Questions to Ask Your Reprocessing Partner

Principles that Guide and Guard Medical Device Reprocessing

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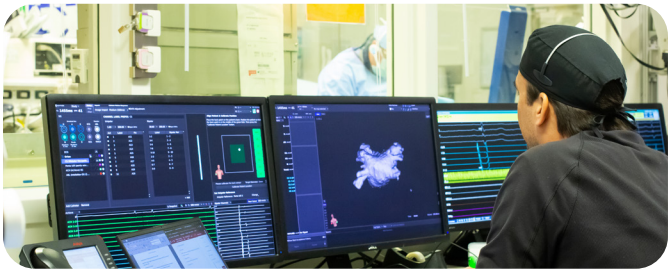
In recent decades, single-use device reprocessing has become standard in hospitals across the country as a valuable tool in reducing the cost and environmental footprint of patient care. How did this happen? It is tough to believe that medical devices marked single-use by the manufacturer can be safely reprocessed after use, and then used on another patient. Consumer products – sure. But medical devices that are used inside a patient's body? It's a tough idea to swallow. And yet, over the past decades, single-use device reprocessing has become standard in hospitals across the country.

How was it possible to convince lawmakers, regulatory agencies, the legal system, physicians, hospitals, and the U.S. population that it can be safe to re-use single-use medical devices?

The short answer: It took a lot of work, substantial oversight, and real commitment to quality on the behalf of reprocessors and the healthcare industry at large. But medical device reprocessing is still a fragile proposition. The market is surging with new entrants, which is fantastic news when it comes to keeping the industry vibrant and competitive. But it also represents a moment of vulnerability in which a lack of diligence could erode the hard-won reputation of reprocessed products.

Now is the time for the healthcare industry—healthcare providers, industry organizations, and established reprocessors—to stand together to maintain the commitment to safety and quality that have guided the reprocessing industry for 25 years.

To do so, let's take a moment to acknowledge the hard work that's gotten us where we are.



The Road to Responsible Single-Use Device Reprocessing

First, following an outcry by the original manufacturers that hospitals were reusing single-use devices, FDA decided around 2000 to regulate the practice (rather than shutting it down). Given the vast financial impact to hospitals of single-use device re-use, this was a sensible decision. FDA erected substantial barriers around the reprocessing of single-use devices, barriers that effectively stopped hospitals from reprocessing and left the practice with an increasingly sophisticated device reprocessing industry that now had to follow strict procedures, resembling those demanded from an original manufacturer, to obtain an FDA clearance to reprocess and sell single-use devices. FDA has since followed up with additional regulation that has put such demanding standards in place that reprocessed devices have been proven to function similar to new devices and represent no added patient risk. It is thanks to FDA regulation (and oversight) that hospitals and doctors have been able to trust the use of reprocessed devices. And it is thanks to FDA that reprocessors that obtain clearances are among the most sophisticated medical technology companies with safety standards and complaint records that are arguably better than those of manufacturers of new devices.

Second, the reprocessing industry came together in the years before 2000 and formed an industry association – the Association of Medical Device Reprocessors (AMDR). AMDR was instrumental initially in eliminating legal challenges to the practice, and later in maintaining high standards for its members and promoting the industry practice of reprocessing. Not everybody becomes a member of AMDR. Bylaws and code of conduct maintain a very high bar for inclusion in the industry and participation in industry activities. It is possible to be a reprocessor without an AMDR membership card, but the association has managed to convince hospitals that such membership means a higher level of integrity, sophistication and performance. AMDR has become the guardian of the founding principles of reprocessing – and, because of this, has contributed in an important way to the development that today makes reprocessing a standard practice across U.S. hospitals.

Third, the conduct of individual reprocessors, their high standards, their transparency, and their commitment to the founding principles behind reprocessing - have enabled the broad acceptance of reprocessing. Regulation is never enough. A commitment to patient safety, to the integrity of the process, and to careful interpretation of regulation characterize reprocessing companies in the United States. It is their belief in founding principles and their self-governance within the guardrails put in place by FDA and guarded by AMDR that continue to make reprocessing a safe, accepted practice.

Yet, medical device reprocessing is still a fragile proposition: If FDA takes the eye off the ball, if AMDR slackens its principles for industry acceptance, or if individual members stray from the founding principles of reprocessing, then the acceptance of single-use device reprocessing can crumble, and hospitals lose access to hundreds of millions of dollars a year. Let me illustrate: If a physician, who has been used to using reprocessed devices, suddenly sees that the devices are inappropriately marked so it is unclear who has reprocessed the

devices, or he experiences devices starting to fail in his hands, he will stop trusting that reprocessing works and stop using the devices. If this happens across physicians and hospitals, single-use reprocessing will cease to exist.

