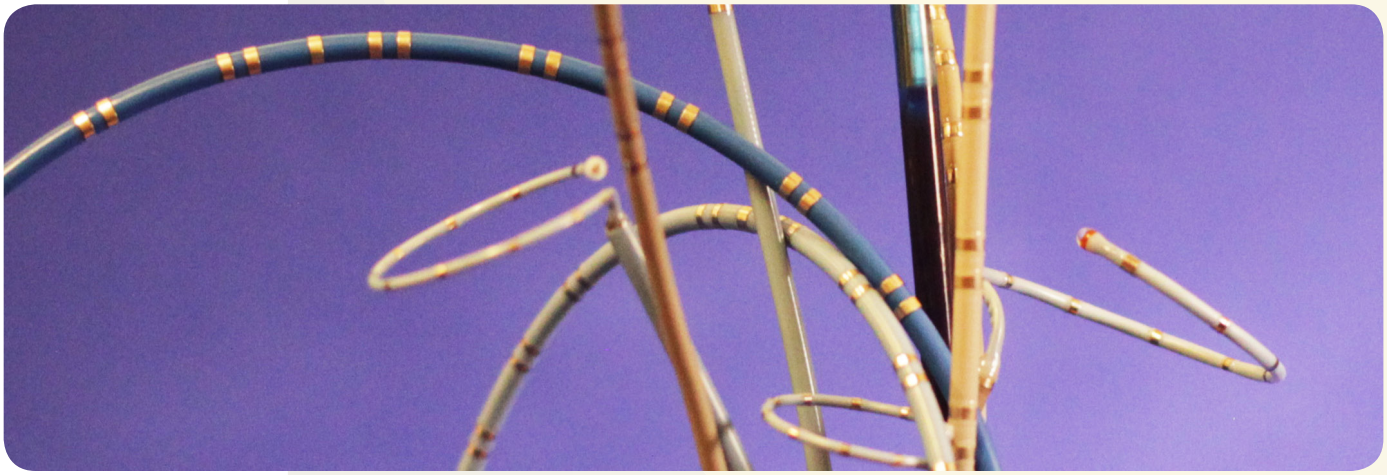
Why Hospital Leaders Should Look to Cardiology for Sustained Future Reprocessing Savings

By: Rafal Chudzik, Dave Distel, Liz Stoneman & Lars Thording

Single-use device (SUD) reprocessing has been a regulated practice for almost 20 years. Since its re-birth under FDA regulation, reprocessors have targeted all the technologies they could from a research & development (R&D) and regulatory perspective: SUDs whose technology physically allowed for cleaning, function testing and sterilization to render them safe for reuse have been pursued for 510(k) clearances. This means that reprocessors are typically operating across several different service lines, clinical areas and locations in the hospital.



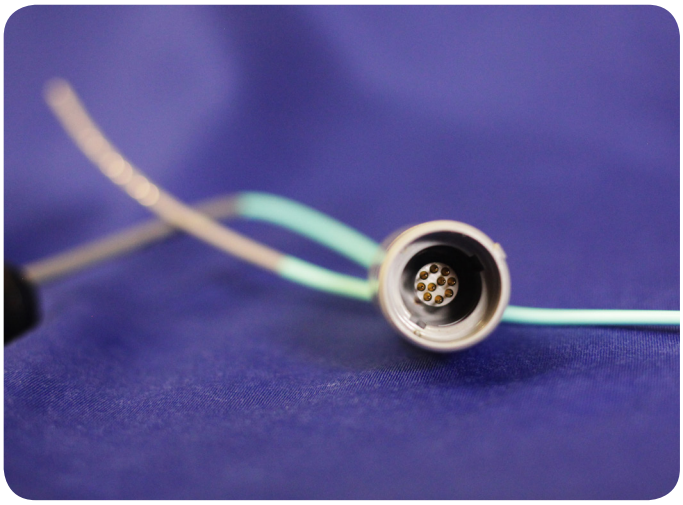
As a result, reprocessing programs, which are highly dependent on focused program management, are rarely optimal since it's difficult to be everywhere at the same time – and tough to be a clinical and technological expert in all areas at the same time. Since the growth potential of reprocessing is in device technologies of ever increasing complexity, this challenge is growing every day: There is a growing need for reprocessors to be focused and sophisticated, deeply involved in the clinical and regulatory aspects of complex technology.

