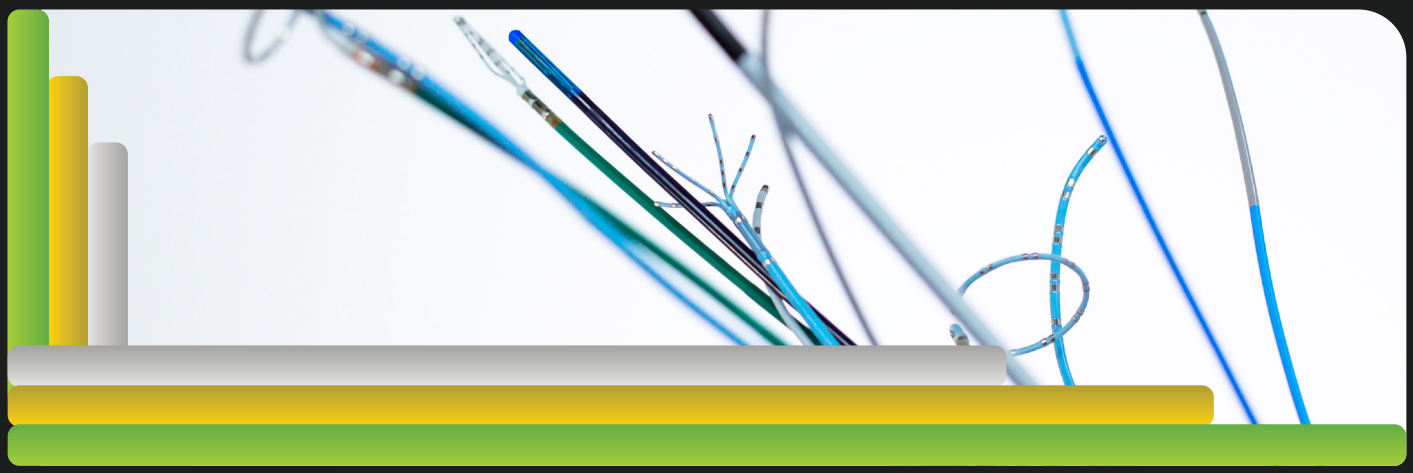
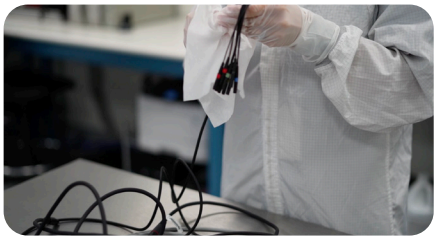


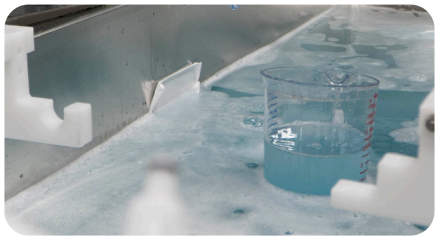
25 Years of Single-Use Device Reprocessing

By: Lars Thording

In 2000, the Association of Medical Device Reprocessors (AMDR) was formed as the first significant step in the formation of an industry that has come to play a major role in the cost control and environmental efforts of most US hospitals. In that year (2000), pressure on FDA to regulate single-use device reprocessing peaked and FDA gave reprocessors 2 years to submit for and receive clearances to reprocess single-use medical devices.

Since 2000, reprocessing has evolved from a miscredited activity associated with high patient risk and zero guardrails to a highly regulated – and highly trusted - routine activity performed by most US hospitals, including the top health systems we associated with top performance. Many would describe single-use device reprocessing as a huge success and encourage the industry to take a victory lab to celebrate the 25-year anniversary.





Before I do so, I would like to take a step back and present an objective review of what the 25 years have meant and where we are today. Are we celebrating that the industry is still alive today, in spite of adversity? Or are we celebrating a true revolution in medical device utilization? In my mind, the adoption of single-use device reprocessing has been far too slow; results are anemic given the potential of the activity; and healthcare still struggles to maintain a practice that is focused on patient care quality balanced with financial and environmental sustainability. I also believe that the future of single-use device reprocessing should be discussed in this anniversary year, where healthcare administrators, medical device manufacturers, lawmakers – and the public – still struggle with the concept of responsible care and hiding behind business-as-usual thinking that may be comforting but allows us all to elude responsibility for securing change that makes sense.

