EP Single-Use Device Reprocessing by the Numbers

By: Lars Thording

Atrial Fibrillation (AFib) and other Electrophysiology (EP) procedures continue to grow at a very fast rate, as more patients get diagnosed and new technology allows EP labs to successfully treat more complicated cases. Over the past 10 years, catheter ablation procedures have grown annually by approximately 10%; AFib procedures alone have grown by almost 17% per year. This makes EP procedures one of the fastest growing procedures in the United States. Growth rates are expected to remain high (even go up) in the following years.

EP procedures are also, for hospitals with the right payer mix, an important and highly profitable service line. Similarly, for hospitals with a less favorable payer mix, they can be a significant strain on the hospital finances, which makes cost reductions a critical strategy. Among strategies to reduce procedure costs, single-use device reprocessing stands out as one of the strategies that can have the largest impact, in some cases making the difference between procedures that result in a financial loss and procedures that result in a profit.

Catheter Ablation procedures in the United States

In 2020, there will be more than 360,000 ablation procedures a year in the United States. More than 2/3 of these (240,000) are Atrial Fibrillation (AFib) procedures. These are very complex procedures that involve the use of advanced (and expensive) instrumentation.

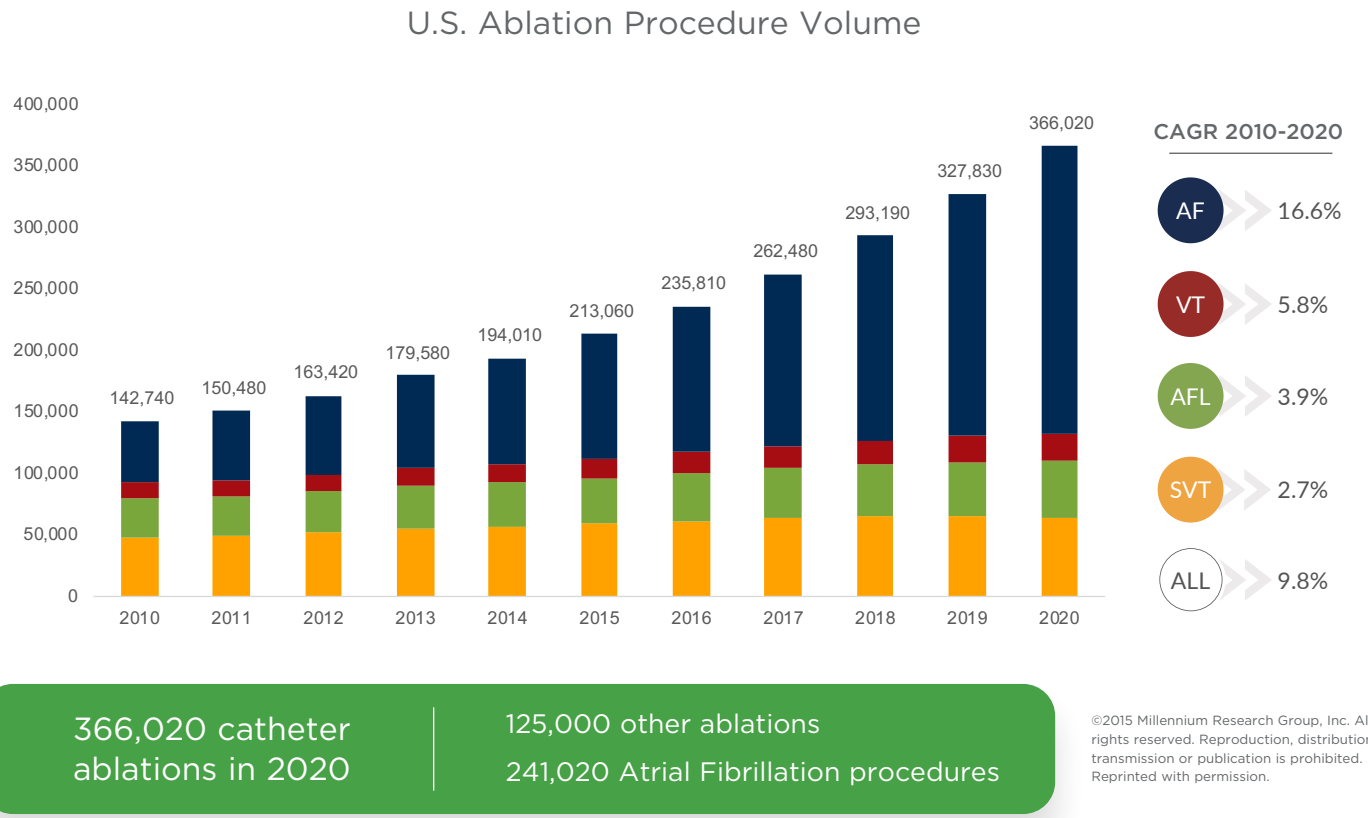


Figure 1: Cost of catheter ablation procedures in the United States

Procedure growth can be explained by several factors:

- More and more patients get diagnosed
- Advancement in catheter ablation technology allows electrophysiologists to treat more complex cases
- Methodological and technological improvements have allowed EP labs to increase efficiencies and made more EP procedures financially viable
- There is increasing evidence that catheter ablation is more effective and more cost efficient than non-curative pharmaceutical regiments

Several emerging technology developments and continued focus by medical device manufacturers on the clinical and technological possibilities in EP suggest that demand as well as supply of EP procedures will continue to grow at a high rate.

The economics of device utilization in catheter ablation procedures

Device costs in AFib procedures are approximately $10,500 per procedure. While device utilization varies based on procedure idiosyncrasies and physician choices, figure 2 below illustrates a typical utilization scenario. Some of the devices used are very expensive, with ablation catheters (~$3,456), ICE catheters (~$2,650) and mapping catheters (~$1,750) making up 75% of procedure device costs. The numbers for other ablation procedures are conservative, as some of these cases may involve ICE catheters as well.

