510(k) SUMMARY

Indications

The Radii Diagnostic Electrophysiology Catheter is intended to be used to record intracardiac electrogram (EGM) signals and to deliver pacing pulses for the purpose of diagnostic provocative stimulation during an electrophysiology procedure.

Device Description

The Radii Diagnostic Electrophysiology Catheter is a 7 F steerable, deflectable, quadrapolar catheter. It has a 4 mm tip electrode and three 1 mm ring electrodes in the flexible distal tip and a handle at the proximal end. The catheter is available in several curve sizes, two shaft stiffnesses, and two electrode spacings. **Figure 1**, depicts the basic configuration of the catheter.

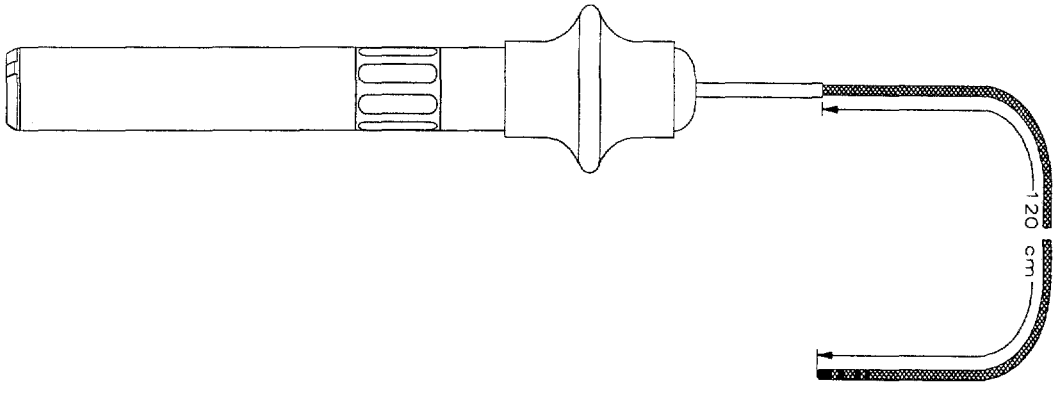


Figure 1: Radii Catheter

The four electrodes at the distal end of the catheter include one 4 mm electrode at the distal tip, and three 1 mm ring electrodes placed at specified distances proximal to the tip electrode. One interelectrode spacing configuration is 2 mm, 5 mm, and 2 mm (2,5,2) and the other interelectrode spacing configuration is 2 mm, 2 mm, and 2 mm (2,2,2). Each of the electrodes is attached to a conductor that extends from the electrode to a specific pin in the connector in the handle.

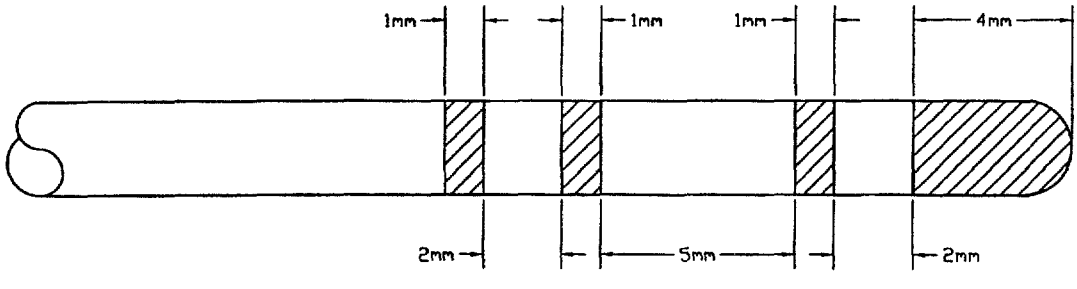


Figure 2: Distal Tip: 2,5,2 interelectrode spacing configuration

The shaft has two lumens, one for the electrode wires and the other for the pull–wire. To facilitate the transmission of rotational force, the shaft includes braiding sandwiched between layers of tubing.

At the proximal end of the handle (i.e., farthest from the shaft), there is a connector for connecting the device to an external stimulator and/or and electrophysiologic recorder. The knob utilized to deflect the tip is on the distal end of the handle (i.e., nearest to the shaft). This knob is connected to the tip by the pull–wire.

Pulling the knob toward the connector causes the tip to deflect, with the extent of deflection controlled by the extent of movement of the knob. Pushing the knob toward the shaft causes the tip to straighten. Rotating the handle to the left or to the right rotates the catheter tip counterclockwise or clockwise, respectively (as viewed from the handle).

Figure 3 depicts the movement of the catheter tip in three–dimensional space.