AMDR, of course, deserves celebrating. The association has battled one wave of opposition after the other, and it has prevailed, maybe even succeeded. I think the next few years will show.

The History of the EP Reprocessing Industry

In this whitepaper, I have first looked at the history of the industry from the perspective of the number of FDA reprocessing clearances (and the number of reprocessors participating in the industry). Why focus on the number of FDA clearances? It is the nature of single-use device reprocessing that as products are obsoleted, prices go down, new technologies are launched, or OMs block reprocessed products, the reprocessor and the reprocessing industry have to replace these savings (and their revenue) with new products or modalities. When the reprocessing industry seizes to do this, savings go down. Different periods in the history of reprocessing have been characterized by very large numbers of FDA clearances. And conversely, in other periods, the industry has slowed down and produced very few. These periods also reflect change in the dynamics of the industry and its market.

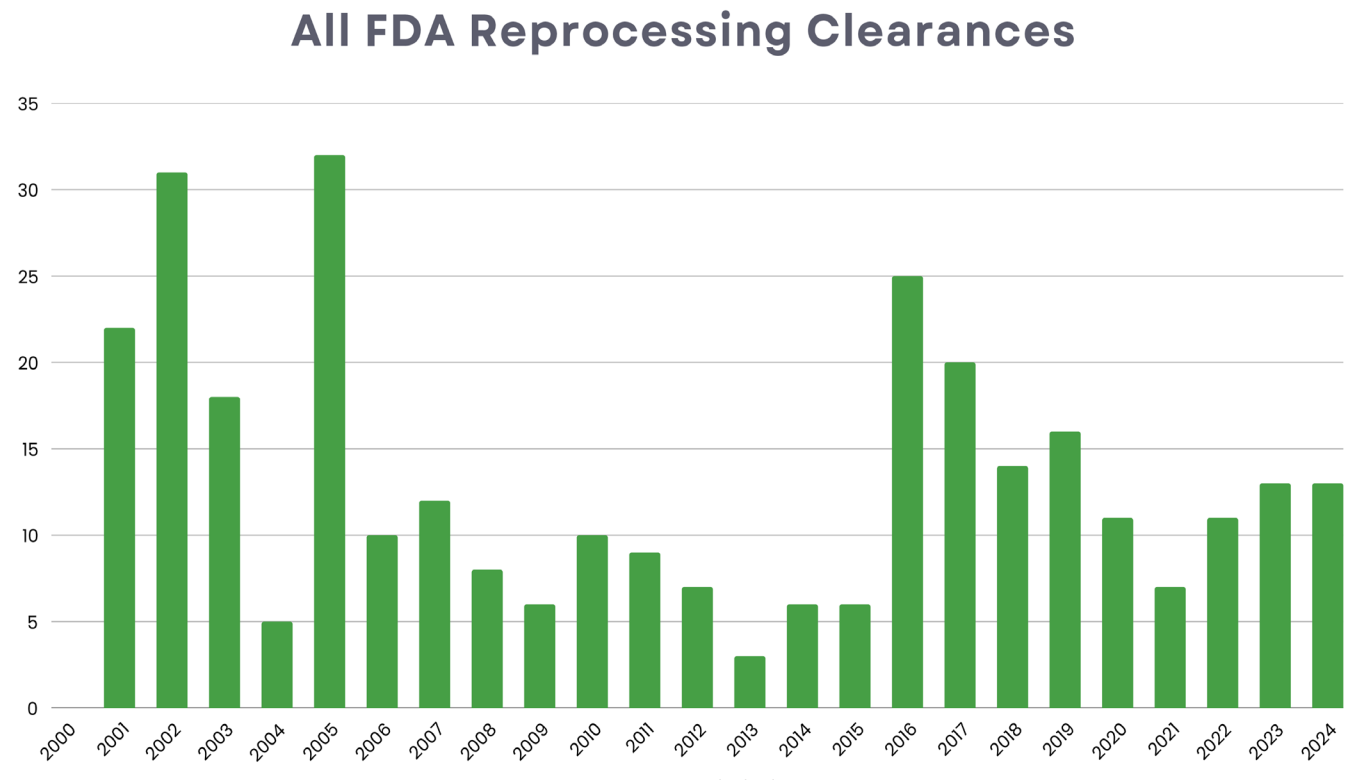
It all started in 2000, when FDA made it clear that by 2002, reprocessors could only market devices for which they had an FDA clearance. This clearance was the same clearance medical device manufacturers had to get – with a demand to demonstrate that the reprocessed device was substantially equivalent to the new device. As a result, overnight, small, start-up reprocessors were asked to conform with the same regulatory requirements as the massive, international corporations that designed the original products.

