INNOVATIVE HEALTH

WHITE PAPER

ELECTROPHYSIOLOGY · SINGLE-USE DEVICE REPROCESSING

Solving the Microlumen Challenge

The Invention that enabled FDA-Cleared Reprocessing of the PentaRay™ Mapping Catheter.

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Innovative Health

THE DETAIL THAT CHANGED REPROCESSING

An irrigation microlumen roughly the diameter of a couple of human hair strands — too small to inspect, too delicate to probe.

SUMMARY

Verifying a lumen that cannot be seen — on every reprocessed device.

Reprocessing of advanced electrophysiology mapping catheters presents a distinct validation challenge when device performance depends on internal microlumen architecture that cannot be directly visualized or mechanically probed after clinical use. The PentaRay mapping catheter, originally manufactured by Biosense Webster, combines a multi-spline, high-density mapping design with an internal irrigation lumen for continuous anticoagulant fluid delivery and compatibility with the CARTO 3 mapping system. In 2019, Innovative Health received U.S. Food and Drug Administration clearance to reprocess this catheter after developing new protocols for microlumen cleaning and verification, including a mass-flow-based method capable of detecting clinically relevant obstructions.

FDA-regulated reprocessing requires reprocessed single-use devices to meet the same regulatory standards for safety and effectiveness as the original device manufacturer. Beyond technical feasibility, successful reprocessing of this device class has implications for hospital cost reduction, waste reduction, and broader adoption of circular supply practices in healthcare.

2019	50µm	US 10,830,682
First FDA clearance to reprocess a microlumen mapping catheter	Single obstruction detectable anywhere along the lumen	Patented mass-flow microlumen verification method

WHAT THIS PAPER COVERS

BACKGROUND · 2017

The channel that broke reprocessing

The year is 2017, Electrophysiology has already entered an era defined by high-density mapping catheters. To achieve this, the catheter architecture had to evolve by incorporating complex design, advanced materials and biosensors. Complex procedures performed with complex devices within the constrained spaces of cardiac chambers could lead to complex problems. One of the design solutions used to address these complexities was the introduction of a channel (or an open tube within the device) that runs the entire length of the device. This tube allowed the delivery of anticoagulants through the device itself during electrophysiology procedures.

This design feature (a lumen for anticoagulant delivery during procedure) addressed the clinical concerns around thrombogenicity. But the same feature (a fluid channel or pathway through the device) introduced challenges that made the standard reprocessing methods used till then ineffective:

> **How will you inspect inside the lumen? How can you establish that the lumen is clean, as in free from clinical or reprocessing residuals or particles?**

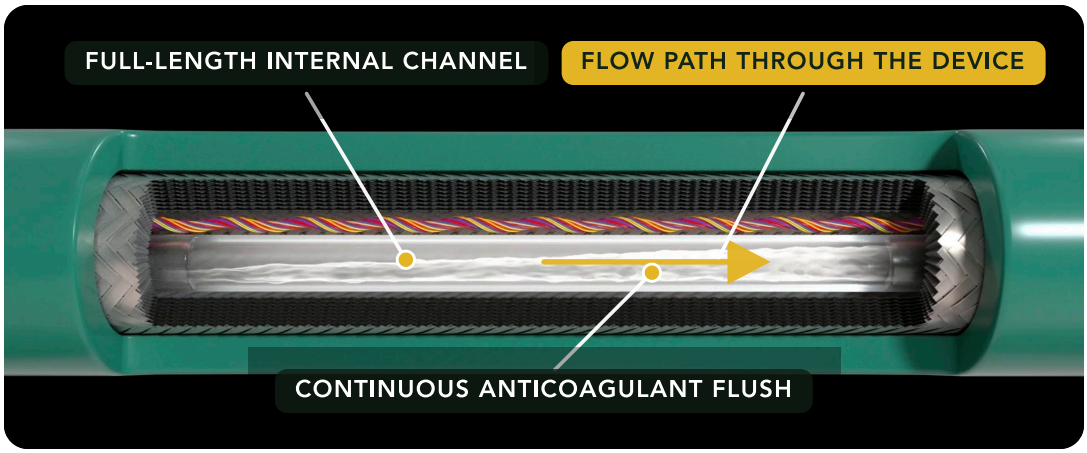
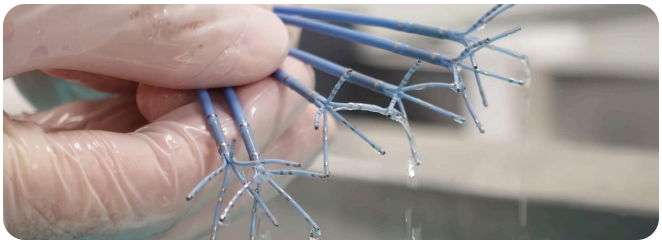
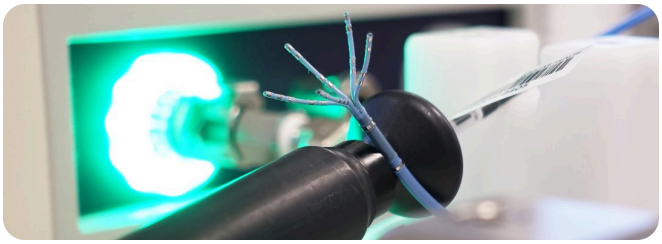


Image 1: A cut-away of the catheter shaft. A single full-length internal channel delivers a continuous anticoagulant flush — the flow path that runs through the entire device.





THE ORIGIN

The Microlumen Challenge

My team was challenged to develop a validated reprocessing method for the Biosense Webster PentaRay mapping catheter. PentaRay is an advanced mapping catheter with an irrigation channel that delivers heparinized saline during the clinical procedure. We called it a microlumen device, as the lumen was too small to inspect visually, too delicate to probe, but were confident that a process can be developed that can clean it. We did and successfully validated our cleaning process for PentaRay Mapping Catheter using "worst case" condition test samples. Worst case here refers to level at which simulated clinical soil is applied onto the samples, process conditions and parameters used (low temperature, low duration, low concentration), excess sterilization cycles, extreme transportation conditions etc. We presented our validation and verification study summaries along with the plan to perform routine cleanliness monitoring via sampling from processed lots while seeking clearance to sell in the 510(k) submission, but the FDA wanted more. The central technical and regulatory hurdle was the ability to demonstrate, with sufficient sensitivity and reliability, that the microlumen was both clean and unobstructed after reprocessing, on every single reprocessed device. We set out to develop a solution ourselves, because no off-the-shelf systems or methods existed at the time.

