Temporary Pacing Electrode Catheter
Information for Use
Temporary Pacing Electrode Catheter Information for Use

Read this document in its entirety prior to use.

Single use.  Sterile, non-pyrogenic unless package opened or damaged.

Caution: Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

Caution: This product contains natural rubber latex which may cause allergic reactions.

Description
Bard temporary pacing catheters are constructed of a woven or extruded polyurethane shaft with platinum or stainless steel electrodes. Certain catheters may incorporate one or more lumens for fluid infusion, pressure monitoring, blood sampling, or balloon inflation. The balloons are manufactured using latex material. Some product may be packaged with accessories such as a needle cannula, safety lead adapter, an ECG adapter, or a balloon inflation syringe.

Indications for use
Bard temporary pacing catheters are designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device. When an internal lumen is present (other than the one used for balloon inflation), it may be used for fluid infusion, pressure monitoring, or blood sampling.

Contraindications
None.

Warnings
General Warnings
These warnings apply to all Bard Electrophysiology temporary pacing electrode catheters.

• Inappropriate electrical connections, e.g., into a wall socket, may pose serious risk of adverse health consequences or death.

• Please ensure that the catheter is connected as recommended for pacing or measuring intracardiac electrogroms.

• This device should be used only by or under the supervision of physicians trained in the techniques of transvenous intracardiac studies and temporary pacing.

• This device is for one-time use only. Reuse or resterilization can impair the structural integrity and/or performance of the catheter.

• The risks of using temporary pacing catheters include those risks associated with introducing any catheter into the heart, such as thromboembolism, perforation, tamponade, infection and the induction of unintended arrhythmias.

Warning for open lumen temporary pacing electrode catheters
If using an open lumen catheter, remove any guidewire/stylet prior to electrical stimulation.

Warnings for balloon temporary pacing electrode catheters
• Do not inflate balloon beyond stated maximum inflation capacity of 1.5 ml.

• Balloon must be completely deflated before withdrawal of the electrode catheter.

• If the balloon catheter has been inflated in vivo for more than one minute, completely deflate the balloon and reinflate it to the recommended capacity of 1.5 ml. This is recommended because carbon dioxide diffuses through the latex balloon.

Warnings for Heparin bonded catheters
• Long-Term Pacing: Although the surface of the catheter has been treated with an anticoagulant to minimize thromboembolic complications, the possibility of thromboembolic and infectious complications increases with the length of time of catheterization. The duration of catheterization should, therefore, be limited to the minimum required by the patient’s condition. Prophylactic systemic anticoagulant and antibiotic protection should be considered in cases with increased risks and when long-term catheterization (longer then 48 hours) is necessary.

The biological activity of the heparin bonding is initiated by blood contact, therefore, efficacy of the bonding is limited to one patient use only.

• It has been reported that heparin induced thrombocytopenia has, in some cases, been associated with the use of heparin bonded catheters. Patients exhibiting symptoms of thrombocytopenia should be monitored for a marked reduction in platelet count and for the presence of heparin associated antiplatelet antibodies. If the condition is confirmed, the physician must remove the catheter if thrombocytopenia is to be reversed and further complications avoided.

Precautions
• Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter including damage to internal wires.

• When using a balloon catheter, use care when removing the protective sleeve from the distal portion of the catheter. Forced removal of this protective sleeve may result in damage to the balloon and the catheters structural integrity.

• For non heparin bonded catheters only: When wiping down this catheter, use only sterile saline.

• For those catheters that are heparin bonded, the following precautions apply:

Anticoagulant Bonding:
- Since the surface of the catheter shaft is treated with a heparin bonding, do not wipe the shaft with alcohol, its esters or ethers, or phenol compounds lest the bonding be rubbed off. If wound closure is prolonged, an appropriate topical hemostatic agent should be used to neutralize the effect of any heparin that may have been wiped off at the edge of the wound.

Longer compression time at the insertion site may be required.

The packaging is designed to avoid crushing of the catheter and to help protect the heparin bonding on the surface of the catheter. The heparin treated surface are fragile. As a result, reasonable care should be employed when removing the catheter from the package.

• After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.

Instructions for use
Inspection instructions
1. Inspect the sterile package carefully for damage during transit or storage. Do not use the catheter if the package is damaged.

2. Visually inspect the catheter, under sterile conditions, for kinks in the catheter shaft, integrity of the connector, condition of electrodes, and any other damage.

3. In case of catheters with a balloon, under sterile conditions, remove the protective sheath and inflate the balloon with 1.5 ml of air or carbon dioxide. Use the inflation syringe included in the package. Completely deflate the balloon after the test.

Insertion instructions using a needle cannula
1. Open the package and place the contents on a sterile field.

2. Prep the skin at the site of insertion and inject a local anesthetic.

3. Remove the protective guard from the needle cannula.

4. Enter the vein with the needle cannula. Simultaneous aspiration into a syringe will help confirm vessel entry.

5. Remove the syringe and the needle.

6. If using an open-lumen catheter, flush the catheter with a heparinized solution. Remove any stylet or stilette prior to insertion.

7. Using the aid of fluoroscopy or an ECG monitor, advance the catheter through the cannula to the desired position. If using a balloon catheter, inflate the balloon when the catheter is in the right atrium. Please note that the balloon can be inflated or deflated only when the stopcock is parallel to the catheter shaft. Do not pull the catheter back through the cannula as it may cause damage to the catheter.

8. If using a balloon catheter, deflate the balloon after the catheter has reached the desired location.

9. Test the pacing characteristics for optimal pacing.

10. Pull the cannula back and secure it to the proximal end of the catheter.

11. Secure the electrode catheter in place at the insertion site.

Insertion Instructions using a percutaneous introducer sheath
Follow the instructions, warnings, and precautions of the introducer manufacturer. If using a balloon temporary pacing catheter, use half or one French size larger introducer, unless otherwise recommended by the introducer manufacturer.

Electrical connections for measuring intracardiac ECGs
1. Insert adapter pin into standard 2 mm (.080”) pin receptable of equipment (See Figure 1) If equipment contains a locking mechanism such as a collet or thumbscrew, tighten down on the adapter. Leave affixed to equipment.

Warning: Inappropriate electrical connections, e.g., into a wall socket, may pose serious risk of adverse health consequences or death.

2. Thread leads of catheter through the adapter eyelet. Connect the negative jack (marked “distal”) to the V-lead of the ECG, and the positive jack (unmarked) to the positive terminal of the external pulse generator.

Electrical connections for pacing
1. Insert adapter pin into standard 2 mm (.080”) pin receptable of equipment (See Figure 1) If equipment contains a locking mechanism such as a collet or thumbscrew, tighten down on the adapter. Leave affixed to equipment.

Warning: Inappropriate electrical connections, e.g., into a wall socket, may pose serious risk of adverse health consequences or death.

2. Thread leads of catheter through the adapter eyelet. Connect the negative jack (marked distal) to the negative terminal of the external pulse generator, and the positive jack (unmarked) to the positive terminal of the pulse generator.

Figure 1

An issued or revision date and a revision number for these instructions are included for the user’s information on the first page directly beneath the address and telephone number of Bard Electrophysiology. In the event two years have elapsed between the date and product use, the user is asked to contact Bard Electrophysiology to see if additional information is available.

Bard and the stylized heart are registered trademarks of C. R. Bard, Inc. or an affiliate.