BIOSTABLE SILICONE POLYURETHANE COPOLYMER PACEMAKER LEAD INSULATION

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Polyether polyurethanes (Pellethane) have highly desirable unique properties for pacing leads, but they are susceptible to surface oxidation, environmental stress cracking (ESC) & metal ion oxidation (MIO). Silicone rubber lead insulation is resistant to these mechanisms but has poor mechanical strength resulting in failures due to compressive creep. A new series of polyurethanes were developed where part of the polyether soft segment is replaced with a telechelic siloxane (PurSil™). PurSil™ tubing was strained 400% and implanted subcutaneously in rabbits for 12 weeks and 6 months. The Pellethane 80A control had massive ESC failures while the PurSil™ showed no evidence of surface cracking or ESC. Accelerated MIO testing over cobalt mandrels in hydrogen peroxide has shown no degradation in PurSil™ after 12 weeks and 1 year. The Pellethane 80A had severe MIO degradation and failures by 12 weeks on test. Because PurSil has engineering properties similar to Pellethane it will be highly resistant to compressive creep and wear. PurSil™ combines the best properties of silicone and polyurethane lead insulation without the failure mechanisms.