Upholding the Principles that Guide and Guard Reprocessing

This is why reputable reprocessors should celebrate, rather than lament, the challenges they encounter when submitting to FDA for a clearance. Stricter rules mean higher standards. Higher standards mean increased trust in reprocessing. When FDA comes back to the reprocessor with additional testing demands, the reprocessor should say "thank you", and meet them.

This is also why reprocessors should stand by AMDR's code of conduct and continue to insist on its enforcement.

However, reprocessing is a growing industry, and in later years, we have seen the entrance of new companies with less experience in the industry – and less closeness with the founding principles of reprocessing. More reprocessing companies is a GREAT thing that should be celebrated, but it also represents a vulnerability, since the conduct of any reprocessing company could create cracks in the trust in reprocessed products.

From a provider standpoint, there's good reason to put trust in existing regulations and AMDR. But, as new reprocessors enter the market, they must also be held to the high standards that have been established in the industry. When evaluating partners, hospitals should demand their reprocessors uphold these principles that have guided—and guarded—the practice of reprocessing over the years:

1

Used devices belong to the hospital: Used devices placed in drawers and other collection containers in the hospital do not belong to the reprocessor. They are assets that belong to the hospital. They only become the property of the reprocessor when the hospital has explicitly allowed the company to collect them. A reprocessor should not collect devices destined for other reprocessors – even devices the hospital has decided to be collected by an original manufacturer. The reprocessing representative is at the hospital as a guest. The hospital decides which devices you s/he collect. If the reprocessor collects more than they have been explicitly allowed to, they engage in theft.

This also means you should expect the reprocessor's representative to refrain from rummaging through rooms to find devices that have not been placed in the designated collection container.

QUESTIONS TO ASK

(ask the collection tech, not the program manager)

- What devices do you collect from our hospital?
- What devices have you been allowed to collect?
- Do you look for used devices outside your branded collection container?
- Is there clear signage by the collection vessel to indicate what devices are collected?

2

Respect the hospital's schedule, practices, and policies: Every hospital is unique in terms of how the rooms are operated, who plays what role, how supplies are stored, how supplies are purchased, etc. More specifically, device acquisition, storage, utilization and collection follow unique paths that the reprocessing company needs to respect. This means ensuring that reprocessing follows smoothly along those same paths. The hospital should expect that purchasing can seamlessly integrate the purchase of reprocessed devices without having to establish new routines or otherwise fit into the reprocessor's preferred way of doing business. Similarly, the reprocessor should provide products in packaging that mimics the original manufacturer's packaging, and product labeling should make it easy to select and obtain the reprocessed devices. If the hospital has specific inventory management systems in place, the reprocessor should fit seamlessly into these.

The same principles should guide the collection of used devices at the hospital. Collections should take place according to what is most practical for the hospital in terms of days and times. The primary consideration here is that hospitals are incredibly busy, and the reprocessor should not add to this by having their collection technologists show up when it is inconvenient. Hospitals should expect that collections always take place on the same day, at the same time, so the staff can be prepared.

QUESTIONS TO ASK

- Do your product codes, etc. integrate with inventory management systems like Wavemark?
- Do your products have UDI codes on the outer box?
- Can you work with our purchasing team to enter reprocessed product codes into our system?
- Does your packaging mimic OM packaging?
- How do I recognize your product as a reprocessed product in the supply room?
- When does your collection tech collect? What is his/her name?

3

Quality, quality, quality: The most important department in a reprocessing company is not the Sales department or the Engineering department. It is the Quality department. Complaint handling and complaint responses must involve the absolutely most conservative principles and follow strict procedures. Handling and responding must be swift: Complaints are an important source of information that can result in manufacturing improvement, product holds, etc. IF something is wrong with a device, you should expect that the reprocessor consider halting production and at least conduct a complete investigation.

Reprocessors play an important role in detecting changes in manufacturer IFUs, designs, and materials. A strong reprocessor will detect these changes quickly and re-validate their processes. In some cases, reprocessors have been able to detect design changes that potentially could result in compromised devices.

Internal and external audits are key to the integrity of the reprocessor's quality system. The goal is to have a quality system that exceeds the standards of any reviewer – and a quality system that exceeds the standards of a new device manufacturer.