Based on the Millennium data from figure 1, this means that in 2020, we will spend more than $2.5B per year on devices used in AFib procedures in the United States. That number increases to more than $3.1 Billion when including other catheter ablation procedures.

	Atrial Fibrillation	Other Ablation
Irrigation Tubing	$100	$100
Ablation Catheter	$3,456	$3,456
Patch	$415	$415
Transseptal Needle	$260	-
Coronary Sinus Catheter	$495	$495
ICE Catheter	$2,650	-
Quads	$220	$220
Guiding Sheath	$200	$200
Steerable Sheath	$930	-
Mapping Catheter	$1,750	-
Total	**$10,476**	**$4,886**

Costs per procedure:

AFib: -$10,476

Other: -$4,886

Total catheter ablation costs per year, US healthcare:

AFib: -$2,525M

Other: -$611M

Total: -$3,136M

Source: Innovative Health national price statistics and interviews with doctors at Mayo Rochester and Mayo Phoenix

Figure 2: Growth of ablation procedures in the United States

“...in 2020, we will spend more than $2.5B per year on devices used in AFib procedures in the United States.

The high costs of single-use devices used in catheter ablation procedures puts severe strain on the economics of an EP lab. Certainly, at hospitals with favorable payer mix, catheter ablation procedures serve as a very profitable service line, in many cases serving to compensate for other service lines that may be less profitable (or not profitable at all). At hospitals with a less favorable payer mix, a thin or non-existing margin on catheter ablation procedures can become a real financial problem, potentially leading to limited patient intake or even closure of the service line.

The economics shift with single-use device reprocessing

Using reprocessed single-use devices in ablation procedures can dramatically reduce the costs of catheter ablation, especially in AFib procedures, were the most expensive devices are used. Specifically, when replacing new mapping catheters and ICE catheters with reprocessed ones, costs are reduced by approximately $2,200 per procedure.

Costs per ablation procedure with reprocessing

	Atrial Fibrillation		Other Ablation	
	Original Price	Reprocessed Price	Original Price	Reprocessed Price
Irrigation tubing	$100	$100	$100	$100
Transseptal needle	$260	$260	-	-
Patch	$415	$415	$415	$415
Irrigated AF ablation catheter	$3,456	$3,456	$3,456	$3,456
Guiding sheath	$200	$200	$200	$200
Coronary sinus catheter	$495	$248	$495	$248
ICE catheter	$2,650	$1,325	-	-
Steerable sheath	$930	$465	-	-
Quads	$220	$110	$220	$110
Mapping catheters	$1,750	$875	-	-
Total	**$10,476**	**$7,454**	**$4,886**	**$4,529**

Costs per procedure:

AFib: -$10,476

Other: -$4,886

Potential savings per procedure:

AFib: -$3,022 (29%)

Other: -$357 (7%)

Source: Innovative Health national price statistics and national price list. Assuming supply = demand: Reprocessed devices 100% available
*Highlighted fields reference reprocessed devices distributed by Innovative Health.

