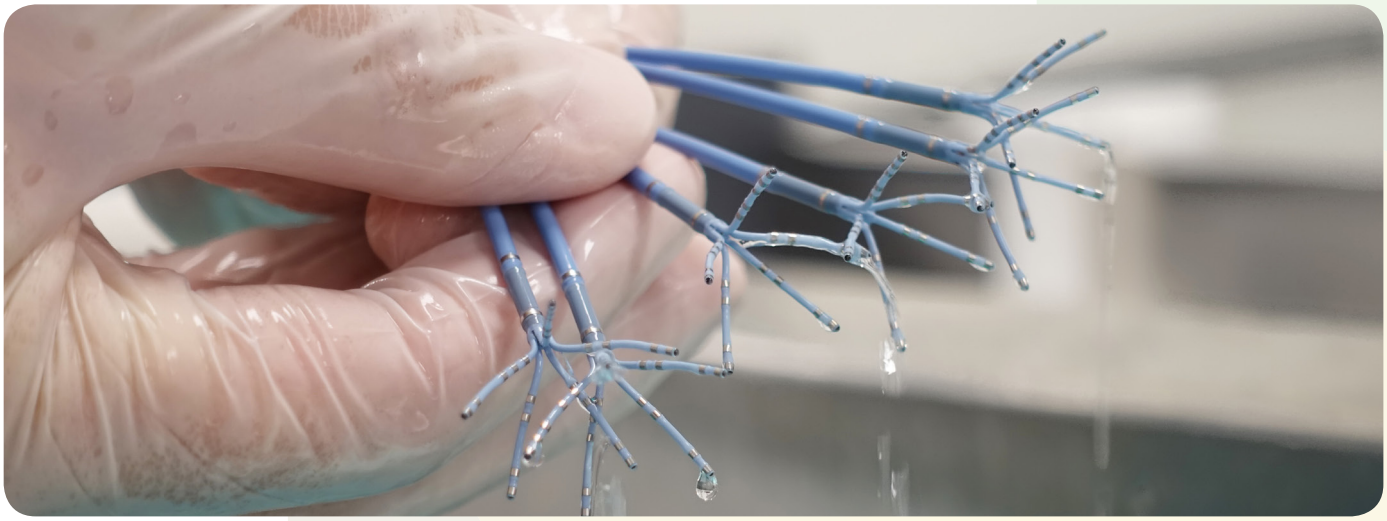
The Case for Specialty Reprocessing

By: Rick Ferreira & Lars Thording



Single-use device reprocessing has become a key supply chain strategy for reducing costs in the hospital. However, the industry is changing, presenting hospitals with new opportunities for higher savings and new challenges with reprocessing programs that stop growing.

To combat rising healthcare costs, the reprocessing of single-use devices has started to expand to more advanced technologies, thereby increasing the amount of savings that reprocessing can deliver on a per-procedure basis. This notable shift has significant implications for the competitive landscape of manufacturers and reprocessors as well as for hospitals. Let's take a look at the trend toward more-advanced device reprocessing, the related rise in specialty reprocessing, and what hospital management needs to understand about the future of this space.

The History of Single-Use Device Reprocessing

Since around 2000, single-use device reprocessing has been targeting fairly simple, mostly commoditized devices that are labeled "single-use" by the manufacturer but usable one more time when reprocessed by FDA regulated third-party reprocessing companies. There have been less than a handful of reprocessing companies, and the largest ones covered all areas of reprocessable "single-use" devices: OR devices, electrophysiology (EP) devices, and commodity items used throughout the hospital, such as compression sleeves and pulse oximeters.

Around 2010, the two largest reprocessors (Ascent Healthcare Solutions and SterilMed) were acquired by large medical device companies. Ascent Healthcare Solutions was acquired by Stryker in 2009 and is now called Stryker Sustainability Solutions; SterilMed was acquired by Johnson and Johnson in 2011. A few smaller reprocessors, mostly focused in the low-tech device area, survived and developed in their regional or device specialty