Industry Formation

This FDA regulatory requirement became the end for small reprocessors without the wherewithal and the stomach to become advanced medical device companies in a matter of months. It also ended the practice of hospitals reprocessing single-use devices, a very high-risk activity that was rightfully terminated.

What remained was really three national reprocessing companies: SterilMed, Alliance, and Vanguard, and the years that followed were really the formation years of single-use device reprocessing.

The graph below shows what happened after the FDA mandate, in terms of the total number of FDA clearances granted to reprocess single-use medical devices.



*Source: FDA's 510(k) database

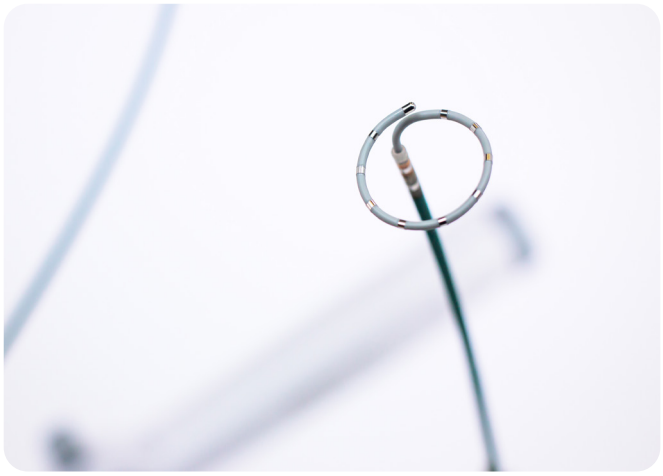
The industry took up FDA's challenge and pushed out more than 30 clearances in 2002 and 2005, the strongest years ever for reprocessing FDA clearances. In the 5 years after the mandate, more than 100 clearances for reprocessing were granted by FDA. The individuals who cleaned up their operations, over-night learned how to operate the regulatory system and pushed through in spite of the seemingly impossible task - are the true pioneers of reprocessing.

In this same time period, the industry battled legal state challenges to reprocessing, which had to be addressed by the industry and the association state by state. The original manufacturers were still rattled by the curious turn of events they experienced: Their pressure on the FDA to outlaw reprocessing, so they could protect their profits, instead became the establishment of regulated reprocessing that not only brought the activity out of the shade, but also brought it up from the dark hospital basement into the regulated medical facility. What they wanted to remove became regulated and professionalized.

Market Growth

Between 2006 and 2011, FDA activities slowed down. This did not mean that the industry was not successful. To the contrary, these were substantial growth years where reprocessors benefitted from their clearances in the early part of the decade and surged into hospital floors, operating rooms and cardiology labs. During this time, hospitals changed their stance towards single-use reprocessing and started adopting it wholesale.

The industry's battle shifted from the state legislation to increasing opposition from the original manufacturers – and a resultant resistance from the doctors they supported, clinically and financially. This was the era of "doubt and confusion": Original manufacturers distributed photos of alleged "reprocessed devices" that were visibly dirty and demonstrably contaminated. Of course, none of these "studies" or "evidence" were real, but they meant reprocessors could not present the hospitals with the levels of savings that were theoretically possible. On average, our studies show, a hospital saved 50 cents while they should save a dollar – due to physician resistance and original manufacturer interference.



Unfortunately, this remains a battle. And one of the biggest challenges today for reprocessing remains the hospital's lack of wherewithal to insist that manufacturers are vendors who shouldn't be allowed to make financial and operational decisions in the henhouse that is the hospital.