Figure 3: Cost per ablation procedure with reprocessing

In total, using reprocessed single-use devices in an AFib procedure reduces costs by almost 30% (more than $3,000), while in other AFib procedures, the cost reduction is 7% (or approximately $350).

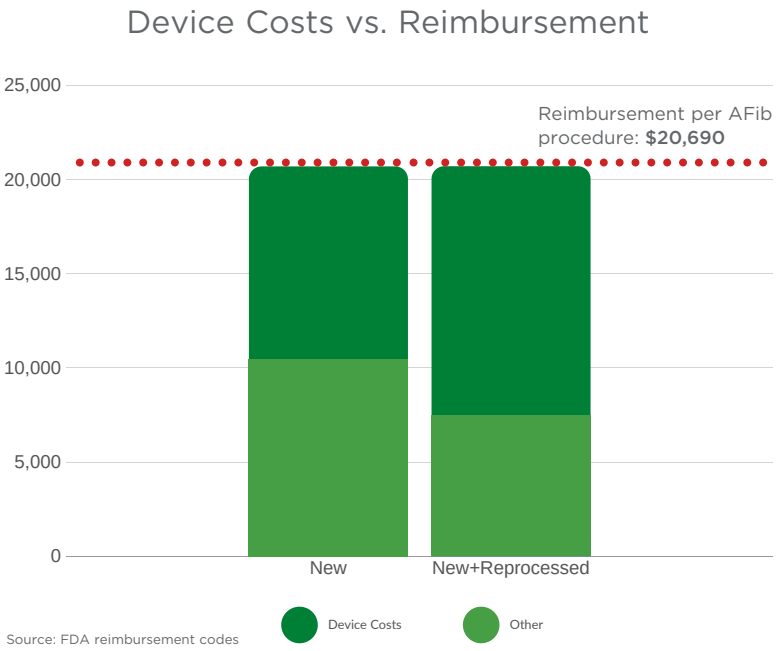
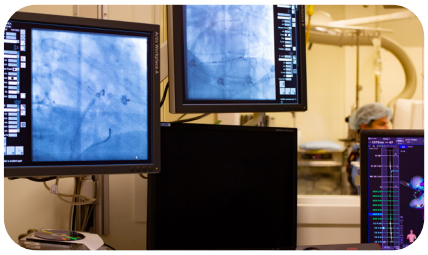


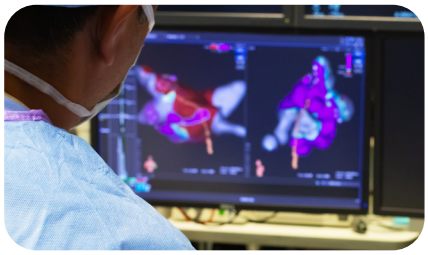
Figure 4: Growth of ablation procedures in the United States

In 2020, CMS reimbursement on AFib procedures was increased to $20,690 to accommodate increasing device costs and increasing volume. This means hospitals get paid $20,690 for each AFib procedure.

However, device costs are still more than half of the reimbursement amount, which is generally considered unsustainable for any hospital activity.

Using reprocessed single-use devices instead of new drives device costs down to approximately 36% of reimbursement.

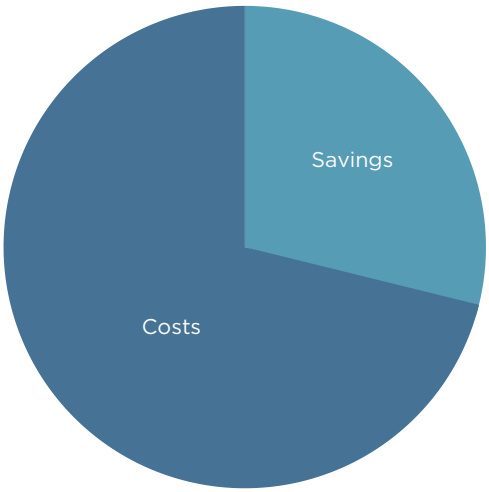




The bigger picture: What can EP reprocessing do at a national scale?