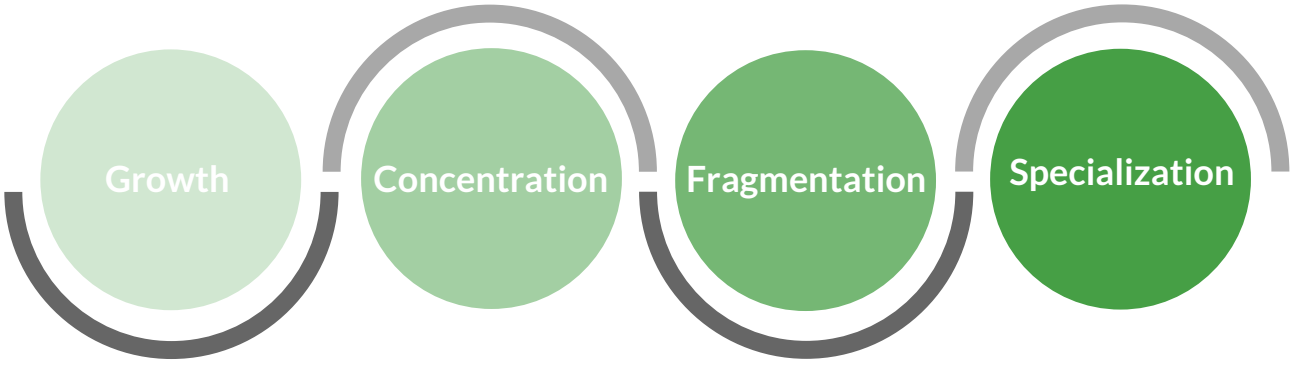
markets. However, in the years that followed, several of these were acquired, and hospitals consequently had to run their reprocessing programs through either Stryker or Johnson & Johnson.

Emerging Trends in the Industry

Over the past four or five years, the industry has begun to change in ways that could have profound impact on hospitals' opportunity to reduce per-procedure costs through reprocessing. Consider the following:

- **The large medical distribution companies have joined the industry:** Medline acquired MEDISISS, a small reprocessing company, in January 2012; Cardinal acquired the reprocessing arm of another technology company and in 2015 formed its *Sustainable Technologies* division. With deep reach into purchasing groups and hospital buyers through their massive distribution presence in the U.S. healthcare market, both companies have rapidly grown to become major players in reprocessing.
- **The reprocessing industry has become more fragmented:** In the past, a reprocessor obtained FDA clearances to reprocess a portfolio of devices, collected those used devices, reprocessed the devices at its plant, sold them back to the customer and sent the reprocessed devices to the facilities. As is often the case in adolescent industries, this concentration of all activities in one firm is being replaced by more specialized reprocessing activities.

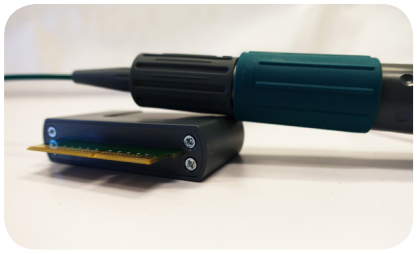
  More and more, reprocessing companies specialize in either distribution, regulatory and R&D, or sales. This means that the reprocessing industry has become an intricate web of business relations among reprocessors: For example, Medline (distributor) sells Innovative Health devices under private label; Northeast Scientific (sales) has leveraged Innovative Health as an R&D partner; Stryker (sales) private labels some product SKUs for Medline, etc. This development is as logical as it is confusing. It's tough to be the best at everything from R&D to sales and distribution, so companies concentrate and "outsource" other activities. What drives the integration among reprocessors is that most hospitals have traditionally wanted to work with only *one* reprocessor, meaning the sales/distribution firm would have to be able to offer the full portfolio of reprocessed devices.

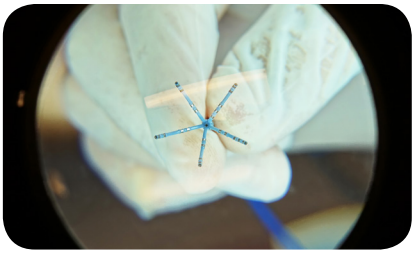


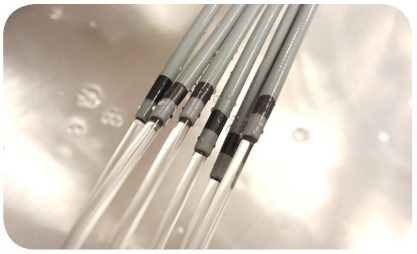
- **A strategic split between volume reprocessors and niche reprocessors has emerged:** During the last half of the 2000s, the major reprocessors all achieved FDA clearances for the devices that were technologically accessible (i.e., relatively easy to reprocess) in the EP lab, in the OR, and on the floor. Since the early 2010s, most reprocessors have not focused on getting more FDA clearances to grow hospital savings. Rather, they have looked to add markets or increase same-store sales (getting more savings for the hospital through program management and education).

