

Analysis of Gel Cohesion and Gel Penetration Test Data

5.0 CONCLUSION

The test data for gel cohesion and gel penetration testing presented in this report represents gel devices currently produced at Inamed Corporation. The data presented in this report demonstrates that Inamed Corporation meets the ASTM F 703 Standard Specification for Implantable Breast Prostheses requirement for gel cohesion.

Gel Cohesion testing by the Cone/Pendant method described in ASTM F703 however does not provide the precision or information necessary to maintain process control and consistency of crosslink density of silicone gel used in devices. Gel Penetration Testing thus is a more useful method for providing this control and is used by Inamed Corporation for this purpose.