exposed to the test medium, do not require preparation of solutions, and/or allow for faster testing and simpler setup.

[0009a] A first aspect of the present invention provides a surgical conduit leak testing system, comprising a manifold assembly mounted on a common support base including a pair of spaced apart manifolds having structure for clamping and sealing onto opposite ends of a surgical conduit, wherein a first manifold is fixed with respect to the support base and a second manifold is mounted on the support base for movement toward and away from the first manifold, and wherein one of the manifolds has gas flow passages between an external fitting and an internal port that opens to an interior of the surgical conduit when clamped thereon, a gas delivery hose connected to the external fitting, and a gas pressure controller to which the gas delivery hose attaches and which has a fitting for connection to a source of pressurized gas, the controller having sensors for measuring the pressure in the gas delivery hose and an output for the measured pressure. The system is configured to measure at least one of a change in gas flow rate or a pressure decay as gas leaks through a wall of the surgical conduit, when the opposite ends of the surgical conduit are sealingly clamped to the manifolds.

[0009b] A second aspect of the present invention provides a surgical conduit leak testing system, comprising a manifold assembly including a first manifold spaced from a second manifold, each of the first and second manifolds sealingly clampable to a respective end of a surgical conduit, the first manifold fluidly coupling a lumen of the surgical conduit to a testing gas port when the surgical conduit is sealingly clamped thereto, and a meter fluidly coupled to the testing gas port, the meter suitable for determining at least one of a change in gas flow rate or a gas pressure decay as gas leaks through a wall of the surgical conduit.

[0009c] A third aspect of the present invention provides a method for leak testing a surgical conduit. The method comprises pressurizing a lumen of a surgical conduit with an inert gas, and measuring at least one of a change in flow rate or a pressure decay as the inert gas leaks through a wall of the surgical conduit.

[0009d] A fourth aspect of the present invention provides a method for leak testing a surgical conduit. The method comprises pressurizing a lumen of a surgical conduit with an inert gas and measuring at least one of a change in flow rate or a pressure decay as the inert gas leaks through a wall of the surgical conduit over a period of time.

[0010] An exemplary embodiment of the leak testing system and method uses air as a medium to test for permeability/leakage of a part, for example, the graft or aortic-valved conduit. The part is first plugged or clamped on both ends to create a seal on each end. A variety of plug/clamp designs may be used for this purpose. One end of the assembly is fluidly connected to an inlet port of a leak tester that is capable of mass-flow testing. A lumen of the part is then pressurized with air, and a mass air-flow test performed. This embodiment of the test method subjects the part to air flow, and the measured change in air flow corresponds to an air leak rate from the part.

[0011] In an alternative embodiment of the test method, the part is internally pressurized with air for a first, typically short, period of time, the pressure is allowed to settle or equilibrate for a second, typically brief period of time, and the pressure decay is measured as air leaks from the part. A pressure decay threshold is identified to distinguish a passing from a failing part. For instance, the part may be internally pressurized to about 16 kPa (about 2.3 psi), and then monitored for a period of time. If the lumen pressure decays by more than 50% from the starting pressure within a predetermined time period, such as 0.6 seconds, then the part is deemed defective. Of course, these thresholds are variable depending on the type of conduit, application, and starting pressure, among other variables.

[0012] Existing test methods are either destructive or require a drying period for the part. Since embodiments of the test methods disclosed herein use air, they are non-destructive and require no post-test drying period. Therefore, embodiments of the test methods can allow 100% inspection of parts, and/or repeated testing of the same sample. Depending on the clamp design contacting the graft, some slight disruption of the gelatin or collagen may occur at the clamp interface. In some of these cases, a slightly longer graft may be specified for the in-process graft design, and this segment may be trimmed off after the leak inspection, leaving the final desired graft length for the end product. With air, no solution storage or mixing is required. The part may be pressurized relatively quickly, and no solution evacuation or clean-up is required.

[0013] A method of manufacturing a valved conduit is also disclosed, which includes first assembling a valved conduit including a bioprosthetic valve having bioprosthetic tissue coupled to a conduit sealed with a bioresorbable medium. The method includes leak testing

WHAT IS CLAIMED IS:

1. A surgical conduit leak testing system, comprising:

a manifold assembly mounted on a common support base including a pair of spaced apart manifolds having structure for clamping and sealing onto opposite ends of a surgical conduit, wherein a first manifold is fixed with respect to the support base and a second manifold is mounted on the support base for movement toward and away from the first manifold, and wherein one of the manifolds has gas flow passages between an external fitting and an internal port that opens to an interior of the surgical conduit when clamped thereon;

a gas delivery hose connected to the external fitting; and

a gas pressure controller to which the gas delivery hose attaches and which has a fitting for connection to a source of pressurized gas, the controller having sensors for measuring the pressure in the gas delivery hose and an output for the measured pressure

wherein the system is configured to measure at least one of a change in gas flow rate or a pressure decay as gas leaks through a wall of the surgical conduit, when the opposite ends of the surgical conduit are sealingly clamped to the manifolds.

2. The system of claim 1, wherein the manifold that has gas flow passages includes a first mandrel around which the surgical conduit fits and that terminates in the internal port within the surgical conduit, and the other manifold has a mandrel with no gas flow passages.

