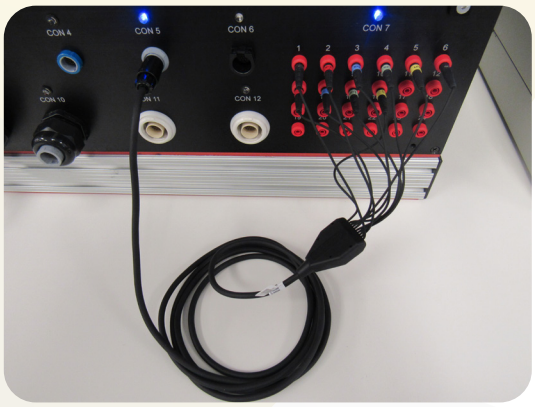
Reprocessing Electrophysiology Cables

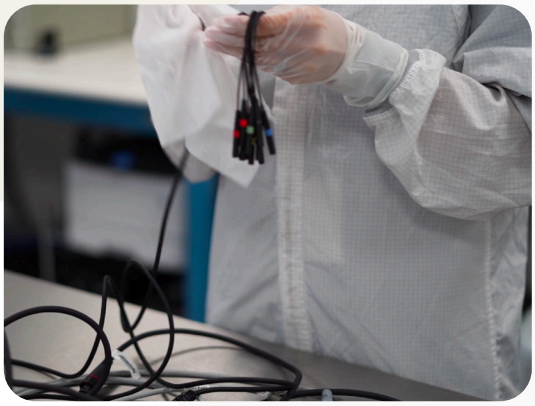
By: Lars Thording

In the electrophysiology (EP) lab, device costs are often more than $10,000 per procedure. Most of these devices are single-use devices that have to be discarded after the procedure. As an alternative, single-use device reprocessing companies like Innovative Health can collect many of these devices, clean, test and inspect them before they are re-sterilized and sent back to the lab at a fraction of the cost of a new device.

This process is sanctioned through the FDA process for clearing reprocessed devices for re-sale and re-use. The process means that FDA cleared reprocessed devices are safe for patients, and that they are substantially equivalent to new devices. The use of reprocessed devices in the EP lab has become increasingly popular as a means of controlling costs in the face of costly new technology, and many EP labs save several hundreds of thousands of dollars every year and depend on these cost savings to remain profitable.

The key components of an EP procedure are the control system, catheters (or other devices), and the cables that connect these to each other. 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.





EP Interface Cables

EP interface cables are (usually) 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 reprocesses many different types of devices, and the process is designed to be efficient and fast.

There are 5 different kinds of cables used in the EP lab that vary slightly in terms of re-use, cleaning, testing, and purpose:

Type	Use	Testing?	Number of uses
Reusable, sterile diagnostic cables	Connects diagnostic catheter with system	Yes	2-25
Reusable, sterile ablation cables	Connects ablation catheter with system	Some	2-25
Reusable, non-sterile ablation cables	Connects ablation catheter with system	Some	2-25
Reusable, sterile ablation extension cables	Connects ablation cable with system	Some	2-25
Reusable, RF puncture connector cables	Connects transseptal needle with system	Some	2-25
Single-use disposable cables	Connects various catheters with system	Some	1

