The Technology of Cable Reprocessing

Choose your Partner Carefully

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In cardiology, electrophysiology (EP) procedures are growing at a faster rate than any other procedure. Multiple EP cables are used in every single EP procedure. Most are reusable and cleaned and sterilized between uses. Others are single-use and must be reprocessed by a reprocessor with FDA clearance – or discarded after a single use.

This is why cable EP reprocessing has become an important activity for EP labs – and this is why the decision-making process is so important.

> ***Using reprocessed tools during electrophysiologic procedures is an important step towards reducing carbon footprint in the EP labs and helping financial stewardship in ever shrinking healthcare delivery budgets. In addition to the catheters, connecting cables are equally important. Having good quality functional cables at one's disposal is critical to procedural performance and lab efficiency. So, it is very important to have the reprocessing companies understand the manufacturers' instructions, properly tested for integrity and performance and not overused. I strongly encourage EP labs that use reprocessed cables to carefully evaluate the quality of the reprocessing technology and deliverables.***
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> *- Dhanunjaya (DJ) Lakkireddy, MD, MBA, Executive Medical Director & Professor of Medicine, The Kansas City Heart Rhythm Institute*

Do You Have Confidence in your EP Cables Reprocessing?

It is critical that every cable works – whether it is reprocessed in the Sterile Processing Department (SPD) or through a reprocessor. If it fails, costly and sometimes critical time is wasted locating a different cable. Innovative Health recommends using a reprocessing company for reprocessing all cables – including reusable cables.

However, not all reprocessors are created equal. Some EP cables require little more than a quick cleaning and a fast test, while others require advanced knowledge of reprocessing technology. All cables currently reprocessed by Innovative Health require sterilization as well. At Innovative Health, our EP cables reprocessing program is focused on patient safety. Thanks to our FDA clearances for very complex devices – and for single-use cables – our process is advanced and safeguards against both cable failure and Joint Commission scrutiny.

Why Not Process Electrophysiology Cables In the Central Sterile Department?

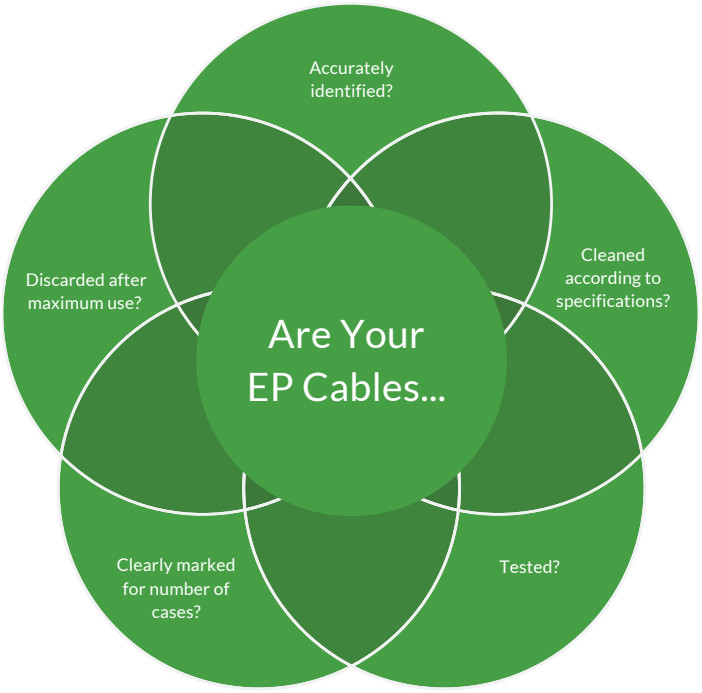
The key components of an EP procedure are the control system, catheters (or other devices), and the cables that connect these to each other. The cable is part of a circuit. All must function for the system to work. Having confidence in your cable limits the number of things that can go wrong. Without the EP cable, the system cannot communicate with the catheters. If an EP cable is missing or malfunctions, a new one has to be found, often with costly waste of time as a consequence. More importantly, patients are exposed to longer procedure times – and potentially longer time under anesthesia.

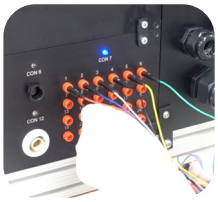
EP interface cables are re-usable accessories designed to connect a diagnostic or treatment catheter (EP catheter, diagnostic ultrasound catheter, transseptal needle, or ablation catheter) with a control system. Cables are designed for specific purposes and should be selected based on the procedure type, catheter, and control unit being used. Cables are used to transmit the electrical signals from the catheter to the appropriate console during the EP study.

