

Fatigue Testing of Thinnest Shell Gel-Filled Breast Implants

9.0 CONCLUSION

For each of the two styles tested (representative of Styles 10, 20, 40, 45, 110, 120 and 153 product lines), the following criteria as stipulated in technical report protocol

"Fatigue Testing of Thinnest Shell Gel-Filled Breast Implants" were met:

- 9.1 100% run-out to 6.5 million cycles at the *in vivo* load requirement, 5 lbs.
- 9.2 100% run-out at twice the *in vivo* load, 10 lbs..
- 9.3 Evidence that the *in vivo* load is past the elbow of the AF/N curves. As stated in the protocol for this testing, section Cyclic Loads, the only true *in-vivo* cyclic activity is walking/jogging/running. The value and derivation of this *in-vivo* load are calculated to be 3.6 pounds, which for test purposes was rounded up to 5 pounds.