

[0011] In one preferred embodiment, a valved conduit comprises a subassembly of a conduit graft and an annular sewing ring. The conduit graft includes a longitudinal tubular portion between an upper end and a lower end, the lower end having a collar portion. The annular sewing ring comprising an inner core and an outer fabric covering, the annular sewing ring being positioned adjacent the lower end of the conduit graft whereby the collar portion contacts and is secured to an inner wall of the annular sewing ring. The subassembly of the conduit graft and the annular sewing ring is independently leak tested. A prosthetic heart valve in the valved conduit has an inner support frame covered with fabric and defining a flow orifice and a plurality of leaflets extending inward from the support frame to ensure one-way blood flow through the heart valve. The heart valve is positioned within the lower end of the conduit graft and the fabric covering the support frame extends downward in a tubular segment and is folded radially outward underneath the subassembly of the conduit graft and the annular sewing ring and secured thereto with sutures. Finally, a holder attaches to the heart valve and extends from the heart valve out of the upper end of the conduit graft.

[0012] In the valved conduit described above, the collar portion may have an undulating shape around its circumference with peaks and valleys, and the annular sewing ring also has an undulating shape around its circumference with peaks and valleys, wherein the peaks and valleys of the collar portion align with the peaks and valleys of the annular sewing ring. The conduit graft may be secured to the annular sewing ring using sutures, by welding, or using an intermediate band which is secured to both the conduit graft and the annular sewing ring. The heart valve leaflets are desirably made of bioprosthetic tissue, and the conduit graft preferably comprises a tubular matrix impregnated with gelatin. The heart valve leaflets are more preferably formed of bovine pericardium that has been cross-linked using glutaraldehyde or other aldehyde containing agents, treated with a capping agent, and is dehydrated with a glycerol solution.

[0013] A method of assembling a valved conduit disclosed herein, comprises the following steps:

- forming a subassembly of a conduit graft and an annular sewing ring, the conduit graft comprising a longitudinal tubular portion between an upper end

and a lower end, the lower end having a collar portion, the annular sewing ring comprising an inner core and an outer fabric covering, the step of forming comprising positioning the annular sewing ring adjacent the lower end of the conduit graft so that the collar portion contacts an inner wall of the annular sewing ring and securing the collar portion thereto;

- leak testing the subassembly of the conduit graft and the annular sewing ring;
- providing a prosthetic heart valve having an inner support frame covered with fabric and defining a flow orifice and a plurality of leaflets extending inward from the support frame to ensure one-way blood flow through the heart valve, the fabric covering the support frame extending downward in a tubular segment;
- attaching a holder to the heart valve; and
- positioning the heart valve within the lower end of the leak tested subassembly of the conduit graft and the annular sewing ring and folding the tubular segment of the fabric covering radially outward underneath the subassembly and secured the tubular segment thereto with sutures, the holder having a length sufficient to extend from the heart valve out of the upper end of the conduit graft.

[0014] A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

Brief Description of the Drawings

[0015] The invention will now be explained and other advantages and features will appear with reference to the accompanying schematic drawings wherein:

WHAT IS CLAIMED IS:

1. A valved conduit, comprising:

a subassembly of:

a conduit graft comprising a longitudinal tubular portion between an upper end and a lower end, the lower end having a collar portion; and an annular sewing ring comprising an inner core and an outer fabric covering, the annular sewing ring being positioned adjacent the lower end of the conduit graft whereby the collar portion contacts and is secured to an inner wall of the annular sewing ring;

wherein the subassembly of the conduit graft and the annular sewing ring is independently leak tested,

a prosthetic heart valve having an inner support frame covered with fabric and defining a flow orifice and a plurality of leaflets extending inward from the support frame to ensure one-way blood flow through the heart valve, wherein the heart valve is positioned within the lower end of the conduit graft and the fabric covering the support frame extends downward in a tubular segment and is folded radially outward underneath the subassembly of the conduit graft and the annular sewing ring and secured thereto with sutures;

a holder attached to the heart valve and extending from the heart valve out of the upper end of the conduit graft.

2. The valved conduit of claim 1, wherein the collar portion has an

undulating shape around its circumference with peaks and valleys, and the annular sewing ring also has an undulating shape around its circumference with peaks and valleys, wherein the peaks and valleys of the collar portion align with the peaks and valleys of the annular sewing ring.

3. The valved conduit of claim 1, wherein the conduit graft is secured to the

annular sewing ring using sutures.

4. The valved conduit of claim 1, wherein the conduit graft is secured to the annular sewing ring by welding.

5. The valved conduit of claim 1, wherein the conduit graft is secured to the annular sewing ring using an intermediate band which is secured to both the conduit graft and the annular sewing ring.

6. The valved conduit of any preceding claim, wherein the heart valve leaflets are made of bioprosthetic tissue.

7. The valved conduit of claim 6, wherein the conduit graft comprises a tubular matrix impregnated with gelatin.

8. The valved conduit of claim 5, wherein the heart valve leaflets are formed of bovine pericardium that has been cross-linked using glutaraldehyde or other aldehyde containing agents, treated with a capping agent, and is dehydrated with a glycerol solution.

9. A method of assembling a valved conduit, comprising:

forming a subassembly of a conduit graft and an annular sewing ring, the conduit graft comprising a longitudinal tubular portion between an upper end and a lower end, the lower end having a collar portion, the annular sewing ring comprising an inner core and an outer fabric covering, the step of forming comprising positioning the annular sewing ring adjacent the lower end of the conduit graft so that the collar portion contacts an inner wall of the annular sewing ring and securing the collar portion thereto;

leak testing the subassembly of the conduit graft and the annular sewing ring;

providing a prosthetic heart valve having an inner support frame covered with fabric and defining a flow orifice and a plurality of leaflets extending inward

from the support frame to ensure one-way blood flow through the heart valve, the fabric covering the support frame extending downward in a tubular segment; attaching a holder to the heart valve; and positioning the heart valve within the lower end of the leak tested subassembly of the conduit graft and the annular sewing ring and folding the tubular segment of the fabric covering radially outward underneath the subassembly and secured the tubular segment thereto with sutures, the holder having a length sufficient to extend from the heart valve out of the upper end of the conduit graft.

10. The method of claim 9, wherein the collar portion has an undulating shape around its circumference with peaks and valleys, and the annular sewing ring also has an undulating shape around its circumference with peaks and valleys, wherein the peaks and valleys of the collar portion align with the peaks and valleys of the annular sewing ring.

11. The method of claim 9, including securing the conduit graft to the annular sewing ring using sutures.

12. The method of claim 9, including securing the conduit graft to the annular sewing ring by welding.

13. The valved conduit of any preceding claim, wherein the heart valve leaflets are made of bioprosthetic tissue.

14. The method of claim 13, wherein the conduit graft comprises a tubular matrix impregnated with gelatin.

15. The method of claim 13, wherein the heart valve leaflets are formed of bovine pericardium that has been cross-linked using glutaraldehyde or other aldehyde containing agents, treated with a capping agent, and is dehydrated with a glycerol solution.