



Instructions for Use Reprocessed (Reusable) Cables for Cardiac Pacing Systems

Reprocessed Device for Single Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Medtronic Model 2292 cable is a reusable analyzer surgical cable. The cable is designed to connect an analyzer to a cardiac pacing lead system.

The proximal end of each 2292 cable consists of a connector plug with recessed pins that plugs into a Medtronic analyzer.

The distal end of each 2292 cable consists of 4 alligator clips with color-coded alligator clip boots. The alligator clips attach to the connector pins of cardiac leads. The red clips are positive (+). The black clips are negative (-). The atrial alligator clips are indicated by the word "ATRIUM" on a blue band; the ventricular alligator clips are indicated by the word "VENTRICLE" on a white band.

Note: Parts that may come into contact with the patient during normal use of the Medtronic Model 2292 cable include the insulated cable wires, the alligator clip boots, the alligator clips, and the blue and white bands.

The Model 2292 analyzer surgical cable is part of a cardiac pacing system. For more information about the intended use of the cardiac pacing system, refer to the Original Manufacturer's technical manual for the analyzer.

The Medtronic model 2292 cable is intended to be used with Medtronic IS-1/DF-1 and IS4/DF4 style leads.

The Medtronic Model 5492AL and 5492VL cables are reusable patient cables. The cables are designed to connect a temporary pacemaker to atrial and ventricular pacing lead systems.

The proximal end of each 5492AL and 5492VL cable consists of a connector plug with recessed pins that plugs into a temporary pacemaker.

The distal end of each 5492AL and 5492VL cable consisted of a lead connector assembly with two lead ports for connecting endocardial or myocardial pacing leads with connector pins that are 0.38 to 2.41 mm (0.015 to 0.095 in) in diameter and up to 25.4mm (1.0 in) in length.

The Model 5492AL and 54925VL cables are identical except for length, color coding, and markings. The Model 5492AL cable is color-coded in blue for atrial use. The atrial cable has a blue lead connector assembly and a blue strain relief near the connector plug. The Model 5492VL cable is color-coded in white for ventricular use. The ventricular cable has a white lead connector assembly and a white strain relief near the connector plug.

The 5492AL and 5492VL cables are marked with a symbol located on one side of the lead connector assembly, indicating atrial or ventricular use.

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Note: Parts that may come into contact with the patient during normal use of the Medtronic 5492AL and 5492VL cables are the lead connector assembly and the cable jacket.

The Medtronic Model 5492AL and 5492VL cables are part of a temporary cardiac pacing system. For more information about the intended use of and the indications for temporary cardiac pacing systems, refer to the technical manuals for the cardiovascular stimulating instruments.

The Abbott/St. Jude Medical 401748 Threshold cables are accessories which can be used during threshold testing of permanent pacing lead placement at the time of surgery or implantation. The general features of these devices are their ability to extend the distance between permanent pacing leads and a pacing device. The devices are designed to industry standard connection schemes that allow compatibility with a variety of permanent pacing leads.

INDICATIONS FOR USE

The Model 2292 analyzer surgical cable is part of a system that monitors implanted heart device information. The cable itself is not a therapeutic device and therefore does not have an indication for use.

The Medtronic Model 5492AL and 5492VL patient cables are intended for use as part of a temporary cardiac pacing system. They connect atrial and ventricular pacing lead systems to a temporary external pacemaker.

The Abbott/St. Jude Medical 401748 threshold cables are indicated for the electrical connection of permanent pacing leads to external pulse generators and/or pacing system analyzers.

The cable may be re-used subject to the cleaning and sterilization services provided by Innovative Health.

CONTRAINDICATIONS FOR USE

There are no known contraindications for the cables.

WARNINGS

- When handling the cables, do not allow the exposed metal (as applicable) to contact electrically conductive or wet surfaces. Do not touch the exposed metal conductive surfaces.
- Do not bend the cable excessively. Excessive bending or kinking of the cable may damage the integrity of the cable and may lead to patient injury. Care must be taken when handling the cable.
- Do not modify this equipment. Modifications may reduce system effectiveness and impact patient health.