Still, during these years of market growth, reprocessors not only quickly built the market as hospital administrators pursued reprocessing as a key savings strategy, they also gradually evolved business and service formats so that they fit the hospitals optimally. Frequent business reviews were introduced to ensure optimal program oversight; different distribution formats were introduced, in-service and regular presence in the hospital became the norm, and – perhaps

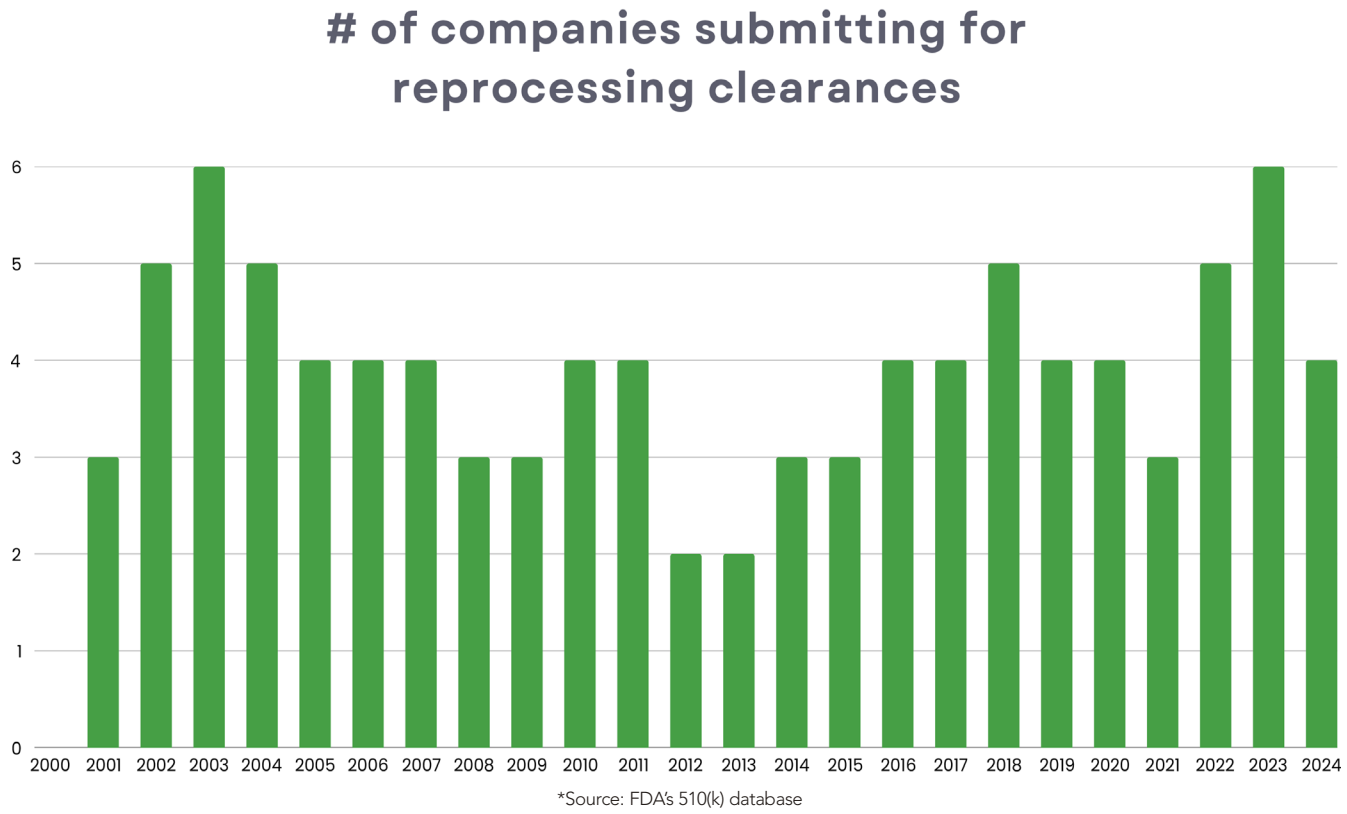
most importantly – a reprocessing culture evolved at the hospitals. Staff understood the system and participated actively with the reprocessors in optimizing the program.

The medical device industry at this point had discovered reprocessing and what threat it constituted. Some embraced it, others sought to kill it off. The largest medical devices reprocessor, Ascent Healthcare Solutions, which had been formed in 2005 in a merger between Vanguard Medical Concepts and Alliance Medical Corporation, was acquired in November 2009 by Stryker, and the second-largest reprocessor. SterilMed, was acquired by Biosense Webster (Johnson & Johnson) in 2011.

The Dormant Era

And then the industry took a nap. From 2011 when large device manufacturers had acquired most of the reprocessing industry, the rate of clearances fell to 6 per year, and consolidation reduced the number of reprocessing companies significantly. FDA clearances were only granted to the three main reprocessors: SterilMed, Stryker, and later Medline.

The chart below shows how between 2012-2015, only these three companies worked to expand the industry. It says a lot about an industry's growth how many small/new participants are active, and these years were not good for the reprocessing industry.



