

Reprocessing in the Cardiac Cath Lab

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In the Electrophysiology (EP) lab, hundreds of thousands of used devices are sent to reprocessors every year to get reprocessed. This practice benefits the EP lab by significantly reducing the cost of “single-use” devices, and as a result, EP procedures remain among the most profitable in the hospital.

In the Cardiac Cath lab, often located right across the hall, no devices are reprocessed. Yet, the potential is as great as the financial need: More focus on mapping and complex interventions with higher device costs are putting pressure on hospitals that see insufficient reimbursement for these procedures. Short term, reprocessing has the potential to reduce costs in these procedures significantly and help create a highly profitable service line.



Electrophysiology and Interventional Cardiology

Using reprocessed devices in the EP lab saves US hospitals an estimated \$140,000,000 per year. This has grown since the 2000s to become a key cost savings strategy and helped hospitals make EP procedures a highly profitable service line. Some hospitals save more than \$1M per year and rely in their budgets on sustained cost savings from the practice of single-use device reprocessing.

Most EP devices are labeled “single-use”. Therefore, hospitals cannot reprocess EP devices through their Central Sterile department. However, registered third-party reprocessing companies can obtain FDA clearance through the 510(k) process to reprocess these devices and sell them back to EP labs at about half the price of a new device.

Here is how it works: Hospital staff collects the reprocessable devices after an EP procedure and places them in collection containers provided by the reprocessor. Staff from the reprocessing company picks up these containers with regular intervals and sends the used devices to the reprocessing plant. Here, they are logged in and checked for number of uses (these are limited, based on the FDA clearance). Then they are cleaned, inspected and tested, before they are sterilized and packaged. EP labs don't get their "own" devices back, but can order reprocessed devices as soon as they need them.

The FDA clearance process is very strict and extensive - it requires that the reprocessor demonstrates to FDA that the devices can be thoroughly cleaned and inspected so that FDA can ascertain that the devices are substantially equivalent to new devices and do not present any added patient risk. It takes several months and several hundreds of thousands of dollars to obtain a clearance to reprocess and sell a used "single-use" device. In the early 2000s, physicians were hesitant to use reprocessed EP devices, but a strong safety record has removed any doubt that reprocessing is safe. In fact, some physicians prefer to use reprocessed devices, since these are all individually tested (FDA mandates this).

In the infancy of EP reprocessing, mostly low-complexity devices such as diagnostic catheters were reprocessed. However, as reprocessing companies have become more advanced and physicians more used to the devices, more complex devices have been added to the portfolio of reprocessing companies. These today include devices such as introducer sheaths, mapping catheters, diagnostic ultrasound catheters, and transeptal needles.

| | New price* | Reprocessed price |
|--------------------------------|----------------|-------------------|
| Diagnostic EP catheter | \$220 | \$110 |
| Coronary sinus catheter | \$495 | \$248 |
| Fixed introducer sheath | \$200 | \$100 |
| Steerable introducer sheath | \$930 | \$248 |
| Diagnostic ultrasound catheter | \$2,650 | \$1,325 |
| Transeptal needle | \$260 | \$130 |
| Mapping catheter | \$1,750 | \$875 |
| Total | \$6,505 | \$3,036 |

*Actual prices vary, prices shown are illustrative



Figure 1: Sample device costs in the EP lab

Figure 1 shows what the cost differences are between new and reprocessed catheters in the EP lab. On some of the more expensive devices, savings per device can be more than \$1,000. In total, in ablation procedures, costs can be reduced by more than \$3,000 or about 30% of total device costs.

| | Electrophysiology | Interventional Cardiology |
|-----------------|-------------------|---------------------------|
| # of procedures | 570,000 | 2,731,000 |
| Device costs | \$4,960,752,000 | \$6,942,850,175 |

Figure 2: Estimated procedures and device costs in EP and Interventional Cardiology

As figure 2 shows, there are more than 5 times as many Interventional Cardiology procedures compared with EP procedures, but given the lower cost of Interventional Cardiology devices, the value of the market is “only” 40% higher than in Electrophysiology.

EP reprocessing has grown tremendously during the past years, with FDA clearances for very complex devices. As a result, EP labs can enjoy quite substantial savings, allowing them to:

- Reduce costs without impacting quality or physician choice,
- Serve more (complex) patients,
- Pay for new systems, or
- Compensate for the increasing cost of some devices
- Compensate for poor or inadequate reimbursement on some procedure types

Some of the same advantages can be found in reprocessing in the Cath lab. However, the Cath lab is very different from the EP lab in terms of procedures, devices, and costs – among other things.

Interventional Cardiology procedures

EP procedures vary, like Cath lab procedures, between the very complex procedures and the less complex procedures. However, some Cath lab procedures are extremely fast (like angiograms) and cost very little. In the EP lab, even the less complex procedures have device costs of \$6,000 or more.

