

Bio Valve™

Sterilization Test Summary



Testing was undertaken to compare the effects of Autoclaving and Gamma Irradiation sterilization on the in-use performance of the Bio Valves™. The durability and robustness was tested before and after the different types of sterilization on the Large and Small Bio Valves™.

Conclusion

From the testing that has been carried out it may be determined that the process of Autoclaving and Gamma Irradiation has no negative effects on the in use durability and robustness of the Bio Valves™ in both Small and Large sizes when tested.

Results Table

| | Test 1 Ambient Pressure Test Results | Test 2 Heat & Pressure Test Results | Test 3 Average Handle Torque Test Results per Size (Nm) |
|-------------------------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------|------------------------------------------------------------------|
| Batch 1 Virgin Clamps | All Clamps Passed Acceptance Criteria. No Leaks Observed. | All Clamps Passed Acceptance Criteria. No Leaks Observed. | Small = 6.47 Large = 19.93 |
| Batch 2 Autoclaved Clamps | All Clamps Passed Acceptance Criteria. No Leaks Observed. | All Clamps Passed Acceptance Criteria. No Leaks Observed. | Small = 7.9 Large = 16.97 |
| Batch 3 Gamma Irradiated Clamps | All Clamps Passed Acceptance Criteria. No Leaks Observed. | All Clamps Passed Acceptance Criteria. No Leaks Observed. | Small = 7.8 Large = 17.87 |



Bio Valve™

Sterilization Test Summary

Acceptance Criteria

| | Test 1 Ambient Pressure Test Results | Test 2 Heat Et Pressure Test Results | Test 3 Average Handle Torque Test Results per Size (Nm) |
|------------------|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Small Bio Valves | Once the system is stable, there must be no leak from the connection when held at 4.4 Bar pressure for 30 seconds | Once the system is stable, there must be no leak from the connection when held at 4.4 Bar pressure for 30 seconds | N/A Record all results from destructive testing |
| Large Bio Valves | Once the system is stable, there must be no leak from the connection when held at 9.65 Bar pressure for 30 seconds | Once the system is stable, there must be no leak from the connection when held at 9.65 Bar pressure for 30 seconds | N/A Record all results from destructive testing |

Test Matrix

| | Test 1 Pressure Test | Test 2 Heat & Pressure Test | Test 3 Handle Torque Test |
|------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|
| Batch 1 Virgin Valves | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests |
| Batch 2 Autoclaved Valves | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests |
| Batch 3 Gamma Irradiated Valves | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests | 2 Sizes of Valve 15 Samples per Size 2 x 15 = 30 Tests |
| | | | Total Number of Tests = 690 |

Batch 1 was made up of un-treated Bio Valves™

Batch 2 was made up of Bio Valves™ that were Autoclaved at 135°C for 30 minutes

Batch 3 was made up of Bio Valves™ that were Gamma Irradiated with a minimum dose of 25 kGy. (Maximum 40 kGy)

The Bio Valves™ tested come in two sizes:

- Large (Part #BV1000NW)
- Small (Part #BV)500NW)

Cont'd on Next Page



P.O. Box 126, Readington, New Jersey, USA
 Phone: +01-908-722-6948 Fax: +01-908-526-3256
www.bioconnex.com

Bio Valve™

Sterilization Test Summary

Test 1

Each of the Valves is to be fitted to the appropriately sized Braid Reinforced Silicone Tube (Small valves to 0.5" tube, Large valves to 1.0" tube). The valves should be tightened to 2.5Nm using a Dial Torque Wrench fully closing off the tube. The valve/tube assembly is then connected to the water pressure test rig and the maximum working pressure associated with the size of the Braid Reinforced Silicone Tubing applied to the tubing (4.48Bar for the 1.0" tube, 9.65 for the 0.5" tube – from the tube manufacturers data sheets). Once at pressure the valve is to be turned off and the gauge allowed to stabilize. A reading is taken of the pressure once it has stabilized and after 30 seconds has elapsed and recorded on the appropriate results sheet.

Test 2

Each of the Valves is to be dry heated in an electric heating cabinet to a temperature of 121°C for a period of no less than 20 minutes. Confirmation of the temperature is via a read out from a thermocouple attached to the inside of the heating cabi-

net. Once the Bio Valves™ have been heated for the required amount of time they are to be removed from the heating cabinet and fitted to appropriately sized Braid Reinforced Silicone Tube (Small valves to 0.5" tube, Large valves to 1.0" tube). The valve should be tightened to 2.5Nm using a Dial Torque Wrench fully closing off the tube. The valve/tube assembly is then connected to the water pressure test rig and the maximum working pressure associated with the size of the Braid Reinforced Silicone Tubing applied to the tubing (4.48Bar for the 1.0" tube & 9.65 for the 0.5" tube from the tube manufacturers data sheets). Once at pressure the valve is to be turned off and the gauge allowed to stabilize. A reading is taken of the pressure once it has stabilized and after 30 seconds has elapsed and recorded on the appropriate results sheet.

Test 3

Test 3 involved the destructive testing of the Bio Valve™ handles. Each handle was torque tested to the point of failure and the results recorded.



P.O. Box 126, Readington, New Jersey, USA
Phone: +01-908-722-6948 Fax: +01-908-526-3256
www.bioconnexx.com