The 3D Diagnostic Ultrasound Catheters (ICE catheters) reprocessed by Innovative Health are a safe and highly effective equivalent to costly options sold by the original equipment manufacturer. This well-established technology aids in intracardic and intraluminal visualization of cardiac anatomy and physiology. Clinical efficacy and safety is improved by enhanced imaging and visualization of the anatomical structures during electrophysiology and structural heart procedures and in monitoring potential complications while reducing reliance on fluoroscopy.

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

Location Sensor Test

The Location Sensor Tester (LST) utilized to function test the location sensors of Biosense Webster SoundStar Diagnostic Ultrasound Catheter at Innovative Health utilizes Navigational technology. The LST simulates a magnetic field similar to Biosense Webster’s Carto XP and Carto 3 console magnetic field generator. The two CARTO systems are based on magnetic fields produced by coils located on a pad placed underneath the patient’s thorax. Magnetic coils in the distal tip of catheters continually measures the strength of the magnetic field and calculates the catheter’s distal tip position in respect to the field. The testing system generate sinusoidal waveforms. Those waves are then amplified and sent to the Magnetic Field Fixture coils to simulate the test magnetic field. The magnetic field is received by EP Catheter Location Sensors and sent to the software that compares the test data to predefined acceptance criteria established using unused OEM catheters to generate a pass/fail result.

Ultrasound Transducer Test

The purpose of the Ultrasound Transducer Test is to provide repeatable and quantifiable data required to determine the operational effectiveness of the Reprocessed Diagnostic Ultrasound Catheter transducer function. The Ultrasound Transducer Test can detect the failure of any element from one of number of root causes, such as dead or weak crystals within the ultrasound array, acoustic performance parameters of the ultrasound array, acoustic lens delamination, broken wires within the probe cable, broken wires within the flex circuit within the probe and also for defective electronics within the probe connector. A widely used probe testing device that is the industry standard for testing the acoustic and electrical properties of ultrasound transducers. By independently exciting each crystal within the array of the probe, the Ultrasound Transducer Test measures the relative sensitivity of each element and analyzes the acoustic signature of the returning pulse for any variations in key performance characteristics.

Inspection

Physical, mechanical and electrical testing is performed to provide objective evidence that the reprocessed device meets specifications and functions as intended.

The following tests are performed on 100% of the devices during reprocessing:

- Visual Inspection
- Curve Template / Functional (Steering Mechanism) Testing
- Location Sensor
- Ultrasound Transducer Testing
- HIPOT / Current Leakage Testing
Exhaustive testing was conducted to verify and validate Innovative Health’s decontamination, cleaning, assembly, packaging and sterilization processes. During the design and development phase, the following functionality tests/assessments are performed as applicable to each device: Visual Inspection, Dimensional Inspection, Packaging Assessment, Valve Leak Testing, Joint Leak Testing, Simulated Use, Catheter Joint Tensile Testing and Radiopacity. These devices and related processes are validated according to accepted FDA and industry standards such as ISO, AAMI, etc. and to meet applicable confidence intervals as required.

The purpose of the HIPOT testing is to evaluate how well the outer shaft of the device contains and insulates from voltage leaks. Sparking or arcing is characterized by rapid variations in voltage or current that typically results in failure. If kinks, cuts or abrasions are present within the material, an escape path is created for the voltage. Maintaining an adequate dielectric barrier between the electrical power and the patient is critical in terms of power surges.

A Validated Process

Estimated Annual Savings: **$113,850**

Estimated Percent Savings: **40%**

*Based on average annual facility usage of 115 SoundStar devices

Innovative Health is proud to offer the following SoundStar devices for reprocessing:

<table>
<thead>
<tr>
<th>Model Number</th>
<th>French Size</th>
<th>Device Family</th>
<th>Catheter Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNDSTR10</td>
<td>10F</td>
<td>SoundStar 3D Diagnostic Ultrasound Catheter</td>
<td>90cm</td>
</tr>
<tr>
<td>SNDSTR10G</td>
<td>10F</td>
<td>SoundStar 3D Diagnostic Ultrasound Catheter</td>
<td>90cm</td>
</tr>
</tbody>
</table>
Developing a 510(k) to achieve FDA Clearance to Reprocess Single-Use Devices

The FDA requires reprocessors 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 contaminates 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.

*SoundStar is a trademark of or licensed to Biosense Webster, Inc or one of its subsidiaries.*

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INNOVATIVE HEALTH

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