*Source: FDA's 510(k) database

During these years, reprocessing changed in other ways as well, with less presence in the hospital, fewer business reviews – and overall declining savings. There were few – if any - new 510(k)s launched to replace 510(k)s on obsoleted devices. Reprocessors did not pay much attention to the fast-growing electrophysiology area during these years, in spite of the rapid growth in demand and technology – and the fact that the highest savings potential from reprocessing were on devices in this area. Many hospitals either stopped focusing on reprocessing or completely abandoned the practice, as disappointment with savings results spread. With reprocessing in the hands of large medical device manufacturers and distributors, the entrepreneurial focus on service and technological advancement was replaced with a focus on sales and cost reduction. This period represented a bit of a setback for the industry.

Industry Disruption and Specialization

The rate of clearances only returned to initial high levels in 2016 and 2017, when the number of reprocessing clearances began to rise again - 15 in 2016 and 8 in 2017. This resurgence in 510(k)s came with the entry of more specialized reprocessors into the reprocessing area, and clearly the increase in 510(k) clearances happened because these companies were building a basic portfolio of clearances to be able to serve hospitals. This industry disruption came with a new approach: An aggressive commitment to seeking 510(k) clearances beyond the industry standard scope of devices and an effort to bring back the virtues of reprocessing as a key supply chain strategy. Specialization allows for focus on specific clinical areas, regulatorily and from an R&D perspective. This meant that in the years 2016-2021, more clearances were granted to specialty reprocessors for devices that had previously been considered impossible to reprocess. Non-specialized reprocessors that assumed their portfolio of clearances had "maxed out" reuse technology capabilities – saw their revenues erode as devices were obsoleted and new reprocessed devices were introduced to the market.

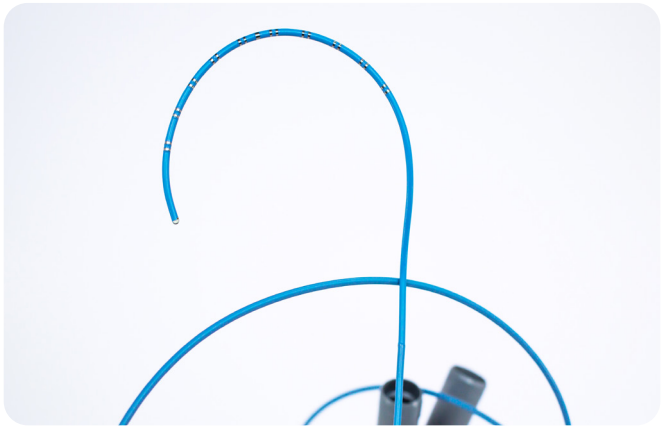
Also, this has had a direct impact on the speed with which clearances were granted. The more proficient the reprocessor is in working with the FDA and understanding regulatory and clinical requirements, the shorter the time it takes for a 510(k) to be cleared.

Fragmentation and Looming Threats

Since 2020, the number of new reprocessing clearances have found a new "normal" level at around 10 clearances per year. However, things are not "normal in reprocessing these years. The industry is undergoing some fragmentation shifts that threaten the otherwise stable industry:

There are more international reprocessors appearing, operating under regulatory regiments that are different from FDAs. Many of these have shown resistance to join the Association of Medical Device Reprocessors (AMDR), threatening the unity of the industry. Similarly, in the domestic (US) market, several smaller companies have appeared over the past two years – and they have chosen to stand outside of AMDR. The industry is strong (partially) because AMDR unifies its participants in a singular regulatory framework and code of conduct. When more and more reprocessors stand outside AMDR, the industry becomes fragmented and loses strength – and the trust associated with AMDR and its membership can crack and become less universal. Certainly, healthcare professionals should know that reprocessors outside of AMDR are NOT bound by a code of conduct and may not act in the healthcare provider's best interest.

At the same time, technological challenges associated with cloud-based device controls and pressures from original manufacturers to stop single-use device reprocessing are growing. To an extent, technological and industry pressures have always existed, and reprocessing has always prevailed, but at this point, the industry is fragile due to fragmentation and may have a hard time withstanding the pressure and remaining intact.



