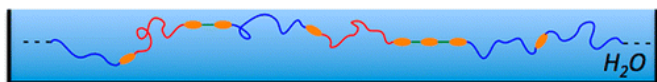


# Plastics used in some medical devices break down in a previously unrecognized way

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Scientists have discovered a previously unrecognized way that degradation can occur in silicone-urethane plastics that are often considered for use in medical devices. Their study, published in ACS' journal *Macromolecules*, could have implications for device manufacturers considering use of these plastics in the design of some implantable devices, including cardiac defibrillation leads.

Kimberly Chaffin, Marc Hillmyer, Frank Bates and colleagues explain that some implanted [biomedical devices](#), such as pacemakers and defibrillators, have parts made of a plastic consisting of polyurethane and silicone. While these materials have been extensively studied for failure due to interaction with oxygen, no published study has looked at interaction with water as a potential [failure mechanism](#) in this class of materials. In a cardiac lead application, these materials may be used as a coating on the electrical wires or "leads" that carry electric current from the battery in the device to the heart. Surgeons implant pacemakers in 600,000 people worldwide and defibrillators in 100,000 people in the United States each year. Since these implants must function reliably for years, the scientists wanted to determine whether the [plastic material](#) was suitable for long-term implants.

Their laboratory tests, including accelerated aging of the materials under conditions that simulated the

inside of the human body, found indications that the material begins to break down within 3-6 years. "By making the conclusions of this novel, scientific research public in a respected peer-reviewed journal, device manufacturers may now consider these important findings in their device designs," says Chaffin, distinguished scientist and lead author of the manuscript.

**More information:** "The Influence of Water on the Structure and Properties of PDMS-Containing Multiblock Polyurethanes", *Macromolecules*, 2012, 45 (22), pp 9110–9120  
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## Abstract

Segmented polyurethane multiblock polymers containing polydimethylsiloxane and polyether soft segments form tough and easily processed thermoplastic elastomers. Two commercially available examples, Elast-Eon E2A (denoted as E2A) and PurSil 35 (denoted as P35), were evaluated for molecular and mechanical stability after immersion in buffered water for up to 52 weeks at temperatures ranging from 37 to 85 °C. Dynamic mechanical spectroscopy experiments, performed in tension and shear, were used to characterize the linear viscoelastic properties of compression-molded (dry) specimens. Small-angle X-ray scattering measurements indicated a disorganized microphase-separated morphology for all test conditions. Upon aging in phosphate buffered saline, samples of E2A and P35 were analyzed by size exclusion chromatography (SEC) and tensile testing as a function of time and temperature. The absolute molar mass of each material prior to aging in water was determined by SEC using a multiangle light scattering detector. Aging at 85 °C and 52 weeks lead to a 67% and 50% reduction in molar mass from the original values for E2A and P35, respectively. We attribute

the reduction in molar mass to hydrolysis of the polymer backbone and have evaluated the data using a pseudo-zero-order kinetics analysis. The temperature dependence of the extracted rate data is consistent with an activated (i.e., Arrhenius) process, and thus all the molar mass reduction data can be reduced to a single master curve. Concomitant with the reduction in molar mass, E2A and P35 transformed with aging from strain-hardening to strain-softening materials, characterized by substantially reduced tensile strength (stress at failure) and ultimate elongation (strain at failure) relative to the original properties.

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