Based on Millennium's data and the calculations above, US healthcare can reduce device costs in AFib procedures by approximately $728M per year if single-use device reprocessing is fully utilized. This means reducing the $2.5B spend to approximately $1.8B. When other catheter ablations are included, total potential savings increase to $773M.

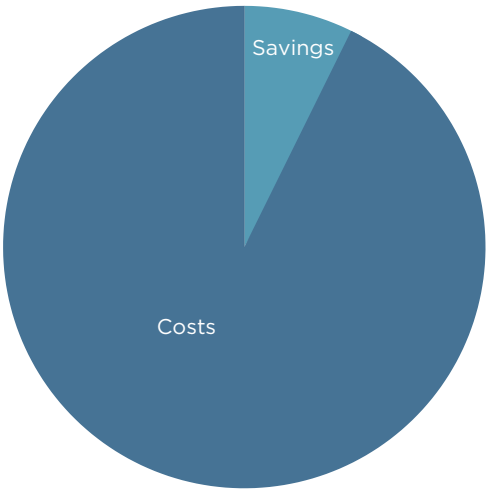
AFib reprocessing savings potential



Potential reprocessing savings:

~$728M

Other ablation reprocessing savings potential



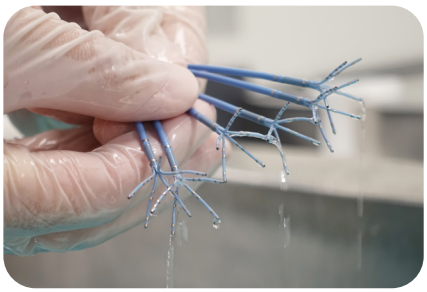
Potential reprocessing savings:

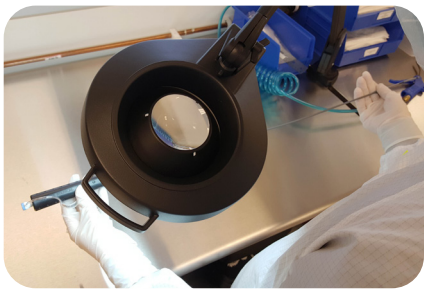
~$45M

Source: Innovative Health national price statistics and national price list. Assuming supply = demand: Reprocessed devices 100% available

Figure 5: Reprocessing savings potential in catheter ablation, US

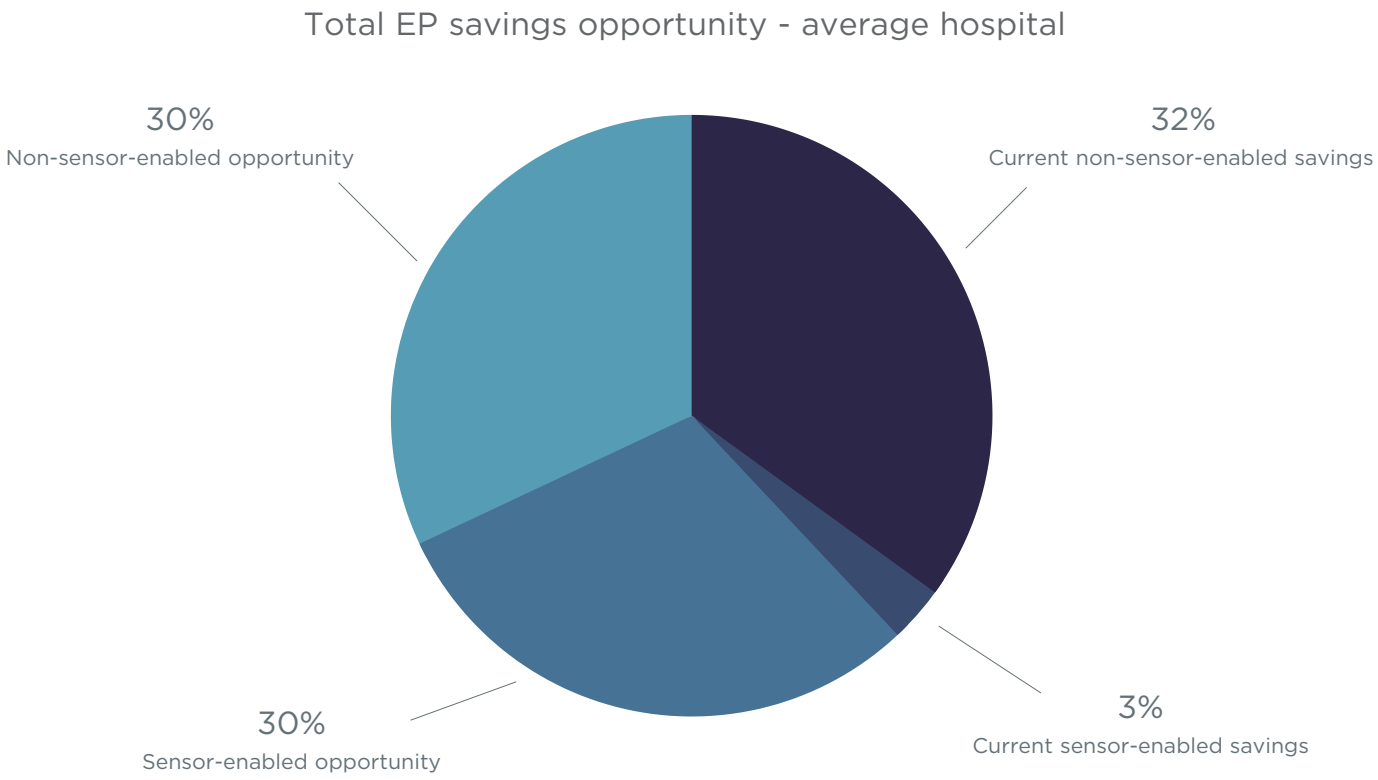
This level of economic infusion into the hospital supply chain would certainly go a long way towards producing the supply chain slack needed to address, as an example, a pandemic. However, this level of savings increase is only possible if the hospitals are successful in taking control of their supply chain and leverage reprocessing as a supply chain strategy.





