RESULTS OF ACCELERATED AGEING OF BIOSPAN® AND BIOMER® SEGMENTED POLYURETHANES (SPU)

BioSpan and Biomer segmented polyurethanes were fabricated by solvent casting diaphragms for a ventricular assist device. Diaphragms were twice-sterilized (EtO) and subjected to accelerated ageing equivalent to two years of real time. Aged diaphragms were characterized by several bulk-sensitive methods: Transmission Infrared Spectroscopy, Tensile Properties, Thermomechanical Analysis, Gel Permeation Chromatography (GPC), Equilibrium Water Absorption and Extractables, Static Creep in Saline @ 37 °C, Accelerated Thermo-Hydrolytic Stability by multiple autoclaving, Differential Scanning Calorimetry, Indentation Hardness, Saline/Ethanol and Methylene Chloride Extractables and Dilute Solution Viscosity. Diaphragms were also characterized four surface-sensitive methods: Contact Angle and Wettability, Scanning Electron Microscopy, Electron Spectroscopy for Chemical Analysis and Attenuated Total Reflection. No significant differences (±2σ) in surface properties were detected among aged or control samples of either SPU. Bulk methods sensitive to the presence of branching and/or crosslinking revealed that Biomer SPU contains more gel when unaged and an has an increased tendency to form gels and embrittle during ageing than BioSpan SPU. By GPC, BioSpan SPU was virtually unaffected by the ageing process with no change in polydispersity, weight average molecular weight (Mw) or solvent solubility. Aged Biomer had increased polydispersity and Mw, and reduced solubility in methylene chloride and DMAC. These results suggest that BioSpan® segmented polyurethane is not significantly different from Biomer® segmented polyurethane in properties relevant to device safety and efficacy.

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