Instructions for Use, AtriAmp® & Accessory Pacing Cables

Intended Use

The AtriAmp is a single-use device that is intended to connect an electrode/lead from a patient to a Type CF, defibrillation-proof Diagnostic Machine and/or an external pacemaker.

The AtriAmp supports pacing by acting as an extension cable between an external pacemaker and cardiac pacing leads. The AtriAmp also supports monitoring of intra-cardiac signals by transmitting signals to one of the unipolar precordial chest leads (leads V1-V6) of a Type CF, defibrillation-proof ECG monitor.

⚠ **Warning:** As a single-use device, the AtriAmp must not be reprocessed or re-sterilized for multiple patient usages. Reprocessing the AtriAmp may damage the device, resulting in inappropriate diagnosis and/or treatment through the AtriAmp.

AtriAmp Pacing Wire Connection

⚠ **Warning:** Before making any electrical connections, touch the patient at a site remote from the pacing lead(s) to discharge any excess static electricity.

1. Connect the AtriAmp to the epicardial wire by inserting a pacing lead into the appropriate (+) or (-) port while pressing the corresponding side button (Figure 1). Release the button to secure the lead.
2. If applicable, replicate step 2 for the other unconnected atrial epicardial wire.
3. Slide apart the grey and blue portions of the AtriAmp until the device "clicks", locking the pacing lead cover in position (Figure 2). **Note: DO NOT lock the pacing lead cover when using pacing wire leads that have wide plastic bases, as this could eject the shrouded pacing wires from the device.**
4. Secure the AtriAmp to the patient's gown or bed linen using the clip attachment (Figure 3).

⚠ **Warning:** The exposed metal portions of the pacing wires, AtriAmp, and accessory cables must not be touched with bare hands or come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the AtriAmp and connected cables.

⚠ **Warning:** Electrical interference caused by electromagnetic or other interference sources (e.g., communication transmitters, cell phones, etc.) and the effects of therapeutic and diagnostic energy sources (e.g., external cardioversion, high-frequency surgical equipment, etc.) can reduce the performance of the external pacemaker. Consult the instructions for use of the pacemaker for specific warnings.

Pacing through AtriAmp

1. After attaching the AtriAmp to the pacing wires as described above, remove the pacemaker connector plug and connect the pacing cable to the temporary pacemaker.

⚠ **Warning:** Risk of patient shock is increased if the pacing cable is connected to the AtriAmp before it is connected to the pacemaker.

2. Connect the pacing cable to the AtriAmp when pacing functionality is needed (blue connector, Figure 4).
3. Confirm that the pacemaker has an effective pacing connection to the patient through the AtriAmp.

Display Atrial Signal on Monitor

Remove the stud cap and connect the precordial V lead wire from a Type CF, defibrillation-proof Monitor (monitor) to the AtriAmp V stud (brown connector, Figure 4).

Consult the monitor IFU for guidance on the following setup tasks:

1. Connect all additional lead wires (e.g., LA, RA, LL, RL) to patient surface electrodes.
2. (a) Modify the monitor display settings so that the precordial V lead (for 5-lead ECG) or other V(1-6) (for 12-lead ECG) lead is displayed.
   (b) If the V lead signal does not adequately fit the available display area, increase or decrease the V lead monitor scaling, as necessary. **Note: The atrial signal may not be visible during pacing due to large pacing signal size.**
3. Configure the monitor to display an additional limb lead at the same time as the V lead, allowing for timing and interval comparison to be performed between the two leads. Confirm that automated monitoring and alarms are detected from the limb lead electrogram.

⚠ **Warning:** The precordial V lead on the ECG monitor now displays the atrial-cardiac signal from the pacing wire, not the standard surface V lead. Consult the monitor's user manual and turn off any analysis functions that specifically include the chosen precordial lead, as monitoring alarms and other patient measurements based on the chosen precordial lead may result in adverse performance.

⚠ **Warning:** Connect the AtriAmp only to Type CF and Defibrillation-Proof ECG Monitors. Risk of cardiac hazard is increased if the AtriAmp is connected to any non-Type CF and non-Defibrillation-Proof ECG Monitor. The AtriAmp and accessory cables do not add any patient isolation. **Note: The defibrillation-proof type CF applied part symbol (IEC 60417-5336) consists of a boxed-in heart centered between two defibrillation symbols (⊣ ⊢). IEC 60417-5336 is found adjacent to or on the ECG connector of the monitor.**
Caution: Ambulatory electrocardiographic systems (e.g., Holter monitors) are not recommended for use with the AtriAmp because they may not meet the necessary safety classification of Type CF, defibrillation-proof.