Are we realizing the reprocessing savings opportunity in catheter ablation?

Reprocessing programs across the US produce nowhere near this level of savings. Innovative Health conducted a study of 50 representative hospitals and analyzed their savings and device utilization. Results show that the average EP lab only realizes about 35% of the reprocessing savings potential:



Source: Innovative Health national price statistics and national price list. Assuming supply = demand: Reprocessed devices 100% available

Figure 6: Average reprocessing savings realization

Most of what is realized is savings from using reprocessed non-sensor-enabled catheters. These are relatively inexpensive catheters based on established technologies. The additional 30% of the savings potential that is accessible for the average hospital simply comes from more diligently purchasing back catheters that have been reprocessed for years, sometimes decades. Proper program management alone could almost double savings for the average hospital.

Only 3% of the reprocessing savings potential is realized through the use of reprocessed sensor-enabled catheters. These are newer technologies, more and advanced, and priced higher.

EP labs that limit their reprocessing program to non-sensor-enabled catheters only save about $822 per AFib procedure. The numbers are detailed in Figure 7. In contrast, EP

labs that include sensor-enabled catheters in their reprocessing program save more than $3,000 per procedure. The $2,200 difference comes from 2 devices alone – the ICE catheter and the mapping catheter.

So, why isn't the average hospital using reprocessed ICE catheters and mapping catheters? The reason is that the largest manufacturer of these devices owns more than 50% of the market and refuses to provide essential, technical mapping support to procedures where these reprocessed catheters are used. Doctors and EP labs depend on this support and feel compelled to accept the loss of the $2,200 in savings per procedure.

Value of savings from sensor-enabled catheters

	Atrial Fibrillation without reprocessed sensor-enabled catheters		Atrial Fibrillation with reprocessed sensor-enabled catheters	
	Original Price	Reprocessed Price	Original Price	Reprocessed Price
Irrigation tubing	$100	$100	$100	$100
Ablation Catheter	$3,456	$3,456	$3,456	$3,456
Patch	$415	$415	$415	$415
Transseptal Needle	$260	$260	$260	$260
Coronary sinus catheter	$495	$248	$495	$248
Steerable sheath	$930	$465	$930	$465
Quads	$220	$110	$220	$110
Guiding sheath	$200	$200	$200	$200
ICE Catheter	$2,650	$2,650	$2,650	$1,325
Mapping catheter	$1,750	$1,750	$1,750	$875
Total	**$10,476**	**$9,654**	**$10,476**	**$7,454**

Savings per procedure:

With sensor-enabled device savings:
$3,022

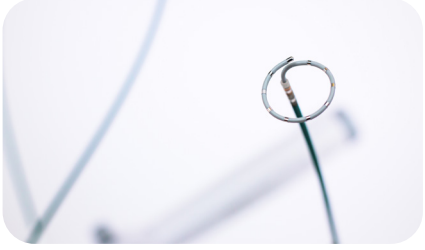
Without sensor-enabled device savings:
$822

Potential loss per procedure:
$2,200

Source: Innovative Health national price statistics and national price list.
*Highlighted fields reference reprocessed devices distributed by Innovative Health.