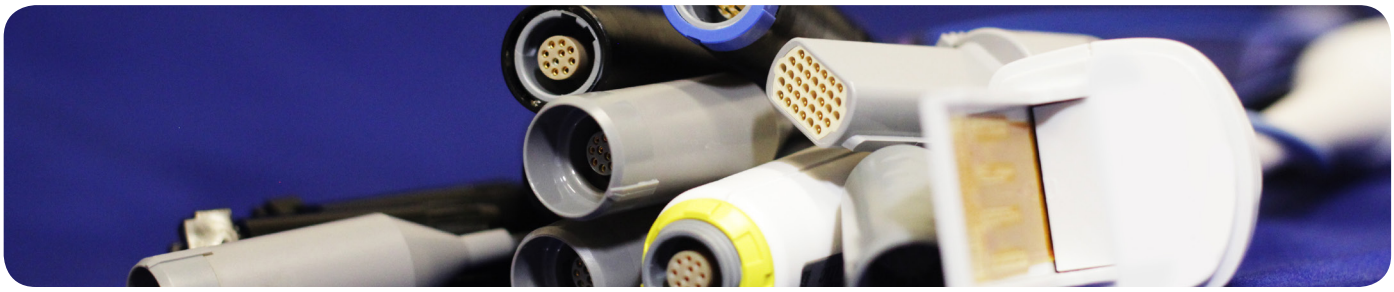
> **Industry maturation and differentiation is now beginning to see the emergence of two different types of reprocessors: commodity reprocessors selling discount devices and specialty reprocessors with targeted programs and advanced technological and regulatory competencies.**

Unfortunately, this has meant that hospitals are not seeing continuous savings growth from reprocessing, and this is why next-generation reprocessors are specialized and focused on specific service lines.

The uneven opportunities from different service lines is underscoring this specialization – the margin between cost and savings for some reprocessed devices isn't substantial and the reprocessing programs for such devices aren't making a big difference – for example compression sleeves, pulse oximeters, and some Operating Room (OR) devices are low cost disposable devices.

This development in the industry has meant that where reprocessors were pretty much doing the same in the past, industry maturation and differentiation is now beginning to see the emergence of two different types of reprocessors: commodity reprocessors selling discount devices (low savings, high volume) and specialty reprocessors with targeted programs and advanced technological and regulatory competencies (high savings, medium volume). This is a typical evolution in most industries. Where commodity reprocessors are focused on maximizing reprocessing volume of devices late in their life cycle, specialty reprocessors are focused on pursuing clearances of complex devices earlier in their life cycle.





Cardiology and Electrophysiology

Savvy hospitals have always regarded reprocessing an important strategic initiative – even since before regulation. And savvy hospitals that use reprocessing strategically as a major savings initiative are seeing the impact of commoditization and the differentiation between reprocessors: Where the large reprocessors used to produce savings almost equally in soft goods, OR devices, and Electrophysiology (EP), the relative contribution to savings

is shifting. An average hospital today can derive 80-90% of their savings from their EP/Cardiology program – because this is where the most premium priced devices can be reprocessed.

There are several reasons why savvy hospitals are banking on the EP/Cardiology area to drive reprocessing savings in the future: This is where highly specialized reprocessing takes place and this is where cost savings are likely to grow in the near future. Here are five reasons why savvy hospital executives are looking to utilize reprocessing programs specific to the EP and Cath Labs:

1. Procedure Growth

Demographics (the so-called "aging population"), lifestyle and technology advancement have made *Electrophysiology* (EP) a financially important service line for many hospitals over the past 10 years: Demand for Atrial Fibrillation (AF) treatment and other early intervention EP procedures is growing rapidly, and with technological advancement, pharmaceutical treatment has increasingly been replaced by curative treatment in the EP Lab. Growth in EP mapping and ablation demand has been fueled by the introduction of new, premium-priced technologies that increase efficiency and effectiveness. These new technologies, such as mapping catheters, imaging catheters, steerable introducers, etc. are often targeted to specific procedure types.[1]