Headwinds and Tailwinds in Single-Use Device Reprocessing

At these crossroads, it is important to celebrate the industry's 25th anniversary, not just with pride, but also with some concern:

Ongoing fragmentation of the industry will result in continued erosion of established standards, goals and ethics associated with single-use device reprocessing. It is important to keep in mind that single-use device reprocessing has not only been successful due to the regulation of reprocessing, but also due to the commitment and responsible behaviors of AMDR member reprocessors. With eroding standards, the general belief that single-use device reprocessing is safe, and responsible healthcare may become weaker as well and send the industry into a crisis.

These years, AMDR members save hospitals about $400 Million every year. This may sound like an impressive number; but over 25 years that really is a fairly humble result. The number should have been at least 3 times bigger, if you look at the average hospital's utilization of reprocessed devices: Only about a third or the savings that could be achieved with existing FDA clearances are achieved. To a hospital administrator, saving, for example, $300,000 per year, is little more than pizza money for the Christmas party, in the light of what is likely a supply spend budget of 100s of millions of dollars. With such anemic results, are lab and OR directors going to continue fighting against the original manufacturers to save their reprocessing program?

New technology is emerging that can threaten reprocessing savings realized through the re-use of devices that plug into hospital consoles and generators. Manufacturers are working on making the software that run these in the Cloud, further taking away control from the hospital to manage the equipment they own. This is illustrative of another powerful headwind in single-use device reprocessing: For 25 years, hospital administrators have continued to allow original device manufacturers to walk all over their business and impact everything from what technologies they use – and whether they reprocess or not. I am not seeing anything that makes me think this will change anytime soon.

Single-use device reprocessing is a market error that I never thought would survive this long. Think about it: A manufacturer designs a device and FDA clears it to be single-use. Then the reprocessor gets a clearance from FDA saying that they can reprocess the device so it can be used more than once… The mere existence of a single-use medical device reprocessing industry should trigger the manufacturer to look at how they a) integrate reprocessing into their design and marketing activities or b) design their devices to be reusable. For 25 years, this has not happened, and while we have seen interest in pursuing these paths in the past, I have never seen a time where manufacturers seemed LESS likely to truly integrate reprocessability into their operations and strategies (I am saying this in spite of the fact that recently at least one device manufacturer has applied for AMDR membership; this was declined given the strong anti-reprocessing behavior of this company).

These are the primary headwinds that are critical to what happens to single-use device reprocessing over the next 5 and 10 years. And they make me concerned. There are, however, things the industry can celebrate and trends that constitute wind in the back:

The increasing interest in environmental benefits of reprocessing have already done amazing things for the industry. For the past 10 years or so, increasingly the environmental benefit has played a key role as driver of reprocessing. This doesn't remove any of the challenges, but it does mean that there are move advocates of the reprocessing program. Further, with Life Cycle Analyses that scientifically demonstrate the reduction in CO2 emissions from reprocessing, not only nurses and technologists are behind the environmental arguments; recently, the physicians have become interested in how they can reduce their carbon footprint through reprocessing.

Almost all US hospitals and many surgery centers and other healthcare facilities have a reprocessing program in place. As different as healthcare facilities are, it is hard to think of many things they all have in common, but reprocessing is one. It has helped tremendously in the growth of the industry that large, renowned healthcare systems became early adopters of reprocessing, and these same top US health systems continue to be great advocates of the practice.

Reprocessors have continued to break the boundaries of reprocessability. At several points in the history of the industry have reprocessors tasked themselves with coming up with ideas that would make it possible to reprocess what was called "unreprocessable" – and several times they have succeeded. This entrepreneurship and impatience with status quo have become a part of the industry's mindset, and if this is harnessed moving forward, it will continue to expand the industry – and the savings provided.

Finally, I believe AMDR is wind in the back for the reprocessing industry. AMDR initially fought legal battles in the different states. Then it had to pivot and help call out manufacturers that sowed 'doubt and fear' about the safety of reprocessing. Lately, the organization is leveraging the environmental message to drive more awareness. And through all these shifts, as mentioned, AMDR has enabled the industry to unite and to maintain standards that protect the strong belief that single-use device reprocessing is responsible healthcare.

The single-use device reprocessing industry is turning 25 this year. To get to this point, the industry has gone through distinctly different periods of formation, growth, slow-downs, specialization and fragmentation. And today, there is as much reason to be concerned about the future of the industry as there is to celebrate. The headwinds of the industry need to be addressed by healthcare leaders, lawmakers, and manufacturers, or a growingly fragmented industry will have a hard time continuing its success.

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