

Sterile Valve Performance Test

THE CHALLENGE: BPI was approached by a client with a new prototype sterile valve. This client sought BPI to answer:

- Will the valve seal – pneumatically and hydraulically?
- Is the valve adversely affected by the testing?
- Will the valve require adjustments over its life cycle?

OUR SOLUTION: BPI custom designed a lifecycle performance test for the client's prototype sterile valve across three sizes with respect to multiple performance criteria. The client's sterile valves were successfully exposed to Steam-In-Place (SIP) cycles.



BPI's facility is uniquely equipped to test both multi-use and single-use equipment used in the BioProcess industry. Its flexible design features custom computer controlled process systems, which are configured and programmed to BPI clients' specific needs. These custom-designed systems utilize BPI's high quality support systems including Clean/Pure Steam, Deionized Water, and Clean Compressed Air. BPI's staff utilized high precision instrumentation including a Borescope and Scanning Electron Microscopy (SEM) to evaluate the results of the performance test.

THE RESULTS: *Seal integrity was never compromised on the sterile valves. BPI recommended some potential design changes to increase performance. After successful follow-up performance exposure testing, the sterile valve will be ready to go to market.*

For more information on testing and analysis or marketing claim support, please contact:

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