> **The microlumen was both clean and unobstructed after reprocessing, on every single reprocessed device.**
>
> THE HURDLE THE FDA SET

Over the next two years, we developed a novel mass-flow detection method capable of identifying a single 50-micron particle inside the microlumen of this device with significantly high confidence and reliability. This invention enabled the first FDA clearance to reprocess an advanced mapping catheter with a microlumen in 2019. Today, this method has evolved and capable of testing several different microlumen devices within electrophysiology, while helping establish a new standard for safety and innovation in medical device reprocessing.

01

SECTION ONE

The Science of Microlumen Reprocessing

The Rise of Advanced Mapping and Sensing Catheters

Electrophysiology mapping catheters have evolved from relatively simple diagnostic tools into highly engineered systems designed to generate high-density anatomical and electrical maps with minimal manipulation. Modern devices may incorporate multi-electrode arrays, embedded location sensors, thermocouples, dense internal wiring, multi-spline architectures, and narrow internal fluid channels:

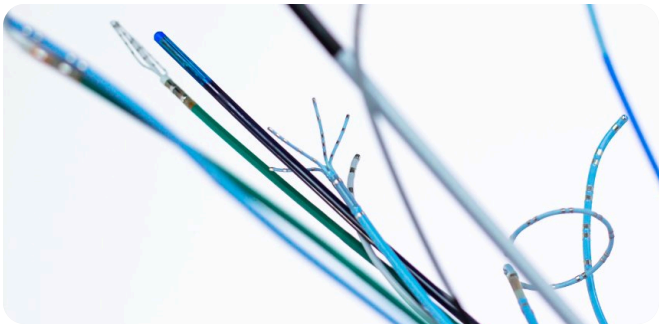
- Multi-electrode arrays
- Embedded thermocouples
- High-density wiring
- Multi-spline architectures
- Microlumen channels to introduce anticoagulants during the procedure

These microlumens and injections of anticoagulants are not optional; they are essential to the device's performance and safe use.

The Microlumen Innovation in the PentaRay Mapping Catheter

The PentaRay mapping catheter stood apart in electrophysiology because of its microlumen-based flushing system and multi-spline design, features that are both clinically essential and engineeringly challenging. Unlike traditional EP introducers with large lumens used for device introduction or high-volume irrigation, the PENTARAY uses a single, ultra-narrow microlumen to deliver a continuous flush of anticoagulant solution during mapping procedures.

> Why it stands apart
>
> A single, ultra-narrow microlumen — not a large introducer lumen — delivers a continuous anticoagulant flush throughout the mapping procedure.



Functional Role of the Microlumen

The PentaRay's five splines radiating from a central hub create numerous small crevices and surface areas where blood can stagnate. During long mapping procedures, especially in the left atrium, stagnant blood can clot rapidly.

To prevent thrombus formation, the PentaRay delivers a low, constant flow of anticoagulants through its central microlumen. This flush continuously washes the neck region where the splines meet, reducing the risk of clot formation.

> The neck region
>
> Where five splines meet the hub, crevices invite stagnation. A constant central flush keeps that junction washed throughout the procedure.

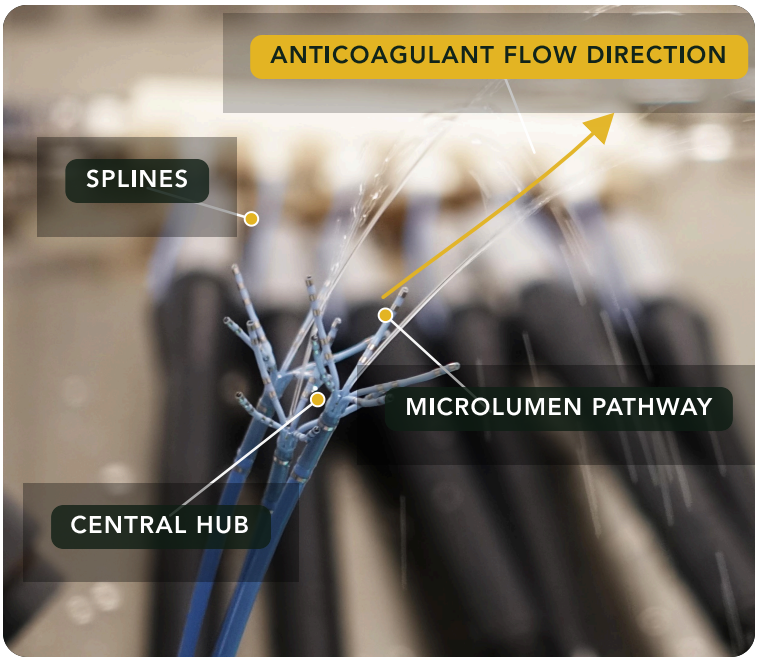
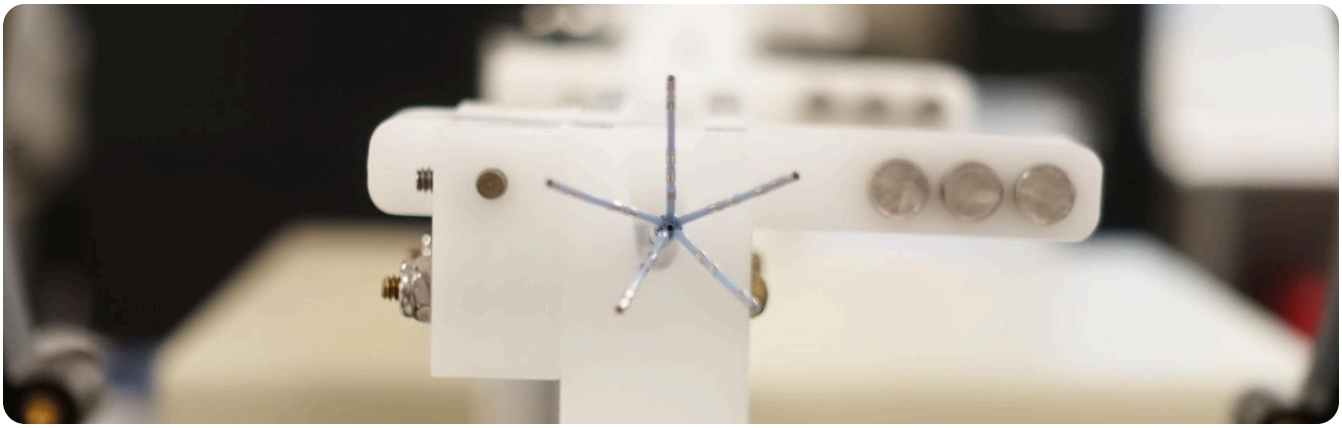