Since EP cables are usually re-usable, hospitals often send the cables to the Sterile Processing Department (SPD) inside the hospital, where the cables are cleaned and sterilized, before they are sent back to the EP lab. The SPD department processes many different types of devices, and the process is designed to be efficient and fast.

Reusable catheter interface cables can be processed by the hospital, following Original Manufacturer "Instructions For Use" (IFU) under FDA guidelines. However, there are several challenges in hospital-based processing of reusable cables:

- Keeping track of how many times a cable has been used
- Time and labor consumption in reprocessing
- Ensuring that cables actually work before they are plugged in
- Expensive EP lab time lost when a cable fails and needs replaced
- Staying compliant with JCAHO standards





The cost of discovering a defective cable during or at the beginning of a procedure is very high – when a cable has to be replaced, it increases time and costs.

SPDs typically do not track number of uses, and cleaning practices are usually based on standard SPD cleaning practices which may not align with JCAHO standards. A JCAHO standards audit could catch this and has the potential of shutting down clinical operations to ensure compliance.

SPD Processing of EP Cables

Central Sterile departments, like so many other departments in hospitals, are under pressure to conduct the processing of reusable devices in an efficient and economical manner, and such objectives can easily clash with the formal demands for safe and effective processing. When processes are standardized to increase efficiency, it is easy to skip steps or fail to accurately identify devices and treat them according to device specific instructions.

Reusable EP cables are a great example of this: There are literally hundreds of different cables connecting EP devices to capital equipment – and they all pretty much look alike. In fact, in some cases, the brand/model is not even clearly displayed on the cable. Some IFUs even differ between cables in the same "family": For example, Carto ablation cables have varied sterilization requirements for autoclaving – and there are Carto cables where the IFU calls for resistance testing, while others don't. Different cable IFUs call for the use of different cleaning agents. SPD departments need to manage 4 or 5 different cleaning processes, conduct testing (without testing, there is no way to know if the connector is dry and the cable is functional), have different sterilization processes, and accurately identify literally hundreds of different cables to follow IFU instructions. Additionally, EP cables are very delicate, even wrapping a cable too tight can cause the cable to malfunction. Further, some EP cables are designated "single-use" by the manufacturer, while reusable cables can be reused 5 times, 15 times, 25 times; it varies from cable to cable. For example, the Boston Scientific PSA cables can be used 50 times, Carto diagnostic cables can be used 20 times, while some Boston Scientific cables can be used 15 times. Central Sterile technicians literally have to know all the different cables, accurately identify them, clean them according to their specific instructions, and count how many times they have been used. Instead, it is tempting to simply process an EP cable as many times as it can before it "breaks"; in fact, this may be the only practical way of handling the cables in a busy Sterile Processing department. However, this can create disruption to routines before or during procedures and cause significant delays while another cable is located.

It further adds to the SPD cable processing challenge that EO sterilization is increasingly difficult to come by and the alternative – autoclaving – opens up for a lot more failures in terms of melting connectors, moisture, and pin corrosion.

Additionally, the hospital risks Joint Commission inspectors catching this practice, which is not a risk worth taking.

It's a real challenge: Most cleaning instructions are very broad, 'The cable can withstand cleaning with soap solutions or alcohol,' while others are more extensive and specific; they may require special treatment of the connector or even that the cable is tested before sterilization and reuse. Add to this that EP cables come with a manufacturer-determined maximum number of times the cable can be used. Most CS/SPD departments just don't have the capacity or work routines to ensure cables are cleaned exactly to instructions, that they are tested, and that the number of uses are counted.

At Innovative Health, we have received reports from several of our hospital partners across different regions of the U.S. that the Joint Commission is "cracking down" on Central Sterile departments that can't accurately track how many times an EP cable has been used and that don't test and clean cables to manufacturer specifications. The focus of the Joint Commission seems to be on confirming that cleaning methodology is standardized across device categories and follow the appropriate instructions for use from the manufacturer. We do not know what has caused this focus, but the introduction of more single-use EP cables that cannot/should not be sent to the Central Sterile could be a contributing factor. Hospitals are just not used to distinguishing between different EP cable types. Central Sterile staff actually need to ensure their staff members can identify individual cables and treat them according to their specific use instructions: Reusable cables are different from non-sterile cables, which are different from single-use cables. If not, there is a risk that single-use cables are reused several times, cleaning is inadequate or no testing is conducted.