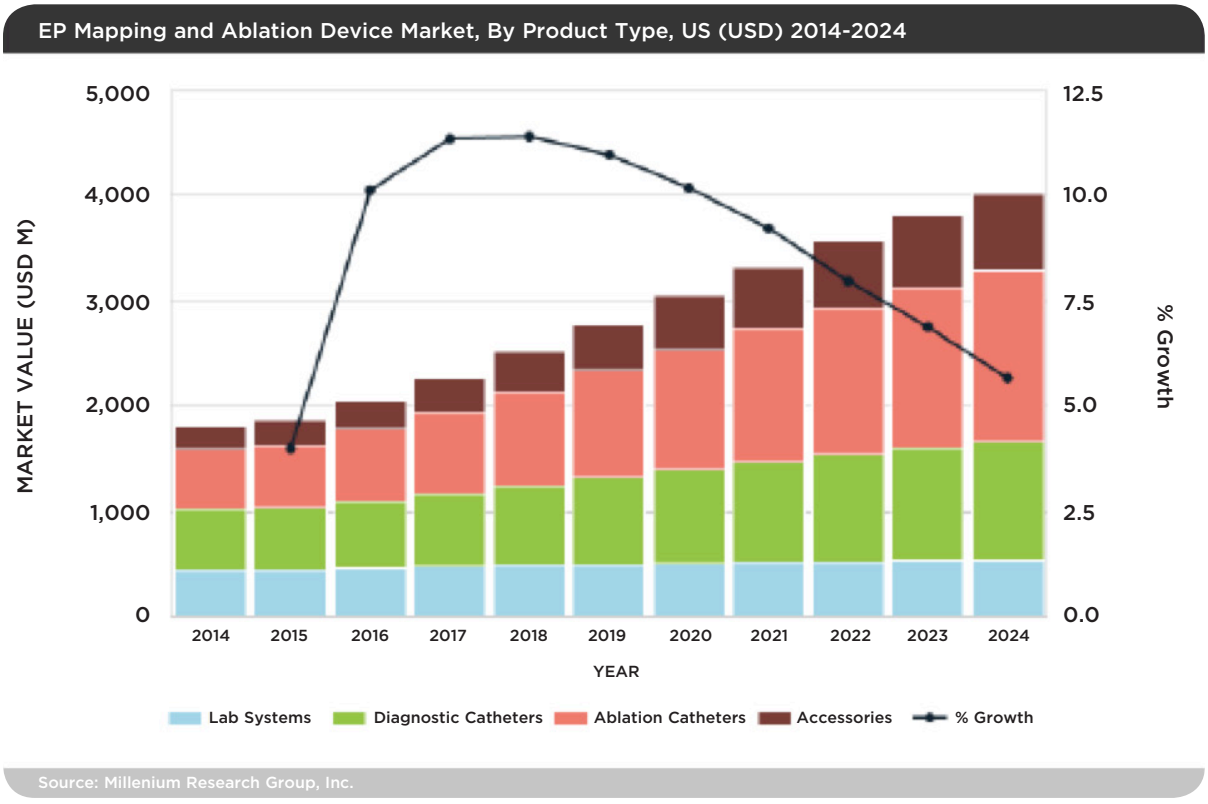


Figure 1: EP Mapping and Ablation Device Market, By Product Type, US (USD) 2014-2024

At the same time, Centers for Medicare & Medicaid Services (CMS) *reimbursement* for AF ablation has increased significantly in recent years, which has broadened access, as more and more hospitals have discovered how financially rewarding electrophysiology procedures are. In 2013, CMS reimbursement for Pulmonary Vein Isolation (PVI) was $11,146 – by 2017, this had increased to $16,778.

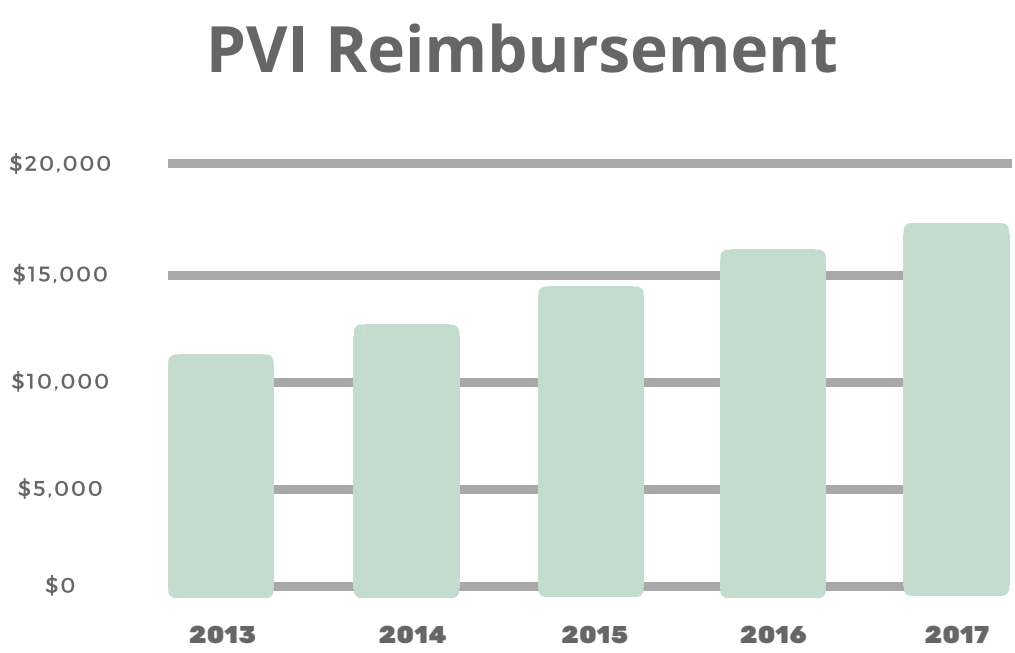


Figure 2: Growth in PVI procedure reimbursement 2013-2017 (CMS)