Image 2: Five splines radiate from a central hub; a single microlumen delivers a continuous anticoagulant flush across the neck region where the splines meet.



The Design Constraint that Drove Reprocessing Innovation

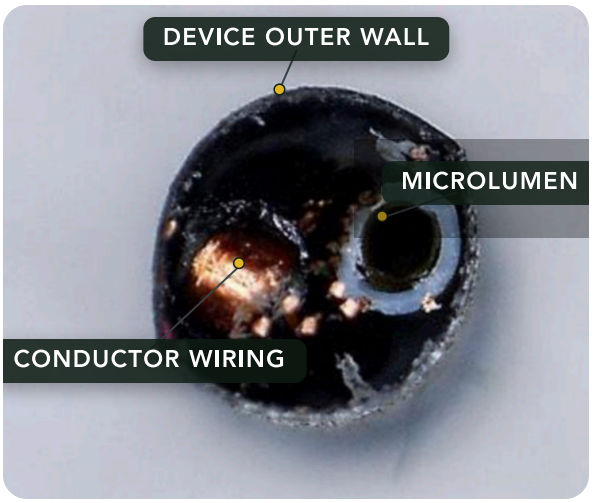


Image 3: An actual device cross-section. The irrigation microlumen sits within the outer wall, alongside the conductor wiring — its bore roughly the diameter of a couple of human hair strands.

The microlumen inside the PentaRay is extremely narrow relative to conventional catheter channels. Roughly the diameter of a couple of human hair strands. Its dimensions were balanced to preserve catheter flexibility, protect internal conductors and sensors, limit overall profile, and maintain distal spline articulation.

- Maintain catheter flexibility
- Protect internal wiring
- Avoid increasing catheter profile
- Preserve spline articulation
- Support multi-electrode mapping without adding bulk

This design is brilliant from a clinical engineering standpoint, but it created a new challenging scenario for reprocessing.

Why Conventional Reprocessing Methods Were Inadequate

From a reprocessing engineering perspective, the device's multi-spline geometry increases surface complexity in the distal region and may create localized conditions in which blood exposure and stagnation become relevant during lengthy procedures. In addition, this lumen cannot be treated as a secondary feature. It is a functional pathway directly tied to both device performance and patient safety and therefore must be shown to be both clean and unobstructed after reprocessing.

Conventional reprocessing approaches were inadequate for microlumen cleaning for three reasons. First, the lumen was too small to permit meaningful direct visualization along its full length. Second, mechanical access using wires, brushes, or probes introduced unacceptable risk of deforming the lumen or damaging adjacent internal components. Third, simple confirmation that fluid could traverse the lumen did not establish the absence of partial obstruction, adherent residue, or clinically relevant particulate matter.

TWO REASONS CONVENTIONAL CLEANING COULD NOT REACH THE MICROLUMEN

Too Small for Visual Inspection

- No borescope or camera in the market that can navigate a lumen this narrow.
- Hard to visualize its internal surface using x-ray or other methodologies.
- Light couldn't reach the full length of the channel.

Too Delicate for Mechanical Cleaning

Any attempt to insert a wire, brush, or probe risks:

- Damaging internal wires or conductors
- Scraping insulation
- Deforming the lumen
- Pushing debris deeper

Mechanical methods are simply incompatible with microlumen devices.

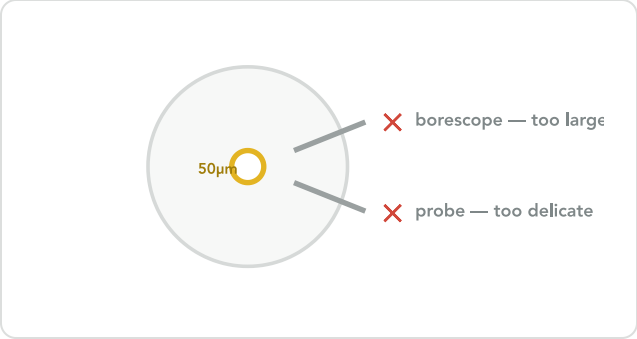


Image 4: Neither optical inspection nor mechanical probing can safely enter a lumen this narrow — the constraint that forced an indirect, quantitative approach.

With the lumen too small to see and too delicate to touch, the only path forward was an indirect method — one that could establish cleanliness and patency without ever entering the channel. That requirement set the agenda for everything that followed.

02

SECTION TWO · THE STAKES

What Happens If a Microlumen Is Not Properly Cleaned

Because the microlumen supports delivery of anticoagulant fluid during use, residual internal material after clinical exposure may present multiple forms of risk if not removed during reprocessing. These potential risks include particulate release, impaired lumen performance, retention of biologic material, and secondary effects on adjacent device structures.

01

Residual Organic and Anticoagulant Material

Blood components and anticoagulant residues may dry within the lumen and form adherent deposits that trap additional material, support biofilm formation, and increase resistance to subsequent cleaning and sterilization steps.

