

K955550

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**510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

K955550

(To be completed by FDA)



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**A. GENERAL INFORMATION**

**Device Classification Name:**

Electrode, Pacemaker, Permanent and Temporary

**Device Trade Name:**

- Intermedics Cardifix™ EZ Model 438-07 Bipolar Implantable Endocardial Pacing Lead
- Intermedics Cardifix™ EZ Model 435-07 Unipolar Implantable Endocardial Pacing Lead

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**B. DESCRIPTION OF THE DISEASES AND CONDITIONS FOR WHICH THE MODELS 438-07 AND 435-07 PACING LEADS ARE INDICATED**

The models 438-07 and 435-07 pacing leads are intended for use with implantable cardiac pulse generators for long-term pacing of the heart. The indications for ventricular pacing include, but are not limited to: Sick sinus syndrome, sinus bradycardia, complete heart block, symptomatic second-degree heart block, and certain conditions of asymptomatic second-degree block.





In the presence of normal A-V conduction the indications for atrial pacing include, but are not limited to: Sinus arrest, sick sinus syndrome, sinus bradycardia and conditions requiring increased cardiac efficiency, enhanced cardiac output or the overdrive of certain cardiac arrhythmias.

Active-fixation leads are specifically indicated for use in cases where passive-fixation leads provide unsatisfactory positional stability in either the atrium or the ventricle, or in cases where the atrial appendage has been sacrificed due to open-heart surgery or is abnormal because of congenital or acquired heart disease.

In the absence of normal A-V conduction, an atrial lead may be used with a ventricular lead in a dual chamber pacing system to restore A-V synchrony.

#### **Contraindications**

The use of endocardial leads may be contraindicated in the presence of tricuspid atresia, Ebstein's malformation, and various forms of atrial or ventricular transposition, and in patients with mechanical tricuspid heart valves.

The use of endocardial leads for atrial applications may be contraindicated in the presence of atrial paralysis, atrial atrophy, or a surgically modified or excised atrial appendage. Atrial pacing is contraindicated in the presence of atrial fibrillation and, except when used in a dual chamber system, in the presence of certain A-V conduction defects.

### **C. DEVICE DESCRIPTION**

The Intermedics Cardifix™ EZ Models 438-07 (bipolar) and 435-07 (unipolar) endocardial pacing leads are designed for use with implantable cardiac pulse generators configured for atrial or ventricular applications for long term cardiac pacing. The nominal length for the model 438-07 lead is 58 cm and is available in lengths from 40 to 110 cm. The nominal length for the model 435-07 lead is also 58 cm and is available in lengths from 40 to 110 cm. The lead connectors are designed to meet VS-1 specifications (an intra-industry agreement standardizing lead-to-pulse generator connection dimensions) for lead connectors.





The models 438-07 and 435-07 pacing leads are packaged with the model 367-01 vein lifter and the following stylets: model 365-11 (straight stylet, limber), model 365-12 (straight stylet, firm), model 365-89 ("J" stylet, limber), and model 365-90 ("J" stylet, firm).

The model 435-07 is also packaged with the following adapters: model 366-29 (Step up adapter, VS-1 unipolar lead to 5 mm unipolar pacer) and model 366-30 (Step up adapter, VS-1 unipolar lead to 6 mm unipolar pacer).

The minimum introducer size recommended for the model 438-07 is 10 French. The minimum introducer size recommended for the model 435-07 is 7.5 French.

The models 438-07 and 435-07 pacing leads are identical to the Intermedics models 438-05 (K922972, K954719) and 435-05 (K922972, K954719) respectively, except for the use of iridium-oxide (IROX) coated titanium for the electrodes. The IROX-coated electrodes are identical to those used in models 430-07 (K902672, K954719) and 431-07 (K902672, K954719) except that the dimensions of the cathode tip have been slightly modified to accommodate the active fixation corkscrew.

## 1. Labeling

The generic Intermedics Endocardial Pacing Leads Package insert accompanies each lead. Along with the generic insert, the models 438-07 and 435-07 are packaged with an insert entitled "Intermedics Endocardial Pacing Leads Package Insert Supplement", which provides detailed information on removing the protective silicone rubber sheath from the Polyethylene Glycol (PEG) encapsulated corkscrew.

The sterile package labeling for the leads contains the nominal product specification for the particular lead model enclosed.

Other than the change in lead model numbers and electrode material; there will be no changes to the labels and/or labeling for these leads.





## 2. Design and Materials

### a. Electrodes

The cathode tip electrodes transfer the electrical charge from the pulse generator to the endocardial surface via the pacing lead. This electrical charge stimulates the myocardium, causing cardiac depolarization.

The cathode tip of the models 438-07 and 435-07 leads is constructed of IROX-coated titanium and has a blunt shape with three radial cross slots and contact surface area of approximately 8 mm<sup>2</sup>. This electrode is identical to the cathode tip of the commercially available Intermedics Models 430-07 and 431-07. In order to accommodate the active fixation corkscrew of the models 438-07 and 435-07 the dimensions of the cathode tip have been slightly modified. This modification is considered minor since the material and contact area of the cathode is identical to that of the models 430-07 and 431-07.