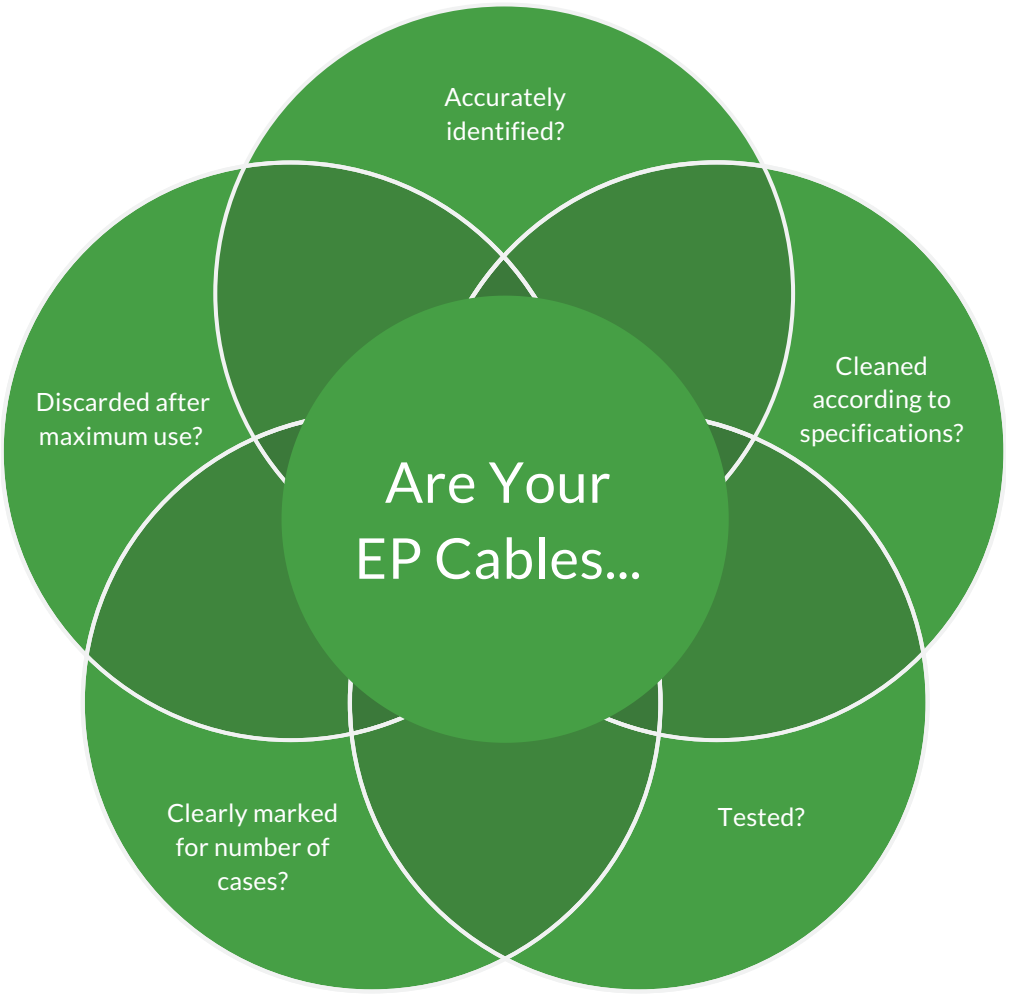
Single-use EP Cables? What?

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.

Challenges in the Reprocessing of EP Cables

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

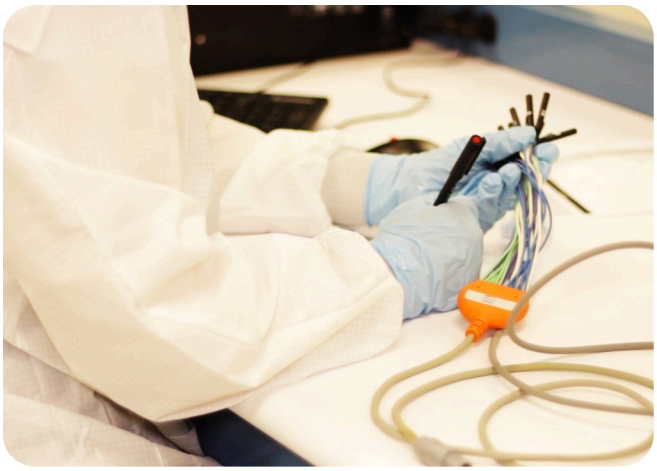


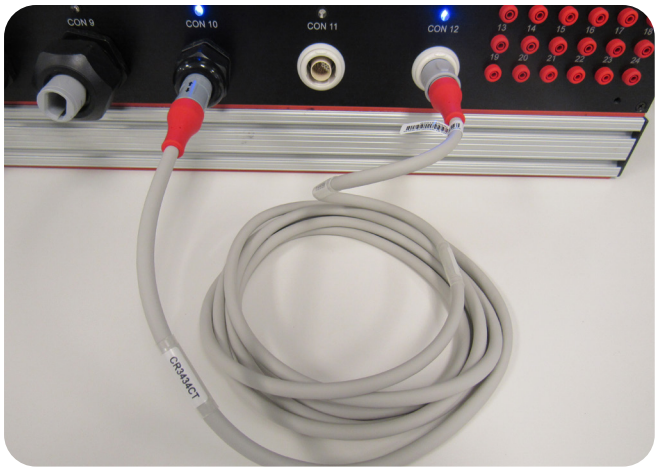
The cost of discovering a defective cable during or at the beginning of a procedure is very high – when a cable has to be replaced, it increases time and costs.