02

Particulate and Embolic Risk

A partial obstruction or dried particle within the lumen may dislodge during subsequent use. At microlumen scale, even a single particle on the order of 50 microns can represent a meaningful restriction during testing and a potentially relevant risk if released into the bloodstream.

03

Device Integrity and Electrical Interference

If residue breaches internal spaces or interacts with adjacent components, it may contribute to corrosion, altered impedance, signal distortion, or reduction in mapping reliability. These considerations reinforce the need for reprocessing methods that protect both cleanliness and functional performance.

- Corrode the internal wiring
- Alter impedance
- Distort mapping signals
- Reduce diagnostic accuracy

04

Device Malfunction

Obstruction can restrict intended flushing, alter internal pressure-flow relationships, and compromise the functional performance of the device. For this reason, lumen patency must be demonstrated quantitatively rather than assumed from gross fluid passage alone.

- Restrict flushing
- Increase internal pressure
- Damage wiring
- Reduce spline articulation

05 · Infection Risk

Residual biologic material may also protect microorganisms within dried proteinaceous matrices, increasing the importance of effective cleaning before terminal disinfection or sterilization. Residual material can harbor **bacteria**, **viral particles**, and **biofilm colonies** — these can survive sterilization if protected inside dried protein matrices.

03

SECTION THREE · THE REGULATORY WALL

The PentaRay Challenge: A Device That Broke the Traditional Reprocessing Cleaning Process

Under FDA oversight, reprocessed single-use devices are regulated to the same standards for safety and effectiveness as devices supplied by the original manufacturer. For a device such as the PentaRay catheter, this means the reprocessor must demonstrate that the reprocessed device can be adequately cleaned, function as intended, and remain equivalent in relevant performance characteristics after reprocessing.

The PentaRay catheter introduced a new level of complexity:

- Five splines
- Several planes of electrodes
- Embedded wiring
- A microlumen channel narrower than a couple of human hair
- No access for borescopes
- No ability to mechanically probe without damage

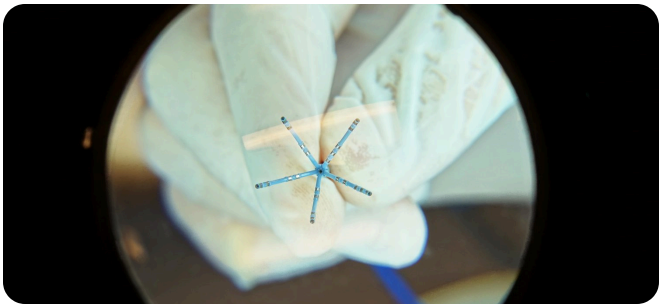
> **"You must prove the microlumen is clean and clear, for every device."**
>
> THE FDA'S REQUIREMENT WAS CLEAR

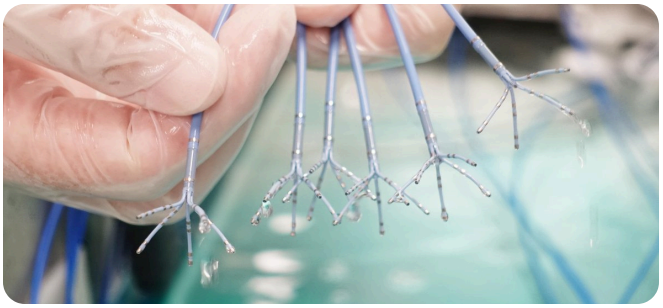
But the lumen was:

Too small to see	**Too fragile to probe**
Too complex to scope	**Too valuable to destroy**

This was the moment we realized advanced mapping catheters had outpaced traditional reprocessing technology.

The challenge was to show that the internal channel was both clean and clear despite the absence of practical visual inspection methodologies. This requirement drove development of new cleaning protocols, worst-case test conditions, device-specific fixtures, and a quantitative verification approach capable of detecting partial occlusion at clinically relevant scale.





04

SECTION FOUR · THE CHEMISTRY

Dissolving the BioGlue: The Chemistry Behind Microlumen Cleaning

Cleaning of the microlumen requires more than simple flushing. During clinical use, the lumen is exposed to blood components and heparinized fluid, both of which can leave deposits that behave differently from ordinary saline residues after drying. Effective reprocessing therefore depends on chemistry, temperature control, and flow conditions capable of removing adherent organic material without damaging the catheter.

Residue Formation and Removal Challenges

When anticoagulants like heparin and biologic residues dry within a microlumen, they can form sticky substances rather than free-flowing particulates. These films may bond to polymeric surfaces and to transition points near joints or spline interfaces, making them more difficult to remove than crystalline salt deposits.

For example, when heparin dries inside a lumen, it forms a sticky, protein-like film that adheres to:

- Pebax, Polyimide or similar polymers that make up the lumen walls
- Junction points where splines meet and
- Spaces between electrodes, bonds or joints

This dried residue behaves like bioglue, trapping:

- Blood proteins
- Cellular debris
- Micro-clots
- Environmental contaminants

If not removed, these deposits may trap blood proteins, cellular debris, and environmental particulates, eventually hardening into material that resists normal detergents and can obstruct the lumen.

Enzymatic Digestion: Breaking Down the Organic Matrix

Enzymatic detergents are used to disrupt organic matrices without degrading device materials. In this application, the objective is not only to dissolve residue but also to release material that has adhered to narrow internal surfaces under low-clearance flow conditions.

To remove this bioglue, enzymatic detergents are used that are specifically formulated to break down:

- Protein bonds
- Polysaccharide chains
- Organic residues
- Heparin matrices

These enzymes digest the residue without degrading the catheter's materials, a critical requirement.

Temperature Control: The Enzyme "Sweet Spot"

Enzymatic activity is temperature dependent. If process temperatures are too low, residue breakdown may be incomplete; if too high, enzymatic function and device material compatibility may be compromised. Maintaining a validated operating range is therefore necessary to achieve consistent cleaning performance while preserving the form, fit and functional characteristics of the catheter.