Figure 4: Cost per ablation procedure with reprocessing

What is the overall loss to US healthcare of this approach by the original manufacturer? If manufacturers are successful at stopping EP labs from using reprocessed sensor-enabled catheters, it would cost US healthcare approximately $530M in lost savings.



What can hospitals do?

In 2019, the average US hospital had an operating margin of around 2%. According to Modern Healthcare, by March, 2020, the average hospital had a year-to-date operating margin of -8%. In the current economic climate, single-use device reprocessing must be part of the supply chain strategy.

Specifically EP labs, which had to completely stop procedures for several weeks, are in dire economic straits. Utililizing reprocessed devices has been shown to potentially have a substantial impact on the economics of catheter ablation procedures. EP labs that want to realize the full potential of EP device reprocessing should follow these three steps:

1. Optimize the existing reprocessing program: As shown in figure 6, simply buying back all available non-sensor-enabled catheters and ensuring proper collection can almost double existing savings
2. Select an independent reprocessing partner that has clearance to reprocess the more expensive sensor-enabled catheters. Reprocessors vary greatly in terms of what they are cleared to reprocess
3. Inform the original manufacturer that you will start using reprocessed sensor-enabled catheters and expect technical mapping support to continue. This will increase savings by more than $2,000 per AFib procedure.

The last step is the most difficult one – but also the most valuable one. It involves having a direct conversation with the manufacturer, and detailing a new mapping support policy:

It is universally understood that mapping support is an integral aspect of an EP lab's vendor partnerships, but this support should not dictate which devices EP labs decide to utilize. That is, the clinical effectiveness and financial sustainability of EP labs depend both on close technical and clinical collaboration with the mapping system vendor AND on controlled, safe cost reduction strategies, such as single-use device reprocessing. In addition to maintaining clinical outcomes, cost control is vital to both superior patient care and the financial viability of EP labs and hospitals.

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Given that FDA has cleared the reprocessing of sensor-enabled catheters by some reprocessors, it is a reasonable expectation that all vendors who have mapping equipment within the clinical practice will continue to provide clinical account specialists to support all 3D mapping cases.

Failure by the vendor to appreciate this perspective should affect the business the vendor has at the hospital.

A mapping support policy could be worded like this:

1. The EP lab expects the vendor and its representatives to appreciate and accommodate the EP lab's simultaneous need to optimize clinical effectiveness and financial sustainability by combining close system vendor collaboration with an aggressive single-use device reprocessing program.
2. The EP lab expects the vendor's mapping technicians to provide mapping support in all procedures where devices originally manufactured by the vendor are used, whether these are reprocessed or new. Using reprocessed catheters does not mean that the vendor loses its revenue, but rather that the full value of its devices is realized in order to sustain hospital finances, and that vendor's total revenue from the EP lab and the hospital is reduced by a very small fraction.
3. The EP lab intends to include sensor-enabled catheters in the EP reprocessing program, as these devices are the most expensive used in EP cases and produce the bulk potential savings.
4. Interference with the EP lab's reprocessing program will not be tolerated; specifically, false allegations about device safety, undocumented statements about functional differences, or mis-leading claims about the difference between reprocessed devices from different vendors – will be considered a threat to the vendor relationship.
5. Optimal savings from the EP reprocessing program is an integral aspect of the vendor choice. Should a vendor choice not allow for simultaneous close technical and clinical collaboration with the EP lab (and its mapping technicians) and an aggressive reprocessing cost savings program, the vendor's business in the EP lab needs to be re-evaluated.
6. The EP lab reserves its right to choose its reprocessing vendor based on overall value and ability to produce cost savings.

With a strong mapping policy in place, EP labs will be able to achieve the maximum potential savings during catheter ablation procedures by utilizing reprocessed devices, and significantly improve the economics of the procedures.

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