Analysts from the Millennium research group predict that the EP mapping and ablation market will increase in procedures from 312,000 in 2015 to 689,000 in 2024, and the value of the medical device market for these will increase from $1,870M to $4,020M in the same time period. Market leaders such as Biosense Webster, St. Jude Medical, Medtronic and Boston Scientific sit on 74% of market revenues, and they are likely to continue their focus on new technology launches to profit from the increase in demand.[1]

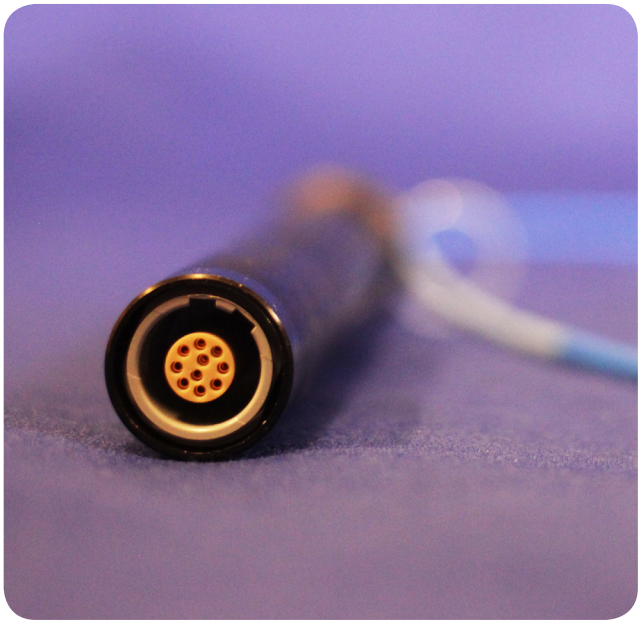
> **...EP mapping and ablation market will increase in procedures from 312,000 in 2015 to 689,000 in 2024...**

Ablation technology, which drives the growth in EP procedures can, nevertheless, still be considered infant technology, given the low level of success rates and the length of procedures (often 5-6 hours or more). This, combined with the high cost of devices, sometimes limits the adoption of curative methodologies in AF and other common electrophysiology disease areas. Availability of reprocessed devices will increase adoption, which is estimated to be less than 10% today.[3]

2. Short technology life cycles and the absence of commoditization

The increasing demand for EP procedures has caused the leading medical device manufacturers of Cardiology devices to increase their investment in R&D as well as Marketing to benefit from this procedure growth.

For key technologies that are used in mapping and ablation procedures, new devices are frequently launched to replace older ones – usually at a higher price justified by marginal improvements in technology: The Biosense Webster Lasso Nav Catheter was cleared by FDA in 2010, and its planned replacement, PentaRay Nav High-Density Mapping Catheter, was cleared two (2) years later in 2012; the SoundStar 3D Diagnostic Ultrasound Catheter was cleared in 2007, and the SoundStar eco Diagnostic Ultrasound Catheter was cleared in 2011.



Such short product life cycles overall mean increasing the cost of procedures – to the benefit of the patient, certainly, when efficiency and outcome is improved due to better devices.

However, ablation for A-Fib success rates are often reported to be as low as 50%. In short: hospitals are picking up the bill for increased manufacturer profitability without experiencing the dramatic increases in efficacy to justify it. This device cost cycle is illustrated in Figure 3. In this context, Paul Martyn, writing for Forbes[2], quoted Use

> **Hospitals are picking up the bill for increased manufacturer profitability without experiencing the dramatic increases in efficacy to justify it.**

Reinhardt for pointing to "unnecessary **innovation** as one of the industry's biggest cost drivers —a tax on the system that protects OEM profits and confounds customer strategies to save money".

Interestingly, other EP devices, such as many quads, have been around for a very long time, without being replaced by new and better technologies (for example, the Bard®Tip Deflecting Electrode Catheter, was cleared in 1989 and the Bard Octapolar Electrode Catheter was cleared in 1987) . These two devices still command a very high price: The usual commoditization through which prices decrease considerably over time is curiously absent in the EP space – due to strategic obsolescence (the short life cycles) and limited competition for legacy devices. Remember Moore's law? Product performance doubles every two (2) years while prices drop to half. Well, Moore's law doesn't work when it comes to cardiology devices. Paul Martyn continues in his Forbes article: "[...] we know that manufacturers will look at a booming device market like cardiology and deliberately invest in programs designed to shorten product life cycles; [...] it is common knowledge that manufacturers are innovating not to improve patient care, but to maximize revenue."