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 Reprocessing of EP Cables

Hospitals routinely reprocess reusable instruments in their Central Service or Sterile Processing & Distribution departments. Routines here are set up to effectively and safely make the reusable devices/instruments ready for another use, theoretically based on manufacturer instructions about cleaning and (sometimes) testing. However, Central Sterile departments, like so many other departments in hospitals, are also under pressure to conduct the reprocessing of reusable devices in an efficient and economical manner, and such objectives can easily clash with the formal demands for safe and effective reprocessing. 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.





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. 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. 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 reprocess 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.

Additionally, the hospital risks Joint Commission surveyors 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.

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>
> - Innovative Health CEO Rick Ferreira

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.

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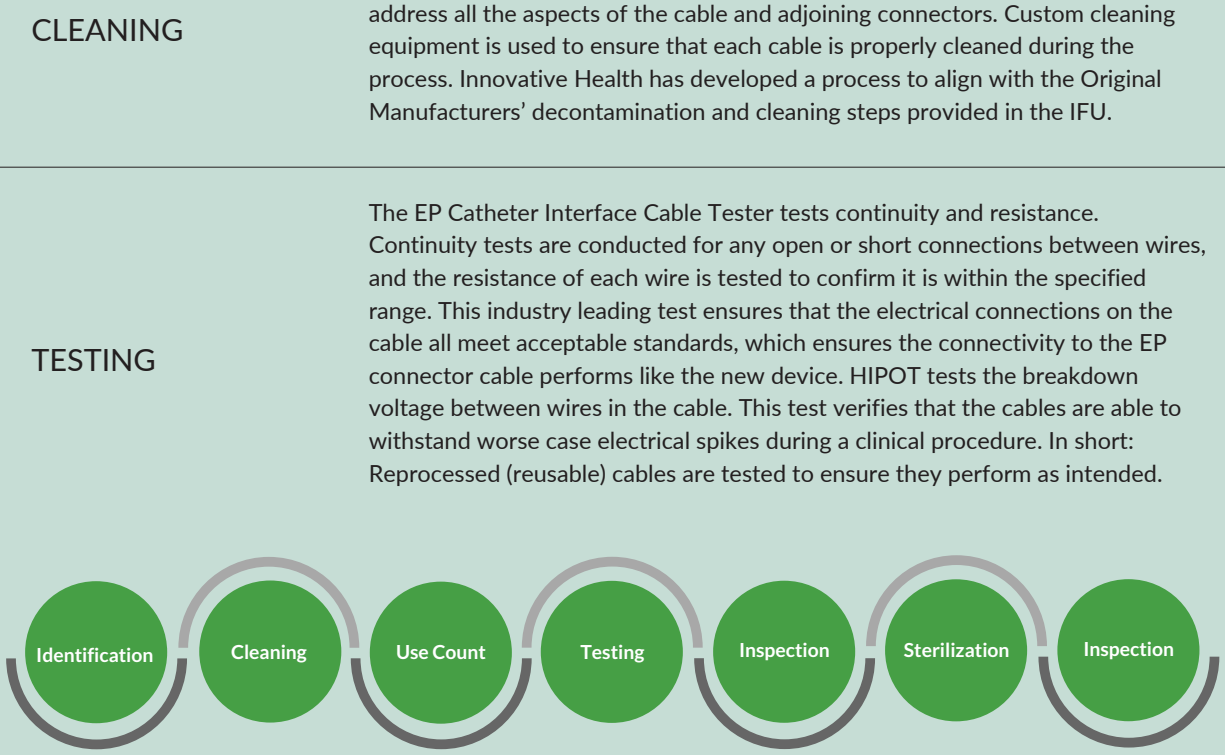
We experience that a growing number of our hospital partners send their EP cables with used single-use EP devices to our reprocessing plant. We have the capacity to clean, test, cycle count and sterilize (as of today) 107 different EP cables to meet all Joint Commission requirements – and to avoid taking a chance that the cable still works...