In the EP lab, we distinguish between simple EP procedures where no ablation takes place, and ablation procedures (for Atrial Fibrillation, for example) that are typically very long (up to 6 hours or more). EP physicians work very closely with their teams during these procedures, and typically rely on support from the original equipment manufacturer’s rep for the mapping technology.

In the Cath Lab about half of the procedures do not result in intervention. These shorter diagnostic procedures use fewer devices and often take less than 45 min. More complex procedures involve opening blockages, etc. in actual interventions. Even simple interventions may require the use of imaging catheters or FFR wires. More complex interventions can involve the use of atherectomy catheters, thrombectomy catheters, and often several micro-catheters.

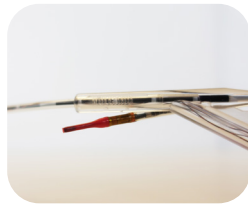


| | Procedures | Share |
|-----------------------|------------|-------|
| Angiogram | 1,248,800 | 46% |
| Heart Cath | 535,200 | 20% |
| Basic Interventions | 568,200 | 21% |
| Complex Interventions | 284,100 | 10% |
| CTOs | 94,700 | 3% |
| Total | 2,731,000 | 100% |

Figure 3: Estimated distribution of Interventional Cardiology procedures

There has been a push for more quantifiable measurements of procedural outcomes, which has seen an increase in the use of imaging catheters to evaluate for proper stent deployment.

There has been a push for more measurement of procedure effects in interventional cardiology, which has meant an increase in the use of imaging catheters and potentially atherectomy and thrombectomy catheters. Interventional cardiology procedures are expected to stay fairly flat over the next several years, however, some procedure types may become more common as the demographic, regulatory, and technological environment changes. Increasing complexity of cardiac disease has seen increased adoption of atherectomy devices to aid in treatment.



Device costs and reimbursement in Interventional Cardiology

In EP procedures, most devices cost hundreds of dollars. In the Cath Lab, many devices, especially those used for diagnostic procedures, are very low cost. This means that even though the total number of Interventional Cardiology procedures is much higher than the number of EP procedures, the cost of the average Interventional Cardiology procedure is much lower, and the total amount of money spent in US healthcare on devices for Interventional Cardiology procedures is \$6.9B versus almost \$5B in EP.

This is because many devices are less costly, and because the most common Interventional Cardiology procedures – diagnostic procedures – use only the low cost devices. A full two thirds of Interventional Cardiology procedures are estimated to be diagnostic (only) procedures, with device costs between \$500 and 600\$. Most Cath Labs will also conduct basic interventions with much higher costs of \$3,700. Complex interventions and CTOs (procedures where Chronic Totally Occluded vessels are addressed) are much rarer and take place in only certain Cath Labs with highly skilled Interventional Cardiologists. However, these are also procedures with very high device costs of \$9-14,000.

| | Procedures | % of procedures | Device Costs | Total Cost | Reimbursement | Device cost % of reimbursement |
|-----------------------|------------|-----------------|--------------|-----------------|---------------|--------------------------------|
| Angiogram | 1,248,800 | 46% | \$512 | \$639,972,536 | \$2,800 | 18% |
| Heart Cath | 535,200 | 20% | \$589 | \$315,484,344 | \$2,800 | 21% |
| Basic Interventions | 568,200 | 21% | \$3,701 | \$2,102,794,560 | \$10,000 | 37% |
| Complex Interventions | 284,100 | 10% | \$8,991 | \$2,554,218,096 | \$16,000 | 56% |
| CTOs | 94,700 | 3% | \$14,048 | \$1,330,380,639 | \$16,000 | 88% |
| Total | 2,731,000 | 100% | N/A | \$6,942,850,175 | N/A | N/A |

Figure 4: Device costs and reimbursement in Interventional Cardiology

Therefore, the total device cost in Interventional Cardiology comes mainly from interventions (86% of the total costs). However, controlling the cost is important for both interventions and for diagnostic procedures:

Interventions:

Device costs are between 37% and 88% of CMS reimbursement. This means that it is extremely difficult for the cath lab to control the costs, especially for CTO procedures, but also for interventions in general. As more advanced (and expensive) mapping, atherectomy and thrombectomy devices are introduced, labs will become under increasing cost pressure.

Diagnostic procedures:

Device costs in diagnostic procedures are fairly low, and reimbursement is ample enough to make these procedures profitable. Further, there is a downward pressure on these device prices (in contrast, the price of devices used in interventions are bound to increase). However, the sheer amount of diagnostic procedures means that overall service line revenue can be significantly impacted if device costs in diagnostic procedures were reduced.