Enzymes are highly temperature-dependent.

Too cold → they are inactive.

Too hot → they denature and lose function.

The optimal range is typically 40°C – 50°C, which:

- Maximizes enzymatic activity
- Accelerates breakdown of heparin residue
- Protects the catheter's shape-memory splines
- Prevents thermal deformation of polymers

This precise temperature control is essential for consistent cleaning performance.

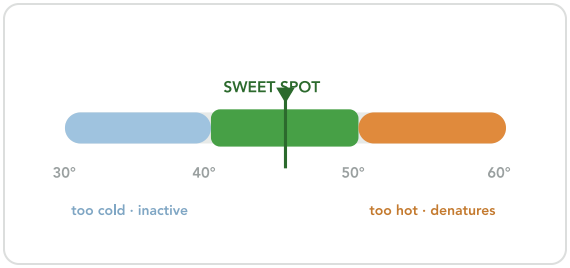


Image 5: Enzyme activity peaks in a narrow validated window of 40–50 °C. Precise temperature control is essential for consistent cleaning.

05

SECTION FIVE · THE BREAKTHROUGH

The "Mass-Flow" Verification: The Method That Changed Everything

Even after validated cleaning, direct visual confirmation of internal microlumen conditions remains impractical because the lumen diameter is only slightly larger than a human hair. Under these conditions, a single microscopic obstruction may be clinically relevant while remaining undetectable through conventional inspection methods.

To address this limitation, a mass-flow-based microlumen verification method was developed and validated for use in the reprocessing of the PentaRay catheter (US 10,830,682).

Mass-Flow Testing: The Principle

At its core, mass flow testing treats the microlumen like what it really is: a long, ultra narrow flow path with a predictable resistance. If the lumen is truly clear, a controlled source of air (or fluid) pushed through that path produces a repeatable flow response under the same pressure and time conditions. But if anything is inside, be it dried heparin film, residue, a micro clot, or a single particle, the effective cross section changes, resistance increases, and the flow response shifts. In a microlumen, small changes matter. A 50-micron obstruction is not "small" relative to the lumen; it is a meaningful restriction.

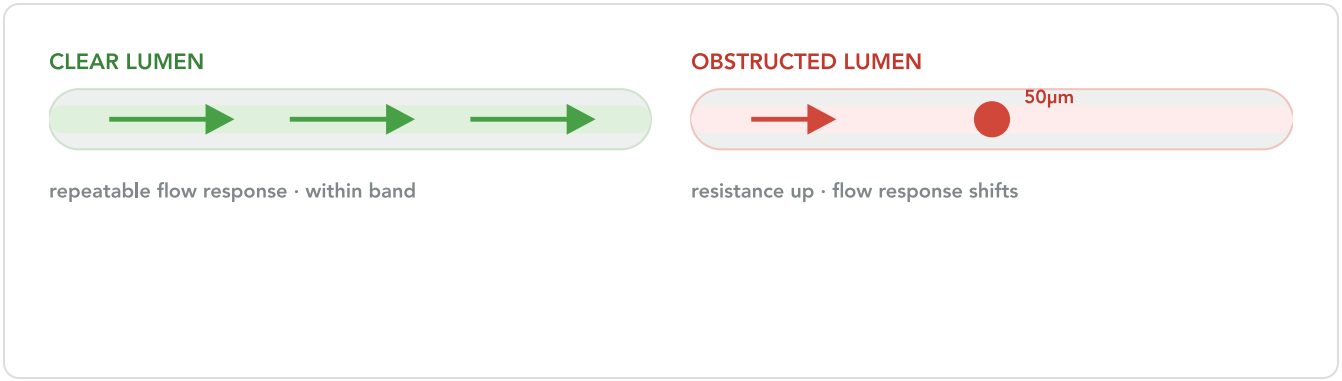
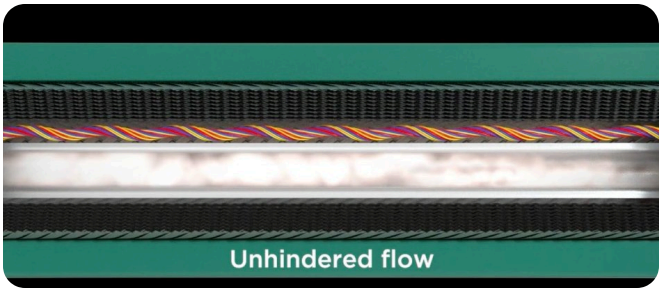
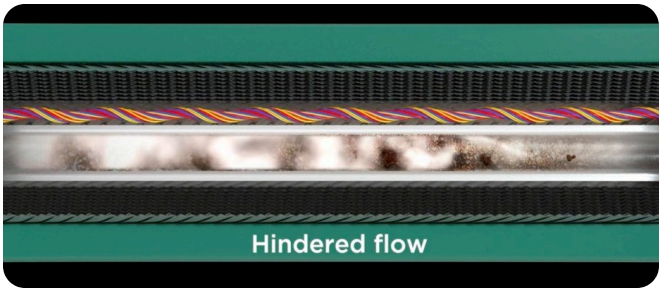


Image 6: The microlumen behaves as a flow path with predictable resistance. A clear lumen returns a repeatable response; any internal obstruction raises resistance and shifts the flow.





Mass-Flow Testing: Beyond "Water Comes Out the End"

A lumen may permit visible outlet flow while still containing dried residue, adherent film, biofilm, micro-clots, or particulate matter that narrows the flow path. Gross flow observation can confirm that fluid passes through the channel, but it cannot reliably detect subtle narrowing that may still be clinically relevant.

A lumen can pass fluid while still containing:

- Dried heparin
- Micro-clots
- Salt crystals
- 50-micron debris
- Biofilm

Quantitative mass-flow testing measures the actual flow rate of air or fluid through the lumen with extreme precision to detect changes that would not be identified through simple pass-through observation. Even a tiny obstruction changes the flow signature.