  Unlike the volume reprocessors, niche reprocessors have focused on growing savings on only a few product lines. Niche reprocessors include Innovative Health (cardiology) and Northeast Scientific (intravascular).
- **The specialty reprocessor has emerged:** From this strategic evolution, the specialty reprocessor has emerged. Today, a reprocessor can grow in one of two ways: either through volume (market growth or market expansion) or by getting more FDA clearances so that more devices can be reprocessed. The challenge for non-volume reprocessors has been that all the low-hanging fruit (in terms of easy-to-reprocess device types) has already been picked. This means that without the market reach of the volume reprocessors, a reprocessor must develop a deep and narrow clinical, regulatory and technological focus on specific devices. This enables them to obtain FDA clearances for devices that in the past have been seen as *not* reprocessable.

> **“To drive higher savings in EP reprocessing, the reprocessor must have a narrow focus on the category and develop specific regulatory, scientific and program management competencies.**







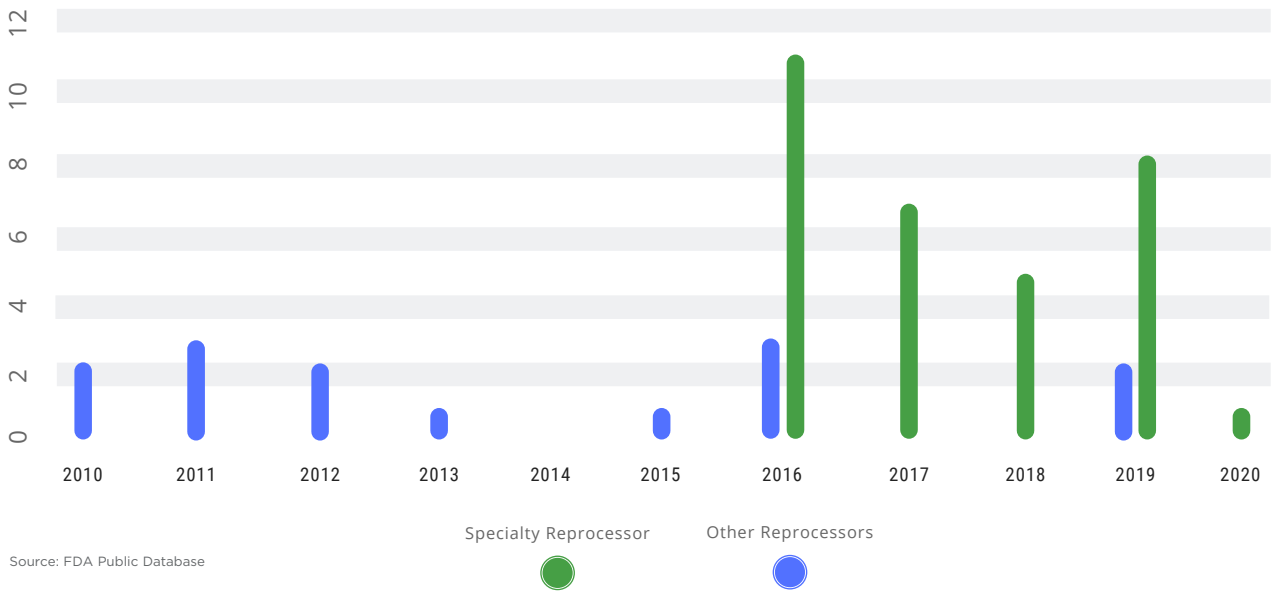
These emerging trends are not surprising. In fact, almost every new industry goes through concentration, fragmentation, and specialization. In our view, these trends are positive for the industry, as well as for hospitals, as reprocessors play to their strengths and increase the savings value to hospitals through refined strategies.

Specialty Reprocessing

Since all the low-hanging fruit has been picked, new FDA clearances are increasingly demanding, both regulatorily and technologically. A company must invest substantial resources in R&D, regulatory affairs and clinical relations to be able to achieve these clearances.