The market for EP devices is dominated by 2-3 very large manufacturers. In fact most labs are really only acquiring technology from one or two manufacturers. This gives the manufacturers enormous power in the EP lab to determine device choices, pricing, etc. Most EP physicians are loyal to a specific brand, whether this is the brand they were trained on during their internship or because they rely on the manufacturer for knowledge and support.

In the Cath Lab, the situation is different. Here, there is a very large number of manufacturers, and brand loyalty and preference are much less pronounced. This means that buyers are a lot more price sensitive – and that physicians may be more willing to switch between brands based on costs.



Main technology, utilization and cost trends in Interventional Cardiology

The number of interventional Cardiology procedures is expected to increase very minimally (1-2%) in the following years. However, several trends in Interventional Cardiology are poised to change how these procedures are done and what technologies dominate:

Compared with EP, where technology innovation is very ambitious and new devices are introduced every 1-2 years, Interventional Cardiology technology has remained fairly stable for the past 15-20 years. This is certainly true for the catheters used in Interventional Cardiology procedures. The development of more advanced micro-catheters and interventional wires is an exception.

There has been some pressure to ensure better accountability and effectiveness measurement for procedures in the Cath Lab. This has led to an increase in the use of fractional flow reserve (FFR) as well as imaging catheters. These will likely continue to be improved upon, with resulting upwards price pressure.

Many Cath labs do not conduct complex interventions, and some do not do interventions at all. This is at least partially due to the high cost of these procedures, which may not be profitable in hospitals with an unfavorable payer mix. This unfortunately means that access to life-saving interventions is not a given. This is not expected to change in the near future, due to the high costs of interventional procedure devices.

We will likely see technology development in mapping devices as well as, as mentioned - microcatheters. When there are price increases for advanced devices - procedure costs go up. In contrast, we are experiencing price erosion for diagnostic devices - and as a result procedure costs go down or remain stable. This may unfortunately pressure smaller labs to stay away from complex cases.

Reprocessing potential in Interventional Cardiology

Although there are significant differences between the economics, the technology, and the procedures of the Cath lab and the EP lab, these trends suggest that reprocessing could be very valuable in the Cath lab. Additionally, the development of new reprocessing technologies makes it technologically feasible to safely reprocess several devices in the Cath lab – for significant financial impact.

There are 3 reasons why single-use device reprocessing should be embraced by Interventional Cardiology and deliver the same impact it has in EP:

1. The high volume of diagnostic procedures in the Cath lab makes it critically important to control costs, even as these procedures are profitable
2. Low reimbursement combined with increasing device costs in interventional procedures is threatening to make these procedures unattractive from a financial perspective
3. High costs of interventional devices may prevent several labs from offering more complex procedures

There are several possible ways of controlling device costs in the Cath lab. However, single-use device reprocessing offers one with an important advantage: No need for the physician to change procedure approach or device brand.

Reprocessing technology and the Cath Lab

In recent years, reprocessing technology has revolutionized EP lab reprocessing, adding devices to the program that traditionally have been viewed as not reprocessable. This includes devices with a microlumen. Patented reprocessing technology today allows EP labs to reprocess several micro-lumened devices.

In the Cath lab, almost all the devices used in interventions are micro-lumened. Thanks to technology advancements on the EP side, these devices can be reprocessed without compromising patient safety or device functionality. Microcatheters, imaging catheters, thrombectomy devices, and atherectomy devices are all good candidates.

Many Cath lab devices are very simple devices. These are, of course, reprocessable, although the simpler devices are also often more fragile and less durable. However, even simple devices must go through an FDA clearance process before they can be re-used. This means that the reprocessing savings potential in the Cath lab will not be realized over-night. It will take several years for this to happen.

The savings potential associated with reprocessing in the Cath lab is substantial. An analysis conducted at an LA county hospital including just 7 devices (a mix of high volume-low cost devices and low volume-high cost devices) showed potential savings of \$87,000 per month. Savings will be different, of course, between diagnostic and interventional procedures: Cost savings in complex or CTO procedures would be \$2,400, while savings in diagnostic (high volume) procedures would be less than \$100.

| | Cost Savings | % of procedure costs |
|-----------------------|--------------|----------------------|
| Angiogram | \$64.30 | 13% |
| Heart Cath | \$64.30 | 11% |
| Basic Interventions | \$504.99 | 14% |
| Complex Interventions | \$2,397.57 | 27% |
| CTOs | \$2,397.57 | 17% |



Figure 5: Potential reprocessing cost savings in Interventional Cardiology

On a national scale, it is realistic to predict that within a fairly short amount of time, single-use device reprocessing could reduce the cost of Interventional Cardiology procedures by hundreds of millions of dollars.

*The third-party trademarks used herein are for device identification and are trademarks of their respective owners.