3. The system of claim 1 or claim 2, wherein the structure for clamping and sealing includes flow channels through both manifolds from external fittings, each manifold having an internal piston arranged to be displaced toward the surgical conduit when pressurized gas is introduced to the respective flow channels, and the structure includes an elastomeric ring that is compressed by piston displacement and positioned to expand inward and clamp and seal the surgical conduit against a rigid mandrel provided within the conduit.

4. The system of any of claims 1–3, wherein the surgical conduit comprises a valved conduit having a tubular graft portion and a one-way valve attached to a second end of the graft portion, the one way valve permitting flow from the second end to the first end but preventing flow in the opposite direction.

5. The system of claim 4, wherein the valved conduit includes a resilient sealing ring adjacent the one-way valve which extends radially outward from the graft, and wherein the structure for clamping and sealing includes a pair of rigid clamps sized and shaped to axially compress the sealing ring.

6. The system of claim 5, wherein the valved conduit is an aortic valve conduit and the sealing ring has a peripheral shape that undulates so as to mimic the aortic annulus, and the rigid clamps each have facing clamp surfaces that undulate to match the contours of the sealing ring.

7. The system of claim 6, wherein the structure for clamping and sealing includes flow channels through both manifolds from external fittings, each manifold having an internal piston arranged to be displaced toward the surgical conduit when pressurized gas is introduced to the respective flow channels, the piston in the manifold that receives the second end of the graft configured to contact one of the rigid clamps and compress it against the other, and the structure on the manifold that receives the first end of the graft includes an elastomeric ring that is compressed by piston displacement and positioned to expand inward and clamp and seal the graft against a rigid mandrel provided within the conduit.

8. A surgical conduit leak testing system, comprising:

a manifold assembly including a first manifold spaced from a second manifold, each of the first and second manifolds sealingly clampable to a respective end of a surgical conduit, the first manifold fluidly coupling a lumen of the surgical conduit to a testing gas port when the surgical conduit is sealingly clamped thereto; and

a meter fluidly coupled to the testing gas port, the meter suitable for determining at least one of a change in gas flow rate or a gas pressure decay as gas leaks through a wall of the surgical conduit.

9. The leak testing system of claim 8, wherein the gas meter includes a mass flow meter.

10. The leak testing system of claim 8 or claim 9, further comprising a pressure controller fluidly coupled to the testing gas port, the pressure controller suitable for controlling a pressure of a testing gas.

11. The leak testing system of any of claims 8–10 wherein

each of the first and second manifolds comprises a piston disposed in a chamber therein,

the piston is reversibly displaceable within the chamber between a first position and a second position,

wherein in the first position, the respective end of the surgical conduit is not sealingly clamped to the respective manifold and in the second position, the respective end of the surgical conduit is sealingly clamped to the respective manifold.

12. The leak testing system of claim 11, wherein

at least one of the first and second manifolds includes a mandrel, a portion of which is dimensioned to receive the respective end of the surgical conduit and an elastomeric clamping ring disposed around the portion of the mandrel,

when the piston in the first position, the elastomeric clamping ring is radially spaced from the portion of the mandrel by a first distance,

when the piston in the second position, the piston compresses the elastomeric clamping ring, urging the elastomeric clamping ring radially towards the portion of the mandrel to a radial space of a second distance, and

the first distance is greater than the second distance.

13. The leak testing system of claim 11, wherein

one of the first and second manifolds includes a first end clamp and a second end clamp, the first end clamp and the second end clamp dimensioned to receive a flange of the surgical conduit therebetween, and

when the piston is in the second position, the piston urges the first end clamp and the second end clamp together to sealingly clamp the flange of the surgical conduit to the manifold.

14. The leak testing system of any of claims 11–13, wherein the piston is displaceable from the first position to the second position by applying fluid pressure thereto.

15. The leak testing system of any of claims 8–14, wherein at least one of the first and second manifolds is moveable towards and away from the other of the first and second manifolds.

16. A method for leak testing a surgical conduit, the method comprising:

pressurizing a lumen of a surgical conduit with an inert gas; and

measuring at least one of a change in flow rate or a pressure decay as the inert gas leaks through a wall of the surgical conduit.

17. The method of claim 16, further comprising sealing a first and a second end of the surgical conduit to a test fixture, wherein the first end and the second end of the surgical conduit are movable relative to each other.

18. The method of claim 16 or claim 17, wherein the pressuring with the inert gas comprises pressuring with air.

19. The method of any of claims 16–18, wherein measuring the change in flow rate comprises measuring a mass flow rate.

20. The method of any of claims 16–19, wherein measuring the pressure decay comprises measuring a pressure drop over time.

21. The method any of claims 16–20, further comprising comparing a measured flow rate and/or pressure with a selected flow rate or pressure.

22. A method for leak testing a surgical conduit, the method comprising:

pressurizing a lumen of a surgical conduit with an inert gas; and

measuring at least one of a change in flow rate or a pressure decay as the inert gas leaks through a wall of the surgical conduit over a period of time.

23. The method claim 22, comprising the steps of:

positioning a surgical conduit within a test fixture including a manifold assembly, the manifold assembly having structure for clamping and sealing onto opposite ends of the surgical conduit, wherein one of the manifolds has gas flow passages between an external fitting and an internal port that opens to an interior of the surgical conduit when clamped thereon;

wherein the step of pressurizing a lumen of a surgical conduit with an inert gas includes introducing the inert gas to the external fitting until a predetermined pressure within the conduit is reached; and

maintaining the internal pressure for the period of time while performing the step of measuring.