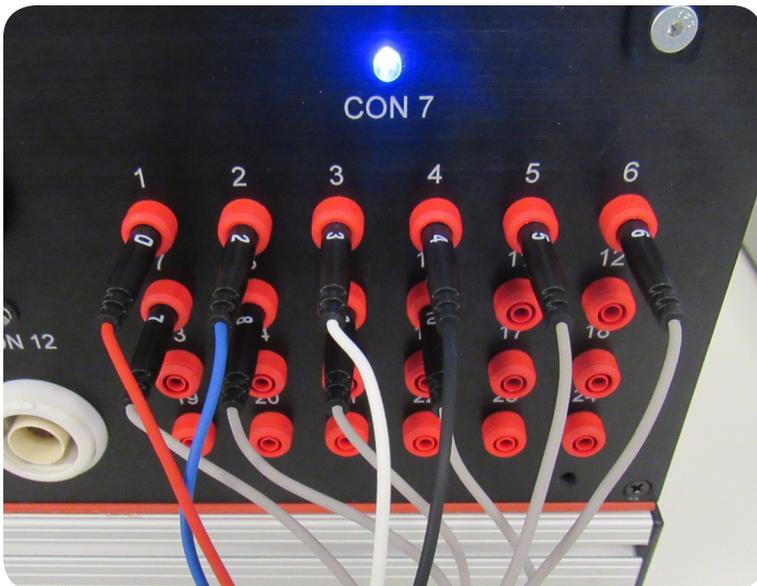
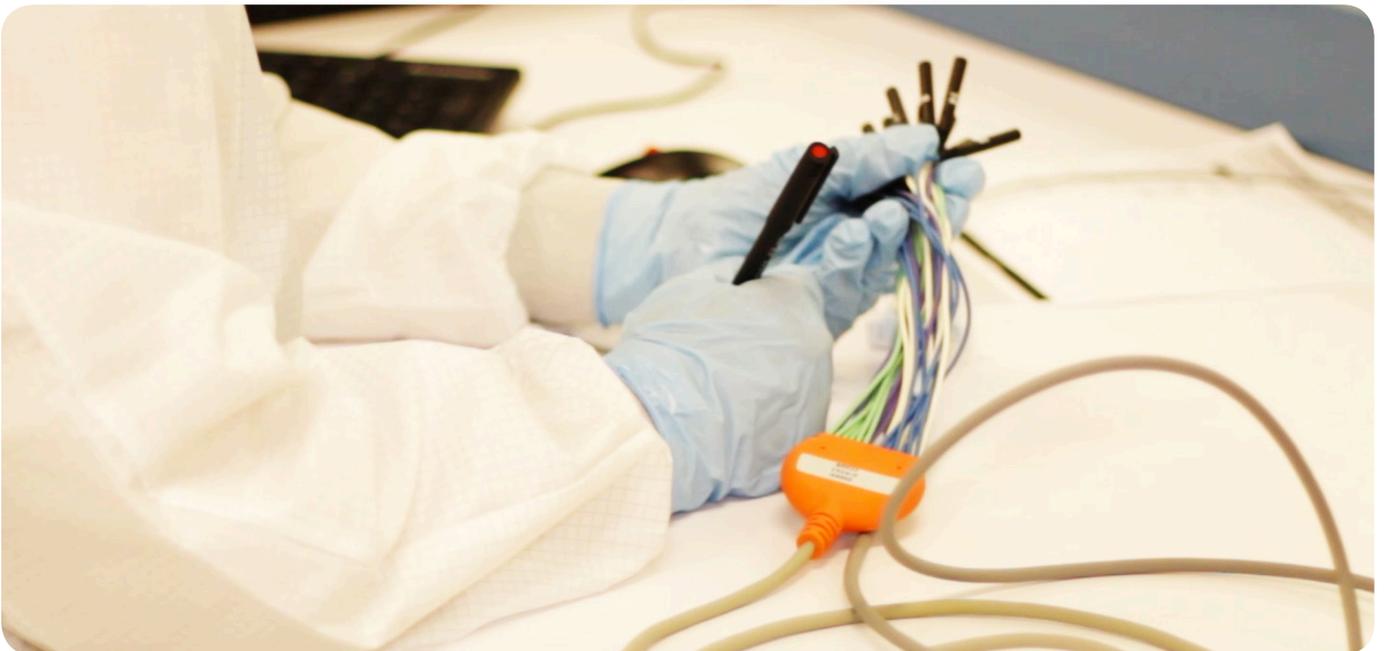




INNOVATIVE  
HEALTH

# Category Spotlight

## Reprocessed (Reusable) Catheter Interface Cables



Reprocessed interface cables are accessories designed to connect a treatment catheter (EP or DUC/ICE) 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 systems from the catheter to the appropriate console during the EP study.

