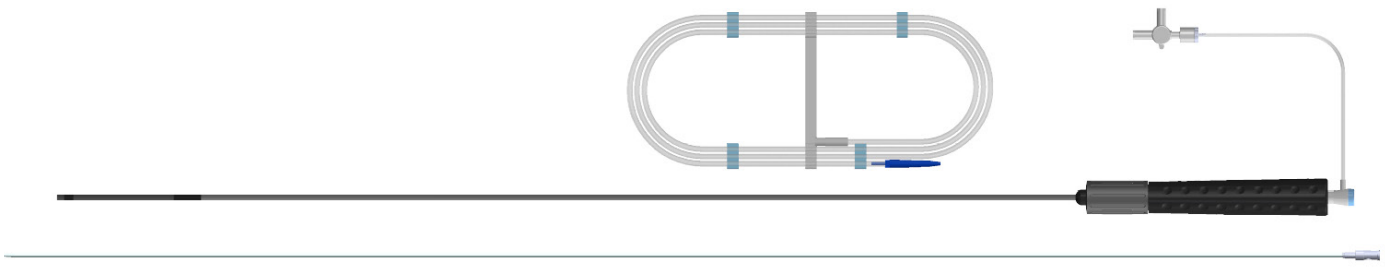
INNOVATIVE HEALTH

Product Spotlight

Agilis NxT Steerable Introducer

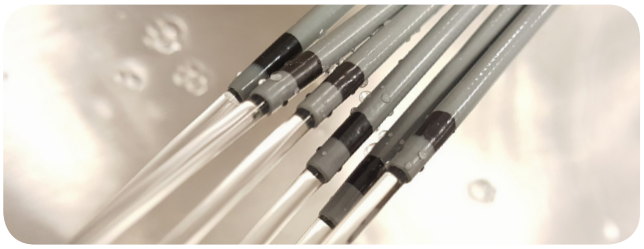
The Agilis NxT steerable introducer consists of a steerable sheath, dilator, and guidewire.The steerable introducer is a bi-directional transseptal guiding sheath utilized by many EP interventionalists for ablation and mapping procedures. It is indicated when introducing various cardiovascular catheters into the heart including the left side of the heart through the interatrial septum. The guiding sheath provides enhanced control, navigation, and rotation for optimal application of ablation therapies to achieve desired clinical results. The braded low profile Agilis NxT sheath provides enhanced stability and durability in combination with an integrated stabilized steering mechanism.



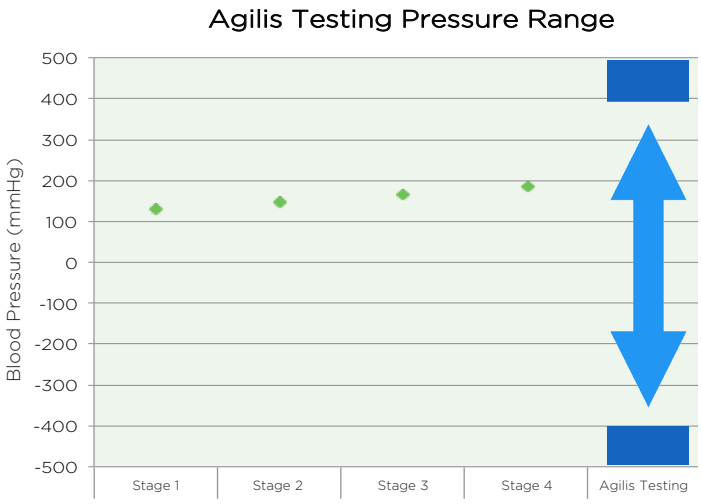
Cleaning

Innovative Health's validated cleaning process has been specifically designed and tested to provide consistent and repeatable results with high confidence and reliability. Upon receipt, the devices are disassembled to allow for access to both lumens and valves. 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.