Over the past five years, specialty reprocessing has largely driven FDA clearances for new devices, thanks to the development of "reprocessing technology," a series of highly specialized methodologies, standards, validation techniques and testing practices. These include, for example: hemostasis detection capability; micro lumen occlusion detection, ultrasound imaging performance characterization and testing; hydrophilic coating performance characterization; electronic programmable memory decryption, read and write capabilities; advanced visual inspection methodologies, 3D mapping location sensor performance characterization and testing; advanced sterile packaging design and development; and advanced non-destructive material identification methodologies.

FDA Clearances to Reprocess Cardiology Devices



Source: FDA Public Database

Reprocessing an advanced electrophysiology mapping catheter with microlumens is a world apart from reprocessing a compression sleeve. This means that beyond optimizing existing reprocessing programs in terms of collection compliance, sound buy-back practices and clinician support, savings can only grow from working with specialty reprocessors or with distributors of specialty reprocessors.

Specialty reprocessors don't just develop new R&D and regulatory competencies; they have to develop deep clinical skills through frequent interaction with clinicians who – rightfully – insist that they feel comfortable with the reprocessed devices – and to understand how the devices should feel and function. Different clinical areas of the hospital have different dynamics. Because of their very narrow focus, specialty reprocessors are also able to create reprocessing programs that are tailored to a specific clinical area. The EP lab is a different landscape than the OR in terms of purchasing decisions, utilization decisions (which device should be used) and others.

Specialty reprocessors optimize reprocessing programs specifically for the dynamics of their clinical area.

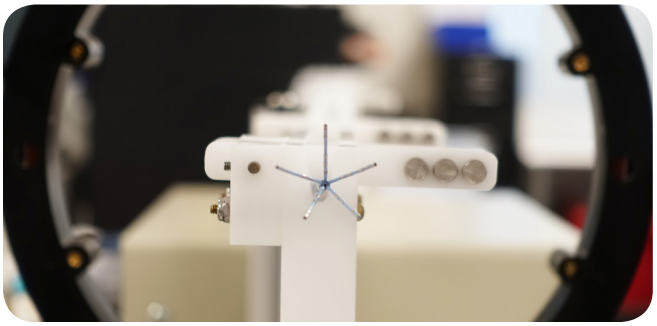
“Reprocessing technology”

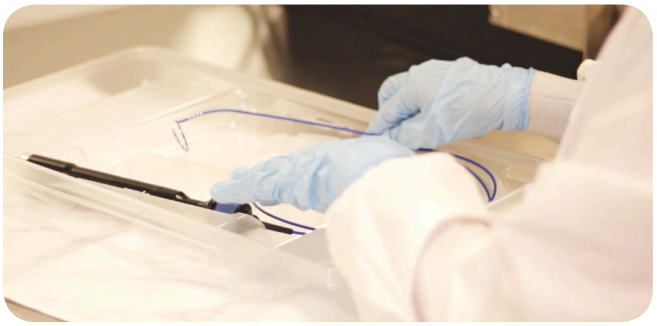
As a specialty reprocessor, Innovative Health is building a new technology paradigm based on single-use device reprocessing that creates new methodologies, standards, and testing/cleaning practices - enabling more devices to be re-used than seen before in reprocessing.

- Hemostasis Detection Capability
- Joint Leak Detection Capability
- Macro Lumen Occlusion Detection, cleaning & inspecting
- Micro Lumen Occlusion Detection, cleaning & inspecting
- Hydrophilic coating performance characterization
- Hydrophilic coating detection, application or removal

- Electronic Programmable Memory decryption, read & write capabilities
- Advanced visual inspection methodologies
- 3D mapping location sensor performance characterization & testing
- Ultrasound Imaging performance characterization & testing
- Dialectric Breakdown assessment for insulation per IEC 60601
- Patient Leakage testing for medical devices per IEC 60601

- Custom & Advanced Cleaning validation methodologies
- Like for Like Component replacements
- Injection molded component replacements
- Mechanical Characterization of Medical Devices
- Advanced Non-destructive material identification methodologies
- Advanced Non-destructive wall thickness measurement for catheters
- Advanced sterile packaging design & development





What Does the Specialty Reprocessor Mean for the Hospital?