The anode sleeve electrode of the model 438-07 (bipolar), also constructed of IROX-coated titanium, has an approximate surface area of 50 mm<sup>2</sup> and is 0.45 inches from the cathode tip. It is identical to the anode sleeve of the commercially available Intermedics Model 430-07.

IROX is a metal oxide of iridium and oxygen. IROX belongs to a family of oxides that has an inherently high surface area because of its sub-micron particle size. Other oxides have sub-micron particle size and a high surface area, but the IROX family has additional beneficial properties that yield a more conductive oxide; they are highly corrosion resistant and undergo reversible oxidation-reduction reactions. IROX-coated titanium is currently used in several Intermedics commercially available bradycardia pacing leads.

### b. Lead Body

The conductor coils, constructed of three nickel-cobalt alloy wires wound uniaxially (trifilar), transmit electrical activity to and from the





heart. Electrical isolation between the connectors and the body environment is provided by a Pellethane polyurethane (80A) insulation sheath surrounding the conductor coil. The polyurethane insulation also contributes to the structural strength of the leads.

The bipolar lead, model 438-07, consists of an inner coil (joining the connector to the cathode) surrounded by silicone rubber insulation. The second coil (joining the connector to the anode) is wound around the insulation of the first coil. Pellethane polyurethane (80A) insulation tubing surrounds this coil and prevents an electrical interface between the body fluids and the coil. The lead body of the model 438-07 is identical in design and material to the commercially available Intermedics Model 438-05.

The model 435-07 unipolar lead, consisting of one nickel-cobalt alloy coil surrounded by Pellethane polyurethane (80A) insulation tubing, is identical in design and material to the commercially available Intermedics Model 435-05.

c. Tip Fixation

The active fixation mechanism of the lead tip consists of a helical corkscrew of approximately 1 ½ turns which is fixed in the endocardium in order to prevent dislodgement or movement of the tip electrode. The tip fixation mechanism, made of nickel-cobalt alloy, is 2 mm in length and is electrically insulated with a polymer coating for electrical insulation and implant ease.

The fixation screw is protected by a soluble Polyethylene Glycol (PEG) 3350 capsule. The PEG capsule protects the corkscrew while the lead is being passed through the venous system. The PEG capsule is protected by a silicone rubber sheath which is removed by the physician at the time of implant. Once within the vein, the PEG dissolves within 2 to 4 minutes allowing fixation of the lead into the cardiac tissue.





The corkscrew fixation mechanism and the protective PEG capsule is identical in design and material to that of the commercially available Intermedics Models 438-05 and 435-05.

d. Connector Assembly

The connector pin, made of 316L stainless steel, provides the electrical and mechanical connection between the pulse generator and pacing lead. The connector sleeve with O-ring seals is made of silicone rubber and provides an insulating seal between the lead and the header of the pulse generator. The connector dimensions are designed to meet the requirements of the VS-1 standard. The connector assembly of the pacing leads is identical in design and material to that of the commercially available Intermedics Models 438-05 and 435-05.

3. **Performance**

The Intermedics Models 438-07 and 435-07 pacing leads with IROX-coated titanium electrodes are intended for use with implantable pulse generators. Their performance is expected to demonstrate equivalent clinical performance to commercially available unipolar and bipolar atrial/ventricular endocardial pacing leads.

D. **ALTERNATIVES**

The alternatives to the use of these devices are similar to those described for pulse generators. Surgery or drug therapy have been stated as alternates to cardiac pacing in certain instances. However, when a cardiac pacing system is employed, the side effects of drugs and/or the risks of surgery make these alternatives less desirable. Commercially available pacing leads provide another alternative to the use of the Intermedics Cardifix™ EZ Models 438-07 and 435-07 endocardial pacing leads.





## E. POTENTIAL ADVERSE EFFECTS

The potential adverse effects associated with the use of the Intermedics Models 438-07 and 435-07 endocardial pacing leads, as well as other pacing leads, may include intermittent or continuous loss of pacing or sensing produced by factors such as displacement of the electrode, unsatisfactory electrode position, breakage of the conductor or its insulation, an increase in thresholds, or poor electrical connection to the pulse generator.

When subclavian venipuncture is used for endocardial lead introduction, "extremely medial" insertion of a lead and/or "anatomic abnormalities" may

contribute to conductor fracture<sup>1,2,3,4,5</sup>. Lateral lead-tip placement in the atrium or perforation of the ventricular or lateral atrial wall may cause phrenic nerve stimulation. Active-fixation endocardial leads, passed transvenously, present the possibility of inadvertently engaging the lead tip with intracardiac structures, such as the tricuspid valve leaflets or chordae tendineae. Lateral lead-tip placement in the atrium or perforation of the ventricular or lateral atrial wall may cause phrenic nerve stimulation. Perforation of the ventricle may also cause diaphragmatic muscle stimulation. Cardiac tamponade has been reported from instances of lead perforation.

