

MAR 10 1997

K964604

## 1.4 Safety And Effectiveness Summary

The BIOTRONIK PX-BP and PX-JBP pacing leads are safe and effective bipolar, transvenous, implantable, endocardial leads used with implantable cardiac pacemakers. The lead body insulation of all PX-BP/PX-JBP endocardial leads is NuSil silicone rubber tubing, with the conductor of quadrafil MP35N.

The PX-BP/PX-JBP endocardial leads provide long-term safe and effective pacing due to the surface structure of the lenticular electrode tip. The tip has undergone a Physical Vapor Deposition (PVD) treatment 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 PX-BP/PX-JBP leads complies with the International Standard ISO 5841.3:1992: Low Profile Connectors. The PX-JBP lead is pre-formed into a "J" shape for optimal positioning in the atrium.

The materials used to manufacture the PX-BP/PX-JBP leads which come into contact with the patient were tested for biocompatibility. Acute and chronic biocompatibility tests were performed, as well as long term implantation studies. Corrosion studies were completed to address both long-term toxicity and durability of the tip and ring iridium material. The testing conducted for biocompatibility as well as extensive clinical experience confirms that iridium is safe for use as an implantable material. Literature has been published illustrating this conclusion. The long term corrosion testing results substantiate that iridium 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 PX-BP and PX-JBP 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 test results were within specifications. An overview of non-clinical testing is found in this premarket notification.

Field clinical experience, the *in-vitro* and qualification testing performed on the PX-BP/PX-JBP leads show that the risk to the patient in using these leads is the same as that of any implantable endocardial lead.

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:

**Lead Complications**

<b>SYMPTOM</b>	<b>POTENTIAL COMPLICATION</b>	<b>POTENTIAL CORRECTIVE ACTION</b>
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 PX-BP/PX-JBP was introduced into the European market in 1996. The lead body design and the size of the tip and the ring (where applicable) is the same for all PX-BP/PX-JBP leads, now representing over 1400 leads sold outside of the United States, as of October 1, 1996.