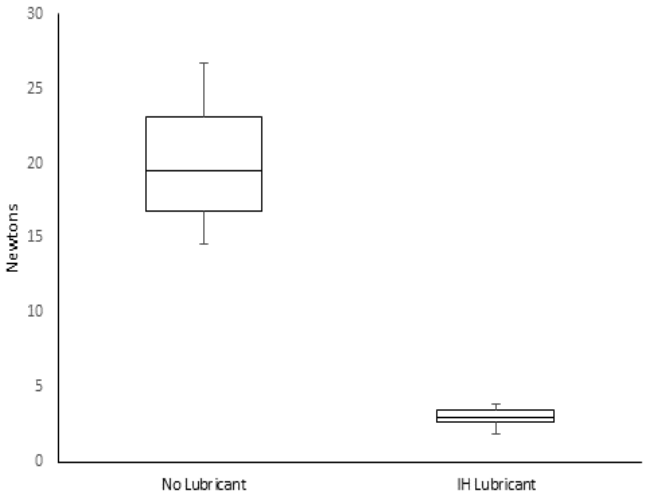
Hemostasis Valves



The hemostasis valves are pressure test challenged on a proprietary leak test system prior to and following assembly. The same system is also used to test dilators and introducers for leaks and occlusions.

Reprocessed introducers are tested to withstand blood pressure ranges greater than those seen in patients presenting with Stage 4 hypertension. The test parameters exceed performance standards to ensure patient safety.

Following extensive inspection and testing, device sets are reassembled. New hemostasis caps are bonded, locking the valves in place. The addition of a new stopcock completes the assembly. The completed device is subjected to a second phase of pressure testing to ensure the device performs as intended and meets Innovative Health's strict quality standards. Following the same phases of cleaning, testing and inspection, Agilis dilators are pressure tested and then coated with a medical grade biocompatible lubricant to enhance crossing profile and reduce insertion forces into the introducer nearly 10x. Dilators are paired with an introducer and packaged with a new *J-tip guidewire.*



The Environment

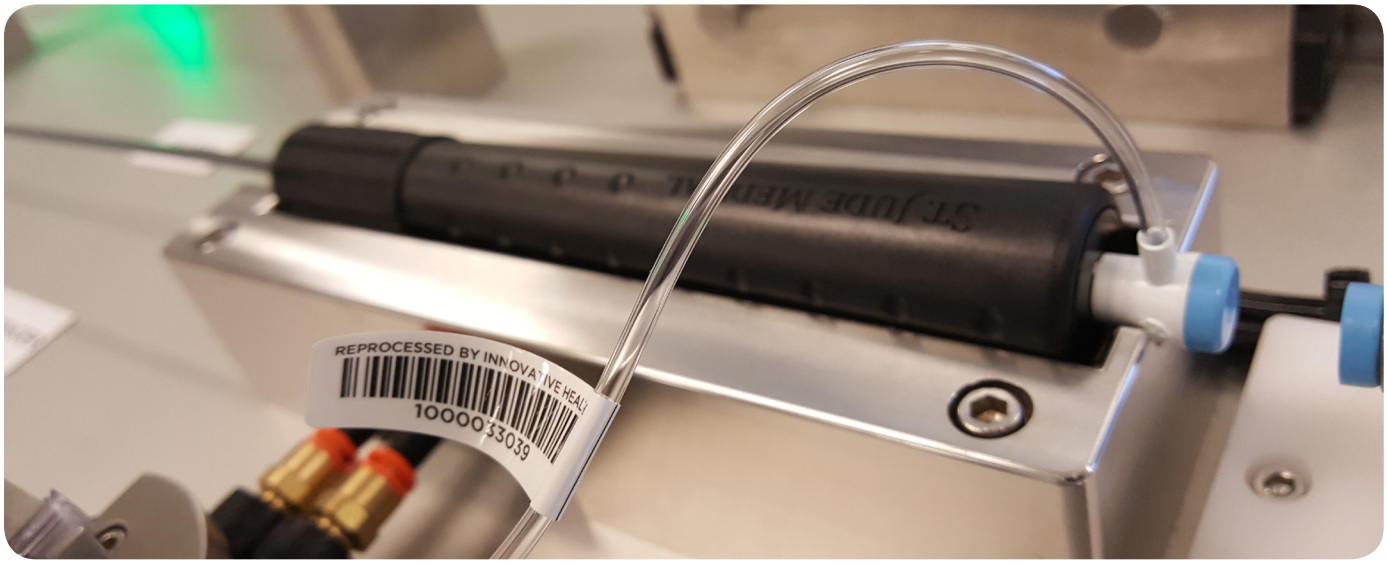
Our logo isn't the only thing that is "green". Our easy-to-open, branded packaging uses considerably less material than the original manufacturer, allowing for nearly twice as many devices to be stored in the same space. We have also replaced the vinyl-based tray with a more eco-friendly polymer, which performs just as well and is 100% recyclable.