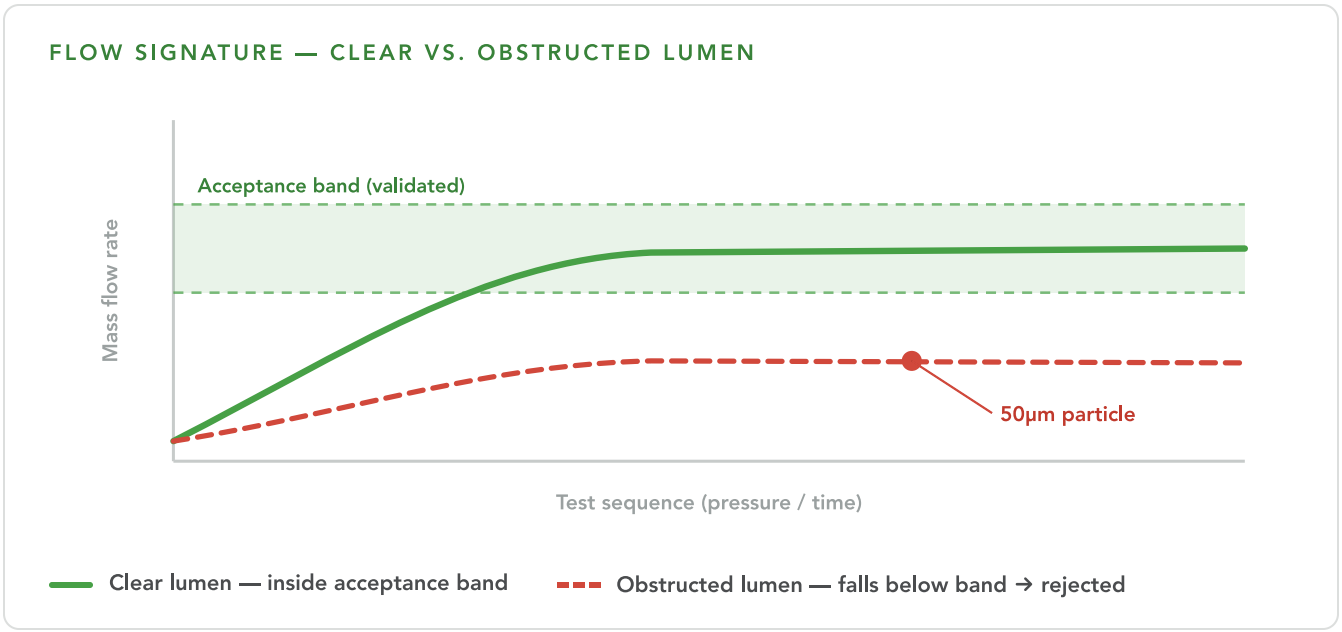
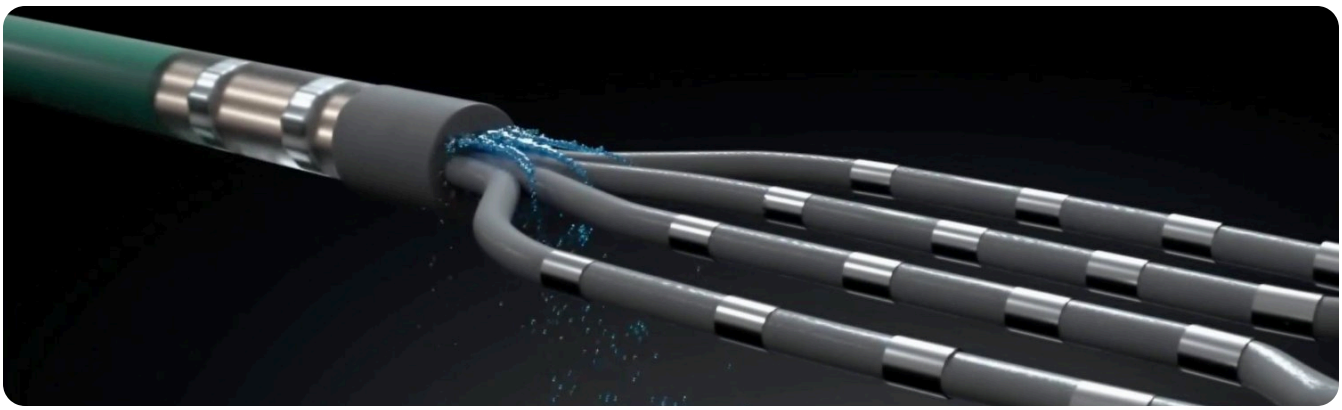


Image 7: A partial blockage can still allow outlet flow, but it distorts the signature in consistent, measurable ways — detecting what the eye can't see and a basic flush can't prove.



The “Signature” Creation

The baseline flow signature for the PentaRay catheter was established through device-specific testing and statistical modeling. The validation set included unused devices, devices challenged with controlled 50-micron particle, and reprocessed devices subjected to the intended cleaning process.

THE BASELINE FLOW PATTERN OF THE PENTARAY CATHETER WAS MODELLED AND DEVELOPED FROM:

60
Flow curves of 60 brand-new devices

60
Flow curves of 60 new devices inoculated with a single 50-micron particle

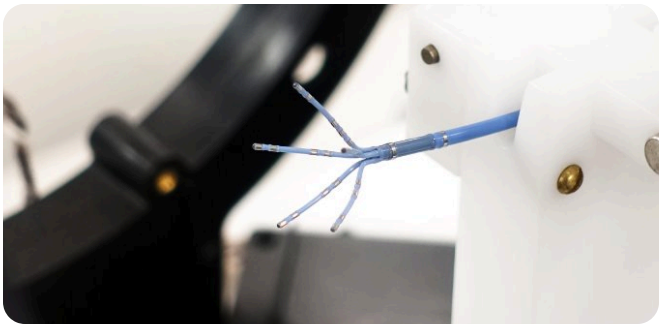
60
Flow curves of 60 reprocessed devices