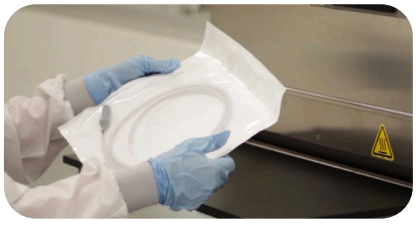
Reprocessing Companies and EP Cable Reprocessing

Innovative Health and other EP reprocessors, however, offer to reprocess EP cables 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 has been used. 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.





Available EP Cables From Innovative Health

Innovative Health constantly releases new EP cables for purchase, so check with us for our most current offering.

Diagnostic Reusable Sterile

Original Manufacturer	Cables used with	Part Number
Biosense Webster	Webster CS Decapolar	CB3410CT
	Webster Decapolar (Fixed and Deflectable) and Webster CS Bi-Directional Catheter Auto ID, VIZIGO	CB3412CT
	Lasso 2515 NAV Catheters, HALO and ISMUS Catheter with Auto ID	CB3434CT
	Soundstar	CG2025CT
	Webster Quadrapolar	CY1210CT, C6MRMST4SA
	Webster CS Uni-Directional Catheter, Webster HIS	D128709
	Webster Octapolar and LASSO Decapolar with Auto ID, VIZIGO	CY1212CT
	Webster Decapolar, Decapolar with Lumen, HALO and ISMUS, Webster Duo-Decapolar, ChristaCath, PentaRay	C6MRMST10SA
	LASSO NAV eco, PENTARY NAV eco	D134401
	Webster Octapolar, Webster Quadrapolar	C6YMRMST4SA, C6TMRMST4SA
	Webster Octapolar	C6MRMST8SA
	QWICKCABLE	C6MRMST6SA
	LASSO 2515 Variable, LASSO Decapolar, Webster Decapolar, Webster Decapolar with Lumen, Webster CS Bi-Directional, Halo and Ismus, Webster Duo-Decapolar, CristaCath, PenatRay HD	C6OMRMST10SA, C6TMRMST10SA
	Reverse Interface Cable	D128622
	LASSO 2515 Variable, HALP XP Tricuspid, ISMUS, CRISTACATH	D128624
	NAVISTAR	C5MHDTCMHS
Boston Sci/Bard	TANGO Fixed Curve, VIKING SOFT TIP Fixed Curve, WOVEN Fixed Curve, Dynamic Tip Steerable, Dynamic XT Steerable, EP XT Steerable	M004560001A0
	VIKING Fixed Curve, VIKING SOFT TIP Fixed Curve, TANGO Fixed Curve, WOVEN Fixed Curve, WOVENFLEXIE Fixed Curve, Dynamic Tip Steerable, EP XT Steerable	M004560002YA0
	WOVEN Fixed Curve, WOVENFLEXIE Fixed Curve, Dynamic Tip Steerable, Dynamic XT Steerable, EP XT Steerable	M004200088P0
	WOVEN Fixed Curve, WOVENFLEXIE Fixed Curve, Dynamic XT Steerable, EP XT Steerable	M004200089P0
	WOVEN Fixed Curve	M004008568P0, M004006590P0
	WOVEN Fixed Curve, ORBITER Fixed Curve, ORBITER HIGH-TORQUE Fixed Curve, Dynamic XT Steerable, EP XT Steerable	M004200774P0
	VIKING Fixed Curve, VIKING SOFT TIP Fixed Curve, TANGO Fixed Curve, WOVEN Fixed Curve, WOVENFLEXIE Fixed Curve, Dynamic Tip Steerable	M004560002A0, M004560002BA0, M004560002RA0
	VIKING Fixed Curve, VIKING SOFT TIP Fixed Curve, TANGO Fixed Curve, WOVEN Fixed Curve, WOVENFLEXIE Fixed Curve, Dynamic Tip Steerable, EP XT Steerable	M004560003A0
	VIKING Fixed Curve, VIKING SOFT TIP Fixed Curve, TANGO Fixed Curve, WOVEN Fixed Curve, Dynamic Tip Steerable, Dynamic XT Steerable, EP XT Steerable	M004560004A0
	Polaris X Steerable, Explorer ST Fixed Curve	M004545480
	Explorer ST Fixed Curve	M004544680
	Polaris DX Steerable	M004544480
	Surelink	M004560002P0
	Orbiter PV	M004390008P0
	ORBITER ST Steerable, Radia Bidirectional Steerable	M004390003P0, M004390004P0
	BLAZER DX-20	M00420S0
	SureLink	M004560001P0, M004560003P0
	STEEROCATH-DX	M004626S0
St Jude Medical	Inquiry, Inquiry Decapolar, Inquiry Afocus	IBI85930 IBI85954
	Inquiry, Inquiry Afocus II	IBI85931
	Inquiry, Inquiry Afocus	IBI85955
	Inquiry	IBI85953
	Livewire, Reflexion HD, Reflexion Spiral, Response	401970, 401971, 401972, 401973, 401974, 401975, 401976, 401977
	Supreme	401980, 401981, 401982, 401983, 401984, 401985, 401986
	Advisor FL	D-AVSE-CBL12
	Advisor HD	D-AVSE-CBL22
Medtronic	STABLEMAPR SM	05508SP, 05518SP, 05504SP, 05514SP