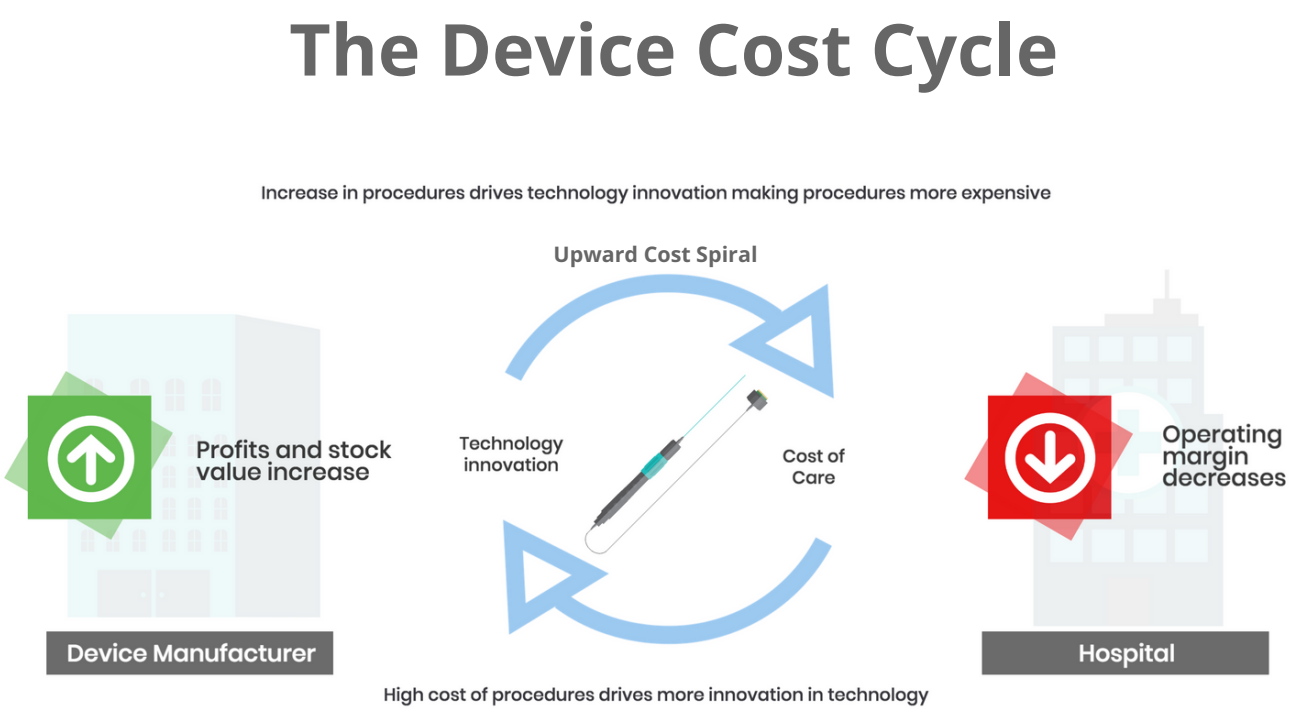


Figure 3: The Device Cost Cycle

The rapid launch of new products combined with the absence of commoditization means constant pressure on the hospital to spend more money per EP procedure. While reprocessing of devices acts with a delay due to the 510(k) process, this underscores the need for reprocessed devices, especially in the leading mapping and ablation categories, where devices are increasingly expensive.

3. Large cost savings opportunity

Cost savings opportunities in the EP and Cath Labs are very large when compared with other service lines or locations in the hospital or surgery center. Many OR devices, such as forceps and trocars are so commercialized that the savings derived from reprocessing are barely noticeable. Reprocessed Pulse Oximeters sell for as little as $5.75, Tourniquet cuffs are down to $9 in some cases, some reprocessed Trocars sell at $10 and biopsy forceps can be found reprocessed for $8 in some cases. In the EP lab, at the same time, new mapping and ablation catheters are launched into the market with price tags of more than $3,000 and a massive savings potential.

This means that in some hospitals, 80-90% of potential reprocessing savings can be found in the EP Lab. But that is not all: When hospital administrators are looking to the EP and cardiology area for future reprocessing savings, it is also because today, only about 30% of the total device costs of an EP case can be impacted by reprocessing.