There are several implications for hospitals to consider when responding to the emergence of the specialty reprocessor and the other trends that are now changing the industry:

- Assuming that the existing reprocessing program is running smoothly, the only way you can increase savings is by working with a specialty reprocessor that can secure more FDA clearances so more devices can be reprocessed. Ask the question to your reprocessing partner: How can you increase our savings? In the electrophysiology lab, some of the newest specialty reprocessing devices have increased savings by $2,000 per procedure – or doubled savings. Reprocessing a few more $50 catheters through program optimization does not reach this level.

	New	Regular Reprocessing Program	Specialty Reprocessing Program
Irrigation tubing	$100	$100	$100
Transseptal needle	$260	$260	$260
Patch	$415	$415	$415
Irrigated AF ablation catheter	$3,456	$3,456	$3,456
Guiding sheath	$200	$200	$200
Coronary sinus catheter	$495	**$248**	**$248**
ICE catheter	$2,650	$2,650	**$1,325**
Steerable sheath	$930	**$465**	**$465**
Quads	$220	**$110**	**$110**
Circular mapping catheter	$1,750	$1,750	**$875**
Total	**$10,476**	**$9,654**	**$7,454**

In a pulmonary vein isolation procedure (the most common electrophysiology procedure), a specialty reprocessor can sometimes triple the savings.

This is because the newest and most complex devices are also the most expensive devices. Only specialty reprocessing is sufficiently advanced to achieve these clearances.

*Restricted reprocessing programs are programs where specific device categories are excluded or where supply is limited.
**Highlighted fields reference reprocessed devices distributed by Innovative Health.

- Yes, we know that it is more convenient to have one reprocessing contract than to have several. However, this efficiency in supply chain management may come with a high cost. If your current reprocessor does not have clinical area focus, it is likely not growing clearances and savings. Carving out a clinical-area-specific specialty reprocessing program that optimizes savings in a key area like electrophysiology may require two contracts, but this can significantly boost your savings.
- Whether working with a reprocessor that covers all clinical areas or one that is specialized, hospitals must demand specialized knowledge of clinical practices as well as technology. If all your reprocessing partner does is to walk into the hospital and pick up devices, you are likely missing out on major savings. A reprocessing program is only as effective as the confidence of the clinical staff and the level of interaction with third-party reprocessing staff.

Innovative Health FDA clearances

Clearance	Date	510(k) Number
Diagnostic Ultrasound Catheter	March 2016	K153090
Electrophysiology Catheter	March 2016	K153153
Polaris X Steerable Catheter	May 2016	K160303
Livewire Steerable Catheter	May 2016	K160242
Inquiry Steerable Catheter	June 2016	K160496
Dynamic Tip Steerable Catheter	September 2016	K161464
Orbiter Steerable Catheter	October 2016	K161393
Inquiry Optima Plus Steerable Catheter	November 2016	K160421
Supreme Diagnostic EP Catheter	December 2016	K161769
Response Diagnostic EP Catheter	December 2016	K161827
Viking Diagnostic EP Catheter	December 2016	K162251
Agilis Nxt Steerable Introducer	June 2017	K170311
Soundstar 3D DUC	June 2017	K170474
Webster CS Bi-Directional Catheter	June 2017	K170922
Acunav DUC	July 2017	K163560
CristaCath Diagnostic EP Catheter	October 2017	K171503
Inquiry Steerable EP Catheter	October 2017	K171277
Halo XP Diagnostic EP Catheter	November 2017	K171788
Viewflex Xtra ICE DUC	March 2018	K173262
** Decanav Diagnostic EP Catheter	June 2018	K180710
Torqr Diagnostic Ep Catheter	October 2018	K181618
** Advisor FL Sensor-Enabled Circular Mapping Catheter	October 2018	K181458
Marinr Diagnostic EP Catheter	November 2018	K181897
** Visions Pv .035 Digital IVUS Catheter	January 2019	K181126
Response Diagnostic Electrophysiology Catheter	February 2019	K182488
Supreme Diagnostic Electrophysiology Catheter	April 2019	K182386
** PENTARAY eco mapping Catheter	June 2019	K190785
Webster Duo-Decapolar Diagnostic EP Catheter	July 2019	K190980
Livewire Steerable Catheter (3X)	August 2019	K190127
Reflexion Spiral Bi-Directional Variable Radius EP	October 2019	K191170
** Achieve Advance Mapping Diagnostic EP Catheter	December 2019	K191880
** Achieve Catheter Connecting Cable	January 2020	K193263

** Unique device clearances

As a specialty reprocessor, Innovative Health has developed a strong partnership with FDA.