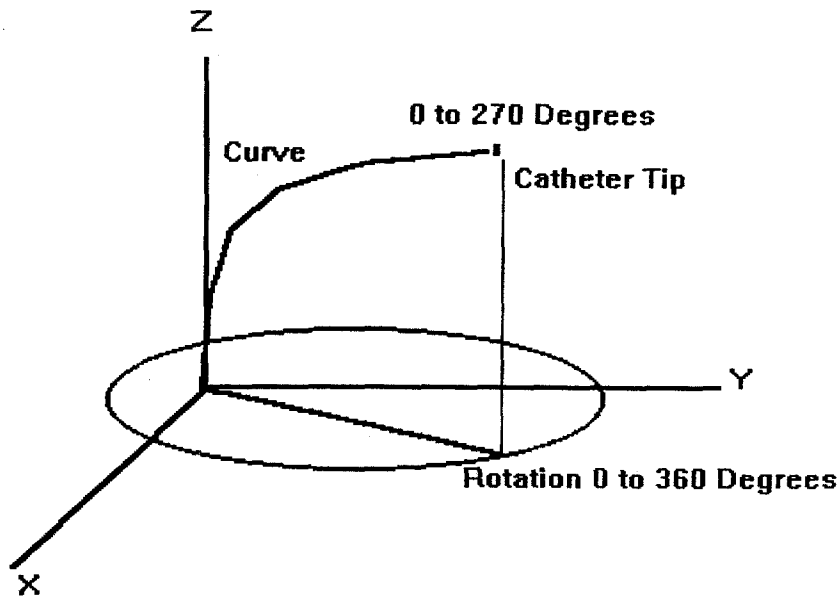
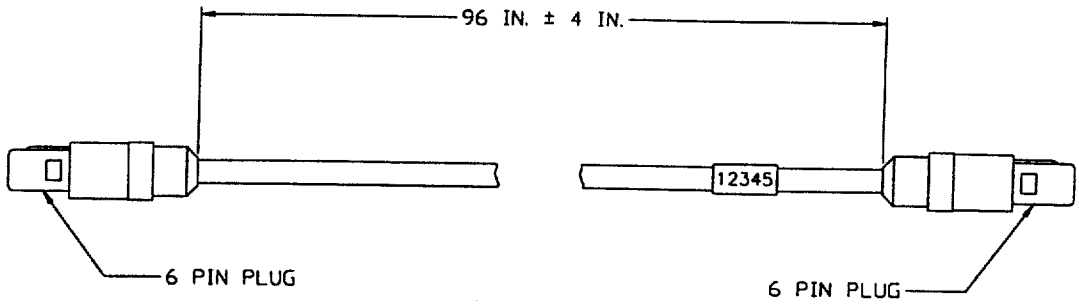


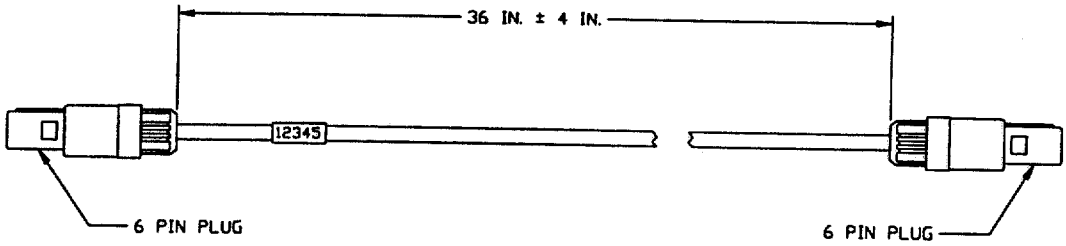
Figure 3: Radii Tip Movement in Three Dimensional Space

Cables

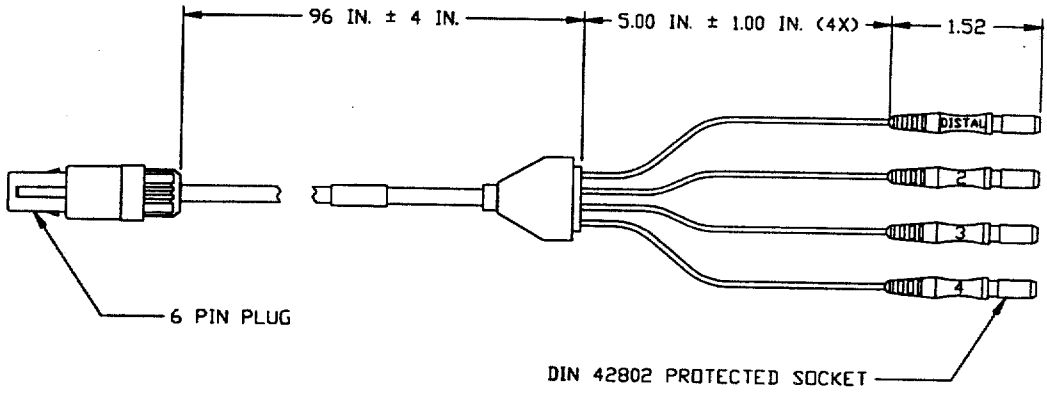
The Radii Catheter connects to an electrophysiologic recorder using an EGM Cable designed specifically for the connector configuration on the recorder. Each cable has a connector on one end that mates to the connector on the Radii Catheter and a connector on the other end that mates to the recorder. Within the insulated cable bundle, each conductor is insulated.