If the connector is cut off when removing an implanted endocardial lead, the lead's insulation tubing (under sufficient traction) may separate from the lead conductor and slide off, leaving an exposed conductor coil in the heart and vein.

As with the introduction of any foreign object into the body, infection can result from the use of endocardial leads.

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<sup>1</sup>Stokes K, et al. A possible new complication of subclavian stick: Conductor fracture. *PACE* 1987; 10:748 (Abstract).

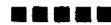
<sup>2</sup>Suzuki Y, Fujimori S, Makoto S, et al. A case of pacemaker lead fracture associated with thoracic outlet syndrome. *PACE* 1988; 11:326.

<sup>3</sup>Furman S. Venous cutdown for pacemaker implantation. *Ann Thorac Surg* 1986; 41:438-439.

<sup>4</sup>Furman S. Subclavian puncture for pacemaker lead placement. *PACE* 1986; 9:467.

<sup>5</sup>Fyke FE, III. Simultaneous insulation deterioration associated with side-by-side subclavian placement of two polyurethane leads. *PACE* 1988; 11:1571.





These complications can occur during implantation, explantation, or at any time postoperatively and may require noninvasive or invasive management techniques.

## **F. SUMMARY OF STUDIES**

### **1. Biocompatibility Studies**

The models 438-07 and 435-07 pacing leads have been evaluated for biocompatibility in both *in vitro* and *in vivo* test systems, and were subjected to the following tests:

- Hemolysis Test
- MEM Elution Cytology
- Ames Mutagenicity
- USP Class V
- Intramuscular Implantation Test
- Maximization Sensitization Test
- USP Pyrogen Test

Based upon the test data, the materials above were not found to present any toxic liability under physiological conditions. Therefore, the tissue/fluid contacting materials of this pacing system are considered biocompatible.

### **2. Qualification Testing**

Complete qualification testing was performed on the predicate leads. Due to the slight modification of the IROX cathode tip to accommodate the active fixation corkscrew, qualification testing of the tip to corkscrew joint was performed to verify the strength of this joint. All of the test samples successfully completed the qualification testing.

With the exception of the active fixation corkscrew, the design of the new leads only incorporates features of the predicate leads (that have already been subjected to qualification testing). As a result, no further qualification testing is believed to be necessary.





**G. CLINICAL SUMMARY**

The clinical experience of the commercially available Intermedics Models 438-05, 435-05, 430-07, and 431-07 endocardial pacing leads has resulted in an extremely low incidence of clinical complications, demonstrating its effective performance in human implantation. Because of the similarity in design and materials, the models 438-07 and 435-07 pacing leads can be expected to perform with comparable efficacy.

**H. MANUFACTURING/STERILIZATION**

Intermedics utilizes environmental controls in the manufacturing facilities which are designed, maintained and closely monitored to achieve an efficacious environment for manufacturing all products. The manufacturing environment is routinely monitored for particle counts, humidity, temperature, and static electricity controls. Additionally, bioburden testing is performed on all products.

Vendors of purchased material must be "approved" based upon a quality survey in which Intermedics' field engineers determine whether the vendor has the capability of consistently supplying material that will meet Intermedics' standards. Each quantity of purchased material is assigned a lot number and acceptance or rejection is determined based upon an inspection (conducted on a statistical sampling basis) performed to Intermedics' Engineering specifications.

The manufacturing process for the models 438-07 and 435-07 consists of the following assembly processes: lead tip/slug parylene coated assembly, IROX channeled tip assembly, lead tip/electrode assembly, anode sleeve assembly (bipolar model only), pin crimp assembly, molded O-ring assembly, final assembly, and packaging assembly.

The finished pacing lead and accessories are packaged in the formed pockets of an inner blister tray which is closed by heat sealing a peelable cover around the periphery. This inner blister is then placed into an outer blister which is closed by heat sealing a second peelable cover to it. Cover material is microbial





penetration resistant, water resistant, and puncture resistant as suitable for this application.

Intermedics sterilization procedures for pacing leads utilize ethylene oxide (EO) sterilizers set for specific parameters derived using methods described in the 1988 AAMI guideline, Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices.

Upon release from sterilization, pacing leads and accessories are packaged into a carton and the boxed product is inspected prior to being routed to the Finished Goods Inventory area.

#### I. CONCLUSION

The information presented in this submission for the Intermedics Cardifix™ Models 438-07 (bipolar) and 435-07 (unipolar) pacing leads demonstrates that the intended use of these devices does not differ from that of the commercially available models 438-05, 435-05, 430-07, and 431-07.

The clinical experience of the Intermedics endocardial pacing leads has resulted in an extremely low incidence of clinical complications, demonstrating their effective performance in human implantation. Because of the similarity in design and materials, the models 438-07 and 435-07 pacing leads can be expected to perform with comparable efficacy.