PRECAUTIONS

- Connect the cable to the appropriate equipment (i.e. analyzer, temporary external pacemaker) before connecting the cable to pacing leads. When disconnecting the cable, disconnect from the pacing leads before disconnecting from the equipment.
- For the Medtronic 2292 cable, when using only two or three alligator clips, protect the unused clips from contact with any conductive surface or current leakage source.
- For the Medtronic 5492AL and 5492VL cables, finger tighten each terminal knob on the cable lead connector assembly. Do not use any tools.
- Improper insertion of the cable may damage the connector pins.
- Do not pull on the insulated cable wire to disconnect the cable. Tension on the wire may damage the cable.
- Carefully observe the polarity and the atrial and ventricular designations of the pacing leads and the cable connectors when connecting the pacing leads to the cable.
- For reuse of the cable, return to Innovative Health for additional processing.
- Do not expose cable to organic solvents.
- Ensure that the cable connection remains dry throughout the procedure.

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- Inspect the packaging and cable for damage or defects prior to use. Do not use the cable if it appears damaged. Damage includes, but is not limited to, deterioration of the cable insulation (brittleness, cracking, thinning, bare spots).
- Do not use the cable if the conductive wires are exposed.
- The cable is intended for use by trained clinicians in a clinical environment.

ADVERSE REACTIONS

- Allergic reaction
- Cardiac arrest
- Discomfort
- Dizziness
- Fever
- Health care professional or patient experiences discomfort
- Infection
- Lethargy
- Patient cut, or skin pinched or irritated
- Property or environmental damage
- Skin disorders
- Syncope and/or medical intervention
- Toxic reaction

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Before beginning the procedure, verify compatibility of all devices and accessories.
- Inspect the cable and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the cable is damaged or the packaging is compromised, do not use the cable. Do not attempt to repair any damage. Return the cable and packaging to Innovative Health.
- Do not attempt to resterilize.
- Connecting the Cables
 1. Orient the cable plug so that the latch is facing upward.
 2. Insert the cable plug into the receptacle on the analyzer or the applicable equipment until it clicks.
 3. Gently pull on the cable after inserting it to ensure that the connection is secure.
- Disconnecting the Cables
 1. Grasp the cable plug.
 2. Press down on the latch button of the cable plug.
 3. Pull the cable plug straight out of the receptacle on the analyzer or the applicable equipment.
- Connecting Pacing Lead Systems to the Medtronic 2292 Cable
 1. **Unipolar Pacing Leads with IS-1/DF-1 Connectors**
 2. Connect the black (-) clip to the connector pin (Figure 1).
 3. Connect the corresponding red (+) clip to an indifferent electrode that is in contact with subcutaneous tissue (Figure 1).

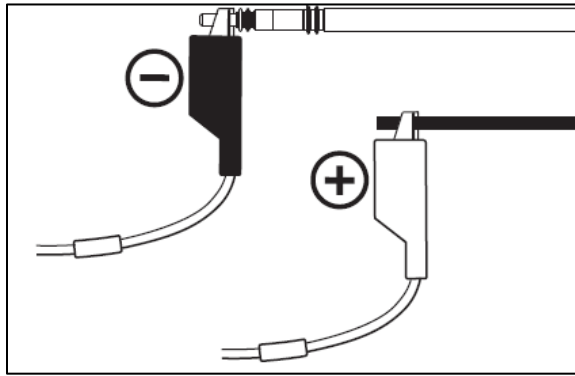


Figure 1. Connection diagram for unipolar pacing leads, type IS-1

Bipolar Pacing Leads with IS-1/DF-1 Connectors

1. Connect the black (-) clip to the connector pin (Figure 2).
2. Connect the corresponding red (+) clip to the connector ring (Figure 2).

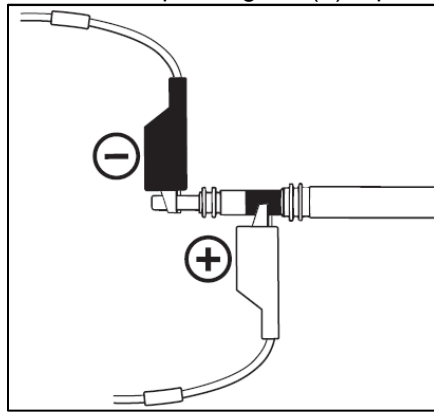


Figure 2. Connection Diagram for Bipolar Pacing Leads, type IS-1

Pacing Leads with IS4 Connectors

1. Connect the black (-) clip to the desired cathode (Figure 3).
2. Connect the corresponding red (+) clip to the desired anode (Figure 3).