QUESTIONS TO ASK

- How rapidly do we get answers to complaints?
- Will your complaint responses contain reports of a full investigation – in every instance?
- How does your complaint handling process work? What is involved?
- What do you do when you find that a device failure/complaint is verified by the investigation?
- Please share your corrective action plan?
- What are your rules for putting a product on hold?
- What findings did you have in your last FDA inspection?
- What findings have your internal audits produced over the past 24 months?
- How many open Corrective and Preventive Actions (CAPAs) do you have? What are they?
- How long on average are your Corrective and Preventive Actions (CAPAs) open?

4

Submissions to and clearances from FDA: The regulatory and engineering process of preparing an FDA submission is time-consuming and expensive. But the reprocessor should not cut any corners. Once again, the reprocessor's standards should be higher than an original device manufacturer. Consider "the n+1 rule": If the reprocessor asks to reprocess a device twice for a total of 3 uses, the company should provide data that shows device integrity after 3 reprocessing cycles (2+1). Likewise, devices should be validated using worst-case scenarios in terms of things like transportation related heat exposure, tensile testing, and electrical testing.

In an FDA submission, transparency and data integrity is important. The reprocessor should only apply for the products and brands that data supports. The rule is that you cannot include two devices in a submission that have different indications or material

design/functionality differences. There have, recently, been situations where clearances have come very easily to new reprocessors, and it could be speculated that "creative" work is the cause. And when the reprocessor utilizes its clearance, you should expect them to be conservative about what devices they consider to fall under that clearance.

Medical device manufacturers and reprocessors use a regulatory pathway called "line extensions" to be able to market devices that may not have received a clearance, but are so similar that they can be "folded in" under a previously received clearance. This is dangerous territory and the practice should be conducted very diligently. Again, from a regulatory standpoint, this is only permissible if the device has the same indication and is materially and functionally similar to the predicate device.

QUESTIONS TO ASK

- How many uses did you test your latest cleared device for? How do you determine how many uses to test for?
- How do you test for material degradation between uses?
- How do you test for the impact of transportation and storage of used devices?
- How do you determine what tests to conduct on a device that is being reprocessed?
- What tests did you go through to obtain your latest clearance?
- What are your last line extensions and which clearances were referenced?
- Did the line extensions have the same indication as the predicate device?
- What are the design differences? Functional differences?

5

Device marking/labeling: Reprocessed devices must be marked so that it is clear that they have been reprocessed and what company has reprocessed them. The reprocessor assumes ownership and liability for the device when it has been reprocessed, so this is important. If the device fails and it is not clearly marked, the hospital cannot determine where to file a complaint or where to look for responsibility. This is a key principle in reprocessing. Different reprocessors use different solutions, including serial stickers, laser etching, QR codes, pad printing, etc. There is no convention in the industry, but each reprocessor must use a clear system for marking the device.

It is important to keep in mind that the device is taken out of its packaging before use: The device itself has to be marked, the reprocessor cannot just mark the packaging.

Manufacturers invest a lot of time and money developing safe and effective products. Their brands have great value to them and to the clinicians. Legitimate reprocessors also invest great amount time and money in producing quality devices. Why would a reprocessor not be proud of their brand and clearly mark it?

QUESTIONS TO ASK

- How do you mark your devices?
- Can I see on a device that it has been reprocessed by your company?
- Do you mark the device itself or just the packaging?
- How do you mark your devices to keep track of number of uses?





6

Double-reprocessing: A reprocessor cannot reprocess a device previously reprocessed by another reprocessor. There are two reasons for this: 1) When an FDA clearance is granted to a reprocessor, that clearance is granted to reprocess the device a certain number of times. Reprocessing and reusing beyond this is against regulations. Since there is no convention in the industry for how devices are marked, you are only able to "read" your own devices and discover their history in terms of number of uses. It follows that you risk going against regulation if you reprocess another reprocessor's device. 2) Different reprocessors with clearance to reprocess the same device may use different methods for cleaning devices. For example, different chemicals may be used in the cleaning process. Using different chemicals may result in reactions in the material that make the device unsafe. For similar reasons, reprocessing open and unused devices is not a safe process unless FDA cleared.

Please note that although a reprocessor does not need an FDA clearance to reprocess 510(k) exempt and reusable devices, the same principle applies here, as the number of uses is controlled by other agencies.