⚠ **Warning:** Use of non-traditional lead calculation settings with the AtriAmp (e.g., EASI™) may result in inaccurate lead calculations for the bipolar and unipolar limb leads (I, II, III, AVR, AVL, AVF).

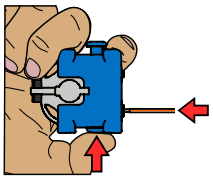

Fig. 1

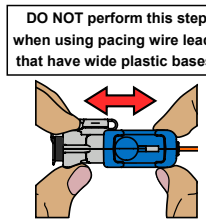

Fig. 2

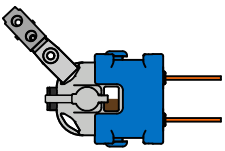

Fig. 3

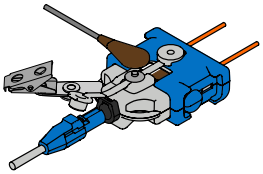

Fig. 4

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Protective Cap/Plug Replacement

The flexible rubber component on the AtriAmp has two protective features: the V stud cap and the pacemaker connector plug. To minimize risk of static discharge, the V stud must be covered when not in use. To minimize occurrence of ingress, the pacemaker connector must be plugged when not in use.

Disconnection

When use of the AtriAmp is no longer necessary, the following steps should be taken to properly disconnect the device and/or accessory cables:

1. Before disconnecting the pacing cable from the pacemaker, disconnect the pacing cable from the AtriAmp. Replace the protective connector plug in the AtriAmp pacemaker connector.
2. Disconnect the ECG V-lead connector and replace the V stud protective cap. If patient requires additional monitoring, reconnect the V-lead to a surface V-positioned electrode.
3. Epicardial wires may be released from the AtriAmp by pressing the button from the corresponding side. The buttons can be pressed while the AtriAmp is in either of the pacing lead cover positions.

⚠ **Warning:** The AtriAmp and accessories must not be submerged in any liquid solution. Exposed metal portions must not be cleaned while the AtriAmp is attached to patient. Failure to comply may cause damage to the device or increase risk to patient.

Rx Only

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

Training

The AtriAmp and accessory cables shall only be used by clinicians or hospital staff who are familiar with the information and warnings listed in this Instructions for Use.

USE OF ATRIAMP AND ACCESSORY CABLES IS GOVERNED BY OUR WARRANTY, DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY, WHICH MAY LIMIT YOUR LEGAL RIGHTS.

The warranty, disclaimer of warranty, and limitation of liability information is provided at:

atrility.com/s/atriampwarranty

The user shall consult the limited warranty, disclaimer of warranty, and limitation of liability product information before use of the AtriAmp and accessories.

General Cable/Pacemaker Accessory Info

Two accessory cables exist for the AtriAmp:

1. Pacing Cable, 6FT, Medtronic Connector
   Pacemaker Connectivity
   (a) Medtronic®: 5348, 5388, 53401, and 5392
2. Pacing Cable, 6FT, 2mm Shrouded Connector
   Pacemaker Connectivity:
   (a) Oscor®: PACE 101H® and 203H®
   (b) St Jude Medical®: 3077 and 3085
   (c) Cardiotronic®: PACE 101® / PACE 101H® and PACE 203® / PACE 203H®

The AtriAmp and accessory cables meet the requirements of the standard ECG Trunk Cables and Patient Leadwires (ANSI/AAMI EC53).

⚠ **Warning:** No modification of the AtriAmp or accessory cables is allowed.

Pacing Wire Information

The AtriAmp device may be connected to pacing wire terminals ranging from 0.84 mm to 2.13 mm in diameter and 15.38 mm to 23.13 mm in length.

Sterilization

The AtriAmp and accessory cables are provided sterile inside the sterile barrier pouches. The products have been sterilized by irradiation.

⚠ **Warning:** Check the sterile barrier pouches before opening. Do not use if pouches have a seal or material breach.

Contra-Indications

Temporary pacing or monitoring through the AtriAmp does not have any known general contra-indications.

Disposal

The AtriAmp and accessory cables should be disposed of according to hospital waste policies and procedures.

Explanation of Symbols

Follow instructions for use	Single use only
Positive polarity wire connection	Negative polarity wire connection
Chest leadwire connection, V	General warning sign

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