For these reasons, a growing number of our hospital partners send their EP cables with used single-use EP devices to our reprocessing plant. We have the capacity to clean, test, cycle count and sterilize (as of today) more than 130 different EP cables to avoid taking a chance that the cable still works.

Reprocessing Companies and EP Cable Reprocessing

Innovative Health and other EP reprocessors offer to reprocess EP cables for the hospital in addition to the single-use devices they reprocess for the hospital. By using an FDA regulated reprocessor for EP cable reprocessing, hospitals can avoid the many challenges associated with hospital-based EP cable reprocessing.

This is the process that Innovative Health uses to reprocess EP cables:

IDENTIFICATION	EP cables are identified by trained EP cable reprocessing staff, in terms of brand, model, serial number, cleaning specifications, testing specifications, and number of times the cable can be reprocesed. This step is very important, as many EP cables look alike, yet may have different cleaning/testing instructions and different number of uses.
CLEANING	All EP Catheter interface Cables are thoroughly decontaminated using neutral enzymatics, manual cleaning and brushing. Cables are thoroughly cleaned to address all the aspects of the cable and adjoining connectors. Custom cleaning equipment is used to ensure that each cable is properly cleaned during the process. Innovative Health has developed a process to align with the Original Manufacturers' decontamination and cleaning steps provided in the IFU.
TESTING	The EP Catheter Interface Cable Tester tests continuity and resistance. Continuity tests are conducted for any open or short connections between wires, and the resistance of each wire is tested to confirm it is within the specified range. This industry leading test ensures that the electrical connections on the cable all meet acceptable standards, which ensures the connectivity to the EP connector cable performs like the new device. HIPOT tests the breakdown voltage between wires in the cable. This test verifies that the cables are able to withstand worse case electrical spikes during a clinical procedure. In short: Reprocessed (reusable) cables are tested to ensure they perform as intended.

STERILIZATION	The cables are then sterilized, inspected again, and made available to the EP lab for another use. Innovative Health uses a third party, FDA regulated EO sterilization company for all cables and catheters.

Other companies offer to reprocess EP cables. However, simply cleaning and labeling an EP cable is not appropriate reprocessing. Are they appropriately tested? Do they material characterize them? Do they follow a validated process based on OEM instructions for use? Do they stay true to the number of times a cable can be reprocessed – or do they reprocess cables that have previously been reprocessed by another reprocessor? Here are key questions to ask:

- Scientifically evaluated in terms of surface characteristics, weight, materials, and construction.
- Follows a validated process based on OM Instructions For Use (IFU).
- Inclusive of cables requested by the hospital.
- 100+ cables available
- Advanced traceability process to ensure cables are accurately identified and are eligible for reuse (haven't exceeded number of uses)
- Serialized labeling for accurate tracking
- Enzymatic cleaning and disinfection
- Multiple visual inspections
- Every single cable undergoes electrical continuity testing and High Potential (HIPOT) testing on validated cable testing equipment

In addition, it is important that the reprocessor leverages advanced EP cable reprocessing technology that checks all the regulatory and functional boxes – and provides the ability to reprocess even very complex cables.

Advanced EP cable reprocessing technology

Some cables used in EP procedures are very simple: They connect the device to the system with off-the-shelf connectors and a few pins. These are easy to reprocess, and recently more reprocessing companies have begun offering this service.

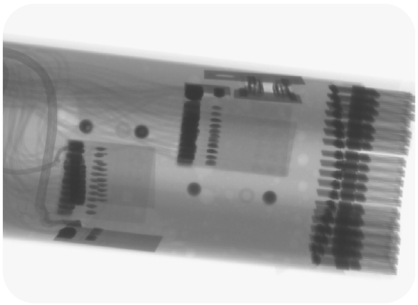
However, even simple EP cables must be accurately identified, tested, and cycle counted, and reprocessors with limited knowledge of regulatory requirements and cable technology will struggle with this. Using a reprocessor with documented advanced cable technology competency ensures that ALL your cables are processed to regulatory and technological standards.

In addition, simple EP cables are relatively inexpensive – so the reprocessors role in making these cables available for another use is less impactful from a financial perspective. Advanced cables, such

as single-use cables, cables with more than a hundred pins, EEPROM, etc., are much more expensive, and the role of the reprocessor equally more important.