Reusable EP cables are an excellent example of this: Although reprocessors are allowed to provide a service to hospitals by utlizing the OM IFU for cleaning and sterilization, getting ready to reprocess one of the more complex cables takes a lot of time and a lot of money. Material characterization is necessary, as it is important to understand the potential degradation from reprocessing and sterilization. In many cases, custom fixtures have to be designed and built. Beware of cable reprocessing sold at very low rates: The safety and quality of the reprocessed cable may not be as you should expect.

QUESTIONS TO ASK

- When you receive a device, how do you determine how many times a device has been used?
- What do you do with devices that have been used the maximum number of times?
- What do you do if a device has been reprocessed by another reprocessor?
- If you reprocess these, how do you know how many times they have been used in the past?

7

Proportional product availability: A fundamental policy in reprocessing is that the hospital should be able to purchase the number of reprocessed devices that corresponds with what was collected – minus devices that had to be taken out of the process due to damage or maximum number of uses. Bad reprocessing practice is to collect from many hospitals and then just sell back to a few that pay the highest price.

Ensuring proportional product availability requires that the reprocessor makes data available in real time about what products and how many have been collected from the hospital, then make data available about what devices, and in which quantities, are available to purchase. Accurate and accessible data are a very important tool in the reprocessing process.

QUESTIONS TO ASK

- How many devices will be available for me to purchase from you? How do you determine this?
- Do you provide access to real-time data about what has been collected?
- Do you provide access to real-time data about what is available to buy back?
- How do you identify devices and facilities from which the device originate?
- How is this information stored and utilized?

8

Transparency in reporting: Hospitals use reprocessing to reduce procedure costs and environmental waste. Because of this, it is important that the hospital sees what cost savings and carbon emission reductions are driven by reprocessing. If this reporting is not transparent or frequent, the motivation for reprocessing goes away. Because environment and costs drive reprocessing behavior, this reporting needs to be done at the level where it can change or validate behaviors – the department must know, the doctor must know.

For the same reason, you should expect from your reprocessor that they do not mix bundle reprocessed product with other products sold by the same company: This hides the impact of reprocessing and usually comes out to the hospital's disadvantage. Some forms of bundling are illegal.

QUESTIONS TO ASK

- Do you report cost savings on a monthly and quarterly basis?
- Do I have access to see my cost savings at any time?
- Do you provide reports that we can share with C-suite and physicians?
- Do you bundle reprocessed products with other products?

9

Discount sellers versus reuse consultants: Your reprocessor should work closely with you to get the maximum out of your reprocessing program. This includes working with physicians, educating technologists, supporting the hospital in financial calculations and value analysis activities, and preparing them for discussions with the original manufacturer. This is a founding principle in reprocessing. In the end, the price of the reprocessed catheter matters little in what level of savings the hospital achieves – what matters more is the physician education (for example) that drives acceptance and volume.

In recent years, some reprocessors have emerged to act much more as discount sellers of cheap devices, and then the discussion is about unit price rather than about the results of the program. Real reprocessing representatives function more as reuse consultants than as discount sellers.

QUESTIONS TO ASK

- Will you work with us to increase utilization of reprocessed catheters?
- Can you work with our value analysis team?
- Do you have analysts that can help us understand the total value of reprocessing versus other, conflicting offerings?
- Do you offer a savings guarantee?

Product development and safety: Some reprocessors have very old FDA clearances and have stopped getting new ones. This is problematic for two: 1) Product lifecycles in electrophysiology are very short, so old clearances rarely have any value to the hospital – because the products simply are not used anymore; and 2) FDA has increased its standards over the years, so a recently cleared product will often be subject to stricter requirements than the same product cleared 10 years ago.

The original idea behind the reprocessing industry was implied constant pursuit of new areas for reprocessing. You should expect that your reprocessor brings new products to you every year, so that you can add to your savings or "replace" savings lost on obsolescent devices.

QUESTIONS TO ASK

- Can I see your list of recently cleared devices?
- Can I see your pipeline and your planned pathway to obtain new clearances?
- Can I expect my reprocessing program to grow year over year?
- How old are your clearances?

These are all principles that have guided the reprocessing industry for 25 years. Observing these principles protects the reprocessing industry (and the associated cost savings) because it enables hospitals and clinicians to trust reprocessing. While FDA, AMDR, and reprocessors themselves must commit to maintaining the high standards that have guided reprocessing to date, hospitals can do their part by demanding that these principles be observed. In doing so, they can help protect the savings that come from reprocessing.

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