K962174

AUG 21 1996

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: [ ]

(To be completed by FDA)

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A. GENERAL INFORMATION

Device Classification Name:
Electrode, Pacemaker, Permanent and Temporary

Device Trade Name:
- Intermedics Model 430-07 Bipolar Implantable Endocardial Pacing Lead
- Intermedics Model 432-03 Bipolar Implantable Endocardial Pacing Lead
- Intermedics Model 436-02 Bipolar Implantable Endocardial Pacing Lead
- Intermedics Model 436-07 Bipolar Implantable Endocardial Pacing Lead
- Intermedics Cardifix EZ Model 438-05 Bipolar Implantable Endocardial Pacing Lead
- Intermedics Cardifix EZ Model 438-07 Bipolar Implantable Endocardial Pacing Lead

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Date of Notification:
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B. DESCRIPTION OF THE DISEASES AND CONDITIONS FOR WHICH THE CFC-FREE MANUFACTURED PACING LEADS ARE INDICATED

The indications for use of Intermedics Models 430-07, 432-03, 436-02, 436-07, 438-05, and 438-07 endocardial pacing leads, manufactured using a Chlorofluorocarbon (CFC) Free process, are identical to those for the commercially available leads with the same model numbers manufactured using Freon-TMS.

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, 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.

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.

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.

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 indications may be contraindicated in the presence of atrial paralysis, atrial atrophy, or a surgically modified or excised atrial appendage.

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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 Models 430-07, 432-03, 436-02, 436-07, 438-05, and 438-07 endocardial pacing leads are designed for use with implantable cardiac generators for long term cardiac pacing. Table 1 summarizes the accessories packaged with each lead model.

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TABLE 1. Accessories packaged with each lead model.

Accessory	Lead Model					
	430-07	432-03	436-02	436-07	438-05	438-07
365-11 Limber Stylet	✓	✓	✓	✓	✓	✓
365-12 Firm Stylet	✓	✓	✓	✓	✓	✓
365-57 Limber Large "J" Stylet					✓	
365-58 Firm Large "J" Stylet					✓	
365-81 Tapered Limber Stylet				✓		
365-82 Tapered Firm Stylet				✓		
365-87 Limber Tight "J" Stylet					✓	
365-89 Limber "J" Stylet						✓
365-90 Firm "J" Stylet						✓
366-14 Lead Cover						
366-29 Step up adapter VS.1 to 5mm						
366-30 Step up adapter VS.1 to 6mm						
367-01 Vein Lifter	✓	✓	✓	✓	✓	✓
Stylet Funnel (no model no.)	✓	✓				

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With the exception of the solution used during the manufacturing process, the listed pacing leads manufactured with the CFC-free process are identically configured to the commercially available Intermedics pacing leads with the same model numbers. Table 2 lists the 510(k) numbers and approval dates for each lead model.

Table 2. 510(k) Numbers and approval dates for each lead model.

Lead Model	510(k) Number	Approval Date
430-07	K890412	3/28/89
	K902672	3/1/91
	K954610	Submitted 10/03/95
	K954719	2/27/96
432-03	K890411	03/28/89
	K912235	09/26/91
	K954610	Submitted 10/03/95
	K954719	2/27/96
436-02	K883602	09/06/88
	K954719	02/27/96
436-07	K955122	Submitted 11/07/95
438-05	K922972	01/22/93
	K954719	02/27/96
438-07	K955550	Submitted 12/04/95

1. Labeling

There are no changes to the product labeling as a result of the modification to the manufacturing process.

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2. Design and Materials

The general characteristics of the pacing leads are summarized below. Table 3 summarizes the characteristics of each lead by model number.

a. Electrodes

The cathode tip electrode transfers the electrical charge from the pulse generator to the desired cardiac surface (endocardium, epicardium, or myocardium) via the pacing lead. This electrical charge stimulates the myocardium, causing cardiac depolarization. The electrodes are either made of iridium-oxide coated titanium (IROX™) (models 430-07, 432-03, 436-07, 438-07), carbon-coated (Biolite[1]) titanium (model 436-02) or a platinum-iridium alloy (model 438-05).

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 an sheath surrounding the conductor coil; which also contributes to the structural strength of the leads. The sheath may be made of polyurethane (models 430-07, 432-03, 438-05, 438-07) or silicone rubber (models 436-02, 436-07).

c. Tip Fixation

The passive fixation mechanism of the lead tip of the models 430-07, 432-03, 436-02, and 436-07 lodges among the trabeculae in order to prevent dislodgement or movement of the tip electrode from the endocardium. The tip fixation mechanism, made of silicone rubber, is a trailing tines design with radial projections 45° to the axis of the lead body.

[1]Biolite is a trademark of Carbomedics, Inc., Austin, TX.

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TABLE 3. Characteristics of Intermedics Pacing Leads by Model Number.