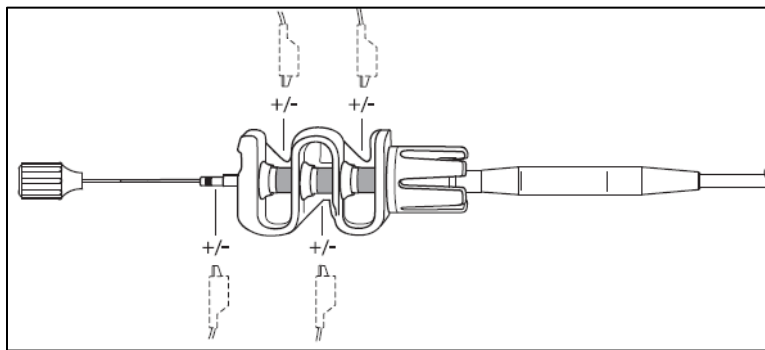


Figure 3. Connection Diagram for Pacing Leads, type IS4

Defibrillation Leads

1. Connect the black (-) clip to the connector pin (Figure 4).
2. Connect the corresponding red (+) clip to the desired ring (Figure 4).

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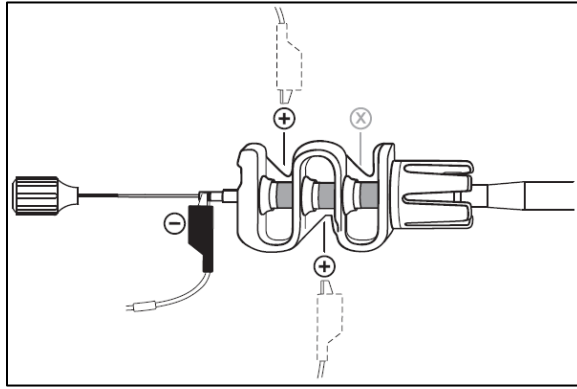


Figure 4. Connection Diagram for Defibrillation Leads, type DF4

Dual Chamber Pacing

1. For dual chamber pacing, use both sets of alligator clips (atrial and ventricular).
- Connecting Pacing Lead Systems to the Medtronic 5492AL and 5492VL Cables
 1. Loosen the connector knobs by twisting each knob counterclockwise until resistance is felt. Observing polarity, insert lead connector pins as shown (see Figure 5).
 2. Finger tighten each terminal knob clockwise until snug. Use gentle traction on each lead conductor to verify a secure connection.

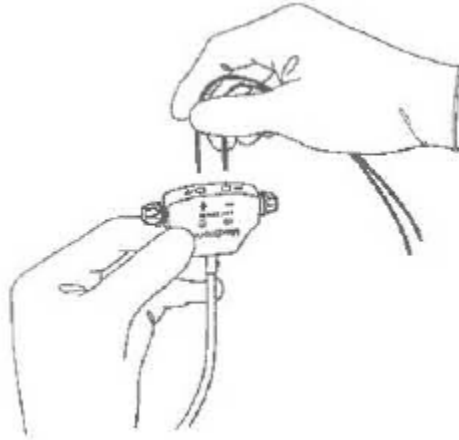


Figure 5. Connecting the pacing lead to the Model 5492AL and 5492VL patient cable

- Ensure that the connection is secure between the cable and connecting equipment.
- Upon use, wipe the cable with a damp cloth or gauze to remove any visible soil and please return the device per Innovative Health's instructions. Do not submerge the cable in a basin with other soiled instruments or devices.

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EXPLANATION OF SYMBOLS



Federal Law in the USA restricts this device to sale by or on the order of a physician



Sterilized by Ethylene Oxide Gas



Catalog Number



Serial Number



Lot Number



Use by Date



Do Not Reuse



Do Not Resterilize



Consult Instructions for Use



Do Not Use if Package is Damaged



Keep Product Dry



Keep Away from Sunlight



Manufacturer



Type CF applied part (as applicable)

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

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

Please refer to www.innovative-health.com for product warranty.