Ablation Reusable Sterile

Original Manufacturer	Cables used with	Part Number
Biosense Webster	NAVISTAR	CR3425CT
	EZ STEER ThermoCool Nav	CR3434CT
	Smartablate	D130302
	ThermoCool SF Uni-Directional Ablation, Celcius	C10MR10MSTKS
	Celsius, EZ Steer, NaviStar	C10MRMSTKDTCS
	NAVISTAR and REFSTAR	C5MHNAVMHS, C5MHREFMHS
	NAVISTAR	C6MR10EPTRS
	BLAZER II, BLAZER II HTD, BLAZER II XP, BLAZER PRIME HTD, BLAZER PRIME XP	M0046130, M0046510
	INTELLANAV XP, INTELLANAV OPEN -IRRIGATED, INTELLANAV MIFI XP	M0045441S0
	Thermistor	M004603S0
	IntellaTip MiFi XP	M004653S0
	BLAZER Open-irrigated	M0046710
	INTELLATIP MiFi	M0046270
	INTELLANAV XP, INTELLANAV OPEN -IRRIGATED, INTELLANAV MIFI XP	M004RARC010
St Jude Medical	Therapy, Therapy Cool Path Duo, Therapy Cool Flex, Therapy Dual-8	IBI85641
	Therapy, Therapy Cool Path Duo, Therapy Cool Flex	IBI85711, IBI85713
	Therapy	IBI85763
	Safire TX	IBI85778
	Therapy Series	IBI85809
	Therapy Dual-8	IBI85739
	Sensor Enabled Bi and Uni-directional Ablation Catheter	A-FASE-CBL4
Medtronic	ATAKR II Generator to RF Cath	05106S

Ablation Reusable Sterile Extension

Original Manufacturer	Cables used with	Part Number
Biosense Webster	Interface Adapter EPT	AESTK
St Jude Medical	Livewire TC	402518
	Safire TX Bi-directional	402549
	Safire Bi-directional	402550, 402553, 402554
	Safire TX Bi-directional, Safire Bi-directional	402570
	Safire TX Bi-directional	A402580, 402569, 402577, 402578, 402579
	Livewire, Reflexion HD, Reflexion Spiral, Response	401661

RF Puncture Devices

Original Manufacturer	Cables used with	Part Number
Baylis	Reusable RFP-100A Connector Cable	RXF-BAY-TS

Single-Use

Original Manufacturer	Cables used with	Part Number
Medtronic	Medtronic Achieve Mapping Catheter	2ACHC

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 IFUs are followed 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. 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.

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

INNOVATIVE HEALTH

Please contact your local Innovative Health representative or our corporate offices.

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