Model No.	Chamber[1]	Polarity	Length[2] (cm)	Electrode Material	Lead Body Material	Fixation	Connector
430-07	Ventricular	Bipolar	58	IROX	Polyurethane	Passive/Tine	VS. 1
432-03	Atrial	Bipolar	52	IROX	Polyurethane	Passive/Tine	VS. 1
436-02	Ventricular	Bipolar	60	Biopore	Silicone	Passive/Tine	VS. 1
436-07	Ventricular	Bipolar	58	IROX	Silicone	Passive/Tine	VS. 1
438-05	A/V	Bipolar	60	Pt/IR	Polyurethane	Active/Screw	VS. 1
438-07	A/V	Bipolar	58	IROX	Polyurethane	Active/Screw	VS. 1

[1]A/V - Atrial and Ventricular

[2]Nominal Lengths. Other lengths available upon request.

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The active fixation mechanism of the lead tips of the models 438-05 and 438-07 consists of a nickel-cobalt helical corkscrew which is fixed in the endocardium in order to prevent dislodgement or movement of the tip. The model 438-07 pacing lead has a unique feature which provides a protective soluble Polyethylene Glycol (PEG) capsule over the fixation mechanism while the lead is passed through the venous system. Within 2 to 4 minutes, the PEG dissolves allowing fixation of the lead into the cardiac tissue.

d. Connector Assembly

For all Intermedics pacing lead models, the connector pin (cathode), made of 316 stainless steel, provides the electrical and mechanical connection between the pulse generator and pacing lead. The connector sleeve and seals are made of silicone rubber and provide 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.

3. Performance

The Intermedics pacing leads are intended for use with implantable pulse generators. Based upon the results of qualification testing, the performance of the leads manufactured with the CFC-free manufacturing process is expected to be equivalent to the performance of the commercially available leads manufactured using Freon-TMS.

D. ALTERNATIVES

The alternatives to the use of pacing leads are similar to those described for pulse generators. Surgery or drug therapy have been stated as alternatives 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.

Other commercially available pacing leads provide another alternative to the use of Intermedics pacing leads manufactured using the CFC-free process.

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E. POTENTIAL ADVERSE EFFECTS

The potential adverse effects associated with the use of 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. As with the introduction of any foreign object into the body, infection can result from the use of pacing leads and accessories. These complications can occur during implantation, explantation, or at any time postoperatively and may require noninvasive or invasive management techniques.

When subclavian venipuncture is used for endocardial lead introduction, "extremely medial" insertion of a lead and/or "anatomic abnormalities" may contribute to conductor fracture[2]. Perforation of the ventricular wall may cause phrenic nerve stimulation or diaphragmatic muscle stimulation. Cardiac tamponade has been reported from instances of lead perforation.

When removing an implanted endocardial lead, if the connector is cut off, 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.

When using an epicardial or myocardial lead, conditions may occur that are associated with risks inherent in open chest surgery, such as pulmonary difficulties and, rarely, cardiac tamponade.

F. SUMMARY OF STUDIES

1. Biocompatibility Studies

All of the tissue/fluid contacting materials of the pacing leads have been evaluated for biocompatibility in both *in vitro* and *in vivo* test systems and subjected to the following tests:

[2]Stokes K, et al: A possible "new" complication of subclavian stick: Conductor fracture, PACE, 10:748, 1987 (Abstract).

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- 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.

In order to ensure continued biocompatibility of these materials when manufactured utilizing the IPA/heptane blend, the hemolysis and cytotoxicity tests were repeated for the following materials:

- Silicone tubing cleaned with IPA/heptane,
- 80A polyurethane tubing cleaned with IPA/heptane,
- 55D polyurethane tubing cleaned with IPA/heptane.

Based upon the results of these tests, the materials continue to be biocompatible when processed with the IPA/heptane blend.

2. Qualification Testing

Qualification testing was performed on the model 430-07. This lead model was selected as it consists of processes representative of the changes in the manufacturing processes of the affected lead models as a result of the elimination of Freon-TMS. These processes include:

- Cleaning (degreasing) of silicone, polyurethane, and metal parts
- Swelling of silicone tubing and parts
- Softening and lubricating of polyurethane tubing
- Mechanical assembly of components

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G. CLINICAL SUMMARY

The clinical experience of the commercially available Intermedics pacing leads has resulted in an extremely low incidence of clinical complications, demonstrating its effective performance in human implantation. Because of the favorable biocompatibility and qualification test results, it is expected that the pacing leads manufactured with the CFC-free process will 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 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 and accessories 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.

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Upon release from sterilization, pacing lead 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 Models 430-07, 432-03, 436-02, 436-07, 438-05, and 438-07 endocardial pacing leads demonstrates that the intended use of these devices does not differ from that of the commercially available predicate models.

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 pacing leads can be expected to perform with