

K953044



B. Safety And Effectiveness Summary

The BIOTRONIK TIR and TIJ pacing leads are safe and effective transvenous, implantable, endocardial leads used with implantable cardiac pacemakers. The leads are manufactured in unipolar and bipolar configurations. The lead body insulation of all TIR/TIJ endocardial leads is NuSil silicone rubber tubing, with the conductor of quadrifilar MP35N.

The TIR/TIJ endocardial leads provide long-term safe and effective pacing due to the surface structure of the lenticular electrode tip. The tip has a Physical Vapor Deposition (PVD) of iridium over titanium, creating a fractal-surfaced ball-like microstructure. Passive fixation in the heart's trabeculae is provided by four flexible silicone rubber tines. The ring electrode (anode) of the bipolar lead is made of platinum-iridium, also with a fractal iridium surface treatment. The IS-1 connection system of TIR/TIJ leads complies with the International Standard ISO 5841.3:1992: Low Profile Connectors. The TIJ lead is pre-formed into a "J" shape for optimal positioning in the atrium.

Pre-clinical testing was performed on the leads to examine biocompatibility and to qualify the manufacturing process of these leads. During biocompatibility testing, cytotoxicity, hemolysis, pyrogenicity (LAL) and other testing were performed, as well as long term studies. Corrosion studies were completed to address both long-term toxicity and durability of the material. The testing conducted for biocompatibility as well as extensive clinical experience confirms that iridium is safe for use as an implantable biocompatible material. Literature has been published illustrating this conclusion. The long term corrosion testing results substantiate that it is a non-toxic and durable material for use in implantable devices.

Qualification testing results validate the safety and effectiveness of the lead design and materials used. The TIR and TIJ leads are tested for crimp and weld strength of connections, fatigue strength, DC resistance, environmental resistance, adherence to IS-1 standards, stylet performance, packaging and transportation durability, lead tip testing, and sterilization validation. All tests

**TIR/TIJ Cardiac Pacing Leads
Response to K053044**

results were within specifications. An overview of pre-clinical testing is found in section III.A. of this premarket notification with additional information provided in the Appendices.

The European version of the TIR/TIJ endocardial leads, models IRTI and IRTJ, were evaluated in European clinical studies to examine the performance characteristics of the unipolar and bipolar leads. The protocol used examined acute and long-term sensing and pacing thresholds, and long-term impedance's. Details of this evaluation can be found in section III.C. of this notification. (APPENDIX 3)

The results of studies, the *in-vitro* and qualification testing performed on the TIR/TIJ leads show that the risk to the patient in using these leads is the same as that of any implantable endocardial lead. [2 sentences stricken from this paragraph]

Potential complications resulting from the use of endocardial leads include, but are not limited to: thrombosis, embolism, body rejection phenomena, cardiac tamponade, muscle/nerve stimulation, valve damage, fibrillation, and infection. Lead perforation through the myocardium has been rarely observed. The table below summarizes some of the potential symptoms indicating a complication and possible corrective actions:

Table 6
Lead Complications

Symptom	Potential Complication	Potential Corrective Action
Loss of pacing or sensing	Electrode displacement Lead fracture Setscrew penetration Improper lead to pacemaker connection	Reposition lead Replace lead Replace lead Reconnect lead to pacemaker
Increase or decrease in threshold	Fibrotic tissue formation	Adjust pulse generator output; Reposition lead

The fractal iridium surface treatment was introduced in Europe on TIR/TIJ on January 20, 1994. The lead body design and the size of the tip and the ring (where applicable) is the same for all leads, now representing over 100,000 leads sold.

**TIR/TIJ Cardiac Pacing Leads
Response to K963044**

Table 7
Number of Devices Sold, Worldwide

Type	1989	1990	1991	1992	1993	1994*	SUM
TIR-UP	430	2370	4790	7840	14790	18880	49080
IRTI-UP				50	650	1090	1790
TIR-BP	70	700	2130	4480	8880	19850	37090
IRTI-BP				60	900	2180	3120
TIJ-UP			210	570	990	2780	4550
IRTJ-UP				30	210	130	370
TIJ-BP			170	700	1140	2580	4570
IRTJ-BP				20	510	900	1430
						TOTAL:	102000

A bibliography of relevant articles on cardiac pacing leads is provided as Appendix 23, with selected copies provided as Appendix 25.