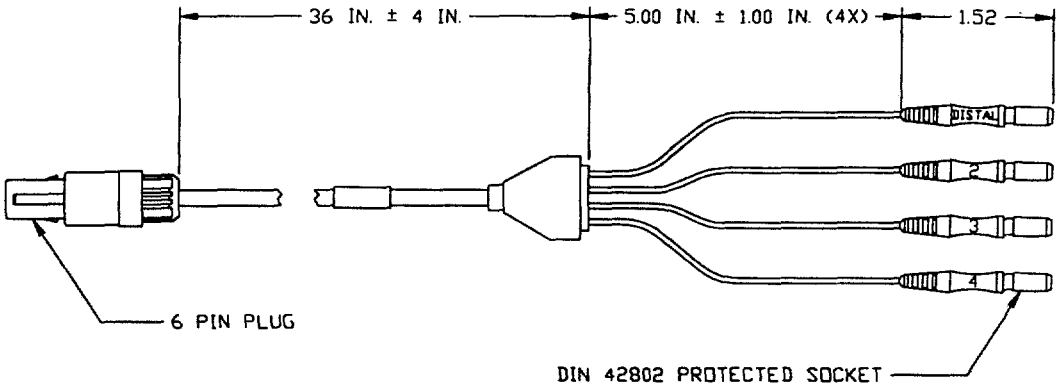
Model 2001 EGM Cable



Model 2028 EGM Cable



Model 2002 EGM Cable

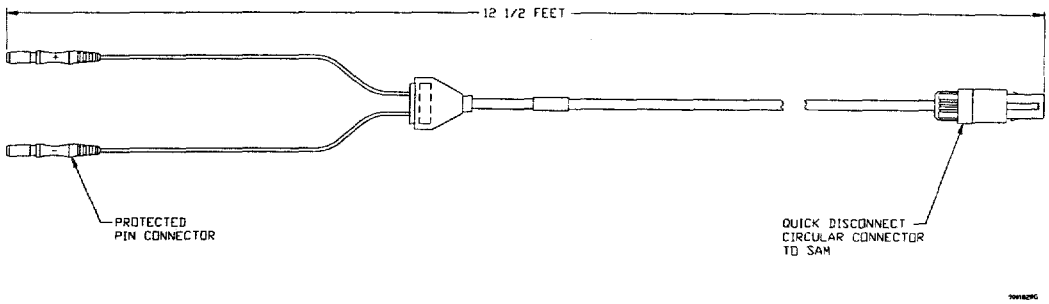


Model 2029 EGM Cable

Figure 4: EGM Cables

A separate cable is utilized for connecting the Radii Catheter to an external stimulator. Like the EGM Cables, this cable has a connector on one end that mates to the connector on the Radii Catheter and a connector on the other end that mates to the stimulator. Each conductor within the insulated cable bundle is insulated. Because many pacing stimulators do not contain protected-pin attachments (these are designed into the Cardiac Pathways cable), a Pin Adaptor is provided with the cable to allow for a variety of connection situations. This pin adaptor is also pictured below.

Pacing Stimulator Cable



Model 2039 Pacing Stimulator Cable

Pin Adaptor (approximately 1 1/8 inch long)

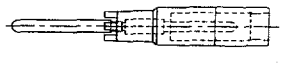


Figure 5: Pacing Stimulator Cable

Predicate Devices

The Radii Diagnostic Electrophysiology Catheter is substantially equivalent to the Polaris–Dx™ Steerable Diagnostic Catheter and the EPT–Dx™ manufactured by EP Technologies, and Diagnostic/Ablation Large & Grooved Dome Delectable Catheters manufactured by Webster Laboratories.

Performance Data

The Radii Diagnostic Electrophysiology Catheter, the EGM Cables, and the Pacing Stimulator Cable were subjected to a battery of electrical and mechanical tests to verify that the devices met the specifications. Electrical testing included, but was not limited to, assessment for continuity and short circuits, DC impedance, AC impedance, capacitance, and dielectric strength and current leakage. The device met the specifications. Mechanical testing included, but was not limited to, assessment of joint strengths and the ability to withstand multiple deflections. The device met the specifications. Biocompatibility testing was performed to verify that the devices did not elicit toxicological responses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1998

Ms. Erin Dignan
Manager, Regulatory Affairs
Cardiac Pathways Corporation
995 Benecia Avenue
Sunnyvale, CA 94086

Re: K983653
Radii Diagnostic Electrophysiology Catheter
Regulatory Class: II (two)
Product Code: DRF
Dated: October 16, 1998
Received: October 19, 1998

Dear Ms. Dignan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K983653

Device Name: Cardiac Pathways Corp., Radii Diagnostic Electrophysiologic Catheter

Indications For Use:

The Radii Diagnostic Electrophysiologic Catheter is intended to be used to record intracardiac electrogram (EGM) signals and to deliver pacing pulses for the purpose of diagnostic provocative stimulation during an electrophysiology procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983653