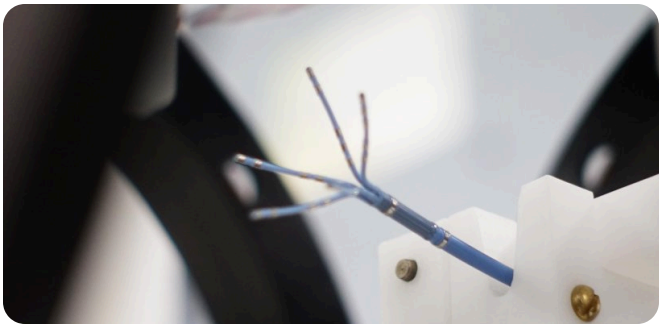
When a reprocessed device is tested:

- Its flow rate is compared to these established baselines
- Mass-flow deviations as small as a 50-micron particle, anywhere along the lumen can now be detected
- The device is automatically rejected if the mass-flow is out of the validated range

This approach provided a validated means of detecting clinically relevant obstruction in a microlumen that could not be assessed adequately by direct visualization or gross flow checks alone. This is the first method capable of detecting clinically relevant obstructions in microlumens.

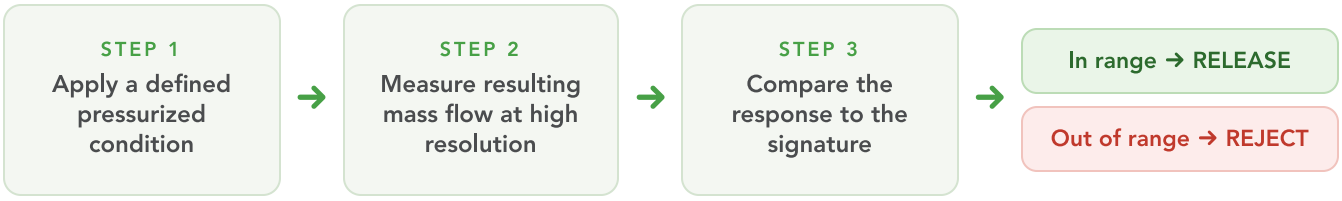
The first method capable of detecting clinically relevant obstructions in microlumens.





Detection Logic and Test Execution

Now you know that the detection is not a guess and it is also not a simple pass/fail "does it flow" check. We built a controlled inspection system that can test a device by applying a defined pressurized condition and measuring the resulting mass flow with high resolution. During testing, the system records the flow response of the reprocessed PentaRay catheter and compares it to the signature. A partial blockage can still allow flow at the outlet, but it will distort the test signature in ways that are consistent and measurable. That is how we detect what the eye can't see and what a basic flush can't prove.



> A partial blockage can still allow flow at the outlet, but it will distort the test signature in ways that are **consistent and measurable** — that is how we detect what the eye can't see and what a basic flush can't prove.

Why "Clear" Is Better Than "Clean"

Absence of visible residue is not equivalent to verified lumen clearance. A microlumen may appear functionally open while still containing residuals capable of altering flow performance or being released during use.

A lumen can be "clean", meaning no visible residue, but still contain:

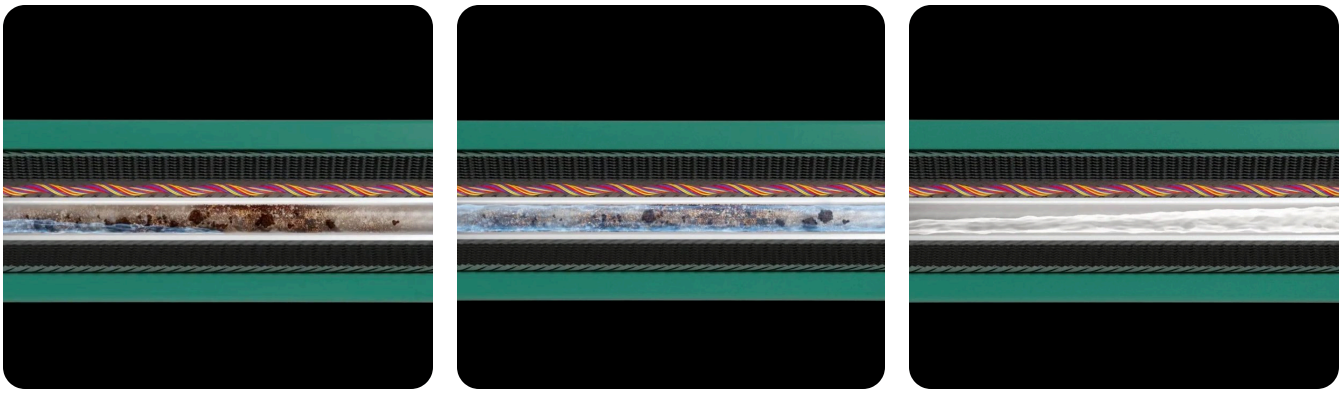
- Salt crystals
- Dried heparin
- Microscopic debris

If any of these breaks loose during a procedure, it can enter the bloodstream and potentially cause embolism. Accordingly, validation must demonstrate more than simple fluid passage. It must show that the lumen has been effectively cleaned, remains free of clinically relevant obstruction, satisfies defined quantitative flow criteria, and can be assessed by a method sensitive enough to detect a single 50-micron particle.

Validation performed needed to prove:

- The lumen is clean,
- The lumen is clear,
- The lumen is free of obstructions,
- The lumen meets quantitative flow criteria,
- The method is validated and can show the capability to detect one 50-micron particle.

Our inspection method satisfied all these requirements.



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SECTION SIX · FROM INVENTION TO CLEARANCE

Inventing the Mass-Flow Detection Method

Implementation of the method required device-specific engineering, fixture design, clearly defined flow parameters, and statistically supported acceptance criteria.

Device-Specific Fixture and Test Design

Because the catheter geometry and internal flow path are device-specific, the verification method required a dedicated fixture, tailored flow parameters, and acceptance criteria derived from the validated response of this device family.

Statistical Validation

Statistical validation incorporated data from new devices, worst-case soiled devices, repeated reprocessing cycles, and controlled obstruction challenges. These data were used to establish confidence- and reliability-based acceptance limits appropriate for routine screening of reprocessed devices. This level of rigor was necessary for a method intended to support regulatory submission and patient-facing release decisions.