Interface cables from Innovative Health are a safe and effective equivalent to costly options sold by the original equipment manufacturer. In addition, reprocessing cables with Innovative Health helps hospitals stay compliant.

EP cables are used in every EP procedure and present an infection risk when re-used if the cable is not cleaned and sterilized properly between uses. FDA has issued guidelines for how the hospital may reprocess EP cables, and IFUs are available for each cable (device). They typically can be re-used/reprocessed 3, 5, 10 or 20 times. The instructions For Use (IFU) also helps the hospital understand how to clean and sterilize cables and the importance of keeping track of how many times a cable is used.



However, many hospitals do not follow these instructions and send the cables through the central processing department (SPD) without tracking device usage and without using prescribed cleaning methods and functional testing. A JCAHO audit will catch this and has the potential of shutting down clinical operations to ensure compliance with FDA regulation. In short, lack of a clear cables reprocessing policy and practice, hospital operations are at risk without compliance with reprocessing rules for cleaning and sterilization. SPDs have no way of tracking use, and cleaning practices are typically based on standard SPD cleaning practices which do not live up to JCAHO standards.

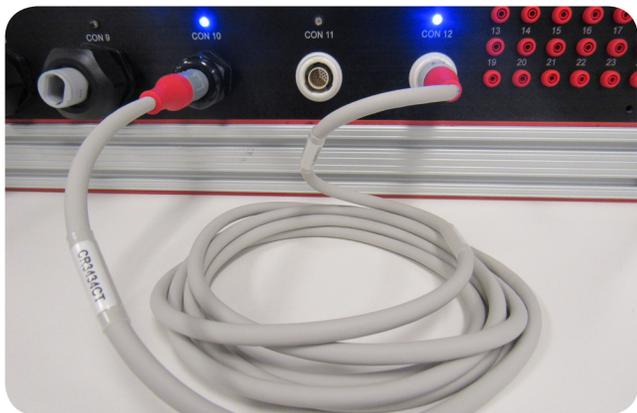
There are three reasons why it makes sense to use the Innovative Health professional reprocessing program as opposed to simply sending cables through regular SPD cleaning before re-use:

- *Cleaning:* Innovative Health cleaning of EP cables rigidly follow OEM IFUs to ensure there is no contamination risk – required chemicals and processes are used, enabling the hospital to observe JCAHO standards
- *Function testing:* Reprocessed Innovative Health cables are function tested, individually, to ensure they work for an additional use. The cost of discovering a disfunctional cable during or at the beginning of a procedure is very high – because a cable has to be replaced; and this takes important and costly time in the EP lab, increasing costs and potential patient risk
- *Cycle count:* JCAHO/FDA have specific requirements about how many times a cable can be re-used. While most hospitals struggle to monitor and manage this, Innovative Health records and tracks every single device so that devices are not used beyond their expected (and JCAHO defined) life.

An average size lab that uses 14 interface cables per week can save \$17,470 per year.

## 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 for any open or short conditions between wires, as well as, the resistance each wire. This industry leading test ensure that the electric connections on the cable all meet acceptable standards which ensure the connectivity to the EP lab equipment performs like an OM 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.

## Inspection

All cables must pass 100% visual inspection using magnification. Cables are checked for damage, kinks, tears and any other damage that would impact the functionality. Cables are serialized to ensure the maximum number of reprocessing cycles are not exceeded. The traceability of each cable provides assurance that customers are receiving the highest quality product possible.



Original Manufacturer	Type
Biosense Webster	Carto 3 interface
	QwikCable
Boston Scientific / Bard	Orbiter PV
	Interface Cable
	SureLink
St.Jude Medical	Easy - Mate
	Response
	Supreme
	1914-SA
	1910-S
	Safire
Medtronic	Safire TX - EPT Generator
	Safire TX - Stockert Generator
Medtronic	Interface Cable



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