Device Costs for Pulmonary Vein Isolation Case

	Original Price	Reprocessed Price
Circular Mapping Catheter	$1,694	$847
Ablation Catheter	$3,456	$3,456
Intracardiac echocardiography Catheter	$2,650	$1,325
Coronary Sinus Catheter	$495	$248
Steerable Sheath	$930	$465
Quads	$220	$110
Irrigation Tubing	$100	$100
Non-steerable Sheath	$200	$200
HIS	$90	$90
Transeptal Needle	$260	$260
Total Device Costs	**$10,095**	**$7,101**

Figure 4: Device Costs for Pulmonary Vein Isolation Case

In other words, there is huge potential for more savings once new device categories are conquered by the reprocessors with applicable 510(k) device clearance. Figure 4 illustrates a Pulmonary Vein Isolation case where reprocessing allows the hospital to reduce costs by 30%. Vascular access catheters, transeptal needles, some intracardiac ultrasound catheters, ablation catheters, intravascular ultrasound catheters, chronic total occlusion devices – these are all device categories that currently cannot be reprocessed and are used in the EP and Cath lab. There is lots of room for the inclusion of more device types in EP.

4. Key EP procedures are not profitable for the hospital

As mentioned, demand for EP cases is increasing dramatically, and that alone points to ongoing reprocessing savings increasingly coming from EP Labs. Device prices are also increasing, which underscores the need to reprocess in the EP Lab. In recent years, however, CMS has increased reimbursement significantly, in response to a close-to impossible economic situation for the hospitals. As an example, figure 5 below shows the evolution in device costs and CMS reimbursement for *Pulmonary Vein Isolation cases* – one of the most common EP cases.

	2013	2014	2015	2016	2017
Reimbursement growth since year before		17.7%	9.5%	8.4%	7.8%
Device cost growth since year before		4.4%	-0.2	0.9%	1.7%
PVI reimbursement	$11,146	$13,115	$14,375	$15,561	$16,778
Device costs	$9,442	$9,857	$9,841	$9,930	$10,095
Device cost % of reimbursement	85%	75%	69%	64%	60%

Figure 5: Device Cost Portion of Reimbursement (Source: National ASP data and CMS)

At first glance, it looks like CMS' increase in reimbursement is working – it has outpaced device cost increases and driven down the device cost share of reimbursement. However, here is why the cost of devices is not sustainable:

1) In 2017, medical device costs represented 60% of CMS reimbursement. Many agree 60% is too high to result in desired profitability with all the additional overhead costs factored into the costs versus reimbursements. Consider that the cost of 1 EP Lab hour is estimated at $2,000-2,100. This covers nurses, depreciation on equipment, lab, and various service contract costs. The math then would indicate that to break even, a PVI case should not take longer than 3 hours and 15 minutes. However, the majority of PVI cases take closer to 5-6 hours to complete for various operational and clinical reasons. This means that in 2017, many CMS cases were done at an operating loss to the hospital. This creates potential pressure on EP teams to speed up the cases, which can potentially result in unintended consequences.

2) Private insurance as the primary payer for patients aged 18 – 44 years went from 50.5% in 2000 to 37.1% in 2015. Private insurance for 44-65 years went from 57% in 2000 to 42% in 20154. The most recent Definitive Healthcare data shows 53.7% private insurance for all cases at hospitals with EP Labs. This means that while the hospital may have been fine in 2000, given a more favorable payer mix, in 2015, the situation is very different, and more cases are done with CMS reimbursement – at a loss to the hospital.