Innovative Health now has more clearances* among EP devices than any other reprocessing company.

The more devices are cleared, the higher the hospital savings.

A constant flow of new clearances ensures constant growth in reprocessing savings.

*32 total clearances since 2016

- Ask your reprocessing partner for its R&D pipeline: What new clearances are being pursued with the FDA so that savings can increase? Here is the concern: your reprocessing partner is not getting more clearances, you will not grow savings, and you are likely to see your savings go down. This is because of the short product life cycles in fast-growing procedural areas: A new technology comes out, replacing a device that could be reprocessed with one that can't. Unless new clearances are achieved, the savings will go down.
- Expect specialized service programs across different hospital units. As mentioned, each area of the hospital functions in its own way in terms of clinical dynamics, purchasing, etc. Your reprocessor should design specific programs to optimize savings in each area.

In general, specialty reprocessing has a lot to offer the hospital in terms of substantially higher cost savings. Thanks to integration in the industry, there are many options to choose from, including working directly with specialty reprocessors or working with companies that collaborate with specialty reprocessors.

The Innovative Health EP Specialty Reprocessing Program

Innovative Health was formed in 2015 by the former Ascent Healthcare Solutions executive team (now Stryker Sustainability Solutions) to focus entirely on reducing costs in Electrophysiology (EP) and cardiology procedures through device re-use. This meant a focus on technology expansion: Investment in the development of reprocessing technology was necessary to get device clearances that would allow the EP lab to significantly grow their savings through reprocessing. A commitment was made to savings growth through continuous pursuit of new device categories early in their lifecycle.

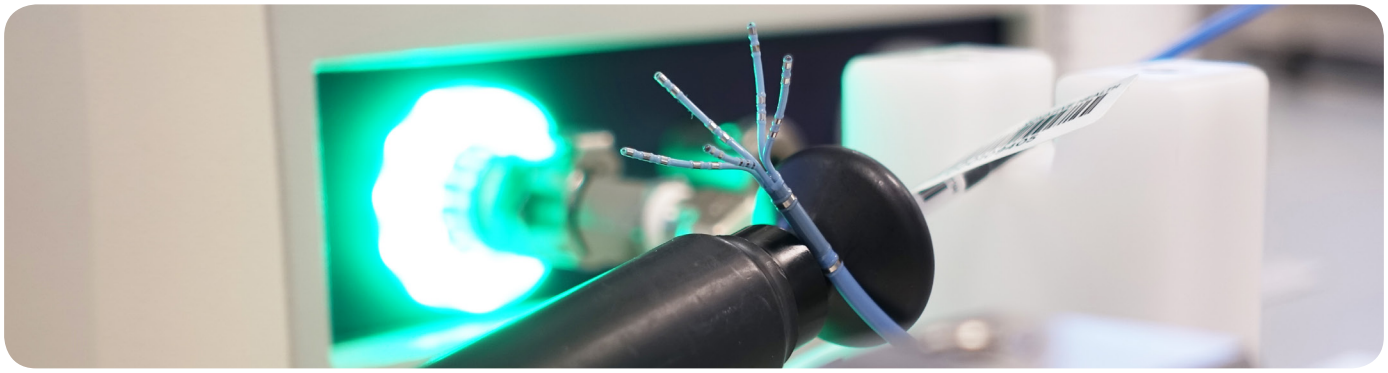
Since March 2016, Innovative Health has achieved a record 31 FDA clearances to reprocess EP devices, translating to 45+ unique device families and 600+ SKUs. We have several submissions under review by FDA – mostly for new devices that have never been cleared before. This is unmatched in an industry where the closest competitors – Stryker Sustainability Solutions and SterilMed/Johnson & Johnson have achieved 2 and 4 clearances, respectively, in the same timeframe.

