

***A Female Fertility and Developmental Toxicity Study of Patched  
BIOCELL® INTRASHIEL® Shell of Gel-Filled Breast Implants in  
Sprague-Dawley Rats***

**Final Report**

**Summary**

The subcutaneous implantation of 2 gm of pulverized Patched Gel Shell in female rats produced only minimal implant site responses; essentially those seen sporadically during recovery, including slight test article loss, alopecia, eschar, edema, and staple loss. For the Sham Control and Patched Gel Shell test article groups, there were no biologically significant effects on mortality, implant site observations, clinical signs of toxicity, weekly health examinations, body weight or body weight change after surgical implantation of the test article, or on body weight or body weight change, or food consumption during gestation. In addition, there were no significant macroscopic lesions observed in any of the females that were C-sectioned. The subcutaneous implantation of 2 gm of Patched Gel Shell did not affect female fertility or fetal development when the implanted group animals were compared to the Sham Control group animals.