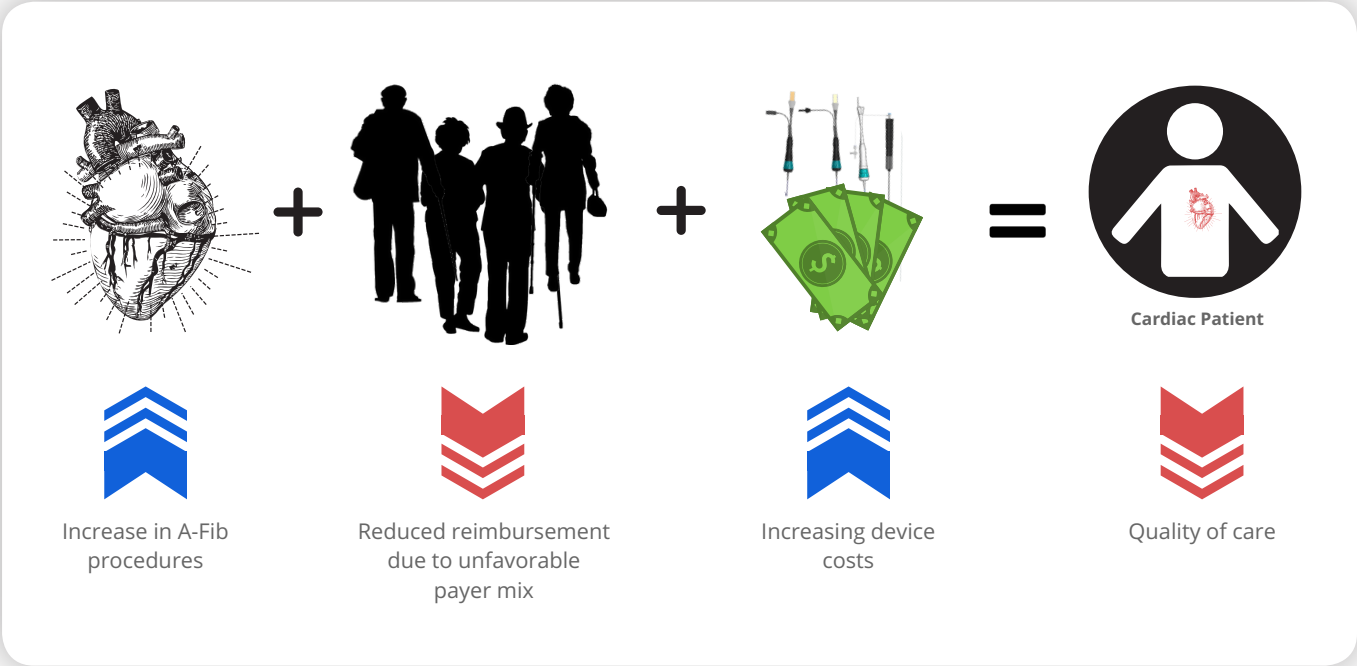


Figure 6: Impact of AF procedure growth, payer mix and device costs on patient care

Currently, reprocessing can reduce the device costs of a PVI case by approximately 30%. This improves the situation, but not enough to make most of these cases profitable. Growth in the number of devices related to ablation procedures that can be reprocessed will not only make PVI cases financially meaningful for hospitals, but also increase penetration of this new treatment option (current penetration is estimated at 10%). Additionally, more reprocessing savings can take some of the pressure off the EP physicians and buy the physician more time for the procedure, theoretically increasing the success rate.

5. 510(k) clearances and reprocessing technology innovation

As shown in figure 7, in the years before 2015, EP clearances were 18% of all reprocessing clearances; since then, the EP share of new reprocessing clearances has risen to 44%. A larger and larger proportion of reprocessing clearances are EP related. This is because it is in the EP lab that the devices are found that produce the largest savings.

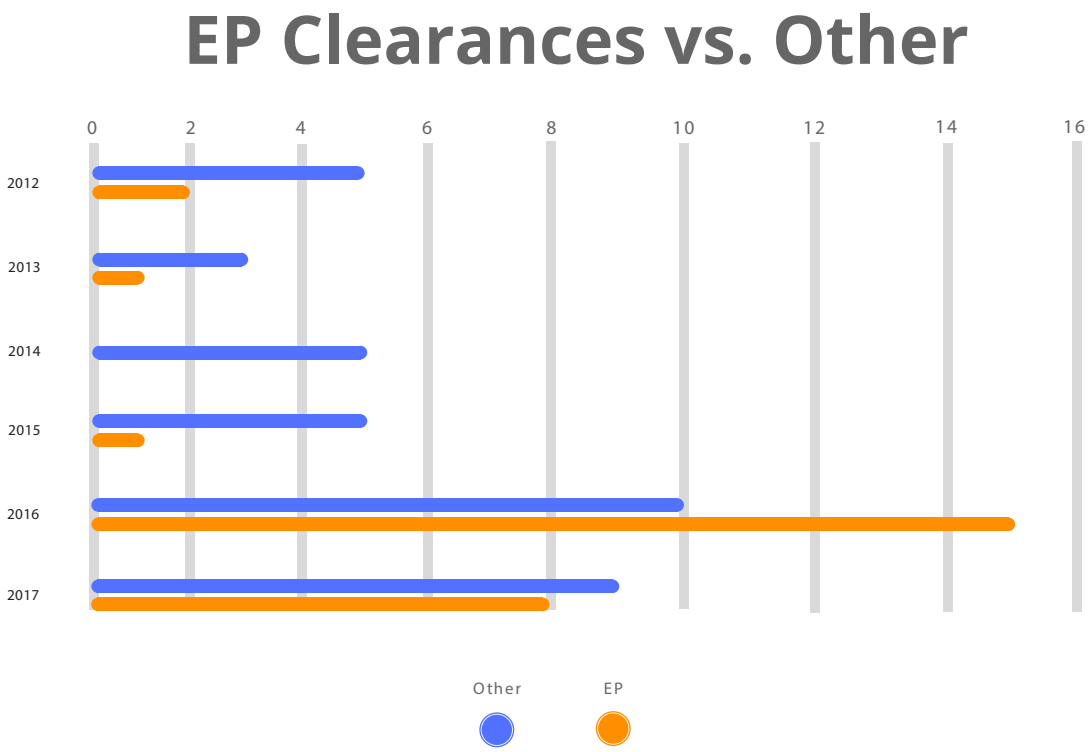


Figure 7: Reprocessing Clearances since 2012

At the same time, reprocessors who are specialized and focused on specific service lines, have increased their submission of 510(k)s, while the commodity reprocessors have slowed down dramatically (see figure 8 below).