Consider these technical complexities associated with some types of EP cables:

- High number of connector pins – most cables have around 20 pins, but some cables can have 34 pins or more with more surface cleaning and testing challenges. The Orion mapping cable has 78 pins, the Octaray cable has 123
- Custom connectors with reverse engineering, 3D X-ray and 3D printing of inverse connectors to allow for testing
- Hardware within the connector, including EEPROMs, thermistors and PCB boards that require understanding changes to the electrical signal
- Custom software that requires advanced understanding of medical device computing and algorithms



X-ray of cable connector containing flexible PCB with room for, for example, an EEPROM chip

Working with an advanced cables reprocessor provides the best option – from a technical, regulatory, and financial perspective.

From a technical perspective, there are five types of EP cables of increasing complexity:

SIMPLE REPROCESSING

1

Simple EP Cables (less than $500)

Simple EP catheters connect quadrapolar, hexapolar or decapolar diagnostic EP cables with the system. They have simple, off-the-shelf connectors with very few pins (4-34 pins) and they are very easy to test for electrical continuity. They are essentially extension cords. These cables include for example cables connecting Supreme or Response diagnostic EP catheters with their system.

2

Basic EP Cables (less than $500)

These cables are slightly more complex to deal with than simple EP cables. They have a larger number of pins (30-72 pins), and while they have off-the-shelf connectors, original manufacturer IFUs require more extensive HIPOT testing – electrical performance needs to be tested against specific requirements as outlined in the IFU (you can't simply plug it in and if it works, all is well). In addition, many of these EP cables have "pigtails" rather than a singular plug, so surface area cleaning is much more demanding (small, tight areas), and it takes longer time to test them.

ADVANCED REPROCESSING

3

Intermediate EP Cables ($500-$,1000)

These are custom cables designed for EP and ablation catheters. These cables come with advanced mapping requirements, and therefore specific original manufacturer testing requirements related to electrical resistance and HIPOT testing. Since they have proprietary connectors, to be able to reprocess these cables, the reprocessor must engage in connector reversed engineering and modification. The intermediate cable can also come with custom software, which has to be interpreted and custom testers have to be developed to conduct the appropriate testing. There is hardware within the connector, including EEPROMs, thermistors and PCB boards – the reprocessor has to understand how to test and how to handle changes resistance.

4

Complex EP Cables ($1,000+)

Complex EP cables have the same characteristics as intermediate cables, but the software and the hardware challenges involved in effectively and safely testing these cables are even harder. Some of these devices come with an EEPROM, thermistors and PCB boards. To make it possible to test the connectors the reprocessor must 3D X-ray scan the connector, then 3D print the inverse of the connector. Frequently the reprocessor must also handle flexible circuit boards. Add to this that these cables come with 120+ pins that all have to be tested using custom methods. The Biosense Webster Octaray cable is an example of a complex EP cable.

5

Specialty Cables (price varies)

In addition to the single-use cables several specialty cables in EP and other cardiology procedures can be reprocessed by an advanced cables reprocessors like Innovative Health.
These include:

- Reusable cables for transseptal needles – these transmit RF energy and require special testing
- Single-use cables – reprocessing of these requires clearance from FDA (see insert)
- Reusable PA (Pulsed Field Ablation) cables - Innovative Health has co-developed a PFA cable including full validation of everything from frequency, to power, and system creation.

Single-use EP cables? What?

The majority of EP cables do not touch the patient and they do not get contaminated the same way as devices that are inserted into the patient. This is why EP cables have always been reusable. However, recently, several manufacturers have launched "single-use" cables, a designation chosen by the manufacturer, not the FDA. Since cables are electrical connectors with little "decay" and contamination during a use, it is hard to understand why manufacturers are launching single-use cables. If it is not about patient safety or device functionality, it may simply be so manufacturers can realize higher profits because a new cable has to be pulled for each new procedure.

Safe, Compliant, and Reliable EP Cable Reprocessing

Reprocessed (reusable) EP catheter interface cables from Innovative Health are a safe and effective equivalent to costly options sold by the original equipment manufacturer. In addition, reprocessing reusable cables with Innovative Health helps EP labs ensure each cable performs as intended for an additional use and maintains compliance with JCAHO standards.

As a result of the increased scrutiny and related potential consequences, Innovative Health recommends a thorough assessment of procedures related to EP cable reprocessing to determine that a validated process based on OM instructions for use is used and, specifically, that cables are tested when specified and counted for number of uses. In this regard, compliant tracking and tracing entails identifying the cable and recording unique barcodes and serial numbers, not simply marking a device. Where needed, Innovative Health can help close the gap between Joint Commission standards and current practices by reprocessing cables following a certified Quality System. Lab managers with questions related to compliance can reach out to Innovative Health.

You already rely on Innovative Health for reprocessing complex EP catheters – simply collect the cables along with the catheters after every case.

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