Image 8: Validated reprocessing operations supporting device-specific fixturing, tailored flow parameters, and statistically derived acceptance criteria.

2019

FIRST-EVER CLEARANCE

FDA Collaboration and Clearance

In 2019, FDA granted the first-ever clearance to reprocess a microlumen device. This was a milestone for the entire reprocessing industry. We worked with FDA through the pre-submission process to define appropriate test methods for the PentaRay catheter and ultimately received clearance after establishing industry first protocols for microlumen specific inspection, patency verification, and compatibility demonstration.

FDA RECOGNIZED

- The novelty of the method
- The sensitivity of detection
- The statistical rigor and
- The extensive validation

07

SECTION SEVEN · WHY IT MATTERS

Environmental and Economic Impact

The significance of this development extends beyond a single device. FDA states that reprocessed single-use devices must remain as safe and effective as the original manufactured devices, and healthcare facilities use regulated reprocessing to reduce both costs and medical waste. In that context, successful reprocessing of a technically challenging mapping catheter suggests that sustainability goals and high-complexity device performance can be aligned when validation requirements are met.

REPROCESSING THE PENTARAY:

- Preserves advanced technology
- Reduces environmental waste
- Saves hospitals millions
- Extends device life
- Supports sustainable healthcare

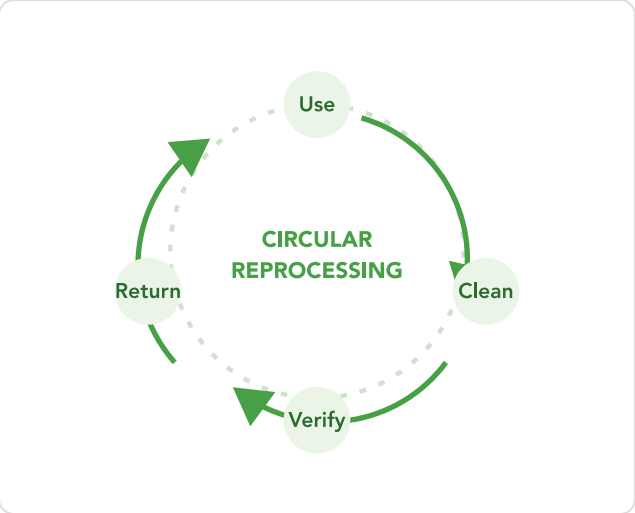


Image 9: Validated reprocessing keeps advanced devices in a circular supply loop — aligning sustainability goals with high-complexity device performance.

> **Without innovation, hospitals would lose these benefits as device complexity increased.**

08

SECTION EIGHT · THE LANDSCAPE

Competitive Landscape: Why This Method Stands Out

There are other methods published that attempts to address microlumen inspection using:

Pressure-based detection	Seal deformation	Mechanical expansion	Contact-based sensing

These methods have inherent limitations that we faced during the FDA review process:

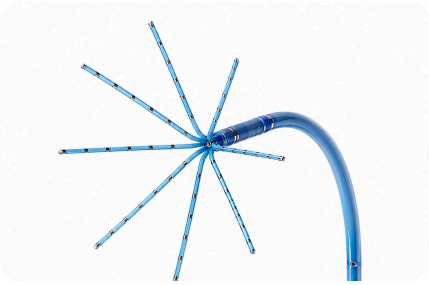
! **Detects Obstructions, But Do Not Validate Cleaning**
Innovative Health's validated method inspects for cleanliness, not just obstruction.

! **Require Physical Contact or probing**
Those risks damaging delicate internal components.

! **Cannot Reliably Detect Particles**
Innovative Health uses a validated detection method capable of detecting one single 50-micron particle.

Expanded Capability

As catheter platforms continue to incorporate smaller lumens, denser sensing arrays, and more complex internal architectures, reprocessing science will increasingly depend on indirect but validated analytical methods. The method described here suggests a practical model for future design architectures involving multi-lumen, pressure-sensing catheters, and other products in which internal cleanliness and patency cannot be established through direct inspection alone.



CONCLUSION

A problem once believed to be impossible — now a standard.

Reprocessing the PentaRay mapping catheter required a solution to a problem that was simultaneously technical, clinical, and regulatory: how to verify the condition of an internal microlumen that could not be directly inspected after use. The invention of the mass-flow microlumen occlusion detection method represents a breakthrough in medical device reprocessing by providing a quantitative, validated means of assessing lumen patency and detecting clinically relevant obstruction. It solved a problem once believed to be impossible, enabled the first FDA clearance of a microlumen device, and established a new standard for safety, efficacy, and innovation.

As advanced mapping and sensing technologies continue to evolve, so must the methods used to preserve their value. This invention ensures that reprocessing remains a viable, safe, and essential part of modern healthcare. Electrophysiology devices with microlumens are among the most expensive devices in electrophysiology, and the solution to the microlumen reprocessing challenge has enabled hospitals to reduce costs significantly by using reprocessed devices, without adding patient risk.

Since the 2019 clearance, Innovative Health has received several patents for the microlumen inspection methodology. The groundbreaking reprocessing methodology can be applied to several other advanced electrophysiology devices that incorporate microlumens, for example:

JnJ MedTech
BIOSENSE WEBSTER

- PentaRay NAV ECO Mapping Catheter, Multi-spine
- OctaRay Mapping Catheter, Multi-spline
- Optrell Mapping Catheter, Fixed electrode array

Abbott
ST. JUDE MEDICAL

- Advisor HD Grid Mapping Catheter, Fixed electrode array
- Advisor HD Grid X Mapping Catheter, Fixed electrode array
- BRK and BRK XS Transseptal Needles

Boston Scientific

- INTELLAMAP ORION Mapping Catheter, Basket
- NRG Transseptal Needles

A NEW STANDARD FOR REPROCESSING

Reprocessing the most advanced devices in electrophysiology — safely, and at scale.

INNOVATIVE HEALTH