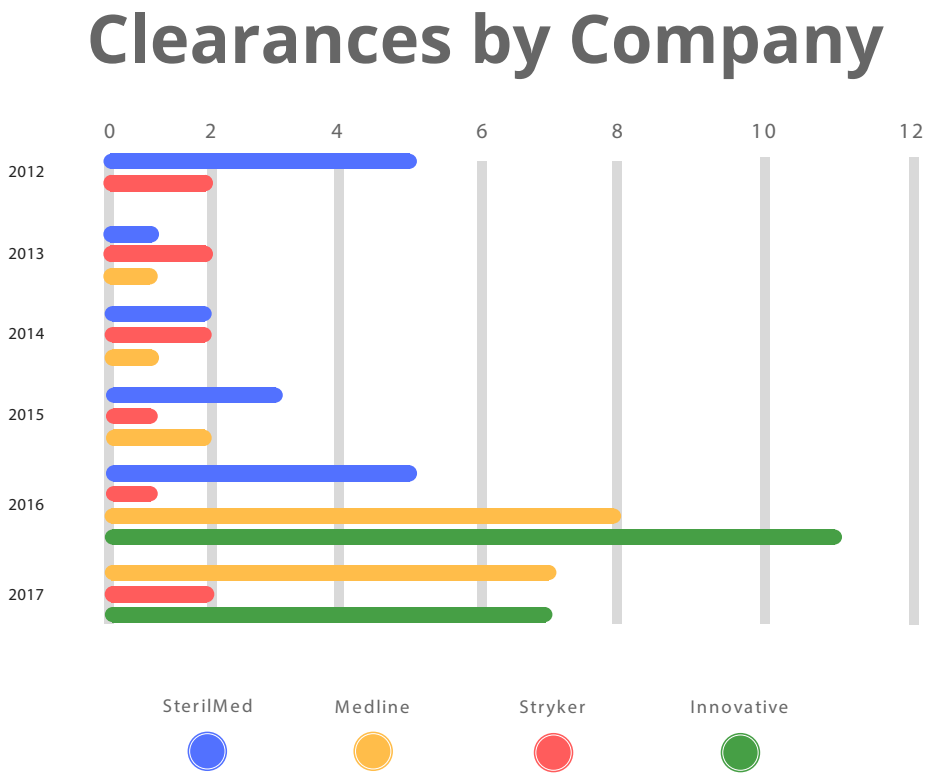


Figure 8: Clearances by reprocessing company 2012-2017

The devices that are currently pursued on the EP side represents not only more of the same, but a venture into new technologies in the EP and Cath Lab. Reprocessing programs specific to EP devices is increasingly breaking the traditional boundaries of reprocessing through investment in R&D and regulatory resources to be able to market more complex devices.

Short life cycles and the absence of commoditization are creating an ever-increasing device cost spiral for typical EP procedures. While the demand for EP procedures is growing rapidly, device costs are increasing and the payer mix is changing making it impossible for hospitals to offer profitable EP procedures without making fundamental changes.

“Short life cycles and the absence of commoditization are creating an ever-increasing device cost spiral for typical EP procedures.

This is making EP and cardiology the focal areas for saving resources through reprocessing. Cost savings opportunities in other service lines is becoming less rewarding for the hospital. A recent surge in FDA clearances of reprocessed EP devices means that hospital leaders should look at reprocessing programs specific to EP and Cath procedures for sustained growth in savings.

References

1) Medtech 360, Electrophysiology Mapping and Ablation Devices | Market Analysis| US | 2016, Millennium Group Ltd.

2) Paul Martyn: Controlling U.S. Healthcare Costs: Hospitals Must Drive The Rescue Plan, Forbes, March 13, 2018

3) Shlomo Ben-Haim: How innovation can unleash tremendous growth in the $3.4 billion AF ablation market, Cardiac Rhythm News, February 26, 2016

4) Ruirui Sun, Ph.D., Zeynal Karaca, Ph.D., and Herbert S. Wong, Ph.D. Agency for Healthcare Research and Quality, HEALTHCARE COST AND UTILIZATION PROJECT, January 2018

INNOVATIVE HEALTH

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

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