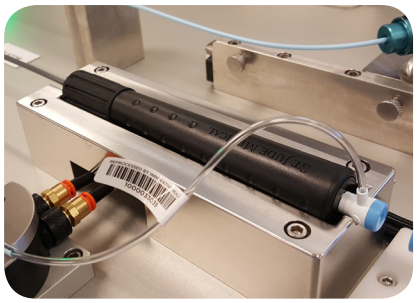
As a result, Innovative Health can now present EP labs with a dedicated EP reprocessing program that far exceed other EP programs in terms of savings results. There are two components to this that sets Innovative Health apart from competition and characterize the value of the specialty reprocessor:

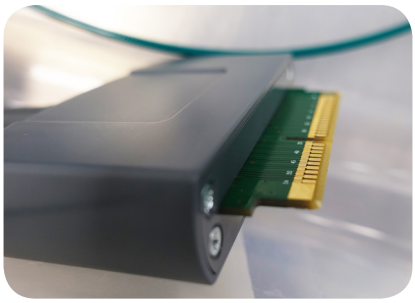
The Promise of a Specialty Reprocessor

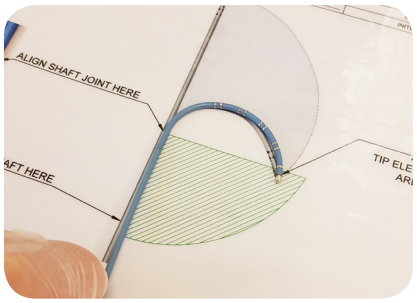
1. **More clearances to reprocess EP devices – earlier in their lifecycle:** When a new technology comes out, Innovative Health is evaluating it in terms of costs, volume and reprocessing technology. We then pursue clearance in close collaboration with FDA, if the technology can be reprocessed and present major cost savings opportunities for the EP lab. This is possible due to the cultivation of strong clinical, regulatory and engineering competencies that allows us to go beyond the simple re-use of basic devices. Innovative Health offers a savings guarantee based on past reprocessing savings, and usually exceeds this by hundreds of 1000s of dollars, due to new reprocessing savings being added to the program from new clearances. Successful EP labs understand that the upside to working with a specialty reprocessor has little to do with prices and everything to do with upside from new clearances. In 2019, we received 8 FDA clearances for mostly unique devices; in 2020, we are expecting to add several new devices and new device categories already in Q1 to boost the savings of our reprocessing partners.
2. **Focused program execution:** Specialty reprocessing is not just about getting more clearances. Program execution is key.
    a. A strong specialty reprocessing partner is *data-driven* and knows about past utilization patterns, national average device prices, rejection and buy-back rates, par levels, and device configurations by case type. You should expect nothing less from your reprocessor than carefully prepared statistics that show these key figures and build on those to design the optimal reprocessing program.
    b. In addition, the specialty reprocessor has deep understanding of the *market dynamics* that drive new product launches, competitive developments and device usage – and knows how to respond. If your reprocessor does not have an economics department, you should ask why.
    c. The specialty reprocessor will boost your reprocessing savings program with operational and technical/engineering support to ensure that you can make the right decisions about the use of new and reprocessed technology. This requires *ongoing presence and interaction with clinicians and administrators* as well as deep knowledge of the clinical area – from an economics as well as from a clinical/technological perspective.
    d. A specialty reprocessor gets INVOLVED in EP lab management. Innovative Health has recently launched a program to enable the reprocessing of sensor-enabled catheters from Biosense Webster (market leader) by providing independent mapping support. Every week, we see customers at our plant to discuss how to manage supply chain decisions.

Optimizing an EP reprocessing program is not a transactional, logistical task, it is a collaborative, organizational task.









Specialty reprocessing enables higher savings in the EP lab, savings that could triple or more – from more clearances and focused program execution. *Optimizing an EP reprocessing program is not a transactional, logistical task*, it is a collaborative, organizational task that involves understanding the dynamics of the EP lab, between clinicians, purchasers and managers - and enabling the best possible results. If all your reprocessor does is send you monthly savings reports and have staff go in to collect devices, you are likely missing an opportunity to manage re-use and reduce per-procedure-costs or boost finances. We have more than a handful of customers who finished 2019 saving more than $1M with our specialty EP reprocessing program. They have one thing in common: They insist on strategically managing their spend to develop a better EP program for patient benefit – by balancing the utility of new technology against the economics of re-use through reprocessing.

INNOVATIVE HEALTH

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

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