Inspection

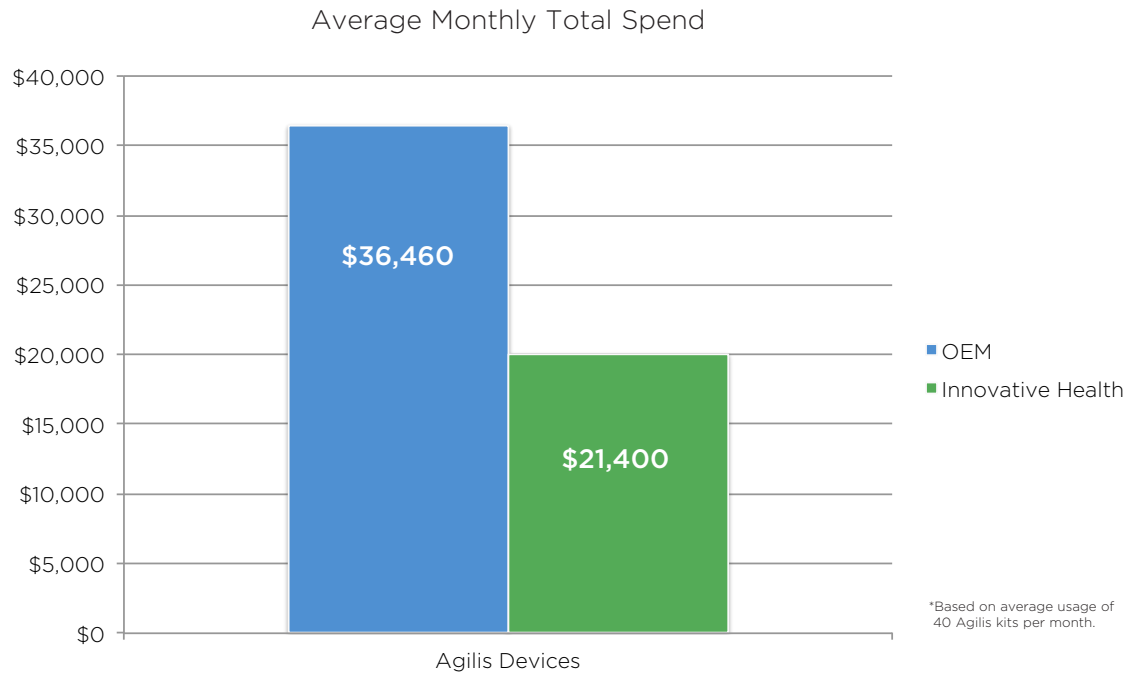
Inspection of the introducer sheath and dilator is performed throughout the process to ensure devices meet Innovative Health's internal requirements. The devices undergo internal and external inspection using lighted magnification, tactile assessment, leak testing, and functional evaluation (i.e. curve deflection, stopcock function, and luer lock connectivity) using specifically designed curve templates to align with the original manufacturer's specifications.

A Validated Process

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: 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.



41% realized savings by partnering with Innovative Health



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 hemocompatability 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.

INNOVATIVE HEALTH

Please contact your local Innovative Health representative or our corporate offices.

877.400.3740
www.innovative-health.com
info@innovative-health.com