



## 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 cable consists of a connector plug with recessed pins that plugs into a Medtronic analyzer.

The distal end of each 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 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 cable is intended to be used with Medtronic IS-1/DF-1 and IS4/DF4 style 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 cable may be re-used subject to the cleaning and sterilization services provided by Innovative Health.

#### **CONTRAINDICATIONS FOR USE**

There are no known contraindications to this cable.

#### **WARNINGS**

- When handling the cables, do not allow the exposed metal 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.

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### **PRECAUTIONS**

- Connect the cable to an analyzer before connecting the cable to pacing leads. When disconnecting the cable, disconnect from the pacing leads before disconnecting from the analyzer.
- When using only two or three alligator clips, protect the unused clips from contact with any conductive surface or current leakage source.
- 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.
- 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**

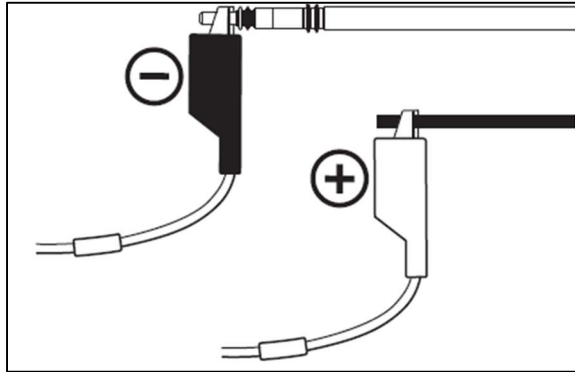
- The package label is detachable and may be affixed to the medical record of the patient.
- Before beginning the procedure, verify compatibility of all devices and accessories.
- Inspect the cable and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. 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.
- For Medtronic 2292 Analyzer Surgical Cables
  - a. Connecting the Cable to the Analyzer
    1. Orient the cable plug so that the latch is facing upward.
    2. Insert the cable plug into the receptacle on the analyzer until it clicks.
    3. Gently pull on the cable after inserting it to ensure that the connection is secure.
  - b. Disconnecting the Cable from the Analyzer
    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.

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c. Connecting Pacing Lead Systems to the Cable

**Unipolar Pacing Leads with IS-1/DF-1 Connectors**

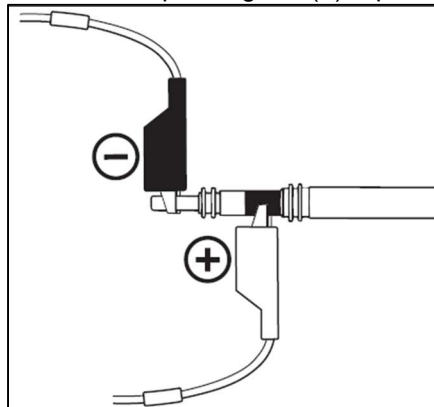
1. Connect the black (-) clip to the connector pin (Figure 1).
2. Connect the corresponding red (+) clip to an indifferent electrode that is in contact with subcutaneous tissue (Figure 1).



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

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

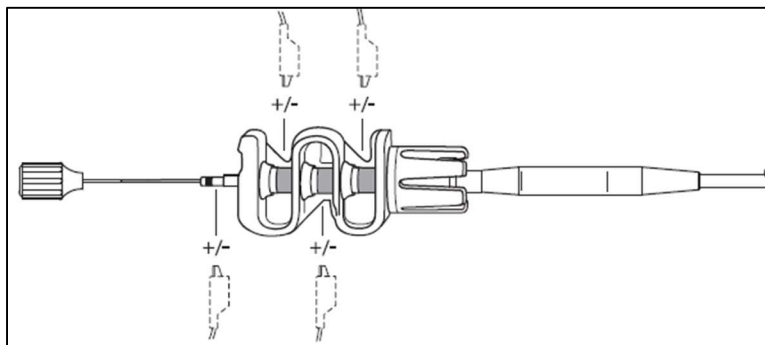
1. Connect the black (-) clip to the connector pin (Figure 2).
2. Connect the corresponding red (+) clip to the connector ring (Figure 2).



**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).

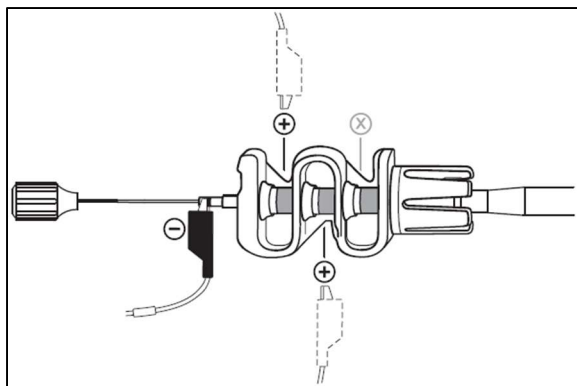


**Figure 3. Connection Diagram for Pacing Leads, type IS4**

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### **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).



**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).
- 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



Type CF applied part



Non-pyrogenic

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](http://www.innovative-health.com) for product warranty.