

Summary of Bio Valve™ Testing

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

	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 No. of Tests = 270			

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:

- Small
- Large

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 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 stabilise. A reading is taken of the pressure once it has stabilised and after 30 seconds has lapsed 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 cabinet.

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 the 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 stabilise. A reading is taken of the pressure once it has stabilised and after 30 seconds has lapsed 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.

Acceptance Criteria

Test 1	Test 2	Test 3
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	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	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	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	

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 Valves	All Valves passed acceptance criteria. No leaks observed.	All Valves passed acceptance criteria. No leaks observed.	Small = 6.47 Large = 19.93
Batch 2. Autoclaved Valves	All Valves passed acceptance criteria. No leaks observed.	All Valves passed acceptance criteria. No leaks observed.	Small = 7.9 Large = 16.97
Batch 3. Gamma Irradiated Valves	All Valves passed acceptance criteria. No leaks observed.	All Valves passed acceptance criteria. No leaks observed.	Small = 7.8 Large = 17.87

Conclusion

From the testing that has been carried out it may be determined that the process of Autoclaving & 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.