USP Biological Reactivity Tests, \textit{In Vivo}

\textbf{USP Plastic Class VI}

\textbf{USP Systemic Toxicity Study in the Mouse}
The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

\textbf{USP Intracutaneous Toxicity Study in the Rabbit}
The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

\textbf{USP Muscle Implantation Study in the Rabbit}
The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 4 g:20 mL and extracted at 70°C for 24 hours. The test article extracts met the requirements of a USP Plastic Class VI.

\textbf{Approval}
Arizona E. Carter, BS, ALAT
Technical Reviewer

\textbf{Date}
10-14-13