxide (EO). The EO sterilization process includes preconditioning, sterilization and aeration. The EO sterilization cycle is validated in accordance with applicable industry standards and requirements such as AAMI/ANSI/ISO 11135 to achieve a minimum Sterility Assurance Level (SAL) of 10^{-6} . In addition, devices are validated to have acceptable sterilant residual levels after aeration.

For a more detailed description of what goes into an Innovative Health 510(